UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Xcelthera, INC.

(Exact Name of Registrant as Specified in its Charter)

California
(State or other jurisdiction of incorporation or organization)

2836
(Primary Standard Industrial Classification Code Number)

46-3006118
(I.R.S. Employer Identification Number)

Xcelthera, INC,
San Diego, CA
(888) 706-5396
(Address, including zip code, and telephone number,
including area code, of registrant principal executive offices)

Xuejun H. Parsons, PhD
Chairman of the Board and Chief Executive Officer
Xcelthera, INC
4539 Donald Ave., San Diego, CA 92117
(858) 457-2046
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Approximate date of commencement of proposed sale to the public:

As soon as practicable after this Registration Statement becomes effective.

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, 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 post-effective amendment filed pursuant to Rule 462(d) 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company:

Large accelerated filer

Accelerated filer

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

Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	**Amount to be Registered(1)**	**Proposed Maximum Offering Price Per Share**	**Proposed Maximum Aggregate Offering Price(1)**	**Amount of Registration Fee(2)**
Common Stock, $0.0001 par value per share	2,000,000	$20	$40,000,000	$5,456

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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 the 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. We 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 we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated March 5, 2014.

Prospectus

2,000,000 shares

Common stock

This is the initial public offering of common stock by Xcelthera, Inc. Prior to this offering, there has been no public market for our common stock. We are offering 2,000,000 shares of common stock pursuant to this prospectus. We expect the initial public offering price to be between $16.00 and $20.00 per share.

We have applied to have our common stock listed on the NASDAQ Global Market under the symbol XCLR.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Initial Public Offering	Per Share	Total Amount of the Offering
Minimal Offering Price	$16	$32,000,000
Maximum Offering Price	$20	$40,000,000

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 13.

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.

Best efforts offering. The underwriters are not required to sell any specific number or dollar amount of securities but will use their best efforts to sell the securities offered.

The ending date of the offering, any minimum purchase requirements, and any arrangements to place the funds in a trust account, have not been made, but will be made if the registration statement filed with the Securities and Exchange Commission become effective, which may have the effect of delaying or preventing potential investors to make a purchase decision on our stock.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with additional information or information different from that contained in this prospectus. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

Prospectus Summary

This summary highlights selected information appearing elsewhere in this prospectus and does not contain all the information you should consider before investing in our common stock. You should carefully read this prospectus in its entirety before investing in our common stock, including the section entitled Risk factors, and our financial statements and related notes included elsewhere in this prospectus.

As used in this prospectus, unless the context otherwise requires, references to we, us, our, *Company, Corporation, PluriXcel, Xcel, XCLR, and Xcelthera, refer to Xcelthera, Inc.*

Overview

We are a biopharmaceutical company moving towards clinical development stage of novel and most advanced stem cell therapy for a wide range of neurological and cardiovascular diseases with leading technology and medical innovation in cell-based regenerative medicine. We have patent and proprietary rights for our novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)**, derived from pluripotent human embryonic stem cells (hESCs) by small molecule induction. Human pluripotent stem cells have the potential to differentiate into all the somatic cell types in the human body by the definition of "pluripotent". Pluripotent hESCs have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for unrestricted differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. Of particular interest to the medical needs is the potential for use of hESC derivatives to heal tissues with naturally limited capacity for renewal, such as the human heart and brain. The Company is the first to hold the breakthrough technology for large-scale production of high quality clinical-grade hESC lines and their functional human neuronal and heart cell therapy derivatives for commercial and therapeutic uses. We plan to enter clinical-stage development or first-in-human studies in cardiac and neural repair for our licensed human stem cell therapy products following completion of this offer. Our strategy is to use cutting-edge human stem cell technology to develop clinical-grade functional neural and cardiac cell therapy products from pluripotent hESCs as cellular medicine or cellular drugs to provide the next generation of cell-based therapeutic solutions for unmet medical needs in world-wide major health problems.

We were recently incorporated in May 2013 as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute

any such products or processes. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. The founder and CEO of the Company is also the founder of San Diego Regenerative Medicine Institute and the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. The Company has acquired proprietary human stem cell assets and we are currently in early stage of our clinical development efforts. Although we have not incurred any deficits, debts, or negative cash flows since recent incorporation, the Company has no revenues and minimal tangible assets, and we have not raised sufficient funds so far to support filing an investigational new drug (IND) application with the Food and Drug Administration (FDA) for our licensed cell therapy products to enter into clinical development stage. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy. We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including investigational new drug (IND) filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing Current Good Manufacturing Practices (cGMP) manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities.

The hESC cell therapy products have emerged as powerful pharmacological agents of cellular entity to offer medicinal utility and capacity for human tissue and function restoration. We have established ground-breaking proprietary human stem cell technology platforms **(PluriXcel Technology)**, including defined culture systems for derivation and maintenance of clinical-grade high quality hESC lines **(PluriXcel-DCS)** and lineage-specific differentiation of pluripotent hESCs by small molecule induction **(PluriXcel-SMI)**. Our **PluriXcel-DCS** technology allows all poorly-characterized and unspecified biological components and substrates in the culture system, including those derived from animals, to be removed, substituted, and optimized with defined human alternatives for *de novo* derivation and long-term maintenance of cGMP-quality xeno-free stable hESC lines and their human cell therapy derivatives, which have never been contaminated with animal cells and proteins, thus suitable for therapeutic development and clinical applications. Our **PluriXcel-SMI** technology platforms include our **PluriXcel-SMI-Neuron** technology and our **PluriXcel-SMI-Heart**. Our **PluriXcel-SMI-Neuron** technology allows neural lineage-specific differentiation of pluripotent hESCs by small molecule induction for high efficient direct conversion of pluripotent hESCs into a large scale of high quality neuronal progenitors and functional neuronal cells adequate for clinical development of safe and effective stem cell therapies for a wide range of neurological disorders. Our **PluriXcel-SMI-Heart** technology allows cardiac lineage-specific differentiation of pluripotent hESCs by small molecule induction

for high efficient direct conversion of pluripotent hESCs into a large scale of high quality heart precursors and functional cardiomyocytes (heart muscle cells) adequate for clinical development of safe and effective stem cell therapies for heart disease and failure. Breakthroughs of our **PluriXcel** technologies transform non-functional pluripotent hESCs into a large scale of high quality fate-restricted functional cell therapy derivatives or products for commercial and therapeutic uses. Our cutting-edge human stem cell technology and medical innovations enable high efficient direct conversion of pluripotent hESCs by small molecule induction into a large scale of clinical-grade high quality human neural or cardiac lineage-specific cell therapy derivatives, including our cell therapy product **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), which is a major milestone towards human trials of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches.

We are currently moving towards clinical development stage or first-in-human studies of our products. **As of the date of this prospectus, we have not raised sufficient funds to support filing an investigational new drug (IND) application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans.** Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy. We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Clinical applications of functional cell therapy products derived from pluripotent hESCs provide the right alternative for many different types of incurable diseases, including neurodegenerative diseases and heart diseases that have been considered as world-wide major health problems. To date, the existing markets lack a clinically-suitable

human neuronal cell source with adequate CNS regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged or lost CNS structure and circuitry in a wide range of neurological disorders. Similarly, the existing markets lack a clinically-suitable human cardiomyocyte (the mature contracting heart muscle cell) source with adequate myocardium (the contractile heart muscle) regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged human heart in cardiovascular disease. Therefore, our proprietary clinical-grade hESC-derived neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), are currently the only available human cell sources in commercial scales with adequate cellular pharmacological utility and capacity to regenerate neurons and contractile heart muscles in the clinical setting, providing potential treatments or cures for a wide range of neurological and cardiovascular diseases, including heart disease and failure, stroke, Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Alzheimer disease, Spinal muscular atrophy, motor neuron diseases, neurodegenerative diseases, brain and spinal cord injuries. The estimated costs of these world-major major health problems for the United States (US) population alone are > $500 billions annually, and currently, there is no treatment option or compound drug of molecular entity that can change the prognosis of most of those diseases, or that will lead to a dramatic functional improvement.

We own or have exclusive rights in a portfolio of intellectual property or license rights related to our novel **PluriXcel** human stem cell technology platforms and **Xcel** human stem cell therapy products, which provide significant competitive advantages for the growth of our business and for the dominance over our target markets. We provide CNS (central nervous system)- and heart-related human stem/progenitor/precursor cells and functional human neurons and heart muscle cells useful for stem cell banking, *in vitro* and *in vivo* stem cell research, transplantation, human CNS and heart tissue and organ engineering, cell-based regenerative medicine or therapies for human CNS and heart disorders or diseases, large-scale and cGMP production for commercial and therapeutic uses, cell-based therapeutics, drug screening, drug development, toxicity and safety testing, and other commercial and therapeutic purposes, which target multiple multi-billion dollar global markets in pharmaceutical, therapeutic, biotechnology, and healthcare sectors.

The inception of Xcelthera is driven by the urgent need for clinical translation of hESC research discoveries and innovations to address unmet medical challenges in major health problems. Our breakthrough developments in hESC research dramatically increase the overall turnover of investments in biomedical sciences to optimal treatment options for a wide range of human diseases. The long-term goal of the Company is to establish Xcelthera, INC as a premier Pharmaceutical/Therapeutic/Biotechnology Company to provide human stem cell-based regenerative medicine or cellular drugs for neurodegenerative diseases, neurological disorders, and cardiovascular diseases. The Company has established proprietary human stem cell technology **(PluriXcel Technology)** for large scale production of high quality clinical-grade hESC lines and their functional human neuronal and heart cell therapy products **(Xcel)**, which will

maintain our global leadership position in cell-based regenerative medicine, sustain the business entity of the Company in life sciences industry, and enable proprietary cell therapy products and tools move along a promising commercialization pathway to therapeutic markets leading to FDA approval of hESC neuronal and heart cell therapy products as treatments or cures for a wide range of CNS and heart disorders.

The Limitations of Existing Approaches and Markets

Cardiovascular and central nervous system (CNS) diseases, including heart disease and failure, stroke, Parkinsons disease, ALS, Alzheimer disease, are major health problems and leading causes of death in the United States (US). The estimated costs for the overall US population are over $500 billion annually. Currently, there is no treatment option or compound drug of molecular entity that can change the prognosis of most of those diseases or that will lead to a dramatic functional improvement. Given the limited capacity of the CNS and the heart for self-repair or renewal, cell-based therapy represents a promising therapeutic approach closest to provide a cure to restore normal tissue and function for neurological and cardiovascular disorders. However, traditional sources of cells for therapy in existing markets have been adult stem cells isolated from tissues or artificially reprogrammed from adult cells, which all have the historical shortcomings of limited capacity for renewal and repair, accelerated aging, and immune-rejection following transplantation. In addition, artificially reprogrammed adult cells have the major drawbacks of extremely low efficiencies and genetic defects associated with high risks of cancers, which have severely limited their utility as viable therapeutic approaches. To date, the existing markets lack a clinically-suitable human neuronal cell source with adequate CNS regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged or lost CNS structure and circuitry in a wide range of neurological disorders. Similarly, the existing markets lack a clinically-suitable human cardiomyocyte (the mature contracting heart muscle cell) source with adequate myocardium (the contractile heart muscle) regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged human heart in cardiovascular disease.

The intrinsic ability of a hESC for both unlimited self-renewal and unrestricted differentiation into clinically-relevant lineages makes it a practically inexhaustible source of replacement cells for human tissue and function restoration. Therefore, it has been regarded as an ideal source to provide a large supply of functional human cells to heal the damaged or lost tissues that have naturally limited capacity for renewal, such as the human heart and brain. Although a vast sum of government and private funding has been spent on looking for adult alternates, such as reprogramming and trans-differentiation of fibroblasts or mature tissues, so far, only human stem/precursor/progenitor cells derived from embryo-originated pluripotent hESCs have shown such cellular pharmacologic utility and capacity adequate for CNS and myocardium regeneration in pharmaceutical development of stem cell therapy for the damaged CNS and heart.

Due to the prevalence of the CNS and heart diseases worldwide, there is intense interest in developing hESC-based therapies. However, pluripotent hESCs themselves are unspecialized non-functional cells that cannot be used directly for therapeutic applications. It has been recognized that pluripotent hESCs must be turned into fate-

restricted specialized functional cells, a process known as differentiation, before use for cell therapy. All other existing or conventional hESC differentiation methods require uncontrollable and unpredictable simultaneous multi-lineage differentiation of pluripotent cells, which yield embryoid bodies or aggregates consisting of a mixed population of cell types of three embryonic germ layers, among which only a very small fraction of cells display targeted differentiation. Those existing or conventional hESC differentiation methods require laborious, costly, and time-consuming purification or isolation procedures to generate only a small quantity of desired cells, impractical for commercial and clinical applications. Growing scientific evidences indicate that those existing or conventional methods result in inefficient, instable, and incomplete hESC differentiation, and poor performance and high tumor risk of such cell derivatives and tissue-engineering constructs following transplantation. Under conventional protocols presently employed in the field, hESC-derived cellular products consist of a heterogeneous population of mixed cell types, including fully differentiated cells, high levels of various degrees of partially differentiated or uncommitted cells, and low levels of undifferentiated hESCs, posing a constant safety concern when administered to humans. In addition, undefined foreign or animal biological supplements and/or feeder cells that have typically been used for the isolation, expansion, and differentiation of hESCs make such cell derivatives unsuitable for clinical applications or human trials. Developing novel strategies to channel the wide differentiation potential of pluripotent hESCs exclusively and predictably to a neural or cardiac phenotype in a lineage-specific manner is not only vital to harnessing the power of hESC biology for neural or cardiac repair, but also crucial for unveiling the molecular and cellular cues that direct human CNS or heart formation in embryogenesis.

The Competitive Advantages of Our Novel PluriXcel Human Stem Cell Technology Platforms

Our novel **PluriXcel** human stem cell technology platforms include our **PluriXcel-DCS** technology and our **PluriXcel-SMI** technology. Our **PluriXcel** technology platforms enable large scale production or manufacture of high quality clinical-grade human neuronal and heart muscle cell therapy products as cellular medicines that can offer pharmacologic utility and capacity adequate for CNS and heart regeneration.

(a) **PluriXcel-DCS** technology: **D**efined **C**ulture **S**ystems for derivation and maintenance of clinical-grade high quality **PLURI**potent **HESC** lines. Our **PluriXcel-DSC** technology allows all poorly-characterized and unspecified biological components and substrates in the culture system, including those derived from animals, to be removed, substituted, and optimized with defined human alternatives for *de novo* derivation and long-term maintenance of cGMP-quality xeno-free stable hESC lines and their human cell therapy derivatives, which have never been contaminated with animal cells and proteins, thus suitable for therapeutic development and clinical applications.

(b) **PluriXcel-SMI** technology: Lineage-specific differentiation of **PLURI**potent **HESCs** by **S**mall **M**olecule **I**nduction. Our **PluriXcel-SMI** technology enables high efficient neural or cardiac lineage-specific differentiation direct from the pluripotent stage of hESCs using small molecule induction, which is a major milestone towards clinical application of hESC cell therapy derivatives, offering the benefits in efficiency, stability,

safety, efficacy, and large-scale production of high quality clinical-grade human stem cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Our **PluriXcel-SMI** technology platforms include our **PluriXcel-SMI-Neuron** technology and our **PluriXcel-SMI-Heart** technology.

(i) **PluriXcel-SMI-Neuron** technology: Well-controlled efficient **NEURON**al lineage-specific differentiation of **PLURI**potent **HESCs** directly and exclusively into cells of a neuronal lineage by **S**mall **M**olecule **I**nduction. Our **PluriXcel-SMI-Neuron** technology enables high efficient direct conversion of pluripotent hESCs into a large scale of high quality neuronal progenitors and functional neuronal cells adequate for clinical development of safe and effective stem cell therapies for a wide range of neurological disorders.

(ii) **PluriXcel-SMI-Heart** technology: Well-controlled efficient **HEART**/cardiac lineage-specific differentiation of **PLURI**potent **HESCs** directly and exclusively to a cardiomyocyte fate by **S**mall **M**olecule **I**nduction. Our **PluriXcel-SMI-Heart** technology enables high efficient direct conversion of pluripotent hESCs into a large scale of high quality heart precursors and functional cardiomyocytes (heart muscle cells) adequate for clinical development of safe and effective stem cell therapies for heart disease and failure.

The Xcel Prototypes of Proprietary Clinical-Grade Human Stem Cell Therapy Products

Our **Xcel prototypes**, generated from hESCs using our novel PluriXcel technology, currently include **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells). We believe that our **Xcel prototypes** represent the next generation of human cell therapy products, offering purity, large-scale production, high quality, safety, and effectiveness for commercial and therapeutic uses over all other existing cell sources.

Therapeutic Products	Product Description	Clinical Applications
Xcel-hNuP	Clinical-grade high purity human neuronal progenitor cells	Cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, motor neuron diseases, neurodegenerative diseases, stroke, brain and spinal cord injuries.
Xcel-hNu	Clinical-grade high purity human neurons	
Xcel-hCardP	Clinical-grade high purity human heart precursor cells	Cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.
Xcel-hCM	Clinical-grade high purity human cardiomyocytes (heart muscle cells)	

Xcel-hNuP (**H**uman **N**e**U**ronal **P**rogenitors): Clinical-grade high purity human neuronal progenitor cells for CNS neuron regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, motor neuron diseases, neurodegenerative diseases, stroke, brain and spinal cord injuries.

Xcel-hNu (**H**uman **N**e**U**rons): Clinical-grade high purity human neurons for CNS neuron regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, motor neuron disease, neurodegenerative diseases, stroke, brain and spinal cord injuries.

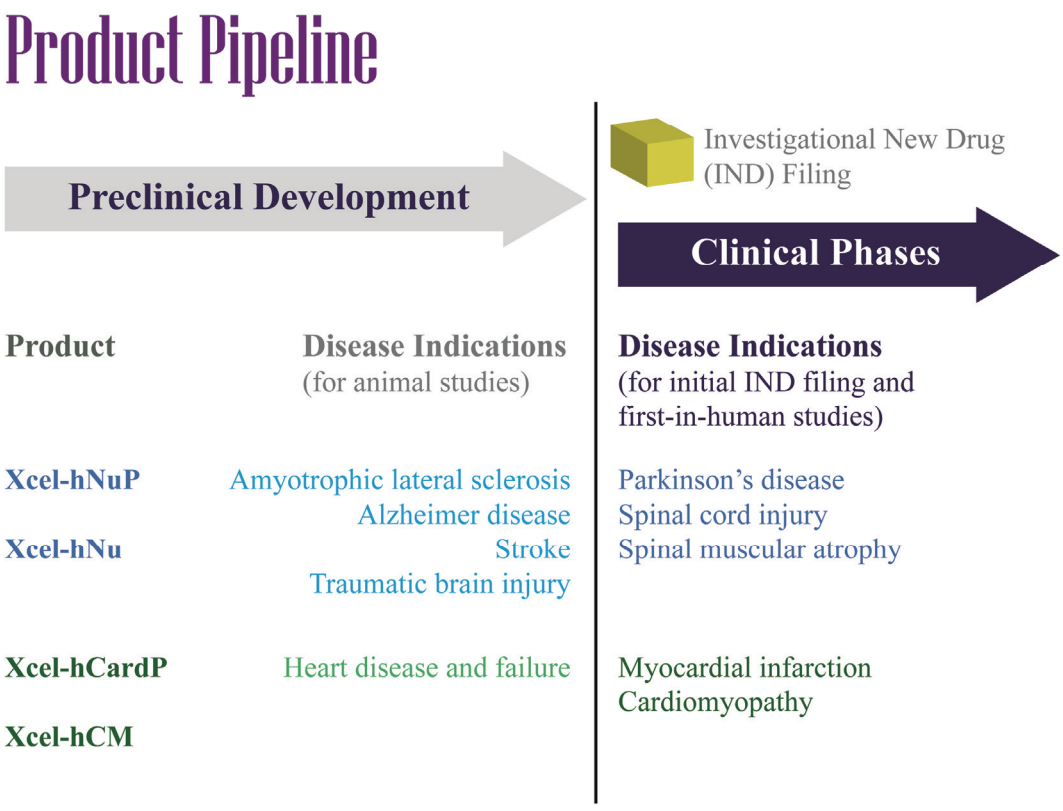
Xcel-hCardP (**H**uman **CARD**iac **P**recursors): Clinical-grade high purity human cardiac (heart) precursor cells for contractile heart muscle regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.

Xcel-hCM (Human **C**ardio**M**yocytes): Clinical-grade high purity human cardiomyocytes (heart muscle cells) for contractile heart muscle regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.

PluriXcel novel human stem cell technology platforms enable large scale production or manufacture of high quality clinical-grade human neuronal and heart muscle cell therapy products as cellular medicines that can offer pharmacologic utility and capacity adequate for CNS and heart regeneration. Currently, our human neuronal and cardiomyocyte cell therapy derivatives or products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), are the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate the CNS neurons and contractile heart muscles, vital for CNS and heart repair for a wide range of neurological and cardiovascular diseases in the clinical setting. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities.

Product Pipeline for Our Lead Clinical-Grade Human Stem Cell Therapy Products from Our PluriXcel Platforms

We were recently incorporated in May 2013 as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. Through acquisition of proprietary human stem cell assets by issuing company stocks, the Company has invested substantially all of our efforts and financial resources in developing our novel human stem cell technology PluriXcel platforms, conducting preclinical studies of our human stem cell therapy products, and pursuing the protection of our intellectual properties on our proprietary human stem cell technologies and cell therapy products in the US and the world (US and PCT international patent filing). We are currently moving towards clinical development stage or first-in-human studies of our stem cell therapy product candidates.



As of the date of this prospectus, we have not raised sufficient funds to support filing an investigational new drug (IND) application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including investigational new drug (IND) filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline) for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Traditional pharmaceutical research & development (R&D) in existing markets usually starts with drug leads discovered in animals or other lower organisms, thus require lengthy and costly both demonstration in animal model testing and establishment of proof-of-concept and safety in human trials. Pluripotent hESCs are derived from the pluripotent inner cell mass or epiblast of the human blastocyst or embryos and, thus, have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. Therefore, unlike traditional pharmaceutical R&D, our novel cellular therapeutic products have been developed directly with human cells or hESCs with proof-of-concept already established in humans, which simplifies the development process and lower the costs for R&D, shortens the time consumption for R&D, and increases the probability of clinical success dramatically. Xcelthera breakthrough human stem cell technologies (PluriXcel Technology), including defined culture systems for *de novo* derivation and long-term maintenance of clinical-grade stable pluripotent hESC lines (PluriXcel-DSC technology) and lineage-specific differentiation of pluripotent hESCs by small molecule induction (PluriXcel-SMI technology), enable clinical applications of hESC therapeutic utility. Our therapeutic products have been developed specifically to address and overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies, including offering the benefits in high efficiency, stability, low tumor risk, high purity, high efficacy in repair, as well as safety and large-scale production or manufacturing over all other existing approaches.

Technology Innovation Award Presented by Frost and Sullivan

Xcelthera, Inc. is the recipient of the prestigious 2013 North American Technology Innovation Award in Stem Cell Technologies presented by Frost & Sullivan. This prestigious recognition by Frost & Sullivan is based on an extensive and independent competitive analysis of the North American Stem Cell Technologies Market and the findings of Best Practices research by Frost & Sullivan competitive analysis.

The Designation of Human Stem Cell therapy Products for Human Trials or First-in-Human Studies

For successful pharmaceutical development of stem cell therapy, the human stem cell therapy product must meet certain commercial criteria in plasticity, specificity, and stability before entry into clinical trials. Moving stem cell research from current studies in animals into human trials must address such practical issues for commercial and therapeutic uses: 1) such human stem cells and/or their cell therapy derivatives/products must be able to be manufactured in a commercial scale; 2) such human stem cells and their cell therapy derivatives/products must be able to retain their normality or stability for a long term; and 3) such human stem cells and/or their cell therapy derivatives/products must be able to differentiate or generate a sufficient number of the specific cell type or types in need of repair or regeneration. Those practical issues are essential for designating any human stem cells as human stem cell therapy products for investigational new drug (IND)-filing and entry into human trials. Our human stem cell therapy products have been developed specifically to address and overcome those major obstacles or issues in clinical applications of hESC therapeutic utility, including the benefits in high efficiency, stability, low tumor risk, high purity, high efficacy in repair, as well as safety and large-scale production of high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Therefore, Xcelthera hESC CNS and heart cell therapy derivatives, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), meet the designation of human stem cell therapy products for commercial development and human trials or first-in-human studies.

Compared to conventional compound drugs of molecular entity, cell therapy products or cellular medicine have very different benchmarks or indicators regarding to safety and efficacy in clinical trials. The safety of a human stem cell therapy product is evaluated by whether it can retain a stable phenotype and karyotype for a long period of time and whether there is no tumor or inappropriate cell type formation following transplantation. The efficacy of a human stem cell therapy product is measured by its pharmacologic activity or cellular ability to regenerate the tissue or organ that has been damaged or lost. Therefore, the pharmacologic utility of human stem cells cannot be satisfied only by their chaperone activity, if any, to produce trophic or protective molecules to rescue existing endogenous host cells that can simply be achieved by a drug of molecular entity, if any.

Our breakthrough human stem cell technologies (PluriXcel Technology), including defined culture systems for *de novo* derivation and long-term maintenance of clinical-grade stable pluripotent hESC lines (PluriXcel-DSC technology) and lineage-specific differentiation of pluripotent hESCs by small molecule induction (PluriXcel-SMI technology), have overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies. Medical innovations in Our PluriXcel Technology enable high efficient direct conversion of non-functional pluripotent hESCs into a commercial scale of clinical-grade high quality functional human neuronal or heart muscle cell therapy derivatives, which is a major milestone towards human trials of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of clinical-grade high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Currently, our hESC neuronal and cardiomyocyte cell therapy derivatives are the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate CNS neurons and contractile heart muscles, vital for CNS and heart repair in the clinical setting. Our breakthrough human stem cell technologies transform non-functional pluripotent hESCs into a large supply of high quality fate-restricted functional human cell therapy derivatives or products, which dramatically increases the clinical efficacy of graft-dependent repair and safety of hESC-derived cellular products, and marks a turning point in cell-based regenerative medicine from current studies in animals towards human trials or first-in-human studies.

FDASIA and FDA Expedited Development Programs

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law, which gave the Food and Drug Administration (FDA) a new and powerful expedited drug development tool, known as the breakthrough therapy designation. This new designation helps FDA assist drug developers to expedite the development and review of new drugs with preliminary clinical evidence that indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases. In addition, the FDA has established a Fast Track program that is intended to facilitate the development and expedite the review of new drugs and biological products that are intended to treat a serious or life-threatening condition or disease and demonstrate the potential to address unmet medical needs for the condition. Xcelthera novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)** are targeting many of those serious or life-threatening diseases or conditions, including heart disease and failure, stroke, Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, brain and spinal cord injuries. So far, those major health problems or incurable life-threatening diseases have relied on breakthrough developments in our stem cell research, particularly our hESC research, to drive the advance of medicine to provide future regeneration and reconstruction treatment options or cures for tissue and function restoration.

Thus far, testing potential therapeutic strategies have largely relied on animal models for behavior, safety, and efficacy evaluation of therapeutic candidates and human cell therapy products. The goal of animal studies is to provide sufficient

evidences of proof-of-concept for prospect of benefit and safety to justify the proposed clinical investigation of a new drug. Large animal models are not always necessary for FDA approval and review of an investigational new drug. Because of interspecies differences, conventional preclinical studies using animal models are often poor predictors of human efficacy and safety. Animal models are xeno-hosts for transplantation of human cells, not ideal for testing the safety and efficacy of therapeutic outcomes of human stem cells. Large primate models are very costly and often taken years to obtain results. In addition, the results of animal studies can be highly variable and difficult to reproduce, making them unreliable as benchmarks for decisions on human trials. Preclinical data using animal models, even results of large animal models, do not necessarily provide the benchmarks or indictors for safety and efficacy in human trials. Those FDA expedited programs do not specifically require evidences from animal models or animal proof-of-concept data to support FDA accelerated approval and priority review, which may help fast-track the development and review of our human stem cell therapy products that have the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to our marketed human stem cell therapy products.

In addition, FDA regulations allow companies to establish expanded access program for the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational drugs for treatment purposes on a case-by-case basis for an individual patient, or for intermediate-size groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial. They also permit expanded access for large groups of patients who do not have other treatment options available, once more is known about the safety and potential effectiveness of a drug from ongoing or completed clinical trials.

We are currently moving towards clinical development stage of our products. As of the date of this prospectus, we have not raised sufficient funds to support filing an IND application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities. As of the date

of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully under the caption Risk factors and include, but are not limited to, the following:

Ethical, social and legal concerns surrounding human embryonic stem cell (hESC) research may lead to volatility in our stock price and adversely affect market acceptance and revenue of our technologies and products related to hESCs.

Our future success is dependent upon our ability to commercialize our technologies and products for research and therapeutic uses. If we fail to file an investigational new drug (IND) application with the FDA, advance to first-in-human studies or clinical trials in humans, complete clinical trials, obtain regulatory approval, or successfully commercialize our cell therapy products from our human stem cell technology platforms, our business would be significantly harmed.

Because our platforms and products are based on novel technologies, it is difficult to predict the time and cost of development and commercialization.

We have a limited operating history. Although we have not incurred any deficit since inception, we expect to incur losses for the foreseeable future due to the regular drug development costs of our planned principal operations associated with clinical development of our licensed products and may never achieve or maintain profitability.

We will need substantial additional funds in the future in order to advance or complete clinical development of our products for one or more disease indications. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We are in early stage of our clinical development efforts. Although we are moving towards clinical development stage of our products, we have not yet filed an investigational new drug application with the FDA. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. If we are unable to successfully develop and commercialize our products or experience significant delays in doing so, our business will be materially harmed.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our products or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired.

Our business is subject to complex and evolving laws and regulations. Any failure to comply with these laws and regulations could have a material adverse effect on our business and financial condition.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and we may be involved in lawsuits to protect or enforce our patent and proprietary rights or to defend against intellectual property infringement claims.

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we will take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

We will follow the smaller reporting company requirements for disclosure and audited financial statement;

We will avail ourselves of the exemption from the requirement to obtain audit or attestation of internal control over financial reporting under the Sarbanes-Oxley Act 404(b);

Reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and

Exemptions from the requirements of holding a nonbinding advisory vote on executive compensation or golden parachute arrangements.

We will take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC.

Corporate Information

We were recently incorporated in May 2013 as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute

that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. San Diego Regenerative Medicine Institute, an nonprofit 501C3 tax exempt status independent biomedical research institute incorporated in California, was founded in 2010 by the same founder of Xcelthera, INC, in part, with supports by government grants to the founder, to facilitate the transition of human stem cell research towards stem cell therapy to provide the next generation of cell-based therapeutic solutions for unmet medical challenges. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. The founder and CEO of the Company is also the founder of San Diego Regenerative Medicine Institute and the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. The Company has acquired proprietary human stem cell assets and we are currently in early stage of our clinical development efforts. Although we have not incurred any deficits, debts, or negative cash flows since recent incorporation, the Company has no revenues and minimal tangible assets, and we have not raised sufficient funds so far to support filing an investigational new drug (IND) application with the FDA for our licensed cell therapy products to enter into clinical development stage. Our website address is *www.xcelthera.com.* Our principal executive offices will be located in San Diego, CA, following completion of this offer, and our telephone number is (888) 706-5396. The information contained in, or accessible through, our website does not constitute a part of this prospectus.

The Offering

Common stock offered by us	2,000,000 shares
Common stock to be outstanding immediately after this offering	5,500,000 shares
Use of proceeds	We intend to use the net proceeds from this offering for funding our operations as follows: approximately $10 million for business real state, facility, equipment, and intellectual property protection; approximately $15 million for activities associated with clinical development of our products, including investigational new drug (IND) filing, regulatory approval, clinical trial, and cGMP banking and production of our clinical-grade

	human stem cell therapy products; approximately $5 million for preclinical research, development, and expansion of our stem cell lines for banking and commercialization; and the remaining proceeds for working capital and other general corporate purposes.
Risk factors	See Risk Factors beginning on page 18 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed NASDAQ Global Market symbol	XCLR

The number of shares of our common stock to be outstanding after this offering is based on 3,500,000 shares of restricted stock awarded subject to the exercise of outstanding options in May 2013, including all preferred shares automatic convertible into common stock immediately prior to the closing of this offering, and excludes:

2,500,000 shares of our common stock awarded upon exercise of outstanding stock options in September 2013 to our affiliates, which will be deemed as

restricted and control securities subject to holding period and volume limitation requirements under Rule 144 of the Securities Act;

200,000 shares of our Series A preferred stock awarded upon exercise of outstanding stock options in September 2013 to our affiliates, which will be deemed as restricted and control securities subject to holding period and volume limitation requirements under Rule 144 of the Securities Act.

Unless otherwise indicated, this prospectus reflects and assumes the following:

the automatic conversion of all outstanding shares of our preferred stock into 3,000,000 shares of our common stock, which will occur immediately prior to the closing of this offering;

no exercise of outstanding options after October 31, 2013.

Risk Factors

Investing in our common stock involves a number of risks of which you should be aware before making an investment decision. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, before deciding whether to purchase shares of our common stock. If any of the following risks is realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment. These risks include, but are not limited to, the following:

Risks Related to Our Business and Strategy

Ethical, social and legal concerns surrounding human embryonic stem cell (hESC) research may lead to volatility in our stock price and adversely affect market acceptance and revenue of our technologies and products related to hESCs.

The human embryonic stem cells (hESCs) are derived from *in vitro* fertilization (IVF) leftover embryos, which has raised controversy and concerns in ethical, social and legal issues, and which has been opposed by the opponents of hESC research. The controversy and politics surrounding hESC research may lead to volatility in our stock price and adversely affect market acceptance and revenue of our technology and products related to hESCs. Demands for our technology and products could be reduced by legal, social and ethical concerns surrounding hESC research. Opponents of hESC research could boycott our technology and products. Governmental authorities could call for limits on or impose regulations on the use or the manufacture of certain biological materials or cellular products related to hESCs. Such concerns or governmental restrictions could limit the use of our products, which could have a material adverse effect on our business, revenue, financial conditions, and results of operations.

Our future success is dependent upon our ability to commercialize our technologies and products for research and therapeutic uses. If we fail to file an investigational new drug (IND) application with the FDA, advance to first-in-human studies or clinical trials in humans, complete clinical trials, obtain regulatory approval, or successfully commercialize our cell therapy products from our human stem cell technology platforms, our business would be significantly harmed.

Our future success depends, in part, on our ability to develop and market hESC-related cellular therapeutic products as treatments or cures for CNS and heart disorders. We are currently moving towards clinical development stage of our products. As of the date of this prospectus, we have not raised sufficient funds to support filing an investigational new drug (IND) application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. We have published and intend to publish the results of our preclinical and clinical studies of our hESC cell therapy products in cardiac and neural repair in

scientific journals. Due in part to the novelty and complexity of our cellular products, it may take a long time, and require significant resources, regulations, and special expertise for our technology and products to achieve market acceptance, meet milestones, advance through clinical trials, obtain regulatory approval, and launch into the commercial markets. All of our products are still in early stage of our clinical development efforts, and we cannot assure you that our clinical trials will ultimately be successful. Clinical drug or cellular product development involves a lengthy and expensive process, with an uncertain outcome, and the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more clinical trials may occur at any stage. We have not completed clinical development for any of our products and will only obtain regulatory approval to commercialize a product if we can demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities in well-designed and conducted clinical trials that the product candidate is safe, pure and potent, or effective, and otherwise meets the appropriate standards required for approval for a particular indication.

Because our platforms and products are based on novel technologies, it is difficult to predict the time and cost of development and commercialization.

The clinical applications of hESC derivatives as novel stem cell therapy products for neural and cardiac repair are new therapeutic market opportunities, which may take several years to develop or mature, and we cannot be certain that these market opportunities will develop as quickly as we expect. There are currently no approved hESC products. Our success in these markets may depend to a large extent on our ability to successfully demonstrate the safety and efficacy of our cellular products to meet the demand for a treatment option or cure for one or more disease indications.

We believe that our hESC research and development dramatically increases the overall turnover of investments in biomedical sciences to optimal treatment options for a wide range of human diseases. Our therapeutic products have been developed specifically to address and overcome some major obstacles in clinical applications of hESC therapeutic utility, including offering the benefits in high efficiency, stability, low tumor risk, high purity, high efficacy in repair, as well as safety and large-scale production over all other existing approaches. However, because our human stem cell technology platforms and cellular therapeutic products are based on novel technologies, it is difficult to predict the time and cost of development and our ability to successfully complete clinical development of these products and obtain the necessary regulatory approvals for commercialization. The average cost of bringing a new compound drug of molecular entity to market for a major pharmaceutical company is approximately $1.3 billion, if not adjusting that estimate for current failure rate. We expect that research and development for our novel hESC therapy products or drugs of cellular entity will have significantly higher success rate in clinical trials than traditional pharmaceutical R&D. Even so, due to the novelty and complexity of our cellular therapeutic products that may require lengthy and complex regulatory compliance, we cannot assure you that the costs will be significantly less. It may turn out to be more costly and time consuming than we expect to obtain FDA approval for our cellular therapeutic products, including substantial

additional R&D, scientific and clinical data, and facility and regulatory compliance, or our products may fail in one or more clinical trials before ultimately succeed.

Risks Related to Our Financial Position

We have a limited operating history. Although we have not incurred any deficit since inception, we expect to incur losses for the foreseeable future due to the regular drug development costs of our planned principal operations associated with clinical development of our licensed products and may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company, formed in May 2013, to commercialize our licensed human stem cell technologies and products with limited operating experience in commercial and therapeutic markets. We lack of a profitable operating history. Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Although we have not incurred any deficit since inception, we anticipate that our business will incur operation and net losses until we successfully implement our commercial and therapeutic development strategy, achieve clinical development milestones and market acceptance, complete clinical trials, gain regulatory approval, launch new therapeutic products to the commercial markets, and generate significant revenues to support our level of operating expenses. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase and revenue could be further delayed if we are required by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our products. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. These net losses will have an adverse effect on our stockholder equity and working capital.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our

product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funds in the future in order to advance or complete clinical development of our products for one or more disease indications. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We are in early stage of our clinical development efforts. Developing biological products or drugs and conducting clinical trials are expensive. The average cost of bringing a new drug to market for traditional pharmaceutical R&D in existing markets is approximately $1.3 billion. The average drug developed by a major pharmaceutical company in existing markets costs at least $4 billion for every drug that is approved, if adjusting that estimate for current failure rate of their drugs. We will require substantial additional capital in order to complete the clinical development of, and to commercialize, one or more of our human stem cell therapy products for one or more disease indications, including research and development, clinical, and regulatory activities necessary to bring our products to market. If the FDA or comparable foreign regulatory authorities require that we perform additional preclinical studies or clinical trials at any point, our expenses would further increase beyond what we currently expect, and the anticipated timing of any future clinical development activities and potential regulatory approvals would likely be delayed. Raising funds in the current economic environment may be difficult and additional funding may not be available on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development activities and operations.

We believe that the net proceeds from this offering will be sufficient to meet our anticipated cash requirements for at least the next 24 months. However, to become and remain profitable, we must succeed in developing and eventually commercializing our products that generate significant revenue. This will require us to be successful in a range of expensive and time-consuming activities that can be challenging, including completing nonclinical testing and clinical trials of our products, obtaining regulatory approval, and manufacturing, marketing and selling any products for which we may obtain regulatory approval, and establishing and managing our operations and collaborations, if any, at various stages of each product development. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and license and collaboration agreements. We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity securities, our shareholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or to our shareholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when required or on acceptable terms, we may

have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or curtail our operations, which will have a material adverse effect on our business, operating results and prospects. Adverse conditions in the global economy and disruption of financial markets may significantly harm our revenue, profitability, results of operations, and ability to raise additional funds. If we do not have, or are not able to obtain, sufficient funds, we may have to delay research and development or clinical trials or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. Any of these factors could harm our operating results.

We need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we hire and increase our product development efforts and advance our products through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative personnel and management systems adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

successfully attract and recruit new employees or consultants with the requisite expertise and experience;

manage our clinical programs effectively;

if we receive regulatory approval for any product candidate, develop a marketing and sales infrastructure; and

improve our operational, financial and management controls, reporting systems and procedures, including those related to being a public company.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

Our technologies and products have been developed, in part, with supports by government grants, which may be reduced, withdrawn, delayed, or eliminated.

Our technologies and products have been developed, in part, with supports by funds under research development programs funded by state and federal governmental agencies. Funding by these governmental agencies may be significantly reduced, withdrawn, delayed, or eliminated in the future for a number of reasons, such as budget cuts, changes in fiscal year appropriation, changes in funding direction and policy, changes in funding priority or allocation, government shutdown, perceived or real conflicts of interest, and ethical or legal issues brought to these governmental funding agencies. A restriction on the government funding available to us would reduce the resources that we would be able to devote to existing and future research and development efforts. Such a reduction or elimination could delay the progress and development of new products and hurt our competitive position.

Risks Related to the Discovery, Development, Regulation, and Commercialization of Our Products

We are in early stage of our clinical development efforts. Although we are moving towards clinical development stage of our products, we have not yet filed an investigational new drug application with the FDA. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. If we are unable to successfully develop and commercialize our products or experience significant delays in doing so, our business will be materially harmed.

We have invested substantially all of our efforts and financial resources in developing our novel human stem cell technology PluriXcel platforms and conducting preclinical studies of our human stem cell therapy products. We are currently in early stage of our clinical development efforts. Although we are moving towards clinical development stage of our products, all of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. We have not yet filed an investigational new drug (IND) for any of our products candidates. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products for major neurological and heart disease indications, including IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing Current Good Manufacturing Practices (cGMP) manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidates, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline) for which we will make our initial IND filing and enter clinical development stage first.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our products. The success of our products will depend on several factors, including the following:

- completion of nonclinical studies and clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our products;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;

launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;

successfully entering into and maintaining collaborations throughout the development process to commercialization as appropriate;

acceptance of the products, if and when approved, by patients, the medical community and third-party payers;

effectively competing with other therapies, if any;

obtaining and maintaining coverage and adequate reimbursement by third-party payers, including government payers, for our products;

maintaining a continued acceptable safety profile of the products following approval; and

maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our products, which would materially harm our business.

Clinical drug or cellular product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our products.

Before obtaining marketing approval from regulatory authorities for the sale of any of our products, we must use our preclinical development results to file an IND and then conduct extensive clinical trials to demonstrate the safety and efficacy of our products in humans. It is difficult to predict when or if any of our products will prove effective and safe in humans or will receive regulatory approval. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failed clinical trial can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our products, including:

FDA may require additional preclinical studies, such as lengthy and costly testing in large animal models or primate models, nonclinical laboratory and animal tests according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations, or may not

give regulatory clearances or approvals, or may delay to clean regulatory issues for approval of clinical trials, or may place the clinical trial on a clinical hold;

regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

clinical trials of our products may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

the number of patients required for clinical trials of our products may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

we may have to use third-party contractors, who may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

we may have to suspend or terminate clinical trials of our products for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

the cost of clinical trials of our products may be greater than we anticipate;

the supply or quality of our products or other materials necessary to conduct clinical trials of our products may be insufficient or inadequate;

our products may have serious adverse or unacceptable side effects or other undesirable characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials; and

regulators may revise the requirements for approving our products, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing of our products beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our products or other testing, if there are safety concerns or we observe limited efficacy, we may:

be delayed in obtaining marketing approval for our products;

lose the support of collaborators, requiring us to bear more of the burden of development of certain products;

not obtain marketing approval at all;

obtain marketing approval in some countries and not in others;

obtain approval for indications or patient populations that are not as broad as we intend or desire;

obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

be subject to additional post-marketing testing requirements; or

have the product removed from the market after obtaining marketing approval.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our products or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our products and harming our business and results of operations.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our products or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired.

Our products are subject to regulation by the U.S. Food and Drug Administration (FDA) or other regulatory agencies as biological products or drugs. We have never obtained marketing approval from the FDA or any comparable foreign regulatory authority for any product. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on recruiting regulatory and clinical personnel and/or third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical or nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

Due in part to the novelty and complexity of our cellular products, the process to obtain regulatory approval can be costly, lengthy, and complex, which may require substantial additional R&D, detailed and comprehensive preclinical or nonclinical research and clinical data, and regulatory compliance of our manufacturing operations to the FDA current good manufacturing practices (cGMP) for biological and drug products. Our ability to obtain regulatory approval of our products depends on, among other things, completion of additional preclinical or nonclinical studies and clinical trials, whether our clinical trials demonstrate statistically significant efficacy with safety issues that do not potentially outweigh the therapeutic benefit of the product candidates, and whether the

regulatory agencies agree that the data from our future clinical trials are sufficient to support approval for any of our products. The final results of our clinical trials may not meet the FDA or other regulatory agency requirements to approve a product for marketing, and the regulatory agencies may otherwise determine that our manufacturing processes or facilities are insufficient to support approval. We may need to conduct more clinical trials than we currently anticipate. Failure to obtain regulatory approval in a timely fashion would limit our ability to meet milestones and advance through the clinical trials. Even if we do receive FDA or other regulatory agency approval, we may not be successful in commercializing approved products. If any of these events occurs, our business could be materially harmed and the value of our common stock would likely decline.

Regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. In addition, adverse developments in clinical trials of potential stem cell therapies conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our products. These regulatory authorities and advisory groups and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our products, we will be required to consult with the FDA and other regulatory authorities, and our products will likely be reviewed by the FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

Our business is subject to complex and evolving laws and regulations. Any failure to comply with these laws and regulations could have a material adverse effect on our business and financial condition.

Our business is subject to complex and evolving laws and regulations regarding privacy and informed consent matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, increased cost of operations or otherwise harm our company. These laws and regulations can be costly to comply with and can delay or impede the development of new products, result in negative publicity, increase our operating costs, require significant management time and attention and subject us to claims or other remedies, including fines or demands that we modify or cease existing business practices.

If we obtain FDA approval for any of our products and begin commercializing those products in the United States, our operations may be subject to various federal and state healthcare fraud and abuse laws and health information privacy and security laws, including, without limitation, the federal anti-kickback statute. Any failure to comply with these regulations could have a material adverse effect on our business and financial

condition. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

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

the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may not be able to take advantage of any expedited development or regulatory review and approval processes available to product candidates granted breakthrough therapy or fast track designation by the FDA.

We may seek breakthrough therapy or fast track designation for our products. A

breakthrough therapy program is for a product candidate intended to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. In contrast, a fast track program is for a product candidate that treats a serious or life-threatening condition, and nonclinical or clinical data demonstrate the potential to address an unmet medical need. The FDA has broad discretion whether or not to grant these designations. Even though we believe our products qualify under either or both of the breakthrough therapy and fast track programs, we cannot assure you that the FDA would decide to grant these designations. Even if we do receive breakthrough therapy or fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy or fast track designation if it believes that the product no longer meets the qualifying criteria. In addition, the breakthrough therapy program is a relatively new program. Although we believe that our products are eligible for breakthrough therapy or fast track designations, we cannot be certain whether any of our products will be granted for any expedited development and regulatory review programs. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

We face competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition from major multinational pharmaceutical companies, established and early-stage biotechnology companies, and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and infrastructure, and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements with leading companies and research institutions in our target markets. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel or alternative therapeutics or to in-license novel or alternative therapeutics that could make the products that we develop obsolete or noncompetitive. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA approval or discovering, developing and commercializing treatments in the disease indications that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Although there are currently no approved pharmaceutical products specifically for the disease indications we are targeting, we are aware of several other companies with product candidates in various stages of development. In addition, many universities and private and public research institutes may develop technologies of interest to us, but license them to our competitors. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drugs or products that may be more

effective or less costly than our products that we are currently developing or that we may develop, which could render our products obsolete or noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

the results of our clinical trials;

the efficacy, safety and reliability of our products;

the speed at which we develop our products;

our ability to design and successfully execute appropriate clinical trials;

our ability to develop and protect intellectual property rights related to our products;

our ability to maintain a good relationship with regulatory authorities;

the timing and scope of regulatory approvals;

our ability to commercialize and market any of our products that receive regulatory approval;

market perception and acceptance of stem cell therapeutics;

acceptance of our products by physicians and the medical community;

the price of our products;

adequate levels of reimbursement under private and governmental health insurance plans; and

our ability to manufacture and sell commercial quantities of any approved products to the market.

If our competitors market products that are more effective, safer or less expensive than our future products, or that reach the market sooner than our future products, we may not achieve commercial success.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate any revenues.

We have no experience in selling and marketing any products. We currently do not have the infrastructure to commercialize any of our products if such products receive regulatory approval. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If any of our products are approved for marketing, we intend to build an internal sales and marketing organization to commercialize these products in target markets, where patient and physician communities are concentrated and product adoption is driven by key opinion leaders. However, we may not have adequate financial resources or expertise to build an effective sales and marketing organization.

We may selectively seek to enter into partnerships with other entities to utilize their marketing and distribution capabilities in larger target markets, but we may be unable to enter into these arrangements on favorable terms, if at all. If we are unable to develop adequate marketing capabilities on our own or effectively partner with third parties, we will be unable to generate revenues from our approved products. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

The commercial success of our products will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

Ethical, social and legal concerns about stem cell therapies could result in additional regulations restricting or prohibiting the use of our products. Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients and third-party payers accepting stem cell therapies in general, and our products in particular, as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

their efficacy, safety and other potential advantages compared to alternative treatments or therapies, if any;

target a serious or life-threatening condition or an unmet medical need where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to our marketed human stem cell therapy products;

substantial improvement on a clinically significant endpoint(s) or patient care over available therapies, if any;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the strength of marketing and distribution support;

the availability of third-party insurance coverage and adequate reimbursement;

the prevalence and severity of their side effects;

any restrictions on the use of our products together with other medications; and

publicity concerning our products or competing products and treatments, if any.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payers on the benefits of the products may require significant resources and may not be successful. Any failure to achieve market acceptance for our product candidates will harm our business, results and financial condition.

If we obtain approval to commercialize our products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our products are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

different regulatory requirements for approval of drugs and biologics in foreign countries;

reduced or uncertain protection for our intellectual property rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

economic weakness, including inflation, or political instability in particular foreign economies and markets;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

workforce uncertainty in countries where labor unrest is more common than in the United States;

complexity and difficulty in coordinating the communications and operations of our business; and

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We expect to face significant uncertainty over pricing of products that we may develop. If pricing policies for our products are unfavorable, our commercial success will be impaired.

Due to novelty and complexity of stem cell therapy products we develop, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for our products will be relatively high due to their anticipated use in a one-time, potentially life-saving procedure with curative intent, the biopharmaceutical industry has recently experienced significant

pricing pressures. We may experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general has become very intense. These pricing pressures have imposed significant barriers to the entry of new products. If pricing is set at unsatisfactory levels, our ability to successfully market and sell our products will be adversely affected.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, which may adversely affect our ability to generate profit from the sales of our products.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new products could limit our ability to market any product that we may develop and decrease our ability to generate revenue.

Our ability to commercialize any drug products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. There is currently no approved hESC product, and it is difficult to predict the level of reimbursement, if any, that would be available for any products that we may develop. The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments, such as stem cell transplants. Sales of our products will depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In particular, there is no body of established practices and precedents for reimbursement of hESC products, and it is difficult to predict what the regulatory authority or private payer will decide with respect to reimbursement levels for novel products such as ours. Our products may not qualify for coverage or direct reimbursement and may be subject to limited reimbursement. Stem cell transplant procedures are typically covered by one-time reimbursement, generally available for a limited number of days after transplant. If reimbursement or insurance coverage is not available, or is available only to limited levels, we may not be able to successfully commercialize our products. Even if coverage is provided, the approved reimbursement

amount may not be sufficient to allow us to establish or maintain pricing to generate income.

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our products. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely impact our ability to achieve commercial success.

We face potential product liability and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our products harms patients, or is perceived to harm patients even when such harm is unrelated to our products, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our products in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by participants in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products and any products for which we obtain marketing approval. There is a risk that our products may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for any drugs or products that we may develop;

damage to our reputation and significant negative media attention;

withdrawal of clinical trial participants;

significant costs to defend the related litigation;

substantial monetary awards to trial participants or patients or other claimants;

loss of revenue;

distraction of management attention from our primary business; and

the inability to commercialize any products that we may develop.

We intend to carry product liability insurance sufficient in light of our clinical programs; however, we may not be able to obtain and maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for products, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to

obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us or any third parties could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our products are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our products. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our products receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

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

Risks Related to Our Intellectual Property

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and we may be involved in lawsuits to protect or enforce our patent and proprietary rights or to defend against intellectual property infringement claims.

Our commercial success depends in part on our ability to protect our intellectual property and proprietary technologies. We rely on patent rights, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, license agreements and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Pending patent applications of ours may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or maintain our competitive advantage. Any patents we obtain or may obtain in the future, or the license rights we have, may be subject to re-examination, reissue, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid or unenforceable. In addition, competitors may be able to design alternative methods or products that avoid infringement of these patents or technologies. If the extent of our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against products of our competitors, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

The patent positions of companies in the life sciences industry can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved.

No consistent policy regarding the breadth of claims allowed in life sciences patents has emerged to date in the United States (US). The laws of some non-US countries do not protect intellectual property rights to the same extent as the laws of the US, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical, which could make it difficult for us to prevent the infringement of our patents. Proceedings to enforce our intellectual property rights could result in substantial cost and divert our efforts and attention from other aspects of our business and we may not prevail. Changes in either the patent laws or in interpretations of patent laws in the US or other countries may diminish the value of our intellectual property. Litigation or other proceedings may be necessary for us to enforce our patent and proprietary rights and/or to determine the scope, coverage and validity of proprietary rights of others. The proceedings could be burdensome and expensive, and we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

The patents of broad claims of others on hESCs and their uses or the manufacture of human cells and their uses may have an adverse effect on our business.

We apply for patents or seek licenses covering our products and technologies and uses thereof, as we deem appropriate, however, we may fail to apply for patents or obtain licenses on important products and technologies in a timely fashion or at all.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of proprietary rights of others or to defend against third party claims of intellectual property infringement, which in each case could require us to spend significant time and money and could have adverse effect or impact on our business, revenue, and stock price. Patent infringement suits can be expensive, lengthy and disruptive to business operations. We could incur substantial costs and divert the attention of our management and technical personnel in prosecuting or defending against any claims, and these claims may harm our reputation. There can be no assurance that we will prevail in any suit. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us, including treble damages and attorney fees and costs in the event that we are found to be a willful infringer of third party patents. In the event of a successful claim of infringement against us, we may be required to obtain one or more licenses from third parties, which we may not be able to obtain at a reasonable cost or on otherwise favorable terms, if at all. In addition, we could encounter delays or interruptions in product development or commercialization while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any required licenses on favorable terms could prevent us from commercializing our products, and the risk of a prohibition on the sale or therapeutic uses of any of our products could adversely affect our ability to grow and gain market acceptance for our products.

The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or on otherwise favorable terms. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and cause delays or interruptions in product development and commercialization.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Since our technology and products are based on human embryonic stem cells (hESCs) that are originated from IVF leftover human embryos, certain of our technology and products may not be eligible for patent protection, particularly in certain non-US countries such as European Countries, which leaves us vulnerable to theft of the technology and products we protect under patent and trade secret laws.

Since our technology and products are based on hESCs derived from IVF leftover human embryos, certain of our technology and products may not be eligible for patent protection, particularly in certain non-US countries such as European Countries, which leaves us vulnerable to theft of the technology and products we protect under patent and trade secret laws. For instance, the European Patent Office (EPO) has historically refused to grant hESC patents based on its interpretation of the European Directive on the Legal Protection of Biotechnological Inventions, which holds unpatentable inventions concerning products of human stem cell cultures that can only be obtained by the use, involving their destruction, of human embryos.

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

In addition to seeking patents for our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect such intellectual property and proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, consultants, collaborators, and advisors. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in such cases we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Common Stock and this Offering

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to this offering, there has been no public market for shares of our common stock. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market or how liquid that market might become. If an active trading market does not develop, you may have difficulty selling any of our shares of common stock that you buy or experience substantial losses for purchasers of our common stock in this offering. We or underwriters, if any, will determine the initial public offering price of our common stock. This price will not necessarily reflect the

price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, the trading price of our common stock following this offering may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- success and competitiveness of our products or technologies;
- cost and timing of regulatory clearances or approvals;
- results of clinical trials of our products or those of our competitors or of other stem cell therapies in general;
- changes in laws or regulations applicable to stem cell therapies in general or our products in particular, including but not limited to clinical trial requirements for approvals;
- changes in legislation and government regulation;
- developments or disputes concerning patent applications, issued patents or other intellectual property and proprietary rights;
- recruitment or departure of key personnel;
- level of expenses related to any of our products or clinical development programs;
- announcements by us or our competitors of new commercial or therapeutic products, significant contracts, commercial relationships or capital commitments;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- financial projections we may provide to the public, any changes to those projections or our failure to meet those projections;
- market conditions in the pharmaceutical, biotechnology, and life sciences sectors;
- issuance of new or changed securities analyst reports or recommendations for our stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concerns regarding the ethics, regulation, safety, efficacy or other aspects of our products;
- entering into, changing or terminating collaborative relationships;
- any major change to the composition of our board of directors or management;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

announcements or expectations of additional debt or equity financing efforts;

sales of our common stock by us, our insiders or our other stockholders; and

general economic conditions and slow or negative growth of our markets.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. A certain degree of stock price volatility can be attributed to being a newly public company. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our shareholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

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

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we obtain equity research analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. In addition, opponents of hESC research may give inadequate or negative perception or opinions or comments through media and social media, unrelated to scientific data or evidences, to hESC research and related technology and products, which may result in unfavorable research coverage or no coverage to us. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Purchasers in this offering may experience substantial dilution in the book value of their investment.

Prior to this offering, there has been no public market for shares of our common stock. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market after this

offering, or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. All outstanding shares of common stock sold by us in this initial public offering will be freely tradable in the public market without restriction or further registration under the Securities Act, except that shares of common stock held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the requirements and volume limitations described in Rule 144 under the Securities Act. The remaining shares of common stock outstanding after this offering will be deemed restricted because of securities laws, the registration rights agreement or lock-up agreements. Following the expiration of the lock-up period and holding period requirements, up to an additional 3,500,000 shares of common stock that are subject to the exercise of outstanding options as of filing date of this offer, including all preferred shares convertible into common stock, will become eligible for sale in the public market to the extent permitted by Rules 144 and 701 under the Securities Act. In addition, up to 4,500,000 shares of common stock, including all preferred shares convertible into common stock, held by our affiliates after this offering will be deemed control and restricted stock because of securities laws, which will be subject to holding period requirements and volume limitations under Rule 144 of the Securities Act. Restricted securities as defined under Rule 144 were issued by us in reliance on exemptions from registration requirements of the Securities Act. These shares may be sold in the public market only if registered or pursuant to an exemption from registration, including requirements subject to holding period and/or volume limitation under Rule 144 under the Securities Act.

Our founding members, directors and executive officers will exercise significant control over our company and could limit your ability to influence the outcome of key transactions, including changes of control.

Following the completion of this offering, our founding members, executive officers, directors and their affiliates will beneficially own or control > 75% of the outstanding shares of our common stock. Accordingly, these founding members, executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring shareholder approval, including the election of directors, bylaws, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These shareholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other shareholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investor perception that conflicts of interest may exist or arise.

Anti-takeover provisions in our bylaws could make an acquisition of us, which may be beneficial to our shareholders, more difficult and may prevent attempts by our shareholders to replace or remove our current management and limit the market price of our common stock. Provisions in our amended and restated articles of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated articles of incorporation and bylaws to become effective upon completion of this offering include provisions that:

authorize our board of directors to issue, without further action by the shareholders, up to 7,000,000 shares of undesignated preferred stock and up to 60,000,000 shares of undesignated common stock, which will ensure the founding members and board of directors of the company to control at least 75% of our outstanding common stock or voting power over the Company, to amend our article of incorporation and bylaws, and to approve any election or replacement of members of board of directors;

establish an advance notice procedure for shareholder approvals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our board of directors;

establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;

provide that our directors may be removed only by the affirmative vote of at least seventy-five percent (75%) of the outstanding shares of capital stock of the Corporation entitled to vote at a meeting of shareholders duly called for such purpose;

provide that vacancies on our board of directors may be filled by a majority of directors then in office, even though less than a quorum; and

require approval by 75% of our outstanding common stock to amend our articles of incorporation and approval by a majority of our board of directors or 75% of our outstanding common stock to amend bylaws.

These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management. As a result, offers to acquire us, which may represent a premium over the available market price of our common stock, may be withdrawn or otherwise fail to be realized.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We intend to use the net proceeds from this offering for funding our operations; business property, facility, equipment; preclinical and clinical research and product development activities, including IND filing and clinical trials; pursuing US and international patents or intellectual property protection; and for working capital and other general corporate purposes. We might not be able to yield a significant return, if any, on any investment of these net proceeds. You will not have the opportunity to influence our management decisions on how to use the net proceeds from this offering, and our failure to apply these funds effectively could have a material adverse effect on our business, delay commercial and therapeutic development of our products, and cause the price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and currently intend to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our financial results may vary significantly from quarter-to-quarter and year-to-year, which may lead to volatility in our stock price as research analysts and investors respond to these fluctuations.

Our financial results may vary significantly from quarter-to-quarter and year-to-year due to various factors, including results of clinical trials; achieving regulatory approval; government policy changes and politics regarding hESC research; our ability to achieve milestones, obtain market approval, introduce new products to the markets, and maintain a competitive advantages and market leading position for our products; and unanticipated increases in costs or expenses, which may lead to volatility in our stock price as research analysts and investors respond to these fluctuations. We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

The requirements of being a public company will increase our expenses and our management burden.

As a public company, we will face increased legal, accounting, administrative and other costs and expenses that we have not incurred as a private company, particularly, after we are no longer an emerging growth company. After the consummation of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the Securities and Exchange Commission (SEC), the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act, the Public Company Accounting Oversight Board and the NASDAQ Market, each of which imposes additional reporting and other obligations on public companies. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming and costly. Until we are able to expand our finance and administrative capabilities and establish necessary financial reporting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures or comply with the Sarbanes-Oxley Act or existing or new reporting requirements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

We are an emerging growth company and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of JOBS Act to avail ourselves of reduced disclosure requirements applicable to emerging growth companies. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, anticipate, could, intend, target, project, contemplate, believe, estimate, predict, potential or continue or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We

have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled Risk Factors and Management Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Use of Proceeds

This is the initial public offering of common stock by Xcelthera, Inc. Prior to this offering, there has been no public market for our common stock. We are offering 2,000,000 shares of common stock pursuant to this prospectus. We expect the initial public offering price to be between $16.00 and $20.00 per share.

Initial Public Offering	Per Share	Total Amount of the Offering
Minimal Offering Price	$16	$32,000,000
Maximum Offering Price	$20	$40,000,000

We estimate that our net proceeds from the sale of the shares of common stock that we are offering will be approximately $36,000,000, based on an assumed initial public offering price of $18 per share, which is the midpoint of the price range on the cover of this prospectus. A $1.00 increase (decrease) in the assumed initial public offering price of

$18 per share, which is the midpoint of the range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from our initial public offering by $2,000,000, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The principal purposes of this offering are to raise funds for our business operation, to create a public market for our common stock and to facilitate our future access to the public equity markets. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds of this offering. However, we intend to use the net proceeds from this offering for funding our operations as follows: approximately $10 million for business real state, facility, equipment, and obtaining domestic and international patents and intellectual property protection (e.g., pursuing current and additional US patent applications, PCT international patent applications and entry into national stage); approximately $15 million for activities associated with clinical development of our products, including investigational new drug (IND) filing, regulatory approval, clinical trial, and cGMP banking and production of our clinical-grade human stem cell therapy products; approximately $5 million for preclinical research, development, and expansion of our stem cell lines for banking and commercialization; and the remaining proceeds for working capital and other general corporate purposes. As to the date of this prospectus, we cannot specify with certainty the costs for obtaining intellectual property protection or the amount of the net proceeds that will be allocated for obtaining domestic and international intellectual property protection.

We are currently in early stage of our clinical development efforts. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including investigational new drug (IND) filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and Phase I and/or Phase II clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline) for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Pending the uses described above, we intend to invest the net proceeds from this offering in short-term investments or hold them as cash. We cannot predict whether the proceeds invested will yield a favorable return. Our management will have broad discretion in the use of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

Dividend Policy

We have never declared or paid and do not anticipate declaring or paying any cash dividends on our common stock in the near future. We currently intend to retain all available funds and future earnings, if any, to finance the operation and expansion of our business. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable law, and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of October 31, 2013, as follows:

on an actual basis;

on a pro forma basis to reflect (1) the total automatic conversion of all outstanding shares of our preferred stock into 5,000,000 shares of common stock immediately prior to the closing of this offering, and (2) the filing of our amended and restated articles of incorporation prior to the closing of this offering; and

on a pro forma as adjusted basis to give further effect to our issuance and sale of 2,000,000 shares of common stock in this offering at an assumed initial public offering price of $18.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the following table together with Management Discussion and Analysis of Financial Condition and Results of Operations, Description of Capital Stock, and other financial information contained in this prospectus.

	As of October 31, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands)		
Cash and cash equivalents	$ 7	$ 7	$ 36,007
Long-term debt	$ –	$ –	$ –
Convertible preferred stock, par value $0.001 per share; 3,000,000 shares authorized, 500,000 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	6	–	–
Common stock, par value $0.0001 per share; 10,000,000 shares authorized, 3,000,000 shares issued and outstanding, actual; 42,000,000 shares authorized, pro forma and pro forma as adjusted; 8,000,000 shares issued and outstanding, pro forma; 10,000,000 shares issued and outstanding, pro forma as adjusted	–	7	36,007
Additional paid in capital	–	–	–
Accumulated deficit	(–)	(–)	(–)
Total stockholder equity	$ 6	7	36,007
Total capitalization	$ 6	7	36,007

Each $1.00 increase (decrease) in the assumed initial public offering price of $18.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholder equity and total capitalization by approximately $2 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of $18.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholder equity and total capitalization by approximately $18.0 million. The above discussion and table are based on estimates prior to deducting the underwriting discounts and commissions, if any, and the offering expenses payable by us.

Dilution

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

We were incorporated as a general stock company under the laws of the state of California in May 2013 to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. In May 2013, we have issued 800,000 shares of our restricted common stock, at a par value of $0.0001 per share, and 300,000 shares of series A preferred convertible stock, at a par value of $0.001 per share, as investment in research and development, to San Diego Regenerative Medicine Institute under an exclusive license agreement to obtain the exclusive rights for commercialization of the human stem cell technology platforms (PluriXcel Technology) and functional human neural and cardiac stem cell therapy products (Xcel) from PluriXcel platforms, with a term of 10 years. Of these options, 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock, total of an aggregate of 2,500,000 shares of common stock, have been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer. Since incorporation in California early this year, we have funded our operations primarily through the issuance and internal private placement of our preferred stock to founding members to avoid giving up a substantial portion of our control rights for the company. As a result, no substantial private funds or net tangible assets have been raised as of October 31, 2013. However, so far, we have not incurred any deficits, debts, or negative cash flows since incorporation in May 2013.

Dilution in the net tangible book value per share represents the difference between the amount per share paid by buyers of shares of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately following this offering. After giving effect to the receipt of the net proceeds from our sale of shares of common stock in this offering at an assumed initial public offering price of $18 per share, which is the midpoint of the range set forth on the cover page of this prospectus, our pro forma as adjusted net tangible book value as of October 31, 2013 would have been approximately $36 million, or approximately $3.6 per share. This amount represents an immediate increase in pro forma net tangible book value of $3.6 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $14.4 per share to new investors purchasing shares of common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock. The following table illustrates this dilution:

Assumed initial public offering price per share		$18.00
Historical net tangible book value (deficit) per share as of October 31, 2013	$ (–)	
Pro forma net tangible book value per share as of October 31, 2013	–	
Increase per share attributable to this offering	3.6	
Pro forma as adjusted net tangible book value per share after this offering		3.6
Dilution per share to new investors in this offering		$ 14.4

Each $1.00 increase (decrease) in the assumed initial public offering price of $18.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately $0.2, and decrease (increase) the dilution in pro forma as adjusted net tangible book value per share to new investors by approximately $0.2, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Each increase of 1.0 million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by approximately $1.6 per share and decrease the dilution to new investors by approximately $1.6 per share, assuming that the assumed initial public offering price remains the same. Each decrease of 1.0 million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value per share after this offering by approximately $2 per share and increase the dilution to new investors by approximately $2 per share, assuming that the assumed initial public offering price remains the same. The above discussion and table are based on estimates prior to deducting the underwriting discounts and commissions, if any, and the offering expenses payable by us.

Selected Financial Data

The following selected financial information should be read together with our audited financial statements and accompanying notes and information under the caption Management Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year.

The summary statements of operation data for the period of six months from May 9, 2013 (inception) through October 31, 2013 and the summary balance sheet data as of October 31, 2013 are derived from our audited financial statements or interim financial statements appearing elsewhere in this prospectus. The financial statements and information after October 31, 2013 are unaudited, which, together with related notes, are included elsewhere in this prospectus. These audited financial statements for the short period that the registrant has been in existence have been prepared in accordance with GAAP (generally accepted accounting principles) and reflect all adjustments necessary for the fair presentation of the Company financial position as of October 31, 2013 and its results of operations for the six months ended October 31, 2013 and the period from May 9, 2013 (inception) to October 31, 2013. In the opinion of management, the unaudited financial statements and information after October 31, 2013 have been prepared on a basis consistent with our audited financial statements included in this prospectus. The results for the six months ended October 31, 2013 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Statements of Operations

		Period (six months) from May 9, 2013 (inception) to October 31, 2013
Revenue	$	6,700
Operating Expenses:		
Research and Development		0
General and Administrative		0
Total Operating Expenses		0
Patent and Organization Costs		(6,700)
Net Loss		(0)
Net Loss Attributable to Common Stock Holders		(0)
Net Loss Per Share Attributable to Common Stock Holders:		
Basic and Diluted	$	(0)
Weighted Average Common Shares Outstanding:		
Basic and Diluted		3,000,000
Pro Forma Net Loss Per Share Attributable to Common Stock Holders:		
Basic and Diluted		(0)
Pro Forma Weighted Average Common Shares Outstanding:		
Basic and Diluted		8,000,000

Balance Sheets Data

	Period (six months) from May 9, 2013 (inception) to October 31, 2013
Assets	
Current Assets:	
Cash and Cash Equivalents	$ 0
Other Current Assets	0
Total Current Assets	0
Property and Equipment	–
Other Assets	
Patent and Organization Costs	6,700
Total Other Assets	6,700
Total Assets	6,700
Liabilities and Shareholder Equity	
Current Liabilities:	
Accounts Receivable	$ 0
Other Current Liabilities	0
Total Current Liabilities	0
Loans	0
Total Long-Term Liabilities	0
Total Liabilities	0
Convertible Preferred Stock, $0.001 par value; authorized shares – 3,000,000 in May 2013; issued and outstanding shares – 300,000 in May 2013 and 200,000 in September 2013; no shares issued and outstanding, pro forma	6,400
Shareholder Equity (Deficit):	
Common Stock, $0.0001 par value; authorized shares – 10,000,000 in May 2013; issued and outstanding shares – 500,000 in May 2013 and 2,500,000 in September 2013; 8,000,000 shares issued and outstanding, pro forma	300
Additional Paid-In Capital	0
Deficit Accumulated	(0)
Total Shareholder Equity	$ 6,700
Total	$ 6,700

Management Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our audited financial statements and related notes thereto included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the Risk Factors section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

We are a biopharmaceutical company moving towards clinical development stage of novel and most advanced stem cell therapy for a wide range of neurological and cardiovascular diseases, with leading technology and medical innovation in human CNS and heart regeneration from pluripotent human embryonic stem cells (hESCs). We have patent and proprietary rights for our novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)**, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), derived from pluripotent hESCs by small molecule induction, which provide significant competitive advantages for the growth of our business and for the dominance over our target markets. Pluripotent hESCs have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for unrestricted differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. Of particular interest to the medical needs is the potential for use of hESC derivatives to heal tissues with naturally limited capacity for renewal, such as the human heart and brain. The Company is the first to hold the breakthrough technology for large-scale production of high quality clinical-grade hESC lines and their functional human neuronal and heart cell therapy derivatives for commercial and therapeutic uses. We plan to enter clinical-stage development or first-in-human studies in cardiac and neural repair for our licensed human stem cell therapy products following completion of this offer. Our strategy is to use cutting-edge human stem cell technology to develop clinical-grade functional neural and cardiac cell therapy products from pluripotent hESCs as cellular medicine or cellular drugs to provide the next generation of cell-based therapeutic solutions for unmet medical needs in world-wide major health problems.

We were recently incorporated in May 2013 as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the

public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. To acquire human stem cell assets from San Diego Regenerative Medicine Institute for our clinical development efforts, in May 2013, we have issued 800,000 shares of our restricted common stock, at a par value of $0.0001 per share, and 300,000 shares of our series A preferred convertible stock, at a par value of $0.001 per share, as research and development expenses, to San Diego Regenerative Medicine Institute under an exclusive license agreement for commercializing the human stem cell technology platforms (PluriXcel Technology) and clinical-grade functional human neural and cardiac stem cell therapy products (Xcel) from PluriXcel platforms, with a term of 10 years. Of these options, 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock, total of an aggregate of 2,500,000 shares of common stock, have been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer. Since incorporation in California early this year, we have funded our operations primarily through the issuance and internal private placement of our preferred stock to founding members to avoid giving up a substantial portion of our control rights for the company. As a result, no substantial private funds or net tangible assets have been raised as of the date of this prospectus. Although we have not incurred any deficits, debts, or negative cash flows since recent incorporation, the Company has no revenues and minimal tangible assets, and we have not raised sufficient funds so far to support filing an IND application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans.

Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy for which we will make our initial IND filing and first-in-human

studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Our novel **PluriXcel Technology** enables high efficient direct conversion of non-functional hESCs from the pluripotent stage into a large scale of high quality functional human neural or cardiac lineage-specific cell therapy derivatives, which is a major milestone towards human trials of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of clinical-grade high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Xcelthera breakthrough stem cell technologies have demonstrated the direct pharmacologic utility and capacity of hESC cell therapy derivatives for human CNS and heart regeneration and, thus, have presented the hESC cell therapy derivatives as a powerful pharmacologic agent of cellular entity for neuronal and heart muscle repair. Currently, our hESC neuronal and cardiomyocyte cell therapy derivatives or products are the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate the CNS neuron and contractile heart muscle, vital for CNS and heart repair for a wide range of neurological and cardiovascular diseases in the clinical setting. Xcelthera breakthrough human stem cell technologies transform non-functional pluripotent hESCs into a large supply of high quality fate-restricted functional human cell therapy derivatives or products, which dramatically increases the clinical efficacy of graft-dependent repair and safety of hESC-derived cellular products, marking a turning point in cell-based regenerative medicine from current studies in animals towards human trials or first-in-human studies.

We provide CNS- and heart-related human stem/progenitor/precursor cells and functional human neurons and heart muscle cells useful for stem cell banking, *in vitro* and *in vivo* stem cell research, transplantation, human CNS and heart tissue and organ engineering, cell-based regenerative medicine or therapies for human CNS and heart disorders or diseases, large-scale and cGMP production for commercial and therapeutic uses, cell-based therapeutics, drug screening, drug development, toxicity and safety testing, and other commercial and therapeutic purposes, which target multiple multi-billion dollar global markets in pharmaceutical, therapeutic, biotechnology, and healthcare sectors. Since inception, we have invested substantially all of our efforts and financial resources in pursuing the protection of our intellectual properties on our proprietary human stem cell technologies (**PluriXcel** platforms) and human stem cell therapy products in the US (US patent filing) and the world (PCT international filing and entry into national stage filing).

The long-term goal of the Company is to establish Xcelthera, INC as a premier Pharmaceutical/Therapeutic/Biotechnology Company to provide human stem cell-based regenerative medicine or cellular drugs for neurodegenerative diseases, neurological disorders, and cardiovascular diseases. The Company has established proprietary human stem cell technology **(PluriXcel Technology)** for large scale production of high quality clinical-grade hESC lines and their functional human neuronal and heart cell therapy products **(Xcel)**, which will maintain our global leadership position in cell-based regenerative medicine, sustain the business entity of the Company in life sciences

industry, and enable proprietary cell therapy products and tools move along a promising commercialization pathway to therapeutic markets leading to FDA approval of hESC neuronal and heart cell therapy products as treatments or cures for a wide range of CNS and heart disorders. Until such time as we can generate substantial product revenues to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements with partners. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our therapeutic product development or future commercialization efforts.

Opportunity for the Market

In the Western World, cardiovascular disease and neurological disorders are major health problems and leading causes of death. The estimated annual costs of cardiovascular disease for the overall United State (US) population are approximately $190 billion. The estimated annual costs of neurological disorders, including Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, stroke, brain and spinal cord injuries, are approximately $1.5 trillion in the US and Europe combined. Currently, there is no treatment option or compound drug of molecular entity that can change the prognosis of most of those diseases, including heart disease and failure, stroke, Parkinsons disease, ALS, Alzheimer disease, brain and spinal cord injuries, or that will lead to a dramatic functional improvement. Given the limited capacity of the CNS and heart for self-repair or renewal, cell-based therapy represents a promising therapeutic approach closest to provide a cure to restore normal tissue and function for neurological and cardiovascular disorders. However, traditional sources of cells for therapy in existing markets have been adult stem cells isolated from tissues or artificially reprogrammed from adult cells, which all have the historical shortcomings of limited capacity for renewal and repair, accelerated aging, and immune-rejection following transplantation. In addition, artificially reprogrammed adult cells have the major drawbacks of extremely low efficiencies and genetic defects associated with high risks of cancers, which have severely limited their utility as viable therapeutic approaches. To date, the existing markets lack a clinically-suitable human neuronal cell source with adequate CNS regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged or lost CNS structure and circuitry in a wide range of neurological disorders. Similarly, the existing markets lack a clinically-suitable human cardiomyocyte (the mature contracting heart muscle cell) source with adequate myocardium (the contractile heart muscle) regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged human heart muscle in cardiovascular disease.

The intrinsic ability of a hESC for both unlimited self-renewal and differentiation into clinically-relevant lineages makes it a practically inexhaustible source of replacement cells for human tissue and function restoration. Therefore, it has been regarded as an ideal source to provide a large supply of functional human cells to heal the damaged or lost tissues that have naturally limited capacity for renewal, such as the human heart and brain. Although a vast sum of government and private funding has been

spent on looking for adult alternates, such as reprogramming and trans-differentiation of fibroblasts or mature tissues, so far, only human stem/precursor/progenitor cells derived from embryo-originated pluripotent hESCs have shown such cellular pharmacologic utility and capacity adequate for CNS and myocardium regeneration in pharmaceutical development of stem cell therapy for the damaged CNS and heart.

Due to the prevalence of the CNS and heart diseases worldwide, there is intense interest in developing hESC-based therapies. However, pluripotent hESCs themselves are unspecialized non-functional cells that cannot be used directly for therapeutic applications. It has been recognized that pluripotent hESCs must be turned into fate-restricted specialized functional cells, a process known as differentiation, before use for cell therapy. All other existing or conventional hESC differentiation methods require uncontrollable and unpredictable simultaneous multi-lineage differentiation of pluripotent cells, which yield embryoid bodies or aggregates consisting of a mixed population of cell types of three embryonic germ layers, among which only a very small fraction of cells display targeted differentiation. Those existing or conventional hESC differentiation methods require laborious, costly, and time-consuming purification or isolation procedures to generate only a small quantity of desired cells, impractical for commercial and clinical applications. Growing scientific evidences indicate that those existing or conventional methods result in inefficient, instable, and incomplete hESC differentiation, and poor performance and high tumor risk of such cell derivatives and tissue-engineering constructs following transplantation. Under conventional protocols presently employed in the field, hESC-derived cellular products consist of a heterogeneous population of mixed cell types, including fully differentiated cells, high levels of various degrees of partially differentiated or uncommitted cells, and low levels of undifferentiated hESCs, posing a constant safety concern when administered to humans. In addition, undefined foreign or animal biological supplements and/or feeder cells that have typically been used for the isolation, expansion, and differentiation of hESCs make such cell derivatives unsuitable for clinical applications. Developing novel strategies to channel the wide differentiation potential of pluripotent hESCs exclusively and predictably to a neural or cardiac phenotype in a lineage-specific manner is not only vital to harnessing the power of hESC biology for neural or cardiac repair, but also crucial for unveiling the molecular and cellular cues that direct human CNS or heart formation in embryogenesis.

Clinical applications of hESC cell therapy derivatives provide the right alternative for many major health problems that have not been resolved by any conventional compound drugs of molecular entity. Our breakthrough developments in hESC research have overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies. We have established novel human stem cell technology platforms, including defined culture systems for derivation and maintenance of clinical-grade stable hESCs and lineage-specific differentiation of pluripotent hESCs by small molecule induction, which enable high efficient direct conversion of non-functional pluripotent hESCs into a large supply of clinical-grade high purity functional human neuronal cells or heart muscle cells for developing safe and effective stem cell therapies as treatments or cures for a wide range of neurological and cardiovascular diseases. Our breakthrough stem cell technologies have demonstrated the direct pharmacologic utility and capacity of hESC cell therapy derivatives for human CNS and

myocardium regeneration and, thus, have presented the hESC cell therapy derivatives as a powerful pharmacologic agent of cellular entity for CNS and heart repair. Our proprietary clinical-grade human neuronal and cardiomyocyte cell therapy products, derived from hESCs by our novel small molecule induction approaches, are currently the only available human cell sources in commercial scales with adequate cellular pharmacological utility and capacity to regenerate CNS neurons and contractile heart muscles, which will greatly facilitate developing safe and effective cell-based regeneration and replacement therapies against a wide range of CNS and heart disorders.

The Competitive Advantages of Our Novel PluriXcel Human Stem Cell Technology Platforms

Our novel **PluriXcel** human stem cell technology platforms include our **PluriXcel-DCS** technology and our **PluriXcel-SMI** technology. Our **PluriXcel** technology platforms enable large scale production or manufacture of high quality clinical-grade human neuronal and heart muscle cell therapy products as cellular medicines that can offer pharmacologic utility and capacity adequate for CNS and heart regeneration.

(a) **PluriXcel-DCS** technology: Defined culture systems for derivation and maintenance of clinical-grade high quality pluripotent hESC lines. Our PluriXcel-DSC technology allows all poorly-characterized and unspecified biological components and substrates in the culture system, including those derived from animals, to be removed, substituted, and optimized with defined human alternatives for *de novo* derivation and long-term maintenance of cGMP-quality xeno-free stable hESC lines and their human cell therapy derivatives, which have never been contaminated with animal cells and proteins, thus suitable for therapeutic development and clinical applications.

(b) **PluriXcel-SMI** technology: Lineage-specific differentiation of pluripotent hESCs by small molecule induction. Our PluriXcel-SMI technology enables high efficient neural or cardiac lineage-specific differentiation direct from the pluripotent stage of hESCs using small molecule induction, which is a major milestone towards clinical application of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of high quality clinical-grade human stem cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Our **PluriXcel-SMI** technology platforms include our **PluriXcel-SMI-Neuron** technology and our **PluriXcel-SMI-Heart** technology.

(i) **PluriXcel-SMI-Neuron** technology: Well-controlled efficient neuronal lineage-specific differentiation of pluripotent hESCs directly and exclusively into cells of a neuronal lineage by small molecule induction. Our **PluriXcel-SMI-Neuron** technology enables high efficient direct conversion of pluripotent hESCs into a large scale of high quality neuronal progenitors and functional neuronal cells adequate for clinical development of safe and effective stem cell therapies for a wide range of neurological disorders.

(ii) **PluriXcel-SMI-Heart** technology: Well-controlled efficient Heart/cardiac lineage-specific differentiation of pluripotent hESCs directly and exclusively to a cardiomyocyte fate by Small Molecule Induction. Our **PluriXcel-SMI-Heart**

technology enables high efficient direct conversion of pluripotent hESCs into a large scale of high quality heart precursors and functional cardiomyocytes (heart muscle cells) adequate for clinical development of safe and effective stem cell therapies for heart disease and failure.

The Xcel Prototypes of Proprietary Clinical-Grade Human Stem Cell Therapy Products

Our **Xcel prototypes**, generated from hESCs using our novel PluriXcel technology, currently include **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells). We believe that our **Xcel prototypes** represent the next generation of human cell therapy products, offering purity, large-scale production, high quality, safety, and effectiveness for commercial and therapeutic uses over all other existing cell sources.

Xcel-hNuP: Clinical-grade high purity human neuronal progenitor cells for CNS neuron regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, motor neuron diseases, neurodegenerative diseases, stroke, brain and spinal cord injuries.

Xcel-hNu: Clinical-grade high purity human neurons for CNS neuron regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, motor neuron disease, neurodegenerative diseases, stroke, brain and spinal cord injuries.

Xcel-hCardP: Clinical-grade high purity human heart precursor cells for contractile heart muscle regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.

Xcel-hCM: Clinical-grade high purity human cardiomyocytes (heart muscle cells) for contractile heart muscle regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.

Product Pipeline for Our Lead Clinical-Grade Human Stem Cell Therapy Products from PluriXcel Platforms

We were recently incorporated as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an 501C3 tax-exempt non-profit biomedical research institute. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. Through acquisition of proprietary human stem cell assets by issuing company stocks,

the Company has invested substantially all of our efforts and financial resources in developing our novel human stem cell technology PluriXcel platforms, conducting preclinical studies of our human stem cell therapy products, and pursuing the protection of our intellectual properties on our proprietary human stem cell technologies and cell therapy products in the US (US patent filing) and the world (PCT international filing and entry into national stage filing). We are currently moving towards clinical development stage or first-in-human studies of our stem cell therapy product candidates.

As of the date of this prospectus, we have not raised sufficient funds to support filing an investigational new drug (IND) application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including investigational new drug (IND) filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline) for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Traditional pharmaceutical research & development (R&D) in existing markets usually starts with drug leads discovered in animals or other lower organisms, thus require lengthy and costly both demonstration in animal model testing and establishment of proof-of-concept and safety in human trials. Pluripotent hESCs are derived from the pluripotent inner cell mass or epiblast of the human blastocyst or embryos and, thus, have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. Therefore, unlike traditional pharmaceutical R&D, our novel cellular therapeutic products have been developed directly with human cells or hESCs with proof-of-concept already established in humans, which simplifies the development process and lower the costs for R&D, shortens the time consumption for R&D, and increases the probability of clinical success dramatically. Xcelthera breakthrough human stem cell technologies (PluriXcel Technology), including defined culture systems for *de novo* derivation and

long-term maintenance of clinical-grade stable pluripotent hESC lines (PluriXcel-DSC technology) and lineage-specific differentiation of pluripotent hESCs by small molecule induction (PluriXcel-SMI technology), enable clinical applications of hESC therapeutic utility. Our therapeutic products have been developed specifically to address and overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies, including offering the benefits in high efficiency, stability, low tumor risk, high purity, high efficacy in repair, as well as safety and large-scale production or manufacturing over all other existing approaches.

We are in the early stages of commercializing our licensed technologies and products, which have been developed, in part, with supports by government grants to the founder of the Company and San Diego Regenerative Medicine Institute, which have expired or discontinued. As of the date of this prospectus, the Company has not received any support from government funding. New funding by these governmental agencies may be significantly reduced, withdrawn, delayed, or eliminated in the future for a number of reasons, such as budget cuts, changes in fiscal year appropriation, changes in funding direction and policy, changes in funding priority or allocation, government shutdown, perceived or real conflicts of interest, and ethical or legal issues brought to these governmental funding agencies (see Risk Factors). A restriction on the government funding available to us would reduce the resources that we would be able to devote to existing and future research and development efforts. Such a reduction could delay the progress and development of new products and hurt our competitive position.

We are a new biopharmaceutical company moving towards clinical development stage with limited operating experience in commercial and therapeutic markets. Although we have not incurred any deficit, we have never been profitable in this short period of existence and anticipate that our business will incur operation and net losses due to regular costs of drug or cellular product development until we successfully implement our commercial and therapeutic development strategy, achieve milestones and market acceptance, complete clinical trials, gain regulatory approval, and launch new therapeutic products to the commercial and therapeutic markets, and generate significant revenues to support our level of operating expenses. Since inception, all our efforts have been devoted to raise sufficient funds to cover expenses for our intended operational, intellectual property protection, regulatory approval, and clinical development activities.

Technology Innovation Award Presented by Frost & Sullivan

Xcelthera, Inc. is the recipient of the prestigious 2013 North American Technology Innovation Award in Stem Cell Technologies presented by Frost & Sullivan. This prestigious recognition by Frost & Sullivan is based on an extensive and independent competitive analysis of the North American Stem Cell Technologies Market and the findings of Best Practices research by Frost & Sullivan competitive analysis.

The Designation of Human Stem Cell therapy Products for Human Trials or First-in-Human Studies

For successful pharmaceutical development of stem cell therapy, the human stem cell therapy product must meet certain commercial criteria in plasticity, specificity, and

stability before entry into clinical trials. Moving stem cell research from current studies in animals into human trials must address such practical issues for commercial and therapeutic uses: 1) such human stem cells and/or their cell therapy derivatives/products must be able to be manufactured in a commercial scale; 2) such human stem cells and their cell therapy derivatives/products must be able to retain their normality or stability for a long term; and 3) such human stem cells and/or their cell therapy derivatives/products must be able to differentiate or generate a sufficient number of the specific cell type or types in need of repair or regeneration. Those practical issues are essential for designating any human stem cells as human stem cell therapy products for investigational new drug (IND)-filing and entry into human trials. Our human stem cell therapy products have been developed specifically to address and overcome those major obstacles or issues in clinical applications of hESC therapeutic utility, including the benefits in high efficiency, stability, low tumor risk, high purity, high efficacy in repair, as well as safety and large-scale production of high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Therefore, Xcelthera hESC CNS and heart cell therapy derivatives, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), meet the designation of human stem cell therapy products for commercial development and human trials or first-in-human studies.

Compared to conventional compound drugs of molecular entity, cell therapy products or cellular medicine have very different benchmarks or indicators regarding to safety and efficacy in clinical trials. The safety of a human stem cell therapy product is evaluated by whether it can retain a stable phenotype and karyotype for a long period of time and whether there is no tumor or inappropriate cell type formation following transplantation. The efficacy of a human stem cell therapy product is measured by its pharmacologic activity or cellular ability to regenerate the tissue or organ that has been damaged or lost. Therefore, the pharmacologic utility of human stem cells cannot be satisfied only by their chaperone activity, if any, to produce trophic or protective molecules to rescue existing endogenous host cells that can simply be achieved by a drug of molecular entity, if any.

Our breakthrough human stem cell technologies (PluriXcel Technology), including defined culture systems for *de novo* derivation and long-term maintenance of clinical-grade stable pluripotent hESC lines (PluriXcel-DSC technology) and lineage-specific differentiation of pluripotent hESCs by small molecule induction (PluriXcel-SMI technology), have overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies. Medical innovations in Our PluriXcel Technology enable high efficient direct conversion of non-functional pluripotent hESCs into a commercial scale of clinical-grade high quality functional human neuronal or heart muscle cell therapy derivatives, which is a major milestone towards human trials of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of clinical-grade high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Currently, our hESC neuronal and cardiomyocyte cell therapy derivatives are the only available human cell sources in commercial scales with adequate cellular pharmacologic

utility and capacity to regenerate CNS neurons and contractile heart muscles, vital for CNS and heart repair in the clinical setting. Our breakthrough human stem cell technologies transform non-functional pluripotent hESCs into a large supply of high quality fate-restricted functional human cell therapy derivatives or products, which dramatically increases the clinical efficacy of graft-dependent repair and safety of hESC-derived cellular products, and marks a turning point in cell-based regenerative medicine from current studies in animals towards human trials or first-in-human studies.

FDASIA and FDA Expedited Development Programs

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law, which gave the Food and Drug Administration (FDA) a new and powerful expedited drug development tool, known as the breakthrough therapy designation. This new designation helps FDA assist drug developers to expedite the development and review of new drugs with preliminary clinical evidence that indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases. In addition, the FDA has established a Fast Track program that is intended to facilitate the development and expedite the review of new drugs and biological products that are intended to treat a serious or life-threatening condition or disease and demonstrate the potential to address unmet medical needs for the condition. Xcelthera novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)** are targeting many of those serious or life-threatening diseases or conditions, including heart disease and failure, stroke, Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, brain and spinal cord injuries. So far, those major health problems or incurable life-threatening diseases have relied on breakthrough developments in our stem cell research, particularly our hESC research, to drive the advance of medicine to provide future regeneration and reconstruction treatment options or cures for tissue and function restoration.

Thus far, testing potential therapeutic strategies have largely relied on animal models for behavior, safety, and efficacy evaluation of therapeutic candidates and human cell therapy products. The goal of animal studies is to provide sufficient evidences of proof-of-concept for prospect of benefit and safety to justify the proposed clinical investigation of a new drug. Large animal models are not always necessary for FDA approval and review of an investigational new drug. Because of interspecies differences, conventional preclinical studies using animal models are often poor predictors of human efficacy and safety. Animal models are xeno-hosts for transplantation of human cells, not ideal for testing the safety and efficacy of therapeutic outcomes of human stem cells. Large primate models are very costly and often taken years to obtain results. In addition, the results of animal studies can be highly variable and difficult to reproduce, making them unreliable as benchmarks for decisions on human trials. Preclinical data using animal models, even results of large animal models, do not necessarily provide the benchmarks or indictors for safety and efficacy in human trials. Those FDA expedited programs do not specifically require evidences from animal models or animal proof-of-concept data to support FDA accelerated approval and priority review, which may help fast-track the development and review of our human stem cell

therapy products that have the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to our marketed human stem cell therapy products.

In addition, FDA regulations allow companies to establish expanded access program for the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational drugs for treatment purposes on a case-by-case basis for an individual patient, or for intermediate-size groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial. They also permit expanded access for large groups of patients who do not have other treatment options available, once more is known about the safety and potential effectiveness of a drug from ongoing or completed clinical trials.

We are currently moving towards clinical development stage of our products. As of the date of this prospectus, we have not raised sufficient funds to support filing an IND application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Revenue

We were recently incorporated in May 2013 as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute

that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. We have not generated any revenues from our therapeutic product commercialization efforts. Although the technologies and products we acquired from San Diego Regenerative Medicine Institute were developed, in part, with supports by government grants to the founder of the Company and San Diego Regenerative Medicine Institute, as of the date of this prospectus, the Company has not received any support from government funding. Disclosure of government funding sources for the development of the technologies and products we acquired from San Diego Regenerative Medicine Institute can be found in the acknowledgment section of the publications disclosed in our "Business" section of this prospectus and the Company's website. New funding by these governmental agencies may be significantly reduced, withdrawn, delayed, or eliminated in the future for a number of reasons, such as budget cuts, changes in fiscal year appropriation, changes in funding direction and policy, changes in funding priority or allocation, government shutdown, perceived or real conflicts of interest, and ethical or legal issues brought to these governmental funding agencies (see Risk Factors). A restriction on the government funding available to us would reduce the resources that we would be able to devote to existing and future research and development efforts. Such a reduction or elimination could delay the progress and development of new products and hurt our competitive position. We do not expect to generate any revenues from our therapeutic product development and commercialization until we successfully complete clinical development and obtain regulatory approval for one or more of our products for one or more disease indications, which we expect will take a number of years. If we obtain regulatory approval for any of our products, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such arrangements when needed would have a negative impact on our financial condition and ability to develop our products.

Costs and Expenses

The Exclusive License Agreement to acquire the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products from San Diego Regenerative Medicine Institute by issuing company stocks as research and development expenses

We were incorporated as a general stock company under the laws of the state of California in May 2013 under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by

San Diego Regenerative Medicine Institute, an non-profit biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. San Diego Regenerative Medicine Institute, an nonprofit 501C3 tax exempt status independent biomedical research institute incorporated in California, was founded in 2010 by the same founder of Xcelthera, INC, in part, with supports by government grants to the founder, to facilitate the transition of human stem cell research towards stem cell therapy to provide the next generation of cell-based therapeutic solutions for unmet medical challenges. The founder and CEO of the Company is also the founder of San Diego Regenerative Medicine Institute and the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products (please see the exclusive license agreement included in the exhibit of this prospectus). The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. In connection with the exclusive license agreement, the Company has issued an aggregate of 3,800,000 shares of common stock subject to the exercise of outstanding options, including all preferred shares convertible into common stock, to San Diego Regenerative Medicine Institute as research and development expenses. Of these options, an aggregate of 2,500,000 shares of common stock, including 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock, convertible into 2,000,000 shares of common stock upon completion of this offer, has been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer. In addition, milestone payments will occur pursuant to the exclusive license agreement upon first achievement of the following milestones:

(i) First regulatory approval for clinical development or an investigational new drug (IND) of first licensed product. COMPANY shall issue an aggregate number of shares equals 1,300,000 shares or 3% of the COMPANY issued and outstanding Common Stock calculated on a Fully Diluted Basis to San Diego Regenerative Medicine Institute (SDRMI) as a one time milestone payment.

(ii) First commercial sale or first market approval for clinical uses of a licensed product for each disease indication. COMPANY shall pay 1,000,000 shares of Common Stock of COMPANY or 1% of the COMPANY then issued and outstanding Common Stock calculated on a Fully Diluted Basis, whichever is larger, to San Diego Regenerative Medicine Institute (SDRMI) as a milestone payment.

As a result of the exclusive license agreement, no costs and expenses for research and development have incurred directly for our company for research and development of our technology and products since our recent incorporation. Research and development expenses include: (i) lab supplies and materials, human cells, reagents and finished goods internally consumed; (ii) salaries and related personnel expenses; (iii) allocated and direct overhead and facilities expenses; and (iv) costs associated with licenses, collaborations,

partnerships and other revenues. We do not track research and development expenses by individual product, nor do we capitalize any research and development expenses. As of the date of this prospectus, no other agreement between San Diego Regenerative Medicine Institute and the Company has been executed.

Following completion of this offer, we expect our expenses will increase substantially in connection with our activities to use the net proceeds from this offering for funding our operations, including,

investigational new drug (IND) filing for our products;

recruit regulatory personnel and obtain regulatory approval for clinical trials, including expenses for regulatory filing preparations and activities, pre-IND and IND meetings with FDA;

conduct clinical trials;

continue our research and development efforts;

continue to pursue the protection of our intellectual property or patents on our technology and therapy products in the US and the world, including US patent applications, PCT international patent applications and entry into national stage, and expenses for patent attorneys;

expansion of our stem cell lines for banking and commercialization;

hire clinical, quality control and technical personnel to conduct our clinical trials;

hire scientific personnel to support our research and product development efforts;

implement operational, financial and management systems; and

hire general and administrative personnel to operate as a public company.

We cannot determine with certainty the timing of initiation, the duration and the completion costs of future preclinical or nonclinical studies and clinical trials of our therapeutic products. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our clinical programs, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in the continued development of our products. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline) for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering. In addition, we cannot forecast which products may be subject to future collaborations or

partnership opportunities, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Liquidity and Capital Resources

We were recently incorporated as a general stock company under the laws of the state of California to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. In connection with the exclusive license agreement, the Company has issued an aggregate of 3,800,000 shares of common stock subject to the exercise of outstanding options, including all preferred shares convertible into common stock, to San Diego Regenerative Medicine Institute as investment in research and development. Although the technologies and products we acquired from San Diego Regenerative Medicine Institute were developed, in part, with supports by government grants to the founder of the Company and San Diego Regenerative Medicine Institute, as of the date of this prospectus, the Company has not received any support from government funding. Since incorporation in California, we have funded our operations primarily through the issuance and internal private placement of our preferred stock to founding members to avoid giving up a substantial portion of our control rights for the company. As a result, no substantial private funds or net tangible assets have been raised as of the filing date of this prospectus. Our company is not profitable and we cannot provide any assurance that we will ever be profitable. However, so far, we have not incurred any deficits, debts, or negative cash flows since incorporation in May 2013.

We believe that the net proceeds from this offering will be sufficient to meet our anticipated cash requirements for at least the next 24 months. Due to the regular costs of drug or cellular product development, we will need to raise substantial additional capital in the future in order to advance or complete clinical development of our products for one or more disease indications, fund our operations, expand our commercialization efforts, and further our research and development activities. Our future funding requirements will depend on many factors, including regulatory approval and market acceptance of our products, the cost of our preclinical and clinical research and development activities, the cost of filing and prosecuting patent applications, the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or violate other intellectual property rights, the cost and timing of regulatory clearances or approvals, the cost and timing of establishing sales, marketing and distribution capabilities, the effect of competing technological and market developments and the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions. We currently expect to use the net proceeds from this offering for funding our operations, including for business real state, facility, equipment, and intellectual property protection; activities associated with clinical development of our products, including IND filing, regulatory

approval, clinical trial, and cGMP banking and production of our clinical-grade human stem cell therapy products; preclinical research, development, and expansion of our stem cell lines for banking and commercialization; and working capital and other general corporate purposes.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we will take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

We will follow the smaller reporting company requirements for disclosure and audited financial statement;

We will avail ourselves of the exemption from the requirement to obtain audit or attestation of internal control over financial reporting under the Sarbanes-Oxley Act 404(b);

We will avail ourselves of the reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;

We will avail ourselves of the exemptions from disclosure obligations regarding executive compensation in periodic reports, proxy statements and registration statements and the requirements of holding a nonbinding advisory vote on executive compensation or golden parachute arrangements; and

We will avail ourselves of the exemptions from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

We will take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC.

We are an emerging growth company and we have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of JOBS Act to avail ourselves of reduced disclosure requirements applicable to emerging growth companies. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our common stock less attractive because we have elected to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Please see risk factors.

Off-Balance Sheet Arrangements

We did not have and do not currently have any off balance sheet arrangements, as defined under Securities and Exchange Commission rules.

Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. We do not hold or issue financial instruments for trading purposes.

Business

Overview

We are a biopharmaceutical company moving towards clinical development stage of novel and most advanced stem cell therapy for a wide range of neurological and cardiovascular diseases with leading technology and medical innovation in cell-based regenerative medicine. We have patent and proprietary rights for our novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)**, derived from pluripotent human embryonic stem cells (hESCs) by small molecule induction. Human pluripotent stem cells have the potential to differentiate into all the somatic cell types in the human body by the definition of "pluripotent". Pluripotent hESCs have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for unrestricted differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. Of particular interest to the medical needs is the potential for use of hESC derivatives to heal tissues with naturally limited capacity for renewal, such as the human heart and brain. The Company is the first to hold the breakthrough technology for large-scale production of high quality clinical-grade hESC lines and their functional human neuronal and heart cell therapy derivatives for commercial and therapeutic uses. We plan to enter clinical-stage

development or first-in-human studies in cardiac and neural repair for our licensed human stem cell therapy products following completion of this offer. Our strategy is to use cutting-edge human stem cell technology to develop clinical-grade functional neural and cardiac cell therapy products from pluripotent hESCs as cellular medicine or cellular drugs to provide the next generation of cell-based therapeutic solutions for unmet medical needs in world-wide major health problems. Our company website is www.xcelthera.com.

We were recently incorporated in May 2013 as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. The founder and CEO of the Company is also the founder of San Diego Regenerative Medicine Institute and the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. The Company has acquired proprietary human stem cell assets and we are currently in early stage of our clinical development efforts. Although we have not incurred any deficits, debts, or negative cash flows since recent incorporation, the Company has no revenues and minimal tangible assets, and we have not raised sufficient funds so far to support filing an investigational new drug (IND) application with the Food and Drug Administration (FDA) for our licensed cell therapy products to enter into clinical development stage. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy. We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including investigational new drug (IND) filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing Current Good Manufacturing Practices (cGMP) manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities.

The hESC cell therapy products have emerged as powerful pharmacological agents of cellular entity to offer medicinal utility and capacity for human tissue and function restoration. We have established ground-breaking proprietary human stem cell technology platforms **(PluriXcel Technology)**, including defined culture systems for derivation and maintenance of clinical-grade high quality hESC lines **(PluriXcel-DCS)**

and lineage-specific differentiation of pluripotent hESCs by small molecule induction **(PluriXcel-SMI)**. Our **PluriXcel-DCS** technology allows all poorly-characterized and unspecified biological components and substrates in the culture system, including those derived from animals, to be removed, substituted, and optimized with defined human alternatives for *de novo* derivation and long-term maintenance of cGMP-quality xeno-free stable hESC lines and their human cell therapy derivatives, which have never been contaminated with animal cells and proteins, thus suitable for therapeutic development and clinical applications. Our **PluriXcel-SMI** technology platforms include our **PluriXcel-SMI-Neuron** technology and our **PluriXcel-SMI-Heart**. Our **PluriXcel-SMI-Neuron** technology allows neural lineage-specific differentiation of pluripotent hESCs by small molecule induction for high efficient direct conversion of pluripotent hESCs into a large scale of high quality neuronal progenitors and functional neuronal cells adequate for clinical development of safe and effective stem cell therapies for a wide range of neurological disorders. Our **PluriXcel-SMI-Heart** technology allows cardiac lineage-specific differentiation of pluripotent hESCs by small molecule induction for high efficient direct conversion of pluripotent hESCs into a large scale of high quality heart precursors and functional cardiomyocytes (heart muscle cells) adequate for clinical development of safe and effective stem cell therapies for heart disease and failure. Breakthroughs of our **PluriXcel** technologies transform non-functional pluripotent hESCs into a large scale of high quality fate-restricted functional cell therapy derivatives or products for commercial and therapeutic uses. Our cutting-edge human stem cell technology and medical innovations enable high efficient direct conversion of pluripotent hESCs by small molecule induction into a large scale of clinical-grade high quality human neural or cardiac lineage-specific cell therapy derivatives, including our cell therapy product **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), which is a major milestone towards human trials of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches.

We are currently moving towards clinical development stage or first-in-human studies of our products. As of the date of this prospectus, we have not raised sufficient funds to support filing an investigational new drug (IND) application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy. We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP

manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Clinical applications of functional cell therapy products derived from pluripotent hESCs provide the right alternative for many different types of incurable diseases, including neurodegenerative diseases and heart diseases that have been considered as world-wide major health problems. To date, the existing markets lack a clinically-suitable human neuronal cell source with adequate CNS regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged or lost CNS structure and circuitry in a wide range of neurological disorders. Similarly, the existing markets lack a clinically-suitable human cardiomyocyte (the mature contracting heart muscle cell) source with adequate myocardium (the contractile heart muscle) regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged human heart in cardiovascular disease. Therefore, our proprietary clinical-grade hESC-derived neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), are currently the only available human cell sources in commercial scales with adequate cellular pharmacological utility and capacity to regenerate neurons and contractile heart muscles in the clinical setting, providing potential treatments or cures for a wide range of neurological and cardiovascular diseases, including heart disease and failure, stroke, Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Alzheimer disease, Spinal muscular atrophy, motor neuron diseases, neurodegenerative diseases, brain and spinal cord injuries. The estimated costs of these world-major major health problems for the United States (US) population alone are > $500 billions annually, and currently, there is no treatment option or compound drug of molecular entity that can change the prognosis of most of those diseases, or that will lead to a dramatic functional improvement.

We own or have exclusive rights in a portfolio of intellectual property or license rights related to our novel **PluriXcel** human stem cell technology platforms and **Xcel** human stem cell therapy products, which provide significant competitive advantages for the growth of our business and for the dominance over our target markets. We provide CNS (central nervous system)- and heart-related human stem/progenitor/precursor cells and functional human neurons and heart muscle cells useful for stem cell banking, *in vitro* and *in vivo* stem cell research, transplantation, human CNS and heart tissue and organ engineering, cell-based regenerative medicine or therapies for human CNS and heart disorders or diseases, large-scale and cGMP production for commercial and

therapeutic uses, cell-based therapeutics, drug screening, drug development, toxicity and safety testing, and other commercial and therapeutic purposes, which target multiple multi-billion dollar global markets in pharmaceutical, therapeutic, biotechnology, and healthcare sectors.

The inception of Xcelthera is driven by the urgent need for clinical translation of hESC research discoveries and innovations to address unmet medical challenges in major health problems. Our breakthrough developments in hESC research dramatically increase the overall turnover of investments in biomedical sciences to optimal treatment options for a wide range of human diseases. The long-term goal of the Company is to establish Xcelthera, INC as a premier Pharmaceutical/Therapeutic/Biotechnology Company to provide human stem cell-based regenerative medicine or cellular drugs for neurodegenerative diseases, neurological disorders, and cardiovascular diseases. The Company has established proprietary human stem cell technology **(PluriXcel Technology)** for large scale production of high quality clinical-grade hESC lines and their functional human neuronal and heart cell therapy products **(Xcel)**, which will maintain our global leadership position in cell-based regenerative medicine, sustain the business entity of the Company in life sciences industry, and enable proprietary cell therapy products and tools move along a promising commercialization pathway to therapeutic markets leading to FDA approval of hESC neuronal and heart cell therapy products as treatments or cures for a wide range of CNS and heart disorders.

Preclinical Research and Clinical Development

The limitations of existing approaches and markets

In the Western World, cardiovascular disease (CVD) and neurological disorders are major health problems and leading causes of death. The estimated annual costs of CVD for the overall United State (US) population are approximately $190 billion. The estimated annual costs of neurological disorders, including Parkinson's disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, stroke, brain and spinal cord injuries, are approximately $1.5 trillion in the US and Europe combined. Currently, there is no treatment option or compound drug of molecular entity that can change the prognosis of most of those diseases, including heart disease and failure, stroke, Parkinsons disease, ALS, Alzheimer disease, brain and spinal cord injuries, or that will lead to a dramatic functional improvement. Given the limited capacity of the CNS and heart for self-repair or renewal, cell-based therapy represents a promising therapeutic approach closest to provide a cure to restore normal tissue and function for neurological and cardiovascular disorders. However, traditional sources of cells for therapy in existing markets have been adult stem cells isolated from tissues or artificially reprogrammed from adult cells, which all have the historical shortcomings of limited capacity for renewal and repair, accelerated aging, and immune-rejection following transplantation. In addition, artificially reprogrammed adult cells have the major drawbacks of extremely low efficiencies and genetic defects associated with compromised genomic integrity and high risks of cancers, which have severely limited their utility as viable therapeutic approaches. To date, the existing markets lack a clinically-suitable human neuronal cell source with adequate CNS regenerative potential, which has been the major setback in developing safe and effective cell-based therapies

for regenerating the damaged or lost CNS structure and circuitry in a wide range of neurological disorders. Similarly, the existing markets lack a clinically-suitable human cardiomyocyte (the mature contracting heart muscle cell) source with adequate myocardium (the contractile heart muscle) regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged human heart in cardiovascular disease.

The human embryonic stem cell (hESC) cell therapy derivatives hold tremendous potential for human tissue and organ regeneration and function restoration. Clinical applications of hESC cell therapy derivatives provide the right alternative for many incurable diseases and world-wide major health problems that the conventional mode of drug and treatment cannot, such as heart disease and failure, Parkinsons diseases, ALS, Alzheimer disease, stroke, neurodegenerative disease, brain and spinal cord injuries. The intrinsic ability of a hESC for both unlimited self-renewal and differentiation into clinically-relevant lineages makes it a practically inexhaustible source of replacement human cells for restoration of the damaged CNS or heart tissue and function. The hESC neural or cardiac cell therapy derivatives are emerging as a new type of pharmacologic agent of cellular entity in cell-based regenerative medicine because they have direct pharmacologic utility and capacity for human CNS or heart tissue and function restoration. The pharmacologic activity of human stem cells is measured by their extraordinary cellular ability to regenerate the functional and structural tissue element that has been damaged or lost. Therefore, the pharmacologic utility of human stem cells cannot be satisfied only by their chaperone activity, if any, to differentiate into non-functional supporting cells, or produce trophic or protective molecules to rescue endogenous dying host neurons or cardiomyocytes that can simply be achieved by a compound drug of molecular entity, if any. Although a vast sum of government and private funding has been spent on looking for adult alternates, such as reprogramming and trans-differentiation of fibroblast cells or mature tissues, so far, only human stem/precursor/progenitor cells derived from embryo-originated hESCs have shown such cellular pharmacologic utility and capacity adequate for CNS or myocardium regeneration in pharmaceutical development of stem cell therapy for the damaged CNS or heart.

Pluripotent hESCs have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for unrestricted differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. Therefore, the pluripotent hESC has been regarded as an ideal source to provide a large supply of functional human cells to heal the damaged or lost tissues that have naturally limited capacity for renewal, such as the human heart and brain. Due to the prevalence of the CNS and heart diseases worldwide, there is intense interest in developing hESC-based therapies. However, pluripotent hESCs themselves are unspecialized non-functional cells that cannot be used directly for therapeutic applications. It has been recognized that pluripotent hESCs must be turned into fate-restricted specialized functional cells, a process known as differentiation, before use for cell therapy. All other existing or conventional hESC differentiation methods require uncontrollable and unpredictable simultaneous multi-lineage differentiation of pluripotent cells, which yield embryoid bodies or aggregates

consisting of a mixed population of cell types of three embryonic germ layers, among which only a very small fraction of cells display targeted differentiation. Those existing or conventional hESC differentiation methods require laborious, costly, and time-consuming purification or isolation procedures to generate only a small quantity of desired cells, impractical for commercial and clinical applications. Growing scientific evidences indicate that those existing or conventional methods result in inefficient, instable, and incomplete hESC differentiation, and poor performance and high tumor risk of such cell derivatives and tissue-engineering constructs following transplantation. Under conventional protocols presently employed in the field, hESC-derived cellular products consist of a heterogeneous population of mixed cell types, including fully differentiated cells, high levels of various degrees of partially differentiated or uncommitted cells, and low levels of undifferentiated hESCs, posing a constant safety concern when administered to humans. In addition, undefined foreign or animal biological supplements and/or feeder cells that have typically been used for the isolation, expansion, and differentiation of hESCs make such cell derivatives unsuitable for clinical applications. Developing novel strategies to channel the wide differentiation potential of pluripotent hESCs exclusively and predictably to a neural or cardiac phenotype in a lineage-specific manner is not only vital to harnessing the power of hESC biology for neural or cardiac repair, but also crucial for unveiling the molecular and cellular cues that direct human CNS or heart formation in embryogenesis.

The genetically stable pluripotent hESCs proffer cures for a wide range of neurological disorders by supplying the diversity of human neuronal cell types in the developing CNS for regeneration and repair. However, although neural lineages appear at a relatively early stage in differentiation, < 5% hESCs undergo spontaneous differentiation into neurons. Retinoic acid (RA) does not induce neuronal differentiation of undifferentiated hESCs maintained on feeder cells. And unlike mouse ESCs, treating hESC-differentiating multi-lineage aggregates or embryoid bodies (EB) with RA only slightly increases the low yield of neurons. Under conventional protocols presently employed in the field, these neural grafts derived from pluripotent cells through multi-lineage differentiation yielded neurons at a low prevalence following engraftment, which were not only insufficient for regeneration or reconstruction of the damaged CNS, but also accompanied by unacceptably high incidents of teratoma and/or neoplasm formation. Similar to human neural stem cells (hNSCs) isolated directly from the human fetal neuroectoderm or CNS *in vivo*, hNSCs derived from hESCs *in vitro* are nestin-positive neuroepithelial-like cells that can spontaneously differentiate into a mixed population of cells containing undifferentiated hNSCs, neurons (<10%), astrocytes, and oligodendrocytes *in vitro* and *in vivo*. Before further differentiation, those hESC-derived hNSCs were laboriously mechanically isolated or enriched from hESC-differentiating multi-lineage aggregates. Previously, co-culturing with stromal cells or telomerase-immortalized midbrain astrocytes as well as exposing to FGF and sonic hedgehog (SHH) signaling have been used to improve the yield of β-III-tubulin- and tyrosine hydroxylase (TH)-positive cells from hESC-derived hNSCs. The signaling factors that operate along the rostrocaudal and dorsoventral axes of the neural tube to specify motor neuron fate *in vivo* have been used to direct hNSCs derived from hESCs through multi-lineage germ-layer induction differentiate into an early motor neuron phenotype, but with low

efficiencies. Early study of those uncommitted hESC-derived hNSCs showed that the grafted cells not only yielded a small number of dopaminergic (DA) neurons *in vivo* following transplantation, but could not acquire a DA phenotype in the lesioned brain. Transplanting DA neurons pre-differentiated from those hESC-derived hNSCs *ex vivo* did not increase the yield of DA neurons in the lesioned brain. Similarly, although a small number of motor neurons were observed following transplantation of the hESC-derived grafts into adult paralyzed rats, there was little evidence of improved behavior. Similar to their CNS counterpart, the therapeutic effect of those hESC-derived hNSCs was mediated by neuroprotective or trophic mechanism to rescue dying host neurons, but not related to regeneration from the graft or host remyelination. Growing evidences indicate that these secondary hNSCs derived from hESCs *via* conventional multi-lineage differentiation *in vitro* appear to have increased risk of tumorigenicity but not improved neurogenic potential compared to primary hNSCs isolated directly from the CNS tissue *in vivo,* remaining insufficient or inadequate for CNS regeneration. Further directed differentiation of those hESC-derived hNSCs into floor-plate precursors of the developing midbrain appeared to increase the efficiency of DA neuron engraftment in Parkinsons disease models, suggesting that the poor *in vivo* performance of those nestin-positive neuroepithelial-like hNSCs derived from hESCs *in vitro* was due to incomplete neuronal lineage specification. Development of a well-controlled strategy for efficiently committing hESCs into a more specific neuronal lineage in high purity and large quantity is vital to harnessing the therapeutic potential of pluripotent hESCs for CNS repair.

Similarly, due to the prevalence of cardiovascular disease worldwide and acute shortage of donor organs or adequate human myocardial grafts, there is intense interest in developing hESC-based therapy for heart disease and failure. However, in hESC-differentiating multi-lineage aggregates embryoid bodies (EB), only a very small fraction of cells (< 4 %) spontaneously differentiate into cardiomyocytes (the contracting heart muscle cells). Immune-selection, co-culturing, and morphogens have been used to laboriously isolate and enrich small populations of immature cardiomyocytes from hESC-differentiating EB. Enriched hESC-derived cardiomyocytes could generate small grafts and function as the biological pacemaker in animal infarcted models. Although such hESC-derived immature cardiomyocytes can be enriched to attenuate the progression of heart failure in acute myocardial infarction model, the grafts generated by cell transplantation have been small and insufficient to restore heart function or to alter adverse remodeling of chronic infarcted models following transplantation. Functional enhancement in preclinical animal models by such hESC-derived cardiomyocytes through conventional multi-lineage germ-layer induction has been limited to mid-term at most, equivalent to perhaps a few months in humans, and there is no evidence that the underlying mechanism depends on the contractile properties of the transplanted human cells. Thus, developing novel strategies to channel the wide differentiation potential of pluripotent hESCs exclusively and predictably to a cardiac phenotype is vital to harnessing the power of hESC biology for cardiac repair.

The future medicine --- human embryonic stem cell neural and cardiac lineage-specific therapy derivatives (Xcel) for CNS and Heart regeneration

Our PluriXcel breakthrough human stem cell technology platforms have overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies. We have established novel human stem cell technology platforms (**PluriXcel** Technology), including defined culture systems for derivation and maintenance of clinical-grade pluripotent hESCs (**PluriXcel-DCS** technology) and lineage-specific differentiation of pluripotent hESCs by small molecule induction (**PluriXcel-SMI** technology). Milestone advances and medical innovations in our PluriXcel technology enable high efficient direct conversion of non-functional pluripotent hESCs into a large supply of clinical-grade high purity functional human neuronal cells or heart muscle cells for developing safe and effective stem cell therapies as treatments or cures for a wide range of neurological and cardiovascular diseases.

To date, the existing markets lack a clinically-suitable human neuronal cell source with adequate CNS regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged or lost CNS structure and circuitry in a wide range of neurological disorders. Similarly, the existing markets lack a clinically-suitable human cardiomyocyte (the mature contracting heart muscle cell) source with adequate myocardium (the contractile heart muscle) regenerative potential, which has been the major setback in developing safe and effective cell-based therapies for regenerating the damaged human heart in cardiovascular disease **(please see the limitations of existing approaches and markets above)**. Therefore, currently, our hESC neuronal and cardiomyocyte cell therapy derivatives are the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate CNS neurons and contractile heart muscles, vital for CNS and heart repair in the clinical setting. The availability of human stem/progenitor/precursor cells in high purity and large quantity with adequate cellular neurogenic or cardiogenic potential will greatly facilitate developing safe and effective cell-based regeneration and replacement therapies against a wide range of CNS and heart disorders. Our breakthrough human stem cell technologies transform non-functional pluripotent hESCs into a large supply of high quality fate-restricted functional human cell therapy derivatives or products, which dramatically increases the clinical efficacy of graft-dependent repair and safety of hESC-derived cellular products, marking a turning point in cell-based regenerative medicine from current studies in animals towards human trials or first-in-human studies.

Our Proprietary PluriXcel-DCS Technology -- Defined platform for well-controlled derivation, maintenance, and differentiation of clinical-grade pluripotent hESCs

Maintaining undifferentiated hESCs in a defined biologics-free culture system that allows faithful expansion and controllable direct differentiation is one of the keys to their therapeutic utility and potential, which requires a better understanding of the minimal essential components necessary for sustaining the pluripotent state and well-being of undifferentiated hESCs. The hESC lines initially were derived and maintained in co-culture with growth-arrested mouse embryonic fibroblasts (MEFs). Using this mouse-support system has compromised the therapeutic potential of those hESCs because of the

risk of transmitting xenopathogens, altering genetic background, and promoting the expression of immunogenic proteins. In addition, the need for foreign biologics for derivation, maintenance, and differentiation of hESCs may make direct use of such cells and their derivatives in patients problematic. To avoid those shortcomings, we have resolved the elements of a defined culture system necessary and sufficient for sustaining the epiblast pluripotence of hESCs, including bFGF, insulin, ascorbic acid, laminin, and activin-A, serving as our **PluriXcel-DCS** technology platform for *de novo* derivation of animal-free therapeutically-suitable hESCs and well-controlled efficient specification of such pluripotent cells exclusively and uniformly towards a particular lineage by small molecule induction (see our proprietary PluriXcel-SMI technology).

We have resolved the minimal essential requirements for the maintenance of pluripotent hESCs to establish a defined platform for *de novo* derivation and long-term stable maintenance of pluripotent hESCs (our proprietary PluriXcel-DCS technology), which has overcome some of the major obstacles in translational biology or clinical application. Good manufacturing practice (GMP) quality, defined by both the European Medicine Agency (EMA) and the Food and Drug Administration (FDA), is a requirement for clinical-grade cells, offering optimal defined quality and safety in cell transplantation. Our proprietary PluriXcel-DCS Technology allows all poorly-characterized and unspecified biological components and substrates in the culture system, including those derived from animals, to be removed, substituted, and optimized with defined human alternatives for *de novo* derivation and long-term maintenance of cGMP-quality xeno-free stable hESC lines and their human cell therapy derivatives, which have never been contaminated with animal cells and proteins and, thus suitable for therapeutic development and clinical applications.

Our Proprietary PluriXcel-SMI-Neuron Technology – Directly turning nonfunctional pluripotent hESCs into a large supply of plastic CNS derivatives of a neuronal lineage for tissue engineering and cell therapy

To date, the lack of a clinically-suitable source of engraftable human stem/progenitor cells with adequate neurogenic potential has been the major setback in developing safe and effective cell-based therapies for restoring the damaged or lost CNS structure and circuitry in a wide range of neurological disorders. The traditional sources of engraftable human stem cells with neural potential for transplantation therapies have been multipotent human neural stem cells (hNSCs) isolated directly from the human fetal neuroectoderm or CNS. However, cell therapy based on CNS tissue-derived hNSCs has encountered supply restriction and difficulty to use in the clinical setting due to their declining plasticity with aging and limited expansion ability, making it difficult to maintain a large scale culture and potentially restricting the tissue-derived hNSC as an adequate source for graft material. Despite some beneficial outcomes, CNS tissue-derived hNSCs appeared to exert their therapeutic effect primarily by their non-neuronal progenies through producing trophic and/or neuro-protective molecules to rescue endogenous host neurons, but not related to regeneration from the graft or host remyelination.

Pluripotent hESCs have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for unrestricted

differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. We discovered that pluripotent hESCs maintained under the defined culture conditions can be uniformly converted into human neuronal progenitors and neurons by small molecule induction, which has generated medical inventions for our PluriXcel-SMI technology. Retinoic acid (RA) was identified as sufficient to induce the specification of neuroectoderm direct from the pluripotent state of hESCs maintained under the defined culture, without going through a multi-lineage EB stage, and trigger a cascade of neuronal lineage-specific progression to human neuronal progenitors (Xcel-hNuP) and neurons (Xcel-hNu) of the developing CNS in high efficiency, purity, and neuronal lineage specificity by promoting nuclear translocation of the neuronal specific transcription factor Nurr-1, which has generated our proprietary PluriXcel-SMI-Neuron technology for directly turning nonfunctional pluripotent hESCs into a large supply of plastic CNS derivatives of a neuronal lineage for tissue engineering and cell therapy.

Our proprietary PluriXcel-SMI-Neuron technology transforms pluripotent hESCs uniformly into a large supply of more neuronal lineage-specific nuclear Nurr1-positive embryonic neuronal progenitor than the prototypical neuroepithelial-like nestin-positive hNSCs derived either from CNS or hESCs. Genome-scale profiling of microRNA differential expression showed that the expression of pluripotence-associated hsa-miR-302 family was silenced and the expression of Hox miRNA hsa-miR-10 family that regulates gene expression predominantly in neuroectoderm was induced to high levels in these hESC-derived neuronal progenitors. Following transplantation, including studies in animal models, they engrafted widely and yielded well-dispersed and well-integrated human neurons at a high prevalence within neurogenic regions of the brain. Studies in non-human primate models of Parkinsonian show consistent and dramatic improvement (i.e., a significant decrease in Parkinsonian symptoms over the entire evaluation period), reflecting a restitution of dopmainergic (DA) function by these hESC-derived neuronal progenitors. Our proprietary PluriXcel-SMI-Neuron technology breakthrough enables well-controlled generation of a large supply of neuronal lineage-specific progenies across the spectrum of developmental stages direct from the pluripotent state of hESCs with small molecule induction, providing an adequate neurogenic source for developing safe and effective stem cell therapy for CNS repair. Our proprietary PluriXcel-SMI-Neuron technology dramatically increase the clinical efficacy of graft-dependent neuron replacement and safety of hESC-derived cellular products for scale-up CNS regeneration. Currently, these hESC neuronal cell therapy derivatives or products are the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate CNS neurons, vital for CNS repair in the clinical setting. The availability of human neuronal progenitors and neuronal cells in high purity and large quantity with adequate neurogenic potential will facilitate CNS tissue-engineering and accelerate the development of safe and effective cell-based therapy against a wide range of neurological disorders.

Schematic Comparison of
Our Proprietary PluriXcel-SMI-Neuron Technology
with
Conventional Multi-Lineage Differentiation Approaches

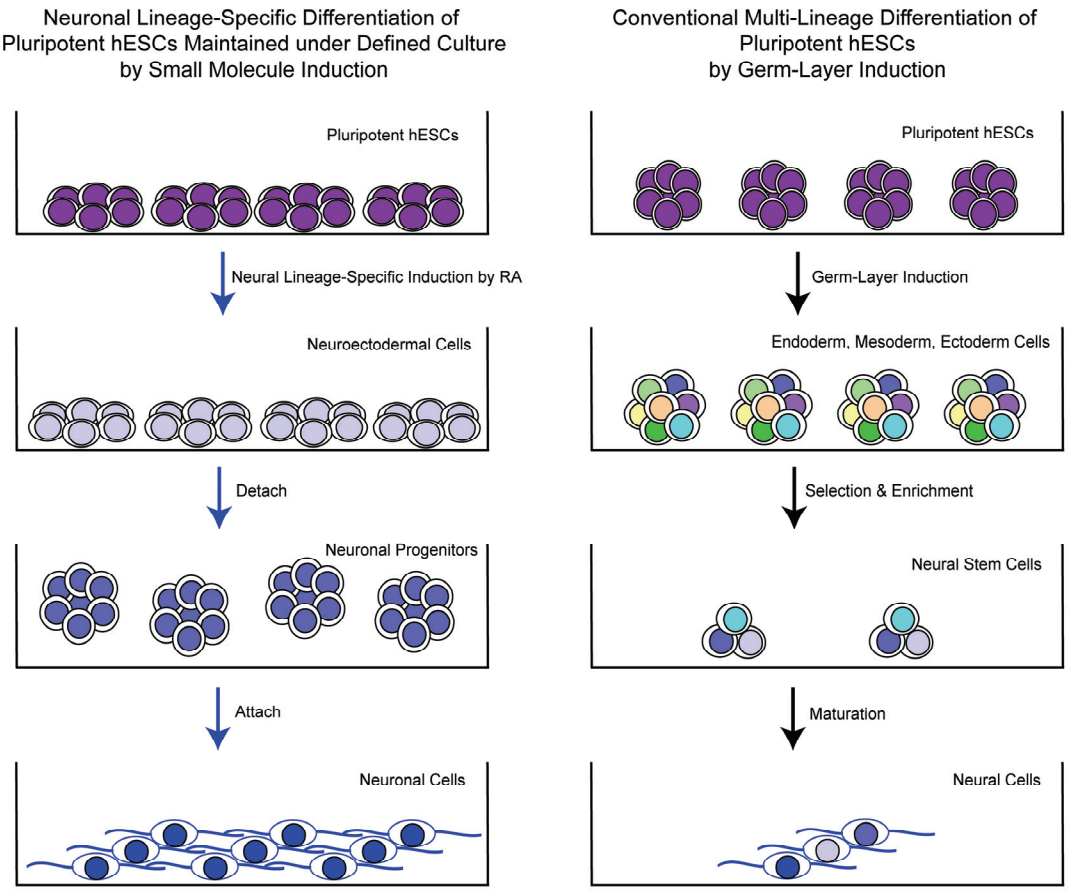


Figure 1. Schematic comparison of our proprietary **PluriXcel-SMI-Neuron Technology** (right panel, well-controlled efficient neuronal lineage-specific differentiation of pluripotent hESCs directly and exclusively into cells of a neuronal lineage by small signal molecule induction) with conventional neural differentiation approach using multi-lineage inclination of pluripotent cells through spontaneous germ-layer induction (left panel) (By courtesy of Parsons, British Biotech. J. 2013;3(4):424-457). Conventional multi-lineage differentiation approaches in the existing markets have the shortcomings of unpredictable, uncontrollable, unrepeatable, low-efficiency, phenotypic heterogeneity and instability, high risk of tumor and/or inappropriate cell type formation following transplantation, and require laborious, costly, and time-consuming purification or isolation procedures to generate only a small quantity of desired cells, impractical for commercial and clinical applications. Our proprietary PluriXcel-SMI-Neuron Technology has been able to overcome those shortcomings of conventional multi-lineage differentiation approaches in the existing markets.

Comparison of Neuronal Differentiation Efficiencies of Pluripotent hESCs by Our Proprietary PluriXcel-SMI-Neuron Technology (NEURONAL) with Conventional Multi-Lineage Differentiation Approaches (CONTROL)

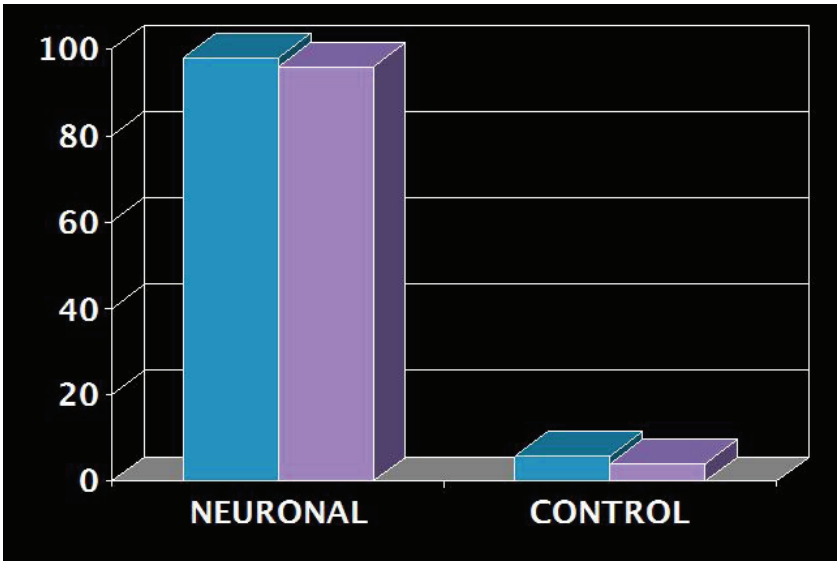


Figure 2. Comparison of neuronal differentiation efficiencies of pluripotent hESCs by our proprietary **PluriXcel-SMI-Neuron Technology (NEURONAL:** neuronal lineage-specific differentiation of pluripotent hESCs directly and exclusively to cells of a neuronal lineage by small signal molecule induction) with conventional multi-lineage differentiation approaches through spontaneous germ-layer induction to neural cells (CONTROL). Our **PluriXcel-SMI-Neuron Technology** shows a drastic increase in neuronal differentiation efficiency (> 90% of cells expressing neuronal markers, e.g., beta-III-tubulin) when compared to similarly cultured cells derived from embryoid bodies (<5% of cells expressing neuronal markers) by conventional multi-lineage differentiation approaches (see Figure 1 for comparison of the methods).

Images of Human Neuronal Cells (Xcel-hNu) Derived from hESCs by Our Proprietary PluriXcel-SMI-Neuron Technology

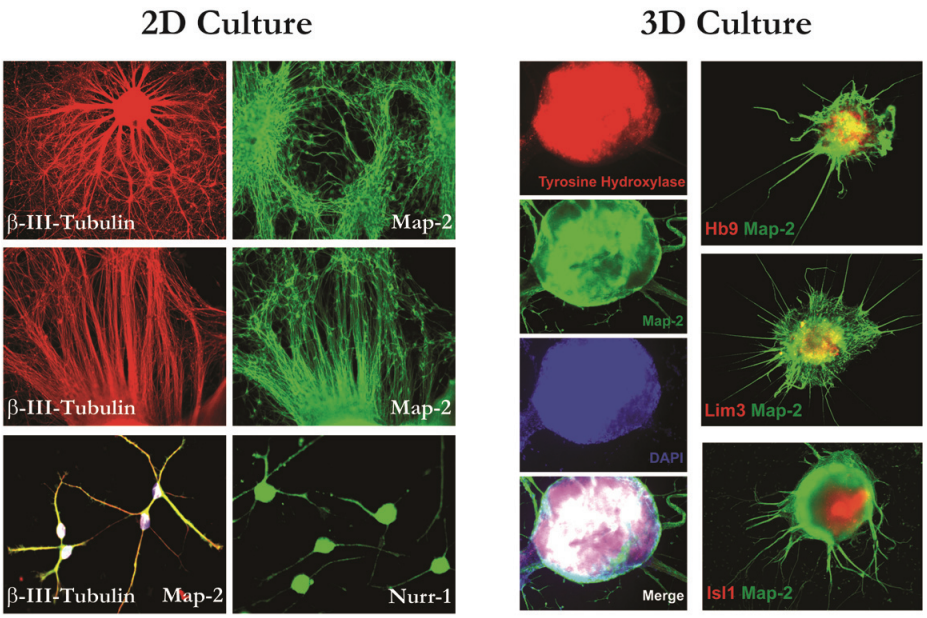


Figure 3. Images of human neuronal cells (Xcel-hNu) derived from hESCs by our proprietary PluriXcel-SMI-Neuron technology show (neuronal markers) the strong expression of typical neuronal markers beta-III-tubulin and co-expression of Map-2 by exuberantly neurite-bearing neuronal cells, and the strong expression and nuclear localization of neuronal specific transcription factor Nurr-1, suggesting activation. Under neuronal subtype specification conditions in 3D culture, these hESC-derived neuronal cells by small molecule induction further proceeded to express subtype neuronal markers associated with ventrally-located neuronal populations, such as dopaminergic (DA) neurons (expressing DA marker tyrosine hydroxylase and co-expressing neuronal marker Map-2) and motor neurons (expressing motor neuron marker Hb9, Lim3, Isl1 and co-expressing neuronal marker Map-2), demonstrating their therapeutic potential for regeneration of CNS neuronal cell types and subtypes *in vivo* as stem cell therapy to be translated to patients in clinical trials.

MicroRNA Signatures of Human Neuronal Progenitor Cells and Neuronal Cells Derived from hESCs by Our Novel PluriXcel-SMI-Neuron Technology

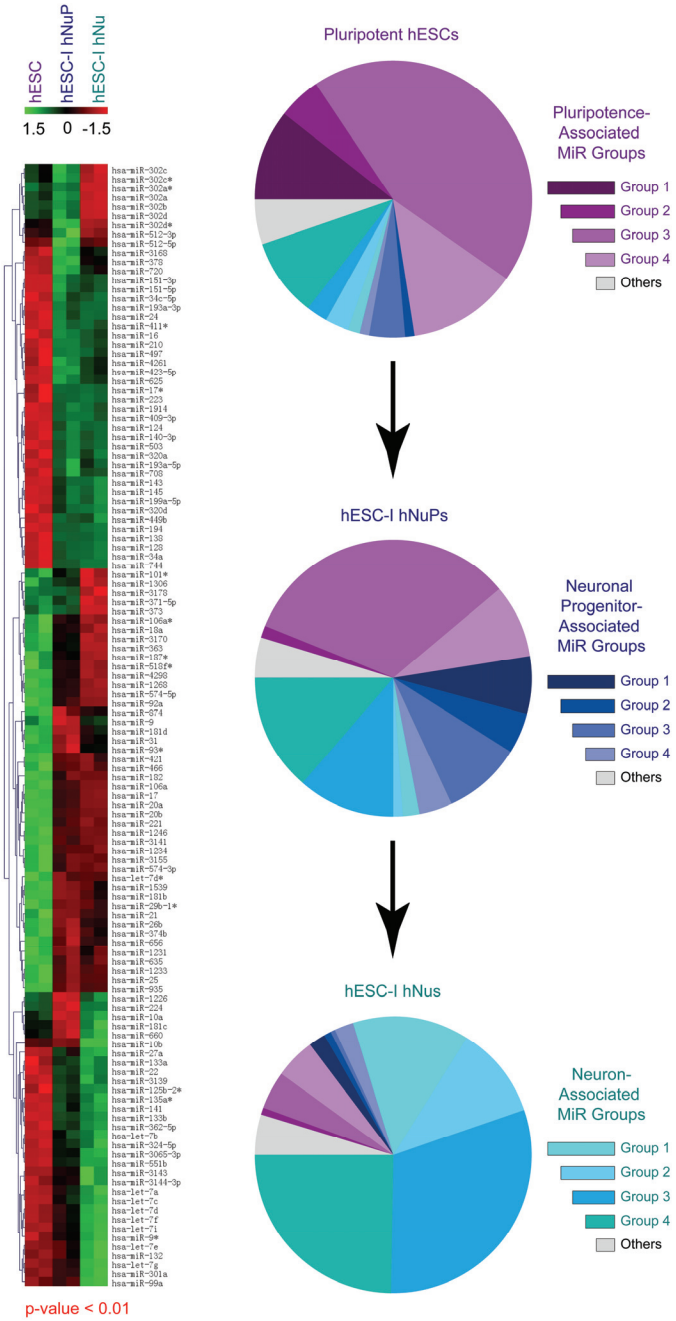


Figure 4. MiRNA (MiR) signatures of human neuronal progenitor cells (Xcel-hNuP or hESC-I hNuP) and neuronal cells (Xcel-hNu or hESC-I hNu) derived from hESCs by our novel PluriXcel-SMI-Neuron technology (By courtesy of Parsons et al., Mol. Med. Ther. 2013;1:2). Right Panel: Hierarchal clustering of differentially expressed miRNAs generated by genome-scale profiling of miRNA differential expression in hESCs neuronal lineage-specific progression. Left Panel: Pie charts showing decreased contribution of a set of pluripotence-associated miRNAs (purple) and increased contribution of distinct sets of neuronal progenitor-associated miRNAs (blue) and neuron-associated miRNAs (cyan) to the entire miRNA populations during hESC neuronal lineage-specific progression. Please note that the expression of pluripotence-associated hsa-miR-302 clusters (dark purple) was silenced and the expression of Hox miRNA hsa-miR-10 cluster (dark blue) was induced to high levels in these *in vitro* neuroectoderm-derived human neuronal progenitors and neurons.

Our Proprietary PluriXcel-SMI-Heart Technology – Directly turning nonfunctional pluripotent hESCs into a large supply of cardiomyocyte derivatives for heart regeneration: the vital source for myocardial tissue engineering and myocardium (heart muscle) repair

Cardiovascular disease (CVD) is a major health problem and the leading cause of death in the Western world. About 600,000 people die of heart disease in the US every year – that is 1 in every 4 deaths. The estimated costs of CVD for the overall US population are approximately $190 billion annually. Given the limited capacity of the heart muscle for self-repair, currently, there is no treatment option or compound drug of molecular entity that can change the prognosis of CVD. In the adult heart, the mature contracting cardiac muscle cells, known as cardiomyocytes, are terminally differentiated and unable to regenerate. There is no evidence that adult stem/precursor/progenitor cells derived from mature tissues, such as bone marrow, cord blood, umbilical cord, mesenchymal stem cells, patient heart tissue, placenta, or fat tissue, are able to give rise to the contractile heart muscle cells following transplantation into the heart. To date, the lack of a suitable human cardiomyocyte source with adequate myocardium regenerative potential has been the major setback in regenerating the damaged human heart, either by endogenous cells or by cell-based transplantation or cardiac tissue engineering. Despite numerous reports about cell populations expressing stem/precursor/progenitor cell markers identified in the adult hearts, the minuscule quantities and growing evidences indicating that they are not genuine heart cells and that they give rise predominantly to non-functional smooth muscle cells rather than functional contractile cardiomyocytes have caused skepticism if they can potentially be harnessed for cardiac repair. Although a vast sum of government and private funding has been spent on looking for adult alternates, such as reprogramming and trans-differentiation of fibroblasts or mature tissues, so far, only human cardiac stem/precursor/progenitor cells derived from embryo-originated hESCs have shown such cellular pharmacologic utility and capacity adequate for myocardium regeneration in pharmaceutical development of stem cell therapy for the damaged heart.

Human embryonic stem cell (hESC) cardiac cell derivatives have emerged as a powerful pharmacologic agent of cellular entity for CVD because they have direct pharmacologic utility and capacity for human myocardium regeneration. Due to the prevalence of heart disease worldwide and acute shortage of donor organs or adequate human myocardial grafts, there is intense interest in developing hESC-based therapy for heart disease and failure. We found that pluripotent hESCs maintained under the defined culture conditions can be uniformly converted into a specific cardiac lineage by small molecule induction. Nicotinamide (NAM) was identified sufficient to induce the specification of cardiomesoderm direct from the pluripotent state of hESCs maintained under the defined culture, without going through a multi-lineage EB stage, by promoting the expression of the earliest cardiac-specific transcription factor Csx/Nkx2.5 and triggering progression to cardiac precursors and beating cardiomyocytes with high efficiency, which has generated our proprietary PluriXcel-SMI-Heart technology for directly turning nonfunctional pluripotent hESCs into a large supply of cardiomyocyte derivatives for tissue engineering and cell therapy. Cells within the beating cardiospheres expressed markers characteristic of cardiomyocytes, including Nkx2.5, GATA-4, α-

Schematic Comparison of
Our Proprietary PluriXcel-SMI-Heart Technology
with
Conventional Multi-Lineage Differentiation Approaches

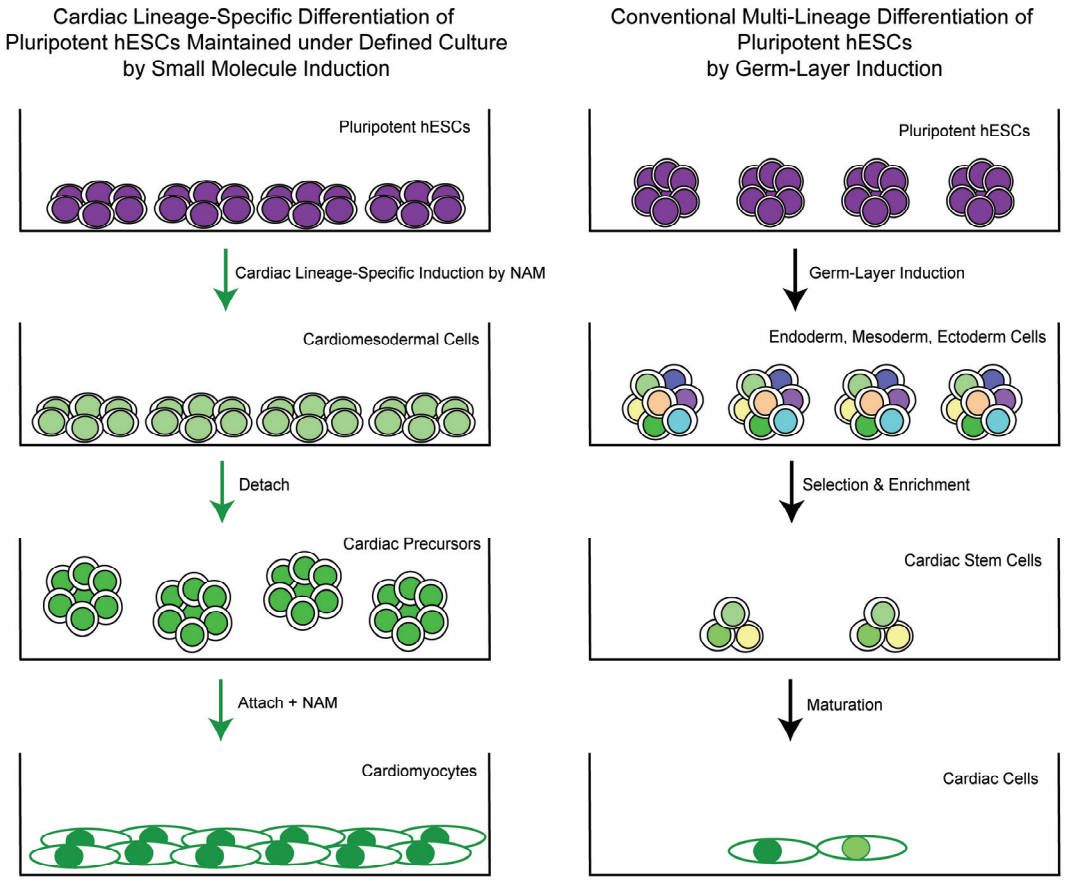


Figure 5. Schematic comparison of our proprietary **PluriXcel-SMI-Heart Technology** (right panel, well-controlled efficient cardiac lineage-specific differentiation of pluripotent hESCs directly and exclusively to a cardiomyocyte fate by small signal molecule induction) with conventional cardiac differentiation approach using multi-lineage inclination of pluripotent cells through spontaneous germ-layer induction (left panel) (By courtesy of Parsons, British Biotech. J. 2013;3(4):424-457). Conventional multi-lineage differentiation approaches in the existing markets have the shortcomings of unpredictable, uncontrollable, unrepeatable, low-efficiency, phenotypic heterogeneity and instability, high risk of tumor and/or inappropriate cell type formation following transplantation, and require laborious, costly, and time-consuming purification or isolation procedures to generate only a small quantity of desired cells, impractical for commercial and clinical applications. Our proprietary PluriXcel-SMI-Heart Technology has been able to overcome those shortcomings of conventional multi-lineage differentiation approaches in the existing markets.

actinin, cardiac troponin I (cTnI), and cardiac troponin T (cTnT). Electrical profiles of the cardiomyocytes confirmed their contractions to be strong rhythmic impulses reminiscent of the p-QRS-T-complexes seen from body surface electrodes in clinical electrocardiograms.

Our proprietary PluriXcel-SMI-Heart technology transforms nonfunctional pluripotent hESCs uniformly into a large supply of cardiomyocyte derivatives for heart regeneration, providing a vital human cardiac cell source for myocardial tissue engineering and myocardium (heart muscle) repair. Our breakthroughs have overcome some major obstacles in bringing hESC therapy to clinics, enabling *de novo* derivation of clinical-grade cGMP compatible stable hESC lines from human blastocysts that have never been contaminated by animal cells and proteins, and direct conversion of such pluripotent hESCs into a large supply of clinical-grade functional human heart precursors and cardiomyocytes to be translated to patients for mending the damaged heart. Our novel approach of hESC cardiac lineage-specific differentiation direct from the pluripotent stage using small molecule induction is a major milestone towards clinical application of hESC cell therapy derivatives, offering the benefits in efficiency, purity, stability, safety, and large-scale production of clinical-grade high quality hESC cell therapy products in cGMP facility over all other existing conventional approaches. Currently, our hESC cardiomyocyte cell therapy derivatives or products are the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate the contractile heart muscles, vital for heart repair in the clinical setting. The availability of human heart precursors and cardiomyocytes in high purity and large quantity with adequate potential for myocardium regeneration will facilitate myocardial tissue-engineering and accelerate the development of safe and effective cell-based therapy for heart disease and failure that affect millions of survivors and so far have no treatment option or cure.

Comparison of Cardiac Differentiation Efficiencies of Pluripotent hESCs by Our Novel PluriXcel-SMI-Heart Technology (CARDIAC) with Conventional Cardiac Differentiation Approaches (CONTROL)

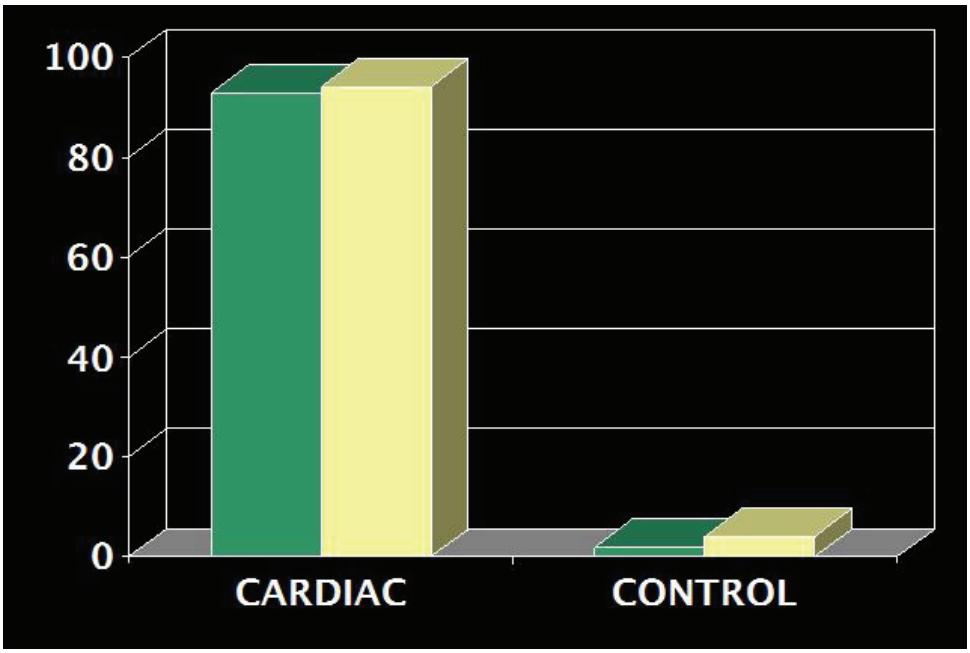


Figure 6. Comparison of cardiac differentiation efficiencies of pluripotent hESCs by our proprietary **PluriXcel-SMI-Heart Technology (CARDIAC:** cardiac lineage-specific differentiation of pluripotent hESCs directly and exclusively to cells of a cardiac lineage by small signal molecule induction) with conventional multi-lineage differentiation approaches through spontaneous germ-layer induction to cardiac cells (CONTROL). Our **PluriXcel-SMI-Heart Technology** shows a drastic increase in cardiac differentiation efficiency (> 90% of cells expressing cardiac markers, e.g., cardiac specific transcriptional factor Csx/Nkx2.5) when compared to similarly cultured cells derived from embryoid bodies (<4% of cells expressing cardiac markers) by conventional multi-lineage differentiation approaches (see Figure 1 for comparison of the methods).

Electrical Profile of the Cardiomyocytes Derived from hESCs by Our Proprietary PluriXcel-SMI-Heart Technology

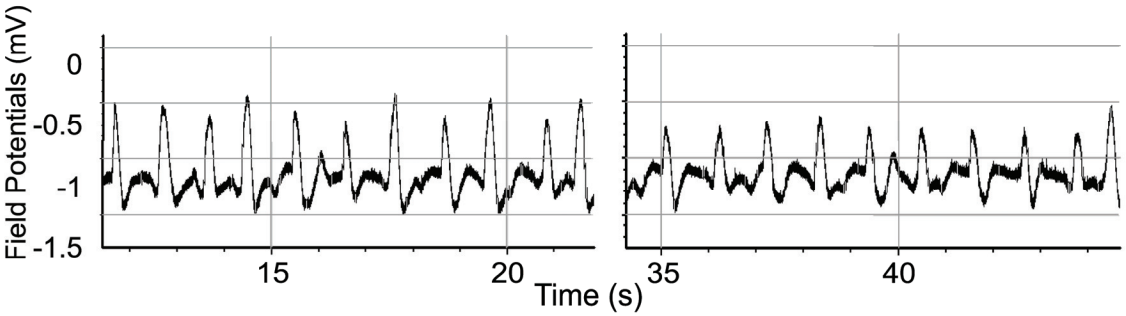


Figure 7. Electrical profiles of the cardiomyocytes derived from hESCs by small molecule-induced cardiac lineage specific differentiation shows strong rhythmic contractions (field potential by electrical recording, also see visual videos in Parsons et al, J. Vis. Exp. 2011 for strong rhythmic contractions) reminiscent of the p-QRS-T-Complexes seen from body surface electrodes in clinical electrocardiograms (By courtesy of Parsons et al, J. Vis. Exp. 2011).

Lineage-specific differentiation of pluripotent hESCs by small molecule induction opens the door to investigate molecular embryogenesis in human development

Understanding the much more complex human embryonic development has been hindered by the restriction on human embryonic and fetal materials as well as the limited availability of human cell types and tissues for study. In particular, there is a fundamental gap in our knowledge regarding the molecular networks and pathways underlying the CNS and heart formation in human embryonic development. The enormous diversity of human somatic cell types and the highest order of complexity of human genomes, cells, tissues, and organs among all the eukaryotes pose a big challenge for characterizing, identifying, and validating functional elements in human embryonic development in a comprehensive manner. Derivation of hESCs provides a powerful *in vitro* model system to investigate the molecular controls in human embryonic development as well as an unlimited source to generate the diversity of human cell types and subtypes across the spectrum of development stages for repair. Development and utilization of hESC models of human embryonic development will facilitate rapid progress in identification of molecular and genetic therapeutic targets for the prevention and treatment of human diseases. However, without a practical strategy to convert pluripotent cells direct into a specific lineage, previous studies are limited to profiling of hESCs differentiating multi-lineage aggregates, such as embryoid bodies (EB) that contain mixed cell types of endoderm, mesoderm, and ectoderm cells or a heterogeneous population of EB-derived cardiac or cardiovascular cells that contain mixed cell types of cardiomyocytes, smooth muscle cells, and endothelial cells. Those previous reports have been limited to a small

group of genes that have been identified previously in non-human systems and, thus, have not uncovered any new regulatory pathways unique to humans or human development. Due to the difficulty of conventional multi-lineage differentiation approaches in obtaining the large number of purified functional cells, particularly neurons and cardiomyocytes, typically required for genome-wide large-scale high-throughput profiling, studies to reveal the mechanism in hESC differentiation towards a functional phenotype remain lacking.

Our innovative small molecule direct induction approach renders a cascade of neuronal or cardiac lineage-specific progression directly from the pluripotent state of hESCs, providing much-needed *in vitro* model systems for investigating the genetic and epigenetic programs governing the human CNS or heart formation in embryogenesis. Recent advances in large-scale profiling of developmental regulators in high-resolution provide powerful genome-wide high-throughput approaches that will lead to great advances in our understanding of the global phenomena of human embryogenesis. Our *in vitro* hESC model systems enable direct generation of large numbers of high purity hESC neuronal or cardiomyocyte derivatives required for genome-scale profiling, including miRNA and ChIP-seq profiling, to reveal the mechanisms responsible for regulating the patterns of gene expression in hESC neuronal or cardiomyocyte specification. It opens the door for further characterizing, identifying, and validating functional elements during human embryonic development in a comprehensive manner. Unveiling genetic and epigenetic programs embedded in hESC lineage specification will not only contribute tremendously to our knowledge regarding molecular embryogenesis in human development, but also allow direct control and modulation of the pluripotent fate of hESCs when deriving an unlimited supply of clinically-relevant lineages for cell-based regenerative medicine.

Developing the 3D human embryonic models of the CNS and the heart as tools for biomedical research

Realizing the developmental and therapeutic potential of hESCs has been hindered by conventional approaches for generating functional cells from pluripotent cells through multi-lineage differentiation in 2-dimentsional (2D) culture, which is uncontrollable, inefficient, instable, highly variable, difficult to reproduce and scale-up. The traditional methods of 2D culture often result in unpredictable stem cell function and behavior *in vivo* following transplantation. Thus far, testing potential therapeutic strategies have largely relied on animal models for behavior, safety, and efficacy evaluation of therapeutic candidates and human cell therapy products. However, because of interspecies differences, conventional studies using animal models are often poor predictors of human efficacy and safety. Animal models are xeno-hosts for transplantation of human cells, not ideal for testing the safety and efficacy of therapeutic outcomes of human stem cells. Large primate models are very costly and often taken years to obtain results. In addition, the results of animal studies can be highly variable and difficult to reproduce, making them unreliable as benchmarks for decisions on human clinical trials. Development and utilization of complex 3D multi-cellular hESC models of human embryogenesis and organogenesis will provide a powerful tool that enables analysis under conditions that are tightly regulated and authentically representing

the *in vivo* spatial and temporal patterns, and thus reduce the reliance on animal models to test potential therapeutic strategies. It will go beyond flat biology to increase the biological complexity of human-based *in vitro* models and assays to mimic the *in vivo* human organ systems and functions, which are controllable, reproducible, and scalable, and can be monitored and validated against responses on multiple hierarchical levels. Our breakthroughs in establishing highly efficient hESC neural or cardiac lineage-specific differentiation by small molecule induction propel hESC research leaping forward to develop the multi-cellular 3D models of the human CNS or heart. Such research programs will provide a powerful tool targeted for rapid and high fidelity safety and efficacy evaluation of human therapeutic candidates and human cell therapy products against CNS and heart diseases, and thus lead to advances in technologies used in the regulatory review. It will dramatically increase the overall turnover of investments in biomedical sciences and facilitate rapid progress on identification of therapeutic targets and approaches for the prevention and treatment of human diseases.

The Competitive Advantages of Our Novel PluriXcel Human Stem Cell Technology Platforms

Our novel **PluriXcel** human stem cell technology platforms include our **PluriXcel-DCS** technology and our **PluriXcel-SMI** technology. Our **PluriXcel** technology platforms enable large scale production or manufacture of high quality clinical-grade human neuronal and heart muscle cell therapy products as cellular medicines that can offer pharmacologic utility and capacity adequate for CNS and heart regeneration.

(a) **PluriXcel-DCS** technology: Defined culture systems for derivation and maintenance of clinical-grade high quality pluripotent hESC lines. Our PluriXcel-DSC technology allows all poorly-characterized and unspecified biological components and substrates in the culture system, including those derived from animals, to be removed, substituted, and optimized with defined human alternatives for *de novo* derivation and long-term maintenance of cGMP-quality xeno-free stable hESC lines and their human cell therapy derivatives, which have never been contaminated with animal cells and proteins, thus suitable for therapeutic development and clinical applications.

(b) **PluriXcel-SMI** technology: Lineage-specific differentiation of pluripotent hESCs by small molecule induction. Our PluriXcel-SMI technology enables high efficient neural or cardiac lineage-specific differentiation direct from the pluripotent stage of hESCs using small molecule induction, which is a major milestone towards clinical application of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of high quality clinical-grade human stem cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Our **PluriXcel-SMI** technology platforms include our **PluriXcel-SMI-Neuron** technology and our **PluriXcel-SMI-Heart** technology.

(i) **PluriXcel-SMI-Neuron** technology: Well-controlled efficient neuronal lineage-specific differentiation of pluripotent hESCs directly and exclusively into cells of a neuronal lineage by small molecule induction. Our **PluriXcel-SMI-Neuron** technology enables high efficient direct conversion of pluripotent hESCs into a large scale of high quality neuronal progenitors and functional neuronal cells adequate for

clinical development of safe and effective stem cell therapies for a wide range of neurological disorders.

(ii) **PluriXcel-SMI-Heart** technology: Well-controlled efficient Heart/cardiac lineage-specific differentiation of pluripotent hESCs directly and exclusively to a cardiomyocyte fate by Small Molecule Induction. Our **PluriXcel-SMI-Heart** technology enables high efficient direct conversion of pluripotent hESCs into a large scale of high quality heart precursors and functional cardiomyocytes (heart muscle cells) adequate for clinical development of safe and effective stem cell therapies for heart disease and failure.

The Xcel Prototypes of Proprietary Clinical-Grade Human Stem Cell Therapy Products

Our **Xcel prototypes**, generated from hESCs using our novel PluriXcel technology, currently include **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells). We believe that our **Xcel prototypes** represent the next generation of human cell therapy products, offering purity, large-scale production, high quality, safety, and effectiveness for commercial and therapeutic uses over all other existing cell sources.

Therapeutic Products	Product Description	Clinical Applications
Xcel-hNuP	Clinical-grade high purity human neuronal progenitor cells	Cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, motor neuron diseases, neurodegenerative diseases, stroke, brain and spinal cord injuries.
Xcel-hNu	Clinical-grade high purity human neurons	
Xcel-hCardP	Clinical-grade high purity human heart precursor cells	Cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.
Xcel-hCM	Clinical-grade high purity human cardiomyocytes	

Xcel-hNuP: Clinical-grade high purity human neuronal progenitor cells for CNS neuron regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, motor neuron diseases, neurodegenerative diseases, stroke, brain and spinal cord injuries.

Xcel-hNu: Clinical-grade high purity human neurons for CNS neuron regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for a wide range of neurological disorders, including Parkinsons disease, Amyotrophic lateral sclerosis (ALS), Spinal muscular atrophy, Alzheimer disease, motor neuron disease, neurodegenerative diseases, stroke, brain and spinal cord injuries.

Xcel-hCardP: Clinical-grade high purity human heart precursor cells for contractile heart muscle regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.

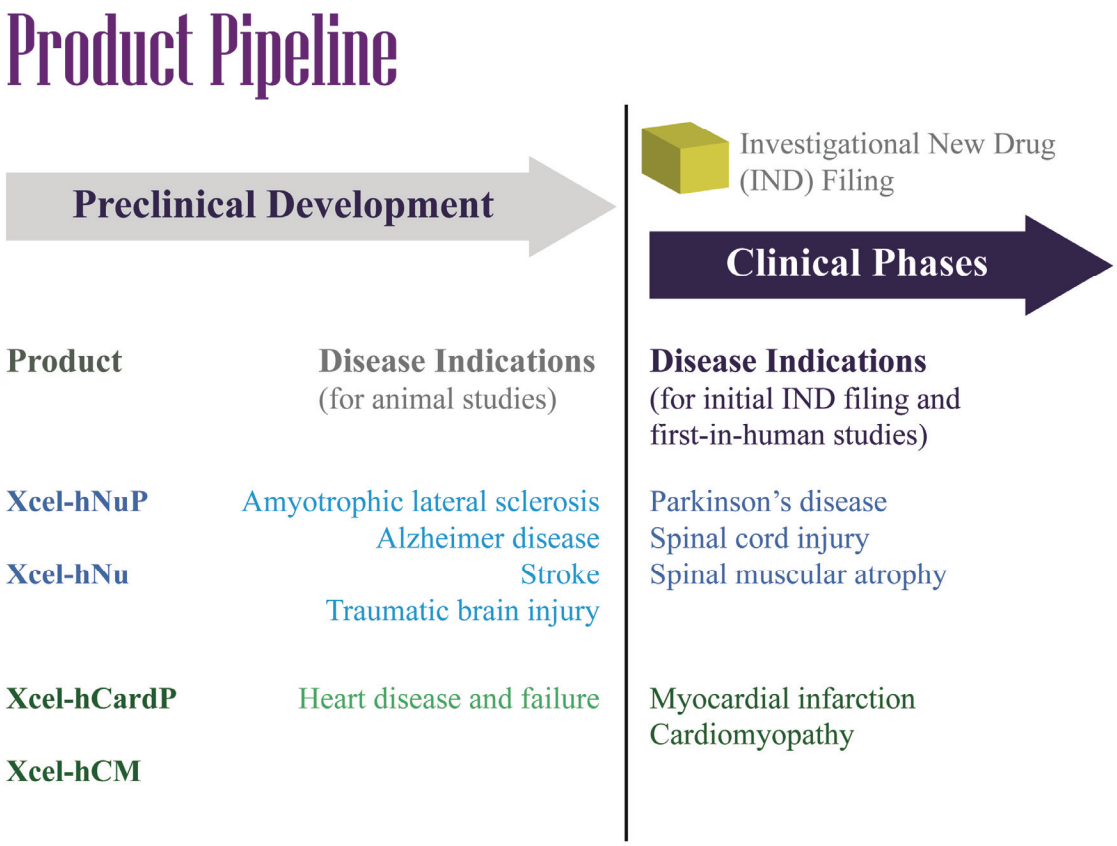
Xcel-hCM: Clinical-grade high purity human cardiomyocytes (heart muscle cells) for contractile heart muscle regeneration. *Therapeutic Sector:* cellular medicine or cell therapy product for cardiovascular disease, including heart disease and failure, Myocardial infarction, Cardiomyopathy, Ischemic heart disease, Congestive heart failure.

Product Pipeline for Our Lead Clinical-Grade Human Stem Cell Therapy Products from PluriXcel Platforms

We were recently incorporated as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an 501C3 tax-exempt non-profit biomedical research institute. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. Through acquisition of proprietary human stem cell assets by issuing company stocks, the Company has invested substantially all of our efforts and financial resources in developing our novel human stem cell technology PluriXcel platforms, conducting preclinical studies of our human stem cell therapy products, and pursuing the protection of our intellectual properties on our proprietary human stem cell technologies and cell therapy products in the US (US patent filing) and the world (PCT international filing and entry into national stage filing). We are currently moving towards clinical development stage or first-in-human studies of our stem cell therapy product candidates.

As of the date of this prospectus, we have not raised sufficient funds to support filing an investigational new drug (IND) application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for

funding our clinical development efforts, including investigational new drug (IND) filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline) for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.



Traditional pharmaceutical research & development (R&D) in existing markets usually starts with drug leads discovered in animals or other lower organisms, thus require lengthy and costly both demonstration in animal model testing and establishment of proof-of-concept and safety in human trials. Pluripotent hESCs are derived from the pluripotent inner cell mass or epiblast of the human blastocyst or embryos and, thus, have both the unconstrained capacity for long-term stable undifferentiated growth in culture and the intrinsic potential for differentiation into all the somatic cell types in the human body, holding tremendous potential for restoring human tissue and organ function. Therefore, unlike traditional pharmaceutical R&D, our novel cellular therapeutic

products have been developed directly with human cells or hESCs with proof-of-concept already established in humans, which simplifies the development process and lower the costs for R&D, shortens the time consumption for R&D, and increases the probability of clinical success dramatically. Xcelthera breakthrough human stem cell technologies (PluriXcel Technology), including defined culture systems for *de novo* derivation and long-term maintenance of clinical-grade stable pluripotent hESC lines (PluriXcel-DSC technology) and lineage-specific differentiation of pluripotent hESCs by small molecule induction (PluriXcel-SMI technology), enable clinical applications of hESC therapeutic utility. Our therapeutic products have been developed specifically to address and overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies, including offering the benefits in high efficiency, stability, low tumor risk, high purity, high efficacy in repair, as well as safety and large-scale production or manufacturing over all other existing approaches.

We are in the early stages of commercializing our licensed technologies and products, which have been developed, in part, with supports by government grants to the founder of the Company and San Diego Regenerative Medicine Institute, which have expired or discontinued. As of the date of this prospectus, the Company has not received any support from government funding. New funding by these governmental agencies may be significantly reduced, withdrawn, delayed, or eliminated in the future for a number of reasons, such as budget cuts, changes in fiscal year appropriation, changes in funding direction and policy, changes in funding priority or allocation, government shutdown, perceived or real conflicts of interest, and ethical or legal issues brought to these governmental funding agencies (see Risk Factors). A restriction on the government funding available to us would reduce the resources that we would be able to devote to existing and future research and development efforts. Such a reduction could delay the progress and development of new products and hurt our competitive position.

Selected Scientific Publications

These peer-reviewed scientific publications are relevant to the invention and R&D of our novel human stem cell technology (PluriXcel Technology) and clinical-grade hESC lines and hESC neuronal and heart cell therapy products (Xcel) acquired by the Company from San Diego Regenerative Medicine Institute by issuing company stocks. Links to the following scientific publications and press releases can be found at the Company website at www.xcelthera.com and the website of San Diego Regenerative Medicine Institute at www.sdrmi.org. The founder, CEO, and Chairman of the Board of the Company is the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products, and the corresponding author and/or first author of all the articles listed in this section.

Parsons XH. Current state of regenerative medicine: moving stem cell research from animals into humans for clinical trials (Critical Review). *Open Access Stem Cell* 2014;2:1.

Parsons XH. The openness of pluripotent epigenome – defining the genomic integrity of stemness for regenerative medicine (Editorial). *Int. J. Cancer Ther. Oncol.* 2014;2(1):020114. DOI: 10.14319/ijcto.0201.14.

Parsons XH. The designation of human cardiac stem cell therapy products for human trials (Editorial). *J. Clin. Trial Cardiol.* 2014;1(1):02.

Parsons XH. Constraining the pluripotent fate of human embryonic stem cells (hESCs) for tissue engineering and cell therapy – the turning point of cell-based regenerative medicine. *British Biotech. J.* 2013;3(4):424-457. Press Release: Direct conversion of pluripotent human embryonic stem cells into functional cell therapy derivatives brings cell-based regenerative medicine to a turning point.

Parsons XH. Embedding the future of regenerative medicine into the open epigenomic landscape of pluripotent human embryonic stem cells. *Ann. Rev. Res. Biol*. 2013;3(4):323-349. Press Release: Embedding lineage-specific developmental programs into the open epigenomic landscape of pluripotent human embryonic stem cells offers efficiency in deriving cell therapy products for the future of regenerative medicine.

Parsons XH. Exploring future cardiovascular medicine: heart precursors directed from human embryonic stem cells for myocardium regeneration (Editorial). *Cardiol. Pharmacol* 2013;2:3:e110. doi: 10.4172/cpo.1000e110.

Parsons XH. Cellular medicine for the heart - the pharmacologic utility and capacity of human cardiac stem cells (Editorial). *J. Clinic. Exp. Cardiology* 2013;4:7:e128. doi: 10.4172/2155-9880.1000e128.

Parsons XH. Reviving cell-based regenerative medicine for heart reconstitution with efficiency in deriving cardiac elements from pluripotent human embryonic stem cells. *Cardiol. Pharmacol.* 2013;2(3):e112. doi: 10.4172/2329-6607.1000e112.

Parsons XH. Human stem cell derivatives retain more open epigenomic landscape when derived from pluripotent cells than from tissues. *J. Regen. Med.* 2013;1:2. DOI: 10.4172/2325-9620.1000103. PMID23936871. PMC3736349. Press Release: Views of hESC epigenomic landscape open up the future of stem cells to transparency.

Parsons XH, et al. Genome-scale mapping of microRNA signatures in human embryonic stem cell neurogenesis. *Mol. Med. Ther.* 2013;1:2. doi: 10.4172/2324-8769.1000105. PMID23543894. PMC3609664. Press Release: HESCs as the model system for understanding molecular controls in human CNS development.

Parsons XH. An engraftable human embryonic stem cell neuronal lineage-specific derivative retains embryonic chromatin plasticity for scale-up CNS regeneration. *J. Reg. Med. & Tissue Eng.* 2012;1:3. doi: 10.7243/2050-1218-1-3. PMID23542901. PMC3609668. Press Release: Turning pluripotent hESCs into a large supply of plastic CNS derivatives for cell therapy.

Parsons XH. MicroRNA profiling reveals distinct mechanisms governing cardiac and neural lineage-specification of pluripotent human embryonic stem cells. *J. Stem Cell Res. Ther.* 2012;2:124. doi: 10.4172/2157-7633.1000124. PMID23355957. PMC3554249. Press Release: Letter to editor: Lineage-specific differentiation of pluripotent hESCs opens the door to investigate molecular embryogenesis in human development.

Parsons XH. Mending the broken heart - Towards clinical application of human embryonic stem cell therapy derivatives (editorial). *J. Clinic. Exp. Cardiology* 2012;3:12:e116. doi: 10.4172/2155-9880.1000e116. Press Release: Editorial: HESC cardiomyocyte derivatives for heart regeneration - the vital source for myocardial tissue engineering and myocardium repair.

Parsons JF, et al. Defining conditions for sustaining epiblast pluripotence enables direct induction of clinically-suitable human myocardial grafts from biologics-free human embryonic stem cells. *J. Clinic. Exp. Cardiology* 2012;S9:001. doi: 10.4172/2155-9880.S9-001. (Special Issue on Heart Transplantation). PMID22905333. PMC3419496. Press Release: Mending the broken heart - Towards clinical application of human embryonic stem cell therapy derivatives.

Parsons XH. The dynamics of global chromatin remodeling are pivotal for tracking the normal pluripotency of human embryonic stem cells. *Anatom. Physiol.* 2012;S3:002. doi: 10.4172/2161-0940.S3-002. (Special Issue on Stem Cell Biology). PMID23543848. PMC3609651. Press Release: Human embryonic stem cells — The most positive stem cells.

Parsons XH, et al. Efficient derivation of human cardiac precursors and cardiomyocytes from pluripotent human embryonic stem cells with small molecule induction. *J. Vis. Exp.* 2011;57:e3274, doi: 10.3791/3274. PMID22083019. PMC3308594. Press Release: Human embryonic stem cells for heart regeneration — The vital source for cardiovascular repair.

Parsons XH, et al. Efficient derivation of human neuronal progenitors and neurons from pluripotent human embryonic stem cells with small molecule induction. *J. Vis. Exp.* 2011;56:e3273, doi: 10.3791/3273. PMID22064669. PMC3227216. Press Release: The players of regenerative medicine — neuron, the star quarterback.

Parsons XH, et al. Patents on technologies of human tissue and organ regeneration from pluripotent human embryonic stem cells. *Recent Patents on Regenerative Medicine* 2011;1:142-163. PMID2335596. PMC3554241. Press Release: Patentability of human embryonic stem cell research.

Selected Presentations of the Company to the Scientific Community as a Small Business Concern before Incorporation

Although we were recently incorporated as a general stock company, the website of the Company as a small business concern was established in 2011 and the Company has broadly presented its human stem cell technologies for commercialization in the scientific community/conferences and open access scientific publications/journals since 2011, which has provided public information about our human stem cell technologies and breakthroughs for other Companies, reporting firms, and investors to conduct their independent analysis. The founder, CEO, and Chairman of the Board of the Company is the speaker of all the presentations listed in this section.

Parsons XH, Speaker, "Deriving cardiac elements from pluripotent human embryonic stem cells for heart reconstitution", The Keystone Symposium on Cardiovascular Development and Repair (2010), Keystone, CO.

Parsons XH, Speaker, “Emerging company & innovators showcase: Xcelthera: Technologies of human tissue and organ regeneration from pluripotent human embryonic stem cells”, Life Science Summit (2010), New York, NY.

Parsons XH, Speaker, “MicroRNA signatures in small molecule induced cardiac and neural lineage-specification direct from pluripotent human embryonic stem cells”, AAAS Pacific 92nd Annual Meeting (2011), San Diego, CA.

Parsons XH, Speaker, testimony at Institute of Medicine (IOM) Committee on a Review of the California Institute for Regenerative Medicine (CIRM) (2012), Irvine, CA;

Parsons XH, Speaker, “Small molecule lineage-specification of pluripotent human embryonic stem cells and its implication for the future of stem cell therapy”, International Conference on Emerging Cell Therapies (2012), Chicago, MI.

Technology Innovation Award Presented by Frost & Sullivan

Xcelthera, Inc. is the recipient of the prestigious 2013 North American Technology Innovation Award in Stem Cell Technologies presented by Frost & Sullivan. This prestigious recognition by Frost & Sullivan is based on an extensive and independent competitive analysis of the North American Stem Cell Technologies Market and the findings of Best Practices research by Frost & Sullivan competitive analysis.

The subsequent discussion relates solely to the report provided by Frost & Sullivan

Please see exhibit for the original report provided by Frost & Sullivan and the award announcement to the Company. The award by Frost & Sullivan was not commissioned by the Company. The Company was not involved in their analysis, nor influenced their report in any way. Please note Frost & Sullivan retains the copyright for their report.

About Frost & Sullivan:

Frost & Sullivan is in its 50th year in business with a global research organization of 1,800 analysts and consultants who monitor more than 300 industries and 250,000 companies. The company research philosophy originates with the CEO 360-Degree Perspective™, which serves as the foundation of its TEAM Research™ methodology. This unique approach enables Frost & Sullivan to determine how best-in-class companies worldwide manage growth, innovation and leadership.

Frost & Sullivan Analysis:

Significance of the Technology Innovation Award

Key Industry Challenges Addressed by Xcelthera Inc.

Pluripotent human embryonic stem cells (hESC) have unrestrained capacity for long-term, stable undifferentiated growth in culture, as well as the intrinsic potential for

differentiation into all somatic cell types in the human body. These characteristics show that hESC has tremendous potential for restoring human tissue and organ function.

A persistent challenge for scientists and researchers is to enable a well-controlled and efficient induction of hESC exclusively to a specific, clinically relevant lineage. These aspects play a key role not only for tissue/organ engineering and regenerative cell-based therapy, but also for drug discovery and development. Indeed, human stem cell therapy products today constitute a new conception of a drug as a cellular entity capable of offering pharmacological activity associated with human tissue and function restoration.

Over the past decade, notable advancements have taken place in stem cell research related to the differentiation of hESC into specific lineages by small molecule induction. Among such small molecules, retinoic acid can be cited, which potentially induces the specification of neuroectoderm directly from hESC, while triggering progression to neuronal progenitors. Nicotinamide, on the other hand, induces the specification of cardiomesoderm directly from pluripotent hSCs, thus triggering progression to cardiac precursors, among many others. These two instances among many others constitute clinically representative progress in both human neuronal and cardiac therapeutic products for central nervous system (CNS) and myocardium repair, respectively.

Nonetheless, a limiting factor in stem cell research is present because of the lack of a clinically suitable source of engraftable human stem/progenitor cells with adequate neurogenic potential. Novel solutions to this issue are crucial for developing safe and effective cell-based therapies for regeneration of the damaged CNS structure and circuitry evidenced in various neurological disorders. Regarding cardiovascular research, the absence of a clinically suitable human cardiomyocyte source with adequate myocardium regenerative potential is also a major drawback for achieving damaged human heart regenerative solutions.

The limited capacity of these two cell systems—neuron circuitry and cardiomyocytes—for self-repair makes them suitable for stem cell derivative-based neuronal and heart therapies. Clinical applications of stem cell therapy derivatives have demonstrated successful alternatives for a wide range of incurable or hitherto untreatable neurodegenerative and heart diseases. Neurodegenerative and heart diseases cost the worldwide healthcare system more than $500 billion annually.

Key Benchmarking Criteria for Technology Innovation Award

For the Technology Innovation Award, the following criteria were used to benchmark Xcelthera performance against key competitors:

Uniqueness of Technology;

Impact on New Products/Applications;

Impact on Functionality;

Impact on Customer Value;

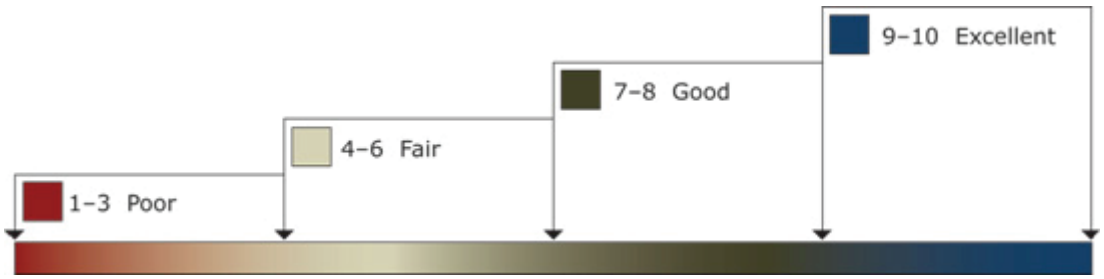
Relevance of Innovation to Industry

Decision Support Matrix and Measurement Criteria

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Matrix (DSM). The DSM is an analytical tool that compares company performance relative to each other with an integration of quantitative and qualitative metrics. The DSM features criteria unique to each Award category and ranks importance by assigning weights to each criterion. The relative weighting reflects current market conditions and illustrates the associated importance of each criterion according to Frost & Sullivan. Fundamentally, each DSM is distinct for each market and Award category. The DSM allows our research and consulting teams to objectively analyze each company performance on each criterion relative to its top competitors and assign performance ratings on that basis.

The DSM follows a 10-point scale that allows for nuances in performance evaluation ratings guidelines are shown in Chart 1.

Chart 1: Performance-Based Ratings for Decision Support Matrix



This exercise encompasses all criteria, leading to a weighted average ranking of each company. Researchers can then easily identify the company with the highest ranking. As a final step, the research team confirms the veracity of the model by ensuring that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

Chart 2: Frost & Sullivan 10-Step Process for Identifying Award Recipients

Best Practice Award Analysis for Xcelthera

The Decision Support Matrix, shown in Chart 3, illustrates the relative importance of each criterion for the Technology Innovation Award and the ratings for each company under evaluation. To remain unbiased while also protecting the interests of the other organizations reviewed, we have chosen to refer to the other key players as Competitor 1 and Competitor 2.

Chart 3: Decision Support Matrix for Technology Innovation Award

Measurement of 1–10 (1 = lowest; 10 = highest) **Award Criteria**	Uniqueness of Technology	Impact on New Products/Applications	Impact on Functionality	Impact on Customer Value	Relevance of Innovation to Industry	**Weighted Rating**
Relative Weight (%)	**20%**	**20%**	**20%**	**20%**	**20%**	**100%**
Xcelthera	9.7	9.5	9.6	9.5	9.6	9.6
Competitor 1	6.2	5.8	5.5	5.0	6.0	5.7
Competitor 2	6.5	5.5	4.8	4.9	5.2	5.0

Criterion 1: Uniqueness of Technology

Xcelthera has been a pioneer in stem cell therapeutics and its technology platform – PluriXcel - is currently the only available human cell source offering products with the pharmacological capacity to regenerate neurons and contractile heart muscles that allow restitution of function of the CNS and heart repair in the clinic.

Along with a group of researchers working at the San Diego Regenerative Medicine Institute, an independent biomedical research institute focused on human stem cell-based regenerative medicine, Xcelthera has specifically worked on the development of a novel technology platform for efficiently converting pluripotent hESC uniformly into a particular clinically relevant lineage by small molecule induction. Overcoming some major issues in bringing hESC therapy derivatives toward clinical applications, these investigations have resulted in remarkable advances and breakthroughs. One of the major achievements was the establishment of unique human stem cell technology platforms. PluriXcel technology has been developed for defined culture systems for *de novo* derivation and maintenance of clinical-grade pluripotent hESC, through the PluriXcel-DCS technology platform, and for lineage-specific differentiation of pluripotent hESC by small signal molecule induction via PluriXcel-SMI. The main goal is to achieve a highly efficient direct conversion of pluripotent hESC into a large supply of high-purity clinical-

grade neuronal cells or heart muscle cells (Xcel), conserving their adequate capacity to regenerate neurons and contractile heart muscles.

Frost & Sullivan recognizes the exemplary efforts of Xcelthera in building the foundation for the development of safe and effective stem cell therapies, thus addressing major concerns in the healthcare industry.

Criterion 2: Impact on New Products/Applications

According to Frost & Sullivan, Xcelthera is shaping the future of medicine by providing novel, unique solutions at a clinical grade. With its exclusive rights in proprietary human stem cell technology and therapy products to provide cellular medicines for neurological and heart diseases, the company has high growth potential, targeting major health problems related to neurological and cardiovascular diseases in the biotechnology and therapeutic sectors. A strong patent portfolio, including not only North America and Europe, but also the Asia Pacific region (AU2011338711) is evidence of the commitment of the company to translate its innovations to the industry.

Frost & Sullivan recognizes Xcelthera as a major innovator in the stem cell research market. A flexible business model, open to partnerships, alliances, and investment opportunities, places this company in an optimal position for paving the way to personalized medicine.

Xcelthera technology platforms have demonstrated tremendous potential for tissue and organ regeneration and function restoration. In fact, untreated diseases or diseases currently considered incurable could now find a strong alternative through the clinical applications of pluripotent hESC therapy derivatives.

Holding a worldwide therapeutic market of over USD 10 billion annually, Xcelthera business strategy is focused on the preclinical and clinical development of human stem cell technology platforms and cell therapy products using pluripotent hESC. Furthermore, the company is developing cell therapeutics for neurological and cardiovascular diseases, including heart disease and failure, Parkinsons diseases, amyotrophic lateral sclerosis (ALS), Alzheimer disease, neurodegenerative diseases, and brain and spinal cord injuries.

Human stem cell technology and cell therapy products represent a new type of drug of cellular medicine capable of providing new pharmacological utility, including tissue and function restoration. PluriXcel technology, Xcelthera proprietary human stem cell technology platform comprises PluriXcel-DCS, the defined culture system for derivation and maintenance of clinical-grade hESC lines, and PluriXcel-SMI, the highly efficient lineage-specific differentiation of pluripotent hESCs. PluriXcel-SMI utilizes small molecule induction for direct conversion of pluripotent hESC into large sources of high purity neuronal/heart muscle cells, highly suitable for developing novel, safe, and cost-effective stem cell therapies.

Among the company products for neurological and cardiovascular applications, Xcel, clinical-grade hESC neuronal cell therapy products for CNS neuron regeneration, Xcel-hNuP and Xcel-hNu, can be mentioned. Similarly, Xcel-hCardP and Xcel-hCM represent the analog, clinical-grade hESC heart muscle cell therapy products for heart regeneration.

Criterion 3: Impact on Functionality

The company technology allows the efficient production of human neuronal progenitors and human neuronal cell types and subtypes from pluripotent hESC for neuronal regeneration and replacement therapies for a wide range of neurological disorders. Similarly, the efficient production of human cardiac precursors and human cardiomyocytes for myocardium regeneration and replacement therapies for heart disease and failure has also been addressed.

Frost & Sullivan recognizes Xcelthera technological breakthrough—enabling the well-controlled induction of pluripotent hESC. Such enhancements allow the achievement of more efficient results by only mediating the simple provision of a series of small molecules, ensuring the proliferation of undifferentiated hESC, exclusively to a particular clinically relevant lineage.

As a demonstration of that, a recent publication of Parsons in the Annual Review & Research in Biology, titled: Embedding the Future of Regenerative Medicine into the Open Epigenomic Landscape of Pluripotent Human Embryonic Stem Cells, the investigators focused their attention on the human stem cell epigenome landscape that helps to elucidate the intrinsic plasticity and regenerative potential of human stem cell derivatives with reference to neural and cardiac lineage-specific differentiation.

Criterion 4: Impact on Customer Value

In regenerative medicine, pluripotent hESC research holds huge promise for treating major human diseases challenging traditional medicine. Neurodegenerative disorders, injury and paralysis, diabetes, heart failure, and cardiovascular diseases represent the major issues.

Millions of people are pinning their hopes on stem cell research to provide novel and effective solutions for such concerns. On that note, the clinical translation of stem cell research and innovation capabilities demonstrated by hESC investigations can extend the lives of patients and reduce the burden of illness.

The PluriXcel technology platform is incomparable, providing life scientists and clinicians with novel, efficient, and powerful resources to address major health concerns. The introduction of novel developments and new business opportunities based on this technology are expected to revolutionize the biomedical industry and bring new therapeutics into the market.

Criterion 5: Relevance of Innovation to Industry

The limited capacity of neuron circuitry and cardiomyocytes for self-repair constitutes a significant challenge in both the scientific and clinical community. As neurodegenerative and heart diseases incur exorbitant costs on the healthcare system worldwide, there is a strong focus on providing newer, more efficient solutions for these therapeutic needs. The clinical applications of stem cell therapy derivatives have demonstrated an ability to provide successful alternatives for a wide range of incurable or hitherto untreatable neurodegenerative and heart diseases. Xcelthera and the SDRMI have jointly translated their developments to the clinical community.

These advancements are expected to transform the biomedical science arena and help develop groundbreaking pluripotent hESC technology platforms and innovative regenerative approaches. Xcelthera technology platform is shaping the future of medicine by providing pluripotent human embryonic stem cell-based technology, and developing optimal regeneration treatment options for human tissue and function restoration.

Conclusion

Xcelthera Inc. is a (bio)-pharmaceutical company committed to clinically translating human stem cell research discoveries for unmet medical challenges in major health problems, particularly neurodegenerative disorders and cardiovascular diseases.

Founded for clinical applications of pluripotent human embryonic stem cells (hESC) therapy derivatives, Xcelthera is translating its stem cell research to clinical applications through the introduction of its proprietary clinical-grade hESC neuronal and cardiomyocyte cell therapy products. In recognition of its efforts, Frost & Sullivan is proud to present the 2013 North America Technology Innovation Award in Stem Cell Technologies to Xcelthera.

The Designation of Human Stem Cell therapy Products for Human Trials or First-in-Human Studies

For successful pharmaceutical development of stem cell therapy, the human stem cell therapy product must meet certain commercial criteria in plasticity, specificity, and stability before entry into clinical trials. Moving stem cell research from current studies in animals into human trials must address such practical issues for commercial and therapeutic uses: 1) such human stem cells and/or their cell therapy derivatives/products must be able to be manufactured in a commercial scale; 2) such human stem cells and their cell therapy derivatives/products must be able to retain their normality or stability for a long term; and 3) such human stem cells and/or their cell therapy derivatives/products must be able to differentiate or generate a sufficient number of the specific cell type or types in need of repair or regeneration. Those practical issues are essential for designating any human stem cells as human stem cell therapy products for investigational new drug (IND)-filing and entry into human trials. Our human stem cell therapy products have been developed specifically to address and overcome those major obstacles or issues in clinical applications of hESC therapeutic utility, including the benefits in high efficiency, stability, low tumor risk, high purity, high efficacy in repair, as well as safety and large-scale production of high quality human cell therapy products

in cGMP facility for commercial and therapeutic uses over all other existing approaches. Therefore, Xcelthera hESC CNS and heart cell therapy derivatives, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), meet the designation of human stem cell therapy products for commercial development and human trials or first-in-human studies.

Compared to conventional compound drugs of molecular entity, cell therapy products or cellular medicine have very different benchmarks or indicators regarding to safety and efficacy in clinical trials. The safety of a human stem cell therapy product is evaluated by whether it can retain a stable phenotype and karyotype for a long period of time and whether there is no tumor or inappropriate cell type formation following transplantation. The efficacy of a human stem cell therapy product is measured by its pharmacologic activity or cellular ability to regenerate the tissue or organ that has been damaged or lost. Therefore, the pharmacologic utility of human stem cells cannot be satisfied only by their chaperone activity, if any, to produce trophic or protective molecules to rescue existing endogenous host cells that can simply be achieved by a drug of molecular entity, if any.

Our breakthrough human stem cell technologies (PluriXcel Technology), including defined culture systems for *de novo* derivation and long-term maintenance of clinical-grade stable pluripotent hESC lines (PluriXcel-DSC technology) and lineage-specific differentiation of pluripotent hESCs by small molecule induction (PluriXcel-SMI technology), have overcome some major obstacles in bringing hESC therapy derivatives towards human trials or first-in-human studies. Medical innovations in Our PluriXcel Technology enable high efficient direct conversion of non-functional pluripotent hESCs into a commercial scale of clinical-grade high quality functional human neuronal or heart muscle cell therapy derivatives, which is a major milestone towards human trials of hESC cell therapy derivatives, offering the benefits in efficiency, stability, safety, efficacy, and large-scale production of clinical-grade high quality human cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches. Currently, our hESC neuronal and cardiomyocyte cell therapy derivatives are the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate CNS neurons and contractile heart muscles, vital for CNS and heart repair in the clinical setting. Our breakthrough human stem cell technologies transform non-functional pluripotent hESCs into a large supply of high quality fate-restricted functional human cell therapy derivatives or products, which dramatically increases the clinical efficacy of graft-dependent repair and safety of hESC-derived cellular products, and marks a turning point in cell-based regenerative medicine from current studies in animals towards human trials or first-in-human studies.

FDASIA and FDA Expedited Development Programs

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law, which gave the Food and Drug Administration (FDA) a new and powerful expedited drug development tool, known as the breakthrough therapy designation. This new designation helps FDA assist drug developers to expedite the development and review of new drugs with preliminary clinical evidence that indicates

the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases. In addition, the FDA has established a Fast Track program that is intended to facilitate the development and expedite the review of new drugs and biological products that are intended to treat a serious or life-threatening condition or disease and demonstrate the potential to address unmet medical needs for the condition. Xcelthera novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)** are targeting many of those serious or life-threatening diseases or conditions, including heart disease and failure, stroke, Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, brain and spinal cord injuries. So far, those major health problems or incurable life-threatening diseases have relied on breakthrough developments in our stem cell research, particularly our hESC research, to drive the advance of medicine to provide future regeneration and reconstruction treatment options or cures for tissue and function restoration.

Thus far, testing potential therapeutic strategies have largely relied on animal models for behavior, safety, and efficacy evaluation of therapeutic candidates and human cell therapy products. The goal of animal studies is to provide sufficient evidences of proof-of-concept for prospect of benefit and safety to justify the proposed clinical investigation of a new drug. Large animal models are not always necessary for FDA approval and review of an investigational new drug. Because of interspecies differences, conventional preclinical studies using animal models are often poor predictors of human efficacy and safety. Animal models are xeno-hosts for transplantation of human cells, not ideal for testing the safety and efficacy of therapeutic outcomes of human stem cells. Large primate models are very costly and often taken years to obtain results. In addition, the results of animal studies can be highly variable and difficult to reproduce, making them unreliable as benchmarks for decisions on human trials. Preclinical data using animal models, even results of large animal models, do not necessarily provide the benchmarks or indictors for safety and efficacy in human trials. Those FDA expedited programs do not specifically require evidences from animal models or animal proof-of-concept data to support FDA accelerated approval and priority review, which may help fast-track the development and review of our human stem cell therapy products that have the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to our marketed human stem cell therapy products.

In addition, FDA regulations allow companies to establish expanded access program for the use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational drugs for treatment purposes on a case-by-case basis for an individual patient, or for intermediate-size groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial. They also permit expanded access for large groups of patients who do not have other treatment options available, once more is known about the safety and potential effectiveness of a drug from ongoing or completed clinical trials.

We are currently moving towards clinical development stage of our products. As of the date of this prospectus, we have not raised sufficient funds to support filing an IND application with the FDA for our licensed cell therapy products to enter into clinical development stage. All of your product candidates are currently in preclinical stage and none have advanced to first-in-human studies or clinical trials in humans. Following completion of this offer, we will use part of the net proceeds from this offering for clinical development enabling activities and entering into early phase clinical trials for our neuronal and cardiomyocyte cell therapy products, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), for major neurological and heart disease indications, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy (see product pipeline). We intend to use a substantial portion of the net proceeds from this offering for funding our clinical development efforts, including IND filing; regulatory and clinical personnel recruiting; IND-related FDA meetings and regulatory activities; establishing cGMP manufacturing facility and achieving cGMP banking and production of our clinical-grade stem cell therapy products; and early phase clinical trials and supporting activities. As of the date of this prospectus, we cannot specify with certainty the cell therapy product candidate, including **Xcel-hNuP** (human neuronal progenitors), **Xcel-hNu** (human neurons), **Xcel-hCardP** (human heart precursors), **Xcel-hCM** (human heart muscle cells), and the disease indication, including Parkinsons disease, spinal cord injury, spinal muscular atrophy, myocardial infarction, and cardiomyopathy for which we will make our initial IND filing and first-in-human studies, and the stage of clinical development or phase of clinical trials (Phase I and/or Phase II) that we will achieve using net proceeds from this offering.

Intellectual Property

We have integrated intellectual property into our business strategy from our inception. We strive to protect our proprietary human stem cell technology platforms and products through assembling a portfolio of patent rights and licenses, including pursuing US and international patents intended to cover our products and compositions, their methods of use and processes for their making or manufacture, our platform technologies and any other inventions that are commercially important to the development of our business. We have entered into an exclusive license agreement with San Diego Regenerative Medicine Institute, which was co-founded by the founder and CEO of the Company, to obtain the exclusive rights for the development and commercialization of our human stem cell technologies and products. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We seek to obtain domestic and international patent protection and endeavor to promptly file patent applications for new commercially valuable inventions to expand our intellectual property portfolio. We believe that our intellectual property portfolio will provide significant competitive advantages for future business operations and dominance over our target markets.

Our intellectual property portfolio is currently composed of US patents and patent applications as well as international patent applications covering our PluriXcel human

stem cell technology platforms and our proprietary clinical-grade neural and cardiac human stem cell therapy products derived from hESCs using PluriXcel platforms. The founder and CEO of the Company is also the founder of San Diego Regenerative Medicine Institute and the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products (please see the exclusive license agreement included in the exhibit of this prospectus). Following completion of this offer, we will use part of the net proceeds from this offering to continue to pursue the protection of our intellectual property or patents on our technology and therapy products in the US and the world, including current and additional US patent applications, PCT international patent applications and entry into national stage. We believe that we have a significant intellectual property position and substantial know-how relating to the derivation and modulation of pluripotent hESCs for commercial and therapeutic uses. We continually assess and refine our intellectual property strategy in order to fortify our position in our target markets. To that end, after completion of this offer, we will use part of the net proceeds from this offering to file additional US and international patent applications, including divisional and continuation patent applications, in any of the above fields if our intellectual property strategy requires such filings, or where we seek to adapt to competition or seize business opportunities. As to the date of this prospectus, we cannot specify with certainty the costs for obtaining intellectual property protection or the amount of the net proceeds that will be allocated for obtaining domestic and international intellectual property protection. Furthermore, we are prepared to file patent applications relating to new technologies we develop soon after the experimental data necessary for a strong application become available and our cost-benefit analyses justify filing such applications. In addition to filing and prosecuting patent applications in the United States, we will file counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial, including Europe, Canada, Australia and Asia.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future. Please see Risk Factors for additional information on the risks associated with our intellectual property strategy and portfolio.

Government Regulation

We are subject to a variety of laws and regulations in the United States and abroad that involve matters central to our business, including obligations to seek informed consent from donors for the use of their unwanted embryos in IVF. In the United States, human subject research that is conducted, funded or otherwise supported by a federal department or agency is subject to laws and certain regulations that embody the Federal Policy for the Protection of Human Research Subjects. In addition, any federal department or agency which takes appropriate administrative action can also subject certain human subject research to certain regulations that embody the Federal Policy for the Protection of Human Research Subjects. When we participate in human subjects research such as clinical trials and research involving derivation of our clinical-grade hESCs from IVF leftover embryos or uses of such hESC derivatives or we participate in a research activity that is subject to the regulation of a particular federal agency (for

example, Investigational New Drug requirements administered by the U.S. Food and Drug Administration (FDA)), the conduct of the research must comply with the relevant Federal Policy for the Protection of Human Research Subjects regulations, which require review and approval by an institutional review board (IRB) operating in accordance with the pertinent requirements of the regulations. U.S. federal and state and foreign laws and regulations are constantly evolving and can be subject to significant change. When we engage in business in markets in countries other than the United States, we may become subject to foreign laws and regulations relating to human subjects research and other laws and regulations that are often more restrictive than those in the United States.

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHS Act, and related regulations. Biological products are also subject to other federal, state, local, and foreign statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biological products. These agencies and other federal, state, local, and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, packaging, labeling, storage, distribution, record keeping, reporting, approval, advertising and promotion of our products. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, including clinical testing, approval process or after approval may subject an applicant to administrative or judicial sanctions.

Government regulation may delay or prevent marketing of our products for a considerable period of time and impose costly procedures upon our activities. The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that the FDA or any other regulatory agency will grant approvals for any of our products on a timely basis, if at all. The FDA policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of any of our products or approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative, judicial, or administrative action, either in the United States or abroad.

Marketing Approval

The process required by the FDA before biological products may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory and animal tests according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND application which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA regulations commonly referred to as good clinical practices, or GCPs, and any

additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use or uses;

submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

satisfactory completion of an FDA pre-approval inspection of manufacturing facilities where the biological product is produced to assess compliance with good manufacturing practices, or GMPs, to assure that the facilities, methods and controls are adequate to preserve the biological product identity, strength, quality and purity and, if applicable, the FDA current good tissue practices, or GTPs, for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases;

potential FDA audit of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA; and

FDA review and approval, or licensure, of the BLA which must occur before a biological product can be marketed or sold.

U.S. Biological Products Development Process

Before testing any biological product candidate in humans, the product candidate enters the nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry (if a molecule or compound), toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

Prior to commencing the first clinical trial, the clinical trial sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an initial IND application. Some nonclinical testing may continue even after the IND application is submitted. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial and places the clinical trial on a clinical hold. In such case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. Further, an independent institutional review board, or IRB, for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. An IRB is charged with protecting the welfare and rights of study subjects and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA or IRB may impose clinical holds on a biological product candidate at any time before or during

clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA or IRB authorization and then only under terms authorized by the FDA and IRB. Accordingly, we cannot be sure that submission of an IND application will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that will result in the suspension or termination of such trials.

Clinical trials involve the administration of the biological product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND and to the IRB.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

Phase 1 - The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These trials may also provide early evidence on effectiveness.

Phase 2 - These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3 - Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency, and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval and labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA now must express statutory authority to require post-market clinical trials to address safety issues. All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial

investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events; any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor initial receipt of the information.

Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. Regulatory authorities, a data safety monitoring board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB requirements or if the biological product has been associated with unexpected serious harm to patients.

Our planned clinical trials for our products may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

obtaining regulatory approval to commence a trial;

reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable trials on a timely basis;

obtaining IRB approval to conduct a trial at a prospective site;

recruiting patients to participate in a trial; and

supply of the biological product.

Typically, if a biological product is intended to treat a chronic disease, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor

must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

In order to obtain approval to market a biological product in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA satisfaction the safety, purity and potency of the investigational biological product for the proposed indication. The application includes all data available from nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product manufacture and composition, and proposed labeling, among other things. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA fee schedule, effective through September 30, 2013, the user fee for an application requiring clinical data, such as a BLA, is $1,958,800 for fiscal year 2013. PDUFA also imposes an annual product fee for biologics ($98,380 for fiscal year 2013), and an annual establishment fee ($526,500 for fiscal year 2013) on facilities used to manufacture prescription biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMPs to assure and preserve the product identity, safety, strength, quality, potency, and purity, and biological product standards. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. For a human cellular or tissue product, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCPs. To assure GMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort. If the FDA determines the manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will require the facility to take corrective action and provide documentation evidencing the implementation of such corrective action. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCPs, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA, and request additional testing or data. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA also has authority to require a Risk Evaluation Mitigation Strategy, or REMS, from manufacturers to ensure that the benefits of a biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA submission. The need for a REMS is determined as part of the review of the BLA. Based on statutory standards, elements of a REMS may include dear doctor letters, a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the BLA approval, and in some cases may delay the approval date. Once adopted, REMS are subject to periodic assessment and modification.

After the FDA completes its initial review of a BLA, it will communicate to the sponsor that the biological product will either be approved, or it will issue a complete response letter to communicate that the BLA will not be approved in its current form. The complete response letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the applicant in a condition for approval. If a complete response letter is

issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The testing and approval process for a biological product usually takes several years to complete.

One of the performance goals agreed to by the FDA under PDUFA is to review 90% of standard BLAs in 10 months and 90% of priority BLAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal data may be extended by three months if the FDA requests or the BLA applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require Phase 4 post-marketing clinical trials, designed to further assess a biological product safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in the imposition of new restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain and maintain, regulatory approval for any of our products, or obtaining approval but for significantly limited use, would harm our business.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to facilitate the development and expedite the review of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition or disease and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biological may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees

upon submission of the first section of the application. Xcelthera novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)** are targeting many of those serious or life-threatening diseases or conditions, including heart disease and failure, stroke, Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, brain and spinal cord injuries. We believe that our products qualify for fast track designations, however, we cannot be certain whether any of our products will be granted for any expedited development and regulatory review programs.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Xcelthera novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)** are targeting many of those serious or life-threatening diseases or conditions, including heart disease and failure, stroke, Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, brain and spinal cord injuries. We believe that our products qualify for fast track designations, priority review and accelerated approval, however, we cannot be certain whether any of our products will be granted for any expedited development and regulatory review programs.

The Food and Drug Administration Safety and Innovation Act of 2012 also amended the FDCA to require FDA to expedite the development and review of a breakthrough therapy. A drug or biological product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement

over existing therapies on one or more clinically significant endpoints. A sponsor may request that a drug or biological product be designated as a breakthrough therapy at any time during the clinical development of the product. If so designated, FDA shall act to expedite the development and review of the product marketing application, including by meeting with the sponsor throughout the product development, providing timely advice to the sponsor to ensure that the development program to gather nonclinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable. Xcelthera novel human stem cell technology platforms **(PluriXcel Technology)** and clinical-grade functional human neural and cardiac cell therapy products **(Xcel)** are targeting many of those serious or life-threatening diseases or conditions, including heart disease and failure, stroke, Parkinsons disease, ALS, Spinal muscular atrophy, Alzheimer disease, brain and spinal cord injuries. We believe that our products may also qualify for breakthrough therapy designations, however, we cannot be certain whether any of our products will be granted for any expedited development and regulatory review programs.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of the use of our products, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product approval date. The period of patent term restoration is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of a BLA, plus the time between the submission date of the BLA and the approval of that application, provided the sponsor acted with diligence. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office, or USPTO, in consultation with the FDA.

A patent term extension is only available when the FDA approves a biological product for the first time. None of our products or hESC-related products has been previously approved by the FDA. However, we cannot be certain that the USPTO and the FDA will agree with our analysis or the USPTO will grant a patent term extension.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, which was part of the Patient Protection and Affordable Care Act, or PPACA, signed into law on March 23, 2010. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which

requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product is biosimilar to the reference biological product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted twelve years of exclusivity from the time of first licensure of the reference product. On April 10, 2013, President Obama released his proposed budget for fiscal year 2014 and proposed to cut this twelve year period of exclusivity down to seven years. He also proposed to prohibit additional periods of exclusivity for brand biological products due to minor changes in product formulation, a practice often referred to as evergreening. The first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant favor of a lawsuit challenging the patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

FDA Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We may rely on third parties for, or establishing commercial manufacturing capabilities for, the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. We cannot be certain that we or our suppliers will be able to comply with the GMP and other FDA regulatory requirements. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA

together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements, by us or our suppliers, may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, suspension or revocation of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMPs and other laws. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Labeling, Marketing and Promotion

The FDA closely regulates the labeling, marketing and promotion of biological products, including direct-to-consumer advertising, promotional activities involving the internet, and industry-sponsored scientific and educational activities. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a biological product that are consistent with FDA approval, and the company is allowed to market a biological product only for the particular use and treatment approved by the FDA. In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety and risk information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions, potential civil and criminal penalties and exclusion from government healthcare programs.

Pediatric Research Equity Act

Under the Pediatric Research Equity Act, or PREA, a BLA or BLA supplement must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and

effective. The intent of PREA is to compel sponsors whose products have pediatric applicability to study those products in pediatric populations, rather than ignoring pediatric indications for adult indications that could be more economically desirable. The FDA may grant deferrals for submission of data or full or partial waivers.

Anti-Kickback and False Claims Laws

In the United States, the research, manufacturing, distribution, sale and promotion of biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, State Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the Anti-Kickback Statute, as amended, the federal False Claims Act, as amended, (the False Claims Act) the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare fraud and abuse, including, but not limited to, the Anti-Kickback Statute, the False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a biological product manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices or our future relationships with physicians might be challenged under anti-kickback laws, which could harm us. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including

Medicare and Medicaid) claims for items or services, including biological products, that are false or fraudulent. Although we likely would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to cause the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party coverage and reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the False Claims Act and certain states have enacted laws modeled after the False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, beginning in August 2013, a similar federal requirement will require manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Other Regulations

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

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payers, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payers are increasingly limiting coverage and reimbursement for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued

implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug products or a decision by a third-party payer to not cover our drug products could reduce physician usage of our products once approved and have a material adverse effect on our revenues, results of operations and financial condition.

Research and Development

The Exclusive License Agreement to acquire the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products from San Diego Regenerative Medicine Institute by issuing company stocks as research and development expenses

We were recently incorporated as a general stock company under the laws of the state of California under the name Xcelthera, Inc., to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. San Diego Regenerative Medicine Institute, an nonprofit 501C3 tax exempt status independent biomedical research institute incorporated in California, was founded in 2010 by the same founder of Xcelthera, INC, in part, with supports by government grants to the founder, to facilitate the transition of human stem cell research towards stem cell therapy to provide the next generation of cell-based therapeutic solutions for unmet medical challenges. The founder and CEO of the Company is also the founder of San Diego Regenerative Medicine Institute and the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products (please see the exclusive license agreement included in the exhibit of this prospectus). The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. In connection with the exclusive license agreement, the Company has issued an aggregate of 3,800,000 shares of common stock subject to the exercise of outstanding options, including all preferred shares convertible into common stock, to San Diego Regenerative Medicine Institute as research and development expenses. Of these options, an aggregate of 2,500,000 shares of common stock, including 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock, convertible into 2,000,000 shares of common stock upon completion of this offer, has been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer. In addition, milestone payments will occur pursuant to the exclusive license agreement upon first achievement of the following milestones:

(i) First regulatory approval for clinical development or an investigational new drug (IND) of first licensed product. COMPANY shall issue an aggregate number of shares equals 1,300,000 shares or 3% of the COMPANY issued and outstanding Common Stock calculated on a Fully Diluted Basis to San Diego Regenerative Medicine Institute (SDRMI) as a one time milestone payment.

(ii) First commercial sale or first market approval for clinical uses of a licensed product for each disease indication. COMPANY shall pay 1,000,000 shares of Common Stock of COMPANY or 1% of the COMPANY then issued and outstanding Common Stock calculated on a Fully Diluted Basis, whichever is larger, to San Diego Regenerative Medicine Institute (SDRMI) as a milestone payment.

As a result of the exclusive license agreement, no costs and expenses for research and development have incurred directly for our company for research and development of our technology and products since our recent incorporation. Research and development expenses include: (i) lab supplies and materials, human cells, reagents and finished goods internally consumed; (ii) salaries and related personnel expenses; (iii) allocated and direct overhead and facilities expenses; and (iv) costs associated with licenses, collaborations, partnerships and other revenues. We do not track research and development expenses by individual product, nor do we capitalize any research and development expenses. As of the date of this prospectus, no other agreement between San Diego Regenerative Medicine Institute and the Company has been executed.

Employees

As of filing date of this prospectus, we had no additional full-time employees besides our directors and officers. Following completion of this offer, additional full-time regulatory, clinical, research and development, and administrative employees will be recruited in pursuing the use of proceed of this offer. None of our employees is represented by a labor union or subject to a collective bargaining agreement, and we consider our employee relations to be good.

Facilities

Our business facility will be located in San Diego, California, following completion of this offer. We plan to use part of the net proceeds from this offering to purchase or lease approximately 10,000 square feet of office and lab space suitable to meet our initial needs for business operation. Additional space will be sought if needed to satisfy our growth.

Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this prospectus, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Management

Directors and Executive Officers

The first board of directors shall consist of two directors pursuant to the provisions of our Bylaws. Our founding directors and initial executive officers as of filing date of this offer are as follows:

Name	Age	Position
Xuejun H. Parsons, PhD	43	Founder, Chief Executive Officer and President, Director and Chairman of the Board, Chief Scientific Officer, and Chief Operating Officer
Dennis A. Moore	75	Director and Vice Chairman of the Board
James F. Parsons	43	Executive Vice President

Xuejun H Parsons, PhD. Dr. Parsons is our scientific founder and has served as Chairman of the Board and as Chief Executive Officer and President since May 2013. Dr. Parsons also co-founded San Diego Regenerative Medicine Institute, and has served as President and Executive Scientific Director since 2010. She is the founder of Xcelthera Initiative, a small business concern before recent incorporation, and California Consortium for Regenerative Medicine Startup. Previously, Dr. Parsons was a stem cell scientist and faculty at University of California and Sanford-Burnham Medical Research Institute from 2003-2010. Dr. Parsons is the inventor of our intellectual property portfolio covering the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. Dr. Parsons received her PhD in Biochemistry, Molecular & Cell Biology from Cornell University in 1998, and completed her PostDoc studies as a Leukemia and Lymphoma Society Research Fellow at University of California, San Diego, in 2002. Since, Dr. Parsons has been supported by grants from National Institutes of Health to become an independent investigator and leader in human embryonic stem cell (hESC) research. Dr. Parsons has many years of experience in biomedical research and life sciences industry, with expertise and leadership in human stem cell research and cell-based regenerative medicine. Dr. Parsons original hESC research breakthroughs have overcome some major obstacles in bringing hESC therapy derivatives towards clinical applications, which have been published in internationally-recognized peer-reviewed stem cell research and therapy journals with ground-breaking impact and which have generated intellectual properties (IP) to enable preclinical and clinical development, commercialization, and clinical practice of proprietary hESC cell therapy tools and products for startup company. Dr. Parsons has also served as our Chief Scientific Officer

and Chief Operating Officer since May 2013. We selected Dr. Parsons to serve on our board of directors due to her exceptional medical innovation, leadership and direction, and valuable expertise in human stem cell research and cell-based regenerative medicine, in-depth understanding of our business in the life sciences industry, entrepreneurship, and operational experience with regenerative medicine and business startup.

Dennis A. Moore. Mr. Moore has served as Director and Vice Chairman of the Board since May 2013. Mr. Moore is also the co-founder and has served as CEO of San Diego Regenerative Medicine Institute since 2010. He is a long-time supporter for human embryonic stem cell (hESC) research. Graduated from the US Naval Academy, he was a Naval Aviator and private pilot Captain, and holds a J.D. from California Western School of Law. We selected Mr. Moore to serve on our board of directors due to his support to hESC research, understanding of our business, understanding of the importance, urgency, and tangible benefits of human embryonic stem cell-based regenerative medicine to improving the function, wellness, and overall quality of life for patients suffering from incurable or devastating diseases, knowledge with business laws and regulations, and experience with business startup.

James F. Parsons. Mr. Parsons has served as Executive Vice President since May 2013. He is also the co-founder and has served as CFO of San Diego Regenerative Medicine Institute since 2010 with experience in human stem cell research, business startup, and financial matters. There is not any business experience for Mr. Moore and Mr. Parsons prior to 2010 in the 5 year period.

Indemnification Agreements

We have entered into indemnification agreements with or have contractual obligations to provide indemnification to each of our directors and intend to enter into such agreements with certain of our executive officers. These agreements require us, among other things, to indemnify these individuals for certain expenses (including attorney fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person status as a member of our board of directors to the maximum extent allowed under California law.

Corporate Governance

Director Independence

Under the listing requirements and rules of the NASDAQ Stock Market LLC (NASDAQ), independent directors must comprise a majority of a listed company board of directors within one year of the closing of this offering, and each member of a listed company audit, compensation and nominating and corporate governance committees must be independent as well. Under the listing rules of NASDAQ, a director will only qualify as an independent director if that company board of directors affirmatively determines that the director has no material relationship with that company, either directly or as a partner, shareholder or officer of an organization that has a relationship with that company.

In addition, following the effectiveness of this registration statement, the members

of our audit committee must satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the Exchange Act). To satisfy the independence requirement of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or be an affiliated person of the listed company or any of its subsidiaries.

Similarly, following the effectiveness of this registration statement, the members of our compensation committee must satisfy the NASDAQ independence requirements. To satisfy these requirements, a member of the compensation committee of a listed company may not, other than in his or her capacity as a member of the board of directors or of a board committee, accept any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or be an affiliated person of the listed company or any of its subsidiaries.

Upon completion of this offering, our board of directors may therefore consider nominating and selecting additional board members and committee members using a broad range of factors relating to the qualifications and background of director nominees as well as the independence requirements under the NASDAQ listing standards and Rule 10A-3 of the Exchange Act. Our board of directors will have undertaken a review of its composition, the composition of its committees and the independence of each director, and exemptions that are applicable. Based upon information requested from and provided by each director concerning his/her background, the beneficial ownership associated with the holders of more than 5% of our common stock, employment, and affiliations, including family relationships, our board of directors will have determined that are independent as that term is defined under the applicable rules and regulations of the Securities and Exchange Commission (SEC) and the listing requirements and rules of NASDAQ. In considering the independence of the directors listed above, our board of directors considered if our directors satisfy the independence requirement under the NASDAQ listing standards and Rule 10A-3 of the Exchange Act. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of The NASDAQ Stock Market and the rules and regulations of the SEC.

Board Composition

Our first board of directors currently consists of two members, all of whom were elected pursuant to the board composition provisions of our Bylaws. Upon completion of this offering, our board of directors may therefore consider nominating and selecting additional board members and committee members to meet our needs for corporation governance using a broad range of factors relating to the qualifications and background of director nominees. Our board of directors priority in selecting additional board members is identification of persons who will further the interests of our share holders through his or her established record of professional accomplishment; support to human embryonic stem cell research; knowledge of our business; understanding of the importance, urgency, and tangible benefits of human embryonic stem cell-based

regenerative medicine to improving the function, wellness, and overall quality of life for patients suffering from incurable or devastating diseases; ability to contribute positively to the collaborative culture among board members; understanding of the competitive landscape in the life sciences industry; and professional and personal experiences and expertise relevant to our business.

In accordance with our amended and restated articles of incorporation and bylaws, our board of directors will:

establish an advance notice procedure for shareholder approvals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our board of directors;

establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;

provide that our directors may be removed only by the affirmative vote of at least seventy-five percent (75%) of the outstanding shares of capital stock of the Corporation entitled to vote at a meeting of shareholders duly called for such purpose;

provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

require approval by 75% of our outstanding common stock to amend our articles of incorporation and approval by a majority of our board of directors or 75% of our outstanding common stock to amend our bylaws.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Election of Officers

Our executive officers are elected by, and serve at the discretion of, our board of directors. Dr. Xuejun H. Parsons and Mr. James F. Parsons are married. There are no other family relationships among any of our directors or executive officers.

Board Committees

Upon the completion of this offering, our board of directors will have an audit committee, compensation committee and a nominating and governance committee. The composition and responsibilities of each committee will be determined by our board of directors to satisfy the independence standards for those committees established by applicable SEC and NASDAQ rules. In making these determinations, our board of directors will have considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deems relevant, including the beneficial ownership of our capital stock by each non-employee director.

The initial composition and responsibilities of our audit committee, compensation committee and nominating and governance committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee will operate under a charter approved by our board of directors. Following this offering, copies of each committee charter will be posted on the Corporate Governance section of our website, at www.xcelthera.com.

Audit Committee

Our audit committee is initially comprised of Mr. Moore, who satisfies the independence requirements under the NASDAQ listing standards and Rule 10A-3 of the Exchange Act. As of the filing date of this offering, our board of directors did not have a separately designated audit committee. Upon completion of this offering, our board of directors will nominate and select additional members who are independent within the meaning of the independent director guidelines of the NASDAQ Stock Market and SEC, including designating one member as an audit committee financial expert, as defined under the applicable rules of the SEC. The audit committee responsibilities include:

- overseeing accounting and financial reporting process;
- selecting, retaining and replacing independent auditors and evaluating their qualifications, independence and performance;
- reviewing and approving scope of the annual audit and audit fees;
- monitoring rotation of partners of independent auditors on engagement team as required by law;
- discussing with management and independent auditors the results of annual audit and review of quarterly financial statements;
- reviewing adequacy and effectiveness of internal control policies and procedures;
- approving retention of independent auditors to perform any proposed permissible non-audit services;
- overseeing internal audit functions and annually reviewing audit committee charter and committee performance; and
- preparing the audit committee report that the SEC requires in our annual proxy statement.

Compensation Committee

Our compensation committee is initially comprised of Mr. Moore, who satisfies the independence requirements under the NASDAQ listing standards and Rule 10A-3 of the Exchange Act. As of the filing date of this offering, our board of directors did not have a separately designated compensation committee. Upon completion of this offering, our board of directors will nominate and select additional members. Each member of this committee will be a non-employee director, as defined pursuant to Rule 16b-3

promulgated under the Exchange Act. The compensation committee responsibilities include:

- retaining or obtaining the advice of a compensation consultant, legal counsel or other adviser, including ones that are not independent;
- determining cash compensation and cash compensation plans, including incentive compensation, amounts and terms of stock option or other equity awards, and terms of any agreements concerning employment, compensation or employment termination matters;
- reviewing and approving corporate goals and objectives relevant to compensation of our Chief Executive Officer and other executive officers and evaluating their performance in light of those goals and objectives;
- monitor the application of retirement and other fringe benefit plans for the Chief Executive Officer and other executive officers;
- administering the issuance of stock options and other awards under our equity incentive plans;
- reviewing and recommending disclosures and providing reports for our annual proxy statement;
- reporting to the board of directors regarding the committee activities; and
- reviewing and evaluating the performance of the compensation committee, including compliance with its charter.

Nominating and Governance Committee

Our nominating and governance committee is initially comprised of Mr. Moore, who is the chair of the committee and who satisfies the independence requirements under the NASDAQ listing standards and Rule 10A-3 of the Exchange Act. As of the filing date of this offering, our board of directors did not have a separately designated nominating and governance committee. Upon completion of this offering, our board of directors will nominate and select additional members who are independent within the meaning of the independent director guidelines of the NASDAQ Stock Market and SEC. The nominating and governance committee responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- identifying new candidates and making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;

overseeing our corporate governance guidelines and reporting and making recommendations to our board of directors concerning governance matters; and

reviewing and evaluating the performance of the nominating and governance committee, including compliance with its charter.

Compensation Committee Interlocks and Insider Participation

As of the filing date of this offering, our board of directors did not have a separately designated compensation committee. As a member of our board of directors, Dr. Parsons participated in executive officer compensation discussions. None of the members of our compensation committee has been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our board or compensation committee.

Board Leadership Structure and Role in Risk Oversight

Our scientific founder currently serves as both principal executive officer and chairman of the board to ensure the global leadership and scientific direction of our Company in the life sciences sector, to enhance the likelihood of continued stability in the composition of our board of directors and its policies, and to deter hostile takeovers or changes in our control or management. However, in accordance with the rules of the Securities and Exchange Commission (SEC), we have also selected a lead independent director to serve as vice chairman of the board in the board leadership structure. Upon completion of this offering, our board of directors will nominate and select additional independent directors to serve in the board leadership structure.

Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functional as designed. The role of our board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on our company, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee report portion of the next board meeting. This enables our board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Code of Ethics

In connection with the completion of this offering, we will adopt a code of ethics that applies to all of our directors, officers and employees. We will post the text of our code of ethics on our internet website at www.xcelthera.com and disclose, in our annual

report, our internet address and the fact that we have posted such code of ethics on our internet website. We intend to disclose future amendments to certain provisions of our code of ethics, or waivers of these provisions, on our website or in filings under the Exchange Act. The Code of Ethics will become effective as of the effective date of this offering.

Executive and Director Compensation

This section discusses the material components of the executive compensation for our named executive officers who are identified in the 2013 Summary Compensation Table below. This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

2013 Summary Compensation Table

This section provides compensation information about the following individuals identified in the table below as of filing date of this offer. In the discussion below, we refer to this group of executives as the named executive officers and directors. This group includes the executive officers and directors for whom disclosure is required under the applicable rules of the Securities and Exchange Commission (SEC).

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)	Stock Awards ($)	All Other Compensation ($)	Total ($)
Xuejun H Parsons, PhD *Chairman of the Board, President and Chief Executive Officer*	2013	—	—	2,450	300	—	2,750
James F Parsons *Executive Vice President*	2013	—	—	490	150	—	640

No public market currently exists for our common stock. These amounts reflect the aggregate grant date par value of the option awards granted during 2013. These amounts

do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options. Amount shown represents the compensation awarded to the named executive officers and directors during 2013 from May 2013 (inception) to October 31, 2103.

Outstanding Equity Awards for Fiscal Year 2013

The following table provides information regarding outstanding equity awards held by each of our named executive officers as of October 31, 2013:

	Option Awards				Stock Awards	
Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price/ Par Value ($)	Option Expiration Date	Number of Shares that Have Not Vested (#)	Market Value of Shares that Have Not Vested ($)
Xuejun H Parsons, PhD *Chairman of the Board, President and Chief Executive Officer*	8,000,000	—	$ 0.0001	5/31/2023	—	—
	—	1,950,000	$ 0.001	5/31/2023	—	—
James F Parsons *Executive Vice President*	1,000,000	—	$ 0.0001	5/31/2023	—	—
	—	540.000	$ 0.001	5/31/2023	—	—

While all options in this table are immediately exercisable, to the extent they are listed in the unexercisable column, the option only entitles the executive to purchase shares of restricted and control stock. Thus, to the extent that the relevant holding period, volume limitation, and vesting requirements are not yet met for each award, the options are over restricted stock. All shares of options have been granted as incentive stock options to founders in connection with the founding and incorporation of our company.

All options in this table have a 10 year term. No public market currently exists for our common stock. These prices reflect the aggregate grant date par value of the option awards granted during 2013. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.

2013 Director Compensation Table

Non-employee directors did not receive any cash compensation in 2013 in their capacities as directors. The table below shows the aggregate numbers of shares subject to option awards held as of October 31, 2013 by the non-employee directors:

	Option Awards				Stock Awards	
Name	Number of Securities underlying Unexercised Options (#) Exercisable	Number of Securities underlying Unexercised Options (#) Unexercisable	Option Exercise Price/ Par Value ($)	Option Expiration Date	Number of Shares that Have Not Vested (#)	Market Value of Shares that Have Not Vested ($)
Dennis A Moore	200,000	—	$ 1	5/31/2023	—	—
Vice Chairman of the Board	—	60,000	$ 3	5/31/2023	—	—

While all options in this table are immediately exercisable, to the extent they are listed in the unexercisable column, the option only entitles the executive to purchase shares of restricted stock. Thus, to the extent that the relevant holding period and vesting requirements are not yet met for each award, the options are over restricted stock. All shares of options have been granted as incentive stock options in connection with the founding and incorporation of our company. All options in this table have a 10 year term. No public market currently exists for our common stock. These prices reflect the aggregate grant date value of the option awards granted during 2013. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.

Employee Confidentiality and Assignment Agreements

The Company agrees to pursue the protection of all technology, including, the pursuit of all appropriate patents, copyrights, trademarks, and other rights. Each of our named executive officers has entered into a standard form agreement with respect to confidential information and assignment of inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our

proprietary information received during the course of employment and to assign to us any inventions conceived or developed during the course of employment. In addition, each officer, director, employee, and consultant of the Company shall have entered into a proprietary information and inventions agreement in a form reasonably acceptable to the Company and the Board of Directors. As part of this agreement, each of our officers, managers, employees and consultants associated with the Company agree to assign all of the technology, patents, and other rights to the Company.

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our founders, executive officers and directors approved by our board of directors in May 2013 in connection with the incorporation of the Company. We have reserved an aggregate of 9,200,000 shares of our common stock and 2,550,000 shares of our series A preferred convertible stock for the issuance of equity awards under the 2013 Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. The 2013 Plan permits us to make grants of restricted and control equity to founders, officers, and directors as incentive stock options, subject to such terms, conditions and restrictions as our board of directors may determine. Our 2013 Plan is administered by our board of directors. Our board of directors has the authority to select the individuals to whom awards will be granted and to determine the numbers, option exercise price, specific terms and conditions of each award. The 2013 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, and (2) options that do not so qualify.

The 2013 Plan provides that upon the occurrence of a change of control, all outstanding stock options will terminate at the effective time or consummation of such change of control, unless the surviving entity agrees to assume such stock options or substitute similar stock awards for those outstanding under the 2013 Plan. If options under the 2013 Plan terminate, option holders will be provided an opportunity to exercise their vested options prior to the consummation of the change of control. Our board of directors may amend, alter, suspend or terminate the 2013 Plan at any time, subject to stockholder approval where such approval is required by applicable law. Our board of directors may also amend, modify or terminate any outstanding award, but no such action may adversely affect rights under an award without the holder consent. No awards may be granted under the 2013 Plan after May 31, 2023.

Limitations of liability and Indemnification

Our amended and restated articles of incorporation and bylaws to be effective upon the completion of this offering will provide that we will indemnify our directors, officers, and certain of our employees to the fullest extent permitted by the General Corporation Law of California (the Law). If the Law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by the Law, as so amended. Our amended and restated articles of incorporation and bylaws will not eliminate a director duty of care and, in appropriate circumstances, equitable remedies,

such as injunctive or other forms of non-monetary relief, will remain available under the Law. This provision also does not affect a director responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our bylaws, we will also be empowered to enter into indemnification agreements with our directors, officers and employees to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification that will be required in our bylaws, prior to the completion of this offering, we will have entered into indemnification agreements with each of the individuals then serving on our board of directors. These agreements will provide for the indemnification of our directors to the fullest extent permitted by law. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors, officers and employees.

The limitation of liability and indemnification provisions in our bylaws to be effective upon the completion of this offering may discourage shareholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our shareholders. Further, a shareholder investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and certain employees 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.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Principal Stockholders

The following table sets forth information with respect to the beneficial ownership of our common stock, as of October 31, 2013, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and

all of our executive officers and directors as a group.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned	
		Prior to Offering	After Offering
5% or Greater Stockholders			
San Diego Regenerative Medicine Institute (1, 6)	2,500,000	31.3%	25%
Parsons Trust (2, 6)	1,000,000	12.5%	10%
Named Executive Officers and Directors			
Xuejun H Parsons, PhD (3)	3,000,000	37.5%	30%
James F Parsons (4)	1,500,000	18.7%	15%
Dennis A Moore (5)	*	*	*
All executive officers and directors as a group (3 persons)	4,500,000	56.2%	45%

* Less than 1%.

(1) Excludes 300,000 shares of common stock and 100,000 shares of series A convertible preferred stock issuable to pursuant to stock options, with a term of 10 years.

(2) Excludes 50,000 shares of series A convertible preferred stock issuable to pursuant to stock options, with a term of 2 years.

(3) Excludes 6,000,000 shares of common stock and 1,850,000 shares of series A convertible preferred stock issuable to pursuant to stock options, with a term of 10 years.

(4) Excludes 500,000 shares of common stock and 440,000 shares of series A convertible preferred stock issuable to pursuant to stock options, with a term of 10 years.

(5) Excludes 200,000 shares of common stock and 60,000 shares of series A convertible preferred stock issuable to pursuant to stock options, with a term of 10 years.

(6) The natural persons with voting and investment control over San Diego Regenerative Medicine Institute and the Parsons Trust are Xuejun H. Parsons, James F. Parsons, and Dennis A. Moore.

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission (SEC). Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 8,000,000 shares of common stock outstanding as of October 31, 2013, which gives effect to the automatic conversion of all outstanding shares of our preferred stock into 5,000,000 shares of our common stock immediately prior to the closing of this offering. Applicable percentage ownership after the offering gives effect to the issuance of 2,000,000 shares of common stock offered by us in this offering. The persons and entities named in the table above have sole voting and investment power with respect to all of the capital stock that they beneficially own. The address of each beneficial owner listed in the table is c/o Xcelthera, Inc., 4530 Donald Ave., San Diego, CA 92117.

Description of Capital Stock

General

Upon the completion of our initial public offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. The following is a description of our capital stock and certain provisions of our amended and restated articles of incorporation and bylaws as each to be effective prior to the closing of this offering. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated articles of incorporation and bylaws, copies of which have been or will be filed with the Securities and Exchange Commission (SEC) as exhibits to the registration statement of which this prospectus forms a part.

As of filing date of this offer, and after giving effect to the conversion of all of our outstanding preferred stock into common stock in connection with our initial public offering and the exercise of our outstanding options prior to the closing of this offering, there were outstanding: (a) 3,000,000 shares of our common stock awarded upon the exercise of outstanding options in connection with the incorporation of the company and an exclusive license agreement, among which 2,500,000 shares of common stock are control and restricted stock hold by 2 persons of our directors and officers; and (b) all the 500,000 shares of our Series A preferred convertible stock awarded upon the exercise of outstanding options issued in connection with the incorporation of the company and an exclusive license agreement, which we anticipate will convert into 5,000,000 shares of common stock immediately prior to the consummation of this offering, among which 2,000,000 shares of common stock are control and restricted stock hold by 2 persons of our directors and officers. All of the foregoing securities are deemed restricted securities under the Securities Act. No transfers or sales of the restricted Stock are allowed prior to 3 years after the Closing of the issuance or the Company initial public offering, whichever is the earliest.

Common Stock

Except as otherwise expressly provided in our articles of incorporation or as required by applicable law, all shares of our common stock will have the same rights and privileges and rank equally, share ratably and be identical in all respects as to all matters, including, without limitation, those described below.

Voting rights: Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of shareholders.

Dividend rights: The holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available, but only if our board of directors, in its discretion, determines to issue dividends and only at the times and in the amounts that our board of directors may determine. Dividends are not cumulative. No dividends shall be paid on any Common Shares unless comparable dividends are paid on all of the Preferred Stock based on the number of Common Shares into which they are convertible. For any other dividends or distributions, Preferred Stock participates with Common Stock on an as-converted basis.

Liquidation rights: Upon our liquidation, dissolution or winding-up, the holders of our common stock will be entitled to share equally, identically and ratably in all assets remaining, subject to the prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

No preemptive or similar rights: Our common stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions.

Restrictions on stock transfers or sales: No transfers or sales of the Common Stock are allowed prior to 3 years after the Closing of the issuance or the Company initial public offering, whichever is the earliest. No transfers or sales are permitted during lock-up period of up to 180 days in connection with stock offerings by the Company.

Preferred Stock

Upon the closing of our initial public offering, we will have 2,500,000 shares of series A preferred convertible stock issuable pursuant to stock options, with a term of 10 years. In addition, we will be authorized, subject to limitations prescribed by California law, to issue up to 7,000,000 shares of undesignated preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors can increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our shareholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of our common stock and the voting and other

rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

Dividend provisions: Dividends shall be payable pro rata on the Preferred Stock based on the number of shares of Common Stock into which they are convertible, but only if and when declared by the Company Board of Directors; dividends are not cumulative. No dividends shall be paid on any Common Shares unless comparable dividends are paid on all of the Preferred Stock based on the number of Common Shares into which they are convertible. For any other dividends or distributions, Preferred Stock participates with Common Stock on an as-converted basis.

Conversion: One share of the Series A Preferred Stock shall be convertible into 10 shares of the Company Common Stock. The conversion rate of each series of preferred stock issuable pursuant to stock option in future, if any, will be determined by our board of Directors.

Liquidation preference: In the event of any liquidation or winding up of the Company, the holders of the Preferred Stock shall be entitled to receive in preference to the holders of Common Stock the amount based on the number of Common Shares into which they are convertible. The remaining balance of the proceeds from the liquidation will then be allocated the Common Stock holders on an as-converted basis. At the option of the holders of the Preferred Stock, a merger, sale of all or substantially all of the assets of the Company, reorganization or other transaction in which control of the Company is transferred may be treated as a liquidation, dissolution or winding up for purposes of the liquidation preference.

Redemption: The Preferred Stock will not be redeemable.

Anti-dilution provisions: The conversion price of the Preferred Stock shall be subject to appropriate adjustment in the event of a stock split, stock dividend or similar event; and shall be adjusted on a weighted average basis to prevent dilution, in the event that the Company sells additional shares of Common Stock, preferred stock or convertible debt convertible into Common Stock or preferred stock at a purchase price less than the applicable conversion price of the Preferred Stock. No adjustment shall be made for the sale of Common Stock to employees, directors or consultants. Proportional adjustments will be made for stock splits and stock dividends.

Voting rights: Except as set forth herein, each holder of Preferred Stock shall have the right to that number of votes equal to the number of shares of Common Stock issuable upon conversion of the Preferred Stock held by such holder and shall vote with the Common Stock.

Right of first refusal: In the event that any of the existing shareholders, managers, employees or other shareholders propose to sell to a third party or parties a number of shares of their preferred stock, then the stock to be sold will be offered first to the Company to purchase the shares on the same terms as the third-party offer. If the Company does not purchase any, or all, of the available shares, then the Preferred Stock shareholders have the right to purchase the remaining portion at the same terms. If the

Preferred Stock shareholders and/or the Company do not purchase all of the shares, then they may be offered to the third party. These rights of refusal shall terminate upon the Company initial public offering or upon sale of the Company through merger, sale of stock or assets or otherwise.

Preemptive rights: Holders of Preferred Stock shall have the right to participate in any future sales of securities by the Company (other than (a) options and shares granted or sold to employees, directors and consultants, (b) issuance of stock in connection with corporate acquisitions or joint ventures) on the basis of maintaining their pro rata share of all outstanding common and preferred shares of the company. Such right shall expire upon and shall not apply to an initial public offering of Common Stock, and shall not apply to: (i) shares issued under stock options plans approved by the Board of Directors in an amount not to exceed shares; or (ii) shares exchanged for assets or securities of another corporation in any acquisition of assets, merger, or other reorganization.

Co-sale rights: Each holder of Preferred Stock will have a co-sale right to sell shares in the event that any of the existing shareholders propose to sell to a third party or parties a number of shares of their Common Stock or securities convertible into Common Stock. This clause does not apply to any holders of less than 10,000 shares of stock or any manager, board member, employee selling less than 10,000 shares of stock in any 12 month period. This number of shares will be adjusted for any stock splits and combinations authorized by the Company. The co-sale rights shall terminate upon the Company initial public offering or upon sale of the Company through merger, sale of stock or assets or otherwise.

Board representation: The holders of Preferred Stock shall have the right to designate one director. The remaining directors will be designated by holders of the Common Stock. One director shall be jointly elected by a majority of common stock and a majority of preferred stock, voting as separate classes; and the holders of preferred stock and common stock voting together as a single class shall be entitled to elect any additional directors.

Information rights: Each holder of the Preferred Stock shall receive standard information rights including financial reports and, subject to minimum holdings requirements, annual budget and business plan, as well as standard inspection rights. This right to financial information and plans shall terminate upon a public offering.

Restrictions on stock transfers or sales: No transfers or sales of the Preferred Stock are allowed prior to 3 years after the Closing of the issuance or the Company initial public offering, whichever is the earliest. No transfers or sales are permitted during lock-up period of up to 180 days in connection with stock offerings by the Company.

Registration Rights

After the completion of our initial public offering, certain holders of shares of our common stock from this initial public sale will be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities.

Demand Registration Rights: At any time beginning 180 days after the effective date of the registration statement of which this prospectus forms a part, the holders of a majority of the registrable securities may, on not more than two occasions, request that we register all or a portion of their shares. Such request for registration must cover that number of shares with an anticipated aggregate offering price to the public, net of underwriting discounts and commissions, if any, of at least $5.0 million. We will then be obligated to provide the holders of registrable securities with notice of such registration request within 30 days of the request and to use our reasonable best efforts to cause such shares to be registered under the Securities Act. We may postpone the filing of a registration statement for up to 180 days once in a 12-month period if in the good faith judgment of our board of directors such registration would be materially detrimental to us or it would materially interfere with any material transaction involving us, and we are not required to effect the filing of a registration statement during the period beginning 60 days prior to our good faith estimate of the date of the filing of, and ending on a date 180 days following the effective date of, a registration statement pertaining to a public offering of our securities.

Piggyback Registration Rights: If we register any of our securities for public sale, the holders of registrable securities will be entitled to certain piggyback registration rights allowing the holders to include their shares in such registration, other than with respect to a registration related to employee benefit plans or corporate reorganizations or other transactions under Rule 145 of the Securities Act, subject to certain marketing and other limitations.

Form S-3 Registration Rights: Any holder of registrable securities may make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the aggregate price of the public is equal to or would exceed $1.0 million. These shareholders may make an unlimited number of requests for registration on Form S-3. However, we will not be required to cause a registration on Form S-3 during the period starting with the filing of and ending on the date six months following the effective date of a registration statement pertaining to a public offering. We are also not obligated to effect any such registration if within 30 days of receipt of the holder request, we deliver a certificate executed by the Chairman of our board of directors indicating that we are engaged or have fixed plans to engage within 30 days in a firm commitment underwritten public offering of common stock in which registrable securities holders may include such securities. We may postpone the filing of a registration statement for up to 180 days once in a 12-month period if in the good faith judgment of our board of directors it would be materially detrimental to us or it would materially interfere with any material transaction involving us.

Ordinarily, other than underwriting discounts and commissions, if any, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling security holders and blue sky fees and expenses.

The registration rights described above will expire, with respect to any particular shareholder, on the fifth anniversary of the effective date of our initial public offering, or on the first date when the holders and affiliates may sell the registrable securities under Rule 144 of the Securities Act, whichever occurs first. No future registration rights may be granted without consent of a majority of investors unless subordinate to investor rights.

Anti-takeover Provisions

Our amended and restated articles of incorporation and bylaws to be in effect upon the closing of this offering will provide that only our board of directors may call a special meeting of the shareholders.

Our amended and restated articles of incorporation and bylaws will require a 75% shareholder vote for amendment, repeal or modification of articles of incorporation and bylaws. The 75% shareholder voting requirements will make it more difficult for our existing shareholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing shareholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change of control of our company.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in our management.

Listing

We are applying to have our common stock listed on the NASDAQ Global Market under the symbol XCLR.

Determination of Offering Price

There is no established public trading market for our common stock. This is the initial public offering of common stock by Xcelthera, Inc. We are offering 2,000,000 shares of common stock pursuant to this prospectus. We expect the initial public offering price to be between $16.00 and $20.00 per share.

The amount of our common equity after this filing:

Series A preferred stock: 3,000,000 shares authorized; 500,000 actual shares issued

and outstanding, convertible into 10 shares of Common Stock. Of these outstanding shares, 200,000 shares are restricted and control securities held by our affiliates and will be subject to holding period requirements and volume limitations under Rule 144 of the Securities Act; 300,000 shares are restricted securities and will be subject to holding period requirements under Rule 144 under the Securities Act.

Common stock, 10,000,000 shares authorized; 5,000,000 actual shares issued and outstanding; 10,000,000 shares issued and outstanding on a pro forma basis giving effect to the conversion of all outstanding shares of our Series A preferred stock. Of these outstanding shares, 4,500,000 shares are restricted and control securities held by our affiliates and will be subject to holding period requirements and volume limitations under Rule 144 of the Securities Act; 3,500,000 shares are restricted securities and will be subject to holding period requirements under Rule 144 of the Securities Act.

Determination of offering price for our common stock:

Our common stock has not yet been publicly traded, therefore, we determine the offering price based on the estimation of the fair market value of the common stock underlying our stock options, determined by our board of directors exercising their scientific expertise and judgment in the consideration of a variety of factors. The various factors considered in determining such offering price include,

the limitations of existing approaches and markets;

the medical innovation, technology breakthroughs, and competitive advantages of our novel PluriXcel human stem cell technology platforms;

the novelty of our lead human stem cell therapy products and their dominance over our target markets;

our breakthrough technology for large-scale production of high quality clinical-grade human cells enables moving our research and development efforts into first-in-human studies or human trial of human stem cell therapy products;

our human neuronal and cardiomyocyte cell therapy derivatives or products are currently the only available human cell sources in commercial scales with adequate cellular pharmacologic utility and capacity to regenerate the CNS neurons and contractile heart muscles;

the benefits of our breakthrough technology in efficiency, stability, safety, efficacy, and large-scale production of high quality clinical-grade human stem cell therapy products in cGMP facility for commercial and therapeutic uses over all other existing approaches;

our human stem cell therapy products have the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to our marketed human stem cell therapy products;

the severity, rarity or prevalence of the disease or condition we target;

the availability or lack of alternative treatments;

our human stem cell therapy products target a wide range of neurological and cardiovascular diseases, which are major health problems, world-wide, serious or life threatening conditions, currently no other treatment options available or incurable, and cost the US > $500 billion annually;

our ability to protect our intellectual property and proprietary technology rights through patents and other means;

our lack of operation and financial history;

our limited capital resources, current financial condition, and risks inherent in raising additional capital;

our early stage of clinical development or commercialization;

the risks inherent in the development and expansion of our products;

the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company given prevailing market conditions;

the public market valuation of a selection of stem cell, biotechnology, or pharmaceutical companies that were in the early stages of commercialization, in preclinical development or in early stages of clinical development, and had significant operating losses and were generating little or no revenue; and

public and market perception and acceptance of stem cell therapeutics.

There is no established public trading market for our common stock. There are no existing valuation approaches and/or option pricing models that can predict the fair market value of the common stock underlying our stock options. We believe that the various factors we considered in determining our estimation of initial offering price for our common stock conform with generally accepted practices for the valuation of a privately held company's equity securities. However, our estimation may have significant departs from the fair market value of the common stock underlying our stock options.

Plan of Distribution

We plan to offer the shares of our common stock described in this prospectus through underwriting or booking underwriters, but no underwriter agreement has been made yet. Best efforts offering. The underwriters are not required to sell any specific number or dollar amount of securities but will use their best efforts to sell the securities offered.

The ending date of the offering, any minimum purchase requirements, and any arrangements to place the funds in a trust account, have not been made, but will be made if the registration statement filed with the Securities and Exchange Commission become effective.

Shares Eligible for Future Sale

Prior to this offering, there has been no public market for shares of our common stock. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market after this offering or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

Upon the completion of this offering, based on the number of shares outstanding as of filing date of this offer, we will have up to 10,000,000 shares of common stock outstanding. Of these outstanding shares, all shares of common stock sold by us in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, except that shares of common stock held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

The remaining shares of common stock outstanding after this offering will be deemed restricted because of securities laws, the registration rights agreement or lock-up agreements. Following the expiration of the lock-up period and holding period requirements, up to an additional 3,500,000 shares of common stock that are subject to the exercise of outstanding options as of filing date of this offer, including all preferred shares convertible into common stock, will become eligible for sale in the public market to the extent permitted by the provisions of the lock-up agreements and Rules 144 and 701 under the Securities Act. In addition, up to 4,500,000 shares of common stock, including all preferred shares convertible into common stock, held by our affiliates after this offering will be deemed control and restricted stock because of securities laws, which will be subject to holding period requirements and volume limitations under Rule 144 of the Securities Act. Restricted securities as defined under Rule 144 were issued and sold by us in reliance on exemptions from registration requirements of the Securities Act. These shares may be sold in the public market only if registered or pursuant to an exemption from registration, including requirements subject to holding period and/or volume limitation under Rule 144 of the Securities Act.

Lock-up Agreements

In connection with this offering, each of our officers, directors and substantially all of our shareholders, who together hold substantially all of our outstanding stock and stock options, have agreed, subject to limited exceptions, not to directly or indirectly sell or dispose of any shares of our common stock or any securities exercisable for shares of our common stock for a period of 180 days from the date of this prospectus. We plan to use underwriters to offer the shares of our common stock described in this prospectus, but no underwriter agreement has been made yet. As of the filing date of this offering, no lock-up agreement with underwriters has been made yet.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to

public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person is entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144 as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon the expiration of the lock-up agreements described above and the expiration of the holding period requirement for at least one year, within any three month period after 180 days from the date of this prospectus, a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately 100,000 shares immediately after this offering; or

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 generally allows a shareholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell those shares in reliance upon Rule 144, but without being required to comply with the public information and holding period provisions of Rule 144. Subject to the lock-up agreements described above, Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, must wait until 180 days after the date of this prospectus before selling such shares pursuant to Rule 701.

Registration Rights

Upon the closing of this offering, certain holders of shares of our common stock will be entitled to rights with respect to the registration of the sale of these shares under the Securities Act. Registration of the sale of these shares would cause the shares to become freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See Description of Capital Stock - Registration Rights for additional information.

Material United States Federal Income Tax Consequences to Non-United States Holders

The following discussion describes the material United States (U.S.) federal income and estate tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all the potential U.S. federal income tax consequences relating thereto, nor does it address any estate or gift tax consequences (except to the limited extent provided below under U.S. federal estate tax) or any tax consequences arising under any state, local or foreign tax laws or any other U.S. federal tax laws. This discussion is for general information only and does not constitute tax advice. This discussion is based on the Internal Revenue Code, Treasury Regulations promulgated there under, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service (the IRS) all as in effect as of the date of this offering. These authorities may change, possibly with retroactive effect, resulting in U.S. federal income and estate tax consequences different from those discussed below. We have not sought, nor do we plan to seek a ruling from the IRS with respect to the matters discussed below, and there can be no assurance that the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, or that any such contrary position would not be sustained by a court.

This discussion is limited to non-U.S. holders who purchase our common stock issued pursuant to this offering and who hold our common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code (generally, property held for investment). This discussion does not address all U.S. federal income and estate tax considerations that may be relevant to a particular non-U.S. holder in light of particular circumstances of that holder. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including, without limitation, U.S. expatriates, partnerships and other pass-through entities, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-exempt organizations, tax-qualified retirement plans, persons subject to the alternative minimum tax and persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy.

Prospective investors are urged to consult their tax advisors regarding the particular U.S. federal income tax consequences to them of acquiring, owning and disposing of our common stock, as well as any tax consequences arising under U.S. federal estate and gift tax laws, any state, local or foreign tax laws and any other U.S. federal tax laws.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is a beneficial owner of a share of common stock received that is (i) a foreign corporation, (ii) a nonresident alien individual, or (iii) a foreign estate or trust that in either case is not subject to U.S. federal income tax on a net income basis on income or gain from a note or share of common stock.

If a partnership (or other entity taxed as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock and partners in such partnerships are urged to consult their tax advisors regarding the specific U.S. federal income tax consequences to them.

Distribution on Our Common Stock

We do not expect to declare or pay any dividends on our common stock in the foreseeable future. We have not made any distributions on our common stock and do not plan to make any distributions for the foreseeable future. However, if we do pay dividends on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a tax-free return of capital and will first be applied against and reduce a holder adjusted tax basis in the common stock but not below zero. Any distribution in excess of a holder adjusted basis will be treated as capital gain.

Dividends paid to a non-U.S. holder of our common stock that are not effectively connected with a United States trade or business conducted by such holder generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying such holder qualification for the reduced rate. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide us or our paying agent with the required certification, but which qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States and dividends paid on the common stock are effectively connected with such holder United States trade or business, the non-U.S. holder will generally be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI (or other applicable form).

Any dividends paid on our common stock that are effectively connected with a non-U.S. holder U.S. trade or business generally will be subject to U.S. federal income tax on

a net income basis in the same manner as if such holder were a United States Person unless an applicable tax treaty provides otherwise. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax equal to 30% (or such lower rate specified by an applicable tax treaty) of its effectively connected earnings and profits for the taxable year. Non-U.S. holders are urged to consult any applicable tax treaties that may provide for different rules.

A non-U.S. holder who claims the benefit of an applicable income tax treaty generally will be required to satisfy applicable certification and other requirements prior to the distribution date. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Gain on Disposition of Our Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale, exchange, redemption or other taxable disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder conduct of a trade or business in the United States, and if required by an applicable tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States;

- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or

- our common stock constitutes a United States real property interest by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder holding period for our common stock (the applicable period).

Generally, a corporation is a USRPHC if the fair market value of its United States real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we currently are not and will not become a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. In the event we do become a USRPHC, as long as our common stock is regularly traded on an established securities market, our common stock will be treated as United States real property interests only with respect to a non-U.S. holder that actually or constructively holds more than 5% of our common stock at some time during the applicable period.

Unless an applicable tax treaty provides otherwise, gain described in the first bullet point above in this subsection will generally be subject to U.S. federal income tax on a net income basis in the same manner as if such holder were a United States Person.

Non-U.S. holders that are foreign corporations also may be subject to a branch profits tax equal to 30% (or such lower rate specified by an applicable tax treaty) of their effectively connected earnings and profits for the taxable year. Non-U.S. holders are urged to consult any applicable tax treaties that may provide for different rules.

Gain described in the second bullet point above in this subsection will be subject to U.S. federal income tax at a flat 30% rate, but may be offset by U.S. source capital losses.

Gain described in the third bullet point above in this subsection generally will be taxed in the same manner as gain described in the first bullet point above, except that the branch profits tax will not apply.

U.S. Federal Estate Tax

Any of our common stock that is owned or treated as owned by an individual who is a non-U.S. holder (as defined for estate tax purposes) at the time of death will be included in the individual gross estate for U.S. federal estate tax purposes and may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to such holder and the amount of tax, if any, withheld with respect to such dividends. The IRS may make the information returns reporting such dividends and withholding available to the tax authorities in the country in which the non-U.S. holder is resident.

In addition, a non-U.S. holder may be subject to information reporting requirements and backup withholding tax with respect to dividends paid on, and the proceeds of disposition of (including a redemption), shares of our common stock, unless, generally, such holder certifies under penalties of perjury (usually on IRS Form W-8BEN) that such holder is not a United States person or such holder otherwise establishes an exemption from such reporting and withholding. Additional rules relating to information reporting requirements and backup withholding tax with respect to payments of the proceeds from the disposition of shares (including a redemption) of our common stock are as follows:

If the proceeds are paid to or through the United States office of a broker, they generally will be subject to information reporting requirements and backup withholding tax, unless the non-U.S. holder certifies under penalties of perjury (usually on IRS Form W-8BEN) that such holder is not a United States person or such holder otherwise establishes an exemption from such reporting and withholding.

If the proceeds are paid to or through a non-United States office of a broker that is not a United States person and is not a foreign person with certain specified United States connections (a United States related person), information reporting and backup withholding tax will not apply.

If the proceeds are paid to or through a non-United States office of a broker that is a United States person or a United States related person, they generally will be subject

to information reporting (but not to backup withholding tax), unless the broker has documentary evidence in its records that such holder is not a United States person or such holder otherwise establishes an exemption from such reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding tax rules may be allowed as a refund or a credit against a non-U.S. holder United States federal income tax liability, provided the required information is timely furnished by such holder to the IRS.

Withholding under the Foreign Account Tax Compliance Act

Under the Foreign Account Tax Compliance Act (FATCA) and administrative guidance, we or another withholding agent may be required to withhold a generally nonrefundable 30% tax on dividends paid after December 31, 2013 or the gross proceeds of a sale, exchange, redemption or other disposition of our common stock paid after December 31, 2016 to (i) certain foreign financial institutions unless such foreign financial institution agrees to verify, monitor and report to the IRS the identity of certain of its accountholders, among other things, and (ii) certain non-financial foreign entities unless such entity certifies to us that it does not have any substantial U.S. owners or provides the name, address and taxpayer identification number of each substantial U.S. owner, among other things. Non-U.S. holders are urged to consult their tax advisors regarding the application of this FATCA withholding tax to their investment in our common stock and the potential certification, compliance, due diligence, reporting and withholding obligations to which they may become subject in order to avoid this withholding tax.

Underwriting

We plan to use underwriters to offer the shares of our common stock described in this prospectus, but no underwriter agreement has been made yet. Best efforts offering. The underwriters are not required to sell any specific number or dollar amount of securities but will use their best efforts to sell the securities offered.

Experts

The financial statements as of October 31, 2013, have been audited by independent auditor (CPA) from Peninsula Accounting Services, a certified public accounting firm, as stated in their report appearing herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Where You Can Find More Information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and our common stock offered hereby, please refer to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus regarding the contents of any document are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such document filed as an exhibit to the registration statement. We currently do not file periodic reports with the SEC. Upon closing of our initial public offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Securities Exchange Act of 1934. You may read and copy this information at the Public Reference Room of the SEC, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy statements and other information about issuers that file electronically with the SEC. The address of that website is www.sec.gov.

Xcelthera, Inc.
Index to Financial Statements

Report of Independent Auditor (CPA) from Certified Public Accounting Firm

To the Board of Directors and Shareholders of
Xcelthera, Inc.
San Diego, California

We have audited the accompanying balance sheets of Xcelthera, Inc. (the Company) as of October 31, 2013, and the related statements of operations, shareholder equity, and cash flows for the period then ended. These financial statements are the responsibility of the Company management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of Xcelthera, Inc. as of October 31, 2013, and the results of its operations and its cash flows for the period then ended, in conformity with accounting principles generally accepted in the United States of America.

Peninsula Accounting Services, Inc.
A Certified Public Accounting Firm
December 18, 2013

Balance Sheets

	Period (six months) from May 9, 2013 (inception) to October 31, 2013
Assets	
Current Assets:	
Cash and Cash Equivalents	$ 0
Other Current Assets	0
Total Current Assets	0
Property and Equipment	–
Other Assets	
Patent and Organization Costs	6,700
Total Other Assets	6,700
Total Assets	6,700
Liabilities and Shareholder Equity	
Current Liabilities:	
Accounts Receivable	$ 0
Other Current Liabilities	0
Total Current Liabilities	0
Long-Term Liabilities:	
Loans	0
Total Long-Term Liabilities	0
Total Liabilities	0
Convertible Preferred Stock, $0.001 par value; authorized shares – 3,000,000 in May 2013; issued and outstanding shares – 300,000 in May 2013 and 200,000 in September 2013; no shares issued and outstanding, pro forma	6,400
Shareholder Equity (Deficit):	
Common Stock, $0.0001 par value; authorized shares – 10,000,000 in May 2013; issued and outstanding shares – 500,000 in May 2013 and 2,500,000 in September 2013; 8,000,000 shares issued and outstanding, pro forma	300
Additional Paid-In Capital	0
Deficit Accumulated	(0)
Total Shareholder Equity	$ 6,700
Total	$ 6,700

See notes to financial statements.

Statements of Operations

	Period (six months) from May 9, 2013 (inception) to October 31, 2013
Revenue	$ 6,700
Operating Expenses:	
Research and Development	0
General and Administrative	0
Total Operating Expenses	0
Loss from Operations	(0)
Other Expenses	
Patent and Organization Costs	(6,700)
Net Loss	(0)
Net Loss Attributable to Common Stock Holders	(0)
Net Loss Per Share Attributable to Common Stock Holders:	
Basic and Diluted	$ (0)
Weighted Average Common Shares Outstanding:	
Basic and Diluted	3,000,000
Pro Forma Net Loss Per Share Attributable to Common Stock Holders:	
Basic and Diluted	(0)
Pro Forma Weighted Average Common Shares Outstanding:	
Basic and Diluted	8,000,000

See notes to financial statements.

Statements of Convertible Preferred Stock and Shareholders Equity

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholder Equity
	Shares	Amount	Shares	Amount			
Balance at May 9, 2013 (inception)	–	$ –	–	$ –	$ –	$ –	$ –
Issuance of common stock to SDRMI at $0.0001 per share for exclusive license agreement in May 2013	–	–	500,000	50	–	–	50
Issuance of Series A convertible preferred stock to SDRMI at $0.001 per share for exclusive license agreement in May 2013	200,000	200	–	–	–	–	200
Issuance of Series A convertible preferred stock to founders at average $0.06 per share for cash in May 2013	100,000	6000	–	–	–	–	6000
Issuance of common stock to founders at $0.0001 per share for control in September 2013	–	–	2,500,000	250	–	–	250

Issuance of Series A convertible preferred stock to founders at $0.001 per share for control in September 2013	200,000	200	–	–	–	–	200
Net Loss	–	–	–	–	–	(–)	(–)
Balance at October 31, 2013	500,000	6,400	3,000,000	300	–	(–)	6,700

See notes to financial statements.

Statements of Cash Flows

	Period (six months) from May 9, 2013 (inception) to October 31, 2013
Cash Flows from Operating Activities:	
Net Loss	$ (0)
Change in Net Assets	
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities	0
Net Cash Provided by Operating Activities	0
Cash Flows from Investing Activities:	
Patent and Organization Costs	6,700
Net Cash Used in Investing Activities	(6,700)
Cash Flows from Financing Activities:	
Proceeds from Issuance of Series A Convertible Preferred Stock	6,400
Proceeds from Issuance of Common Stock	300
Net Cash Provided by Financing Activities	6,700
Net Increase in Cash and Cash Equivalents	0
Cash and Cash Equivalents at Beginning of Period	0
Cash and Cash Equivalents at End of Period	0
Noncash Investing and Financing Activities	0

See notes to financial statements.

Notes to Financial Statements

(Financial statements and information after October 31, 2013 are unaudited)

1. Nature of Business

Xcelthera, Inc. (the Company) was recently incorporated in the state of California in May 2013 to commercialize the technologies and products developed, in part, with supports by government grants, by San Diego Regenerative Medicine Institute, an non-profit 501C3 tax-exempt biomedical research institute that is interested in licensing its PATENT RIGHTS in a manner that will benefit the public by facilitating the distribution of useful products and the utilization of new processes, but is without capacity to commercially develop, manufacture, and distribute any such products or processes. Our website address is *www.xcelthera.com* and Xcelthera, INC. has its principal operations in San Diego, California. The Company is a new biopharmaceutical company moving towards clinical development stage of novel and most advanced stem cell therapy for a wide range of neurological and cardiovascular diseases with leading technology and medical innovation in cell-based regenerative medicine. The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. In connection with the exclusive license agreement, the Company has issued an aggregate of 3,800,000 shares of common stock subject to the exercise of outstanding options, including all preferred shares convertible into common stock, to San Diego Regenerative Medicine Institute as research and development expenses. Of these options, an aggregate of 2,500,000 shares of common stock, including 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock, convertible into 2,000,000 shares of common stock upon completion of this offer, has been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer.

Through obtaining exclusive rights for novel human stem cell technology platforms **(PluriXcel Technology)** to derive clinical-grade functional human neural and cardiac cell therapy products **(Xcel)** from pluripotent human embryonic stem cells (hESCs) by issuing company stocks, the Company has become the first to hold the breakthrough technology for large-scale production of high quality clinical-grade hESC lines and their functional human neuronal and heart cell therapy derivatives for commercial and therapeutic uses. The Company plans to enter clinical-stage development or first-in-human studies in cardiac and neural repair for its licensed human stem cell therapy products following completion of this offer. The strategy of the Company is to use cutting-edge human stem cell technology to develop clinical-grade functional neural and cardiac cell therapy products from pluripotent hESCs as cellular medicine or cellular drugs to provide the next generation of cell-based therapeutic solutions for unmet medical needs in world-wide major health problems. The success of the Company is dependent upon its ability to successfully complete clinical development of and obtain regulatory approval of its cellular drug products; successfully commercialize any approved products; generate revenue; meet its milestones and obligations; maintain adequate financing; and, ultimately, attain profitable operations.

2. Summary of Significant Accounting Policies

JOBS Act

We are an emerging growth company, as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of JOBS Act to avail ourselves of reduced disclosure requirements applicable to emerging growth companies. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our common stock less attractive because we have elected to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Basis of Presentation and Use of Estimates

As of October 31, 2013, the Company has devoted substantially all of its efforts to establishing its new business, including technology and product licensing, activities associated with corporate governance and this registrant, issuing stocks and raising capital, and pursuing intellectual property and patent rights protection, and has not generated revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

The Company has a limited operating history. Although the Company has not experienced net losses and negative cash flows from operating activities since its recent incorporation, the Company expects to incur net losses in the foreseeable future due to the regular drug development costs of its planned principal operations associated with clinical development of its licensed drug or cell therapy products. The Company plans to fund its operations and capital funding needs through future equity and debt financing and obtaining grants from government and private foundations. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, delay, suspend or curtail planned operations and activities associated with regulatory approval and clinical development of its licensed human stem cell therapy products. Any of these actions could materially harm the Company business, results of operations, and future prospects.

The Company financial statements are prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of the Company financial statements requires it to make estimates and assumptions that impact

the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company financial statements and accompanying notes. The most significant estimates in the Company financial statements relate to the valuation of intangible assets, intellectual property and license rights, technology, products in preclinical or clinical development, equity awards, and anticipated regulatory and clinical trial expenses. Management bases its estimates on certain assumptions, which it believes are reasonable in the circumstances, and while actual results could differ from those estimates, management does not believe that any change in those assumptions in the near term would have a significant effect on the Company financial position, results of operations or cash flows.

Audited Financial Information or Interim Financial Information

The accompanying balance sheet or interim balance sheet as of October 31, 2013 and the summary statements of operations and cash flows for the six months ended October 31, 2013 and the period from May 9, 2013 (inception) to October 31, 2013 and the summary statements of convertible preferred stock and stockholder equity for the six months ended October 31, 2013 and the related note disclosures are audited financial information or interim financial information. These audited financial statements or interim financial statements for the short period that the registrant has been in existence have been prepared in accordance with GAAP and reflect all adjustments necessary for the fair presentation of the Company financial position as of October 31, 2013 and its results of operations for the six months ended October 31, 2013 and the period from May 9, 2013 (inception) to October 31, 2013. Financial statements and information after October 31, 2013 are unaudited. In the opinion of management, the unaudited financial statements and information after October 31, 2013 have been prepared on a basis consistent with our audited financial statements included in this prospectus. The results for the six months ended October 31, 2013 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Unaudited Pro Forma Balance Sheet Information

The unaudited pro forma balance sheet information as of October 31, 2013 assumes the conversion of all outstanding shares of convertible preferred stock into 5,000,000 shares of the Company common stock, and the issuance of an aggregate of 8,000,000 shares of the Company common stock upon such conversion, assuming an initial public offering price of $18 per share (the mid-point of the price range set forth on the cover of this prospectus). The pro forma balance sheet was prepared as though the completion of the IPO contemplated by this prospectus had occurred on October 31, 2013. Shares of common stock issued in such IPO and any related net proceeds are excluded from the pro forma information.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking and savings accounts, money market accounts and money market funds. The Company considers all highly liquid, short-term investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

Intangible Assets

Intangible assets consist of licenses, patent rights and patents, trade name and a noncompetition agreement with a scientific founder.

Other Assets

Other assets consist of the Company deferred IPO costs. These costs represent legal, accounting and other direct costs related to the Company efforts to raise capital through a public sale of its common stock. Future costs will be deferred until the completion of the IPO. If the Company terminates its plan for an IPO or delays such plan for more than 90 days, any costs deferred will be expensed immediately.

Revenue Recognition

The Company recognizes revenue in accordance with Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, and Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 605, *Revenue Recognition*.

Research and Development Costs

All research and development costs are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as investing activities and expensed as incurred since recoverability of such expenditures is uncertain.

License Agreements

The Company has entered into an exclusive license agreement with San Diego Regenerative Medicine Institute pursuant to which the Company acquired the portfolio of intellectual property or exclusive license rights for commercialization of the PluriXcel human stem cell technology platforms and Xcel human cell therapy products. In connection with the exclusive license agreement, the Company has issued an aggregate of 3,800,000 shares of common stock subject to the exercise of outstanding options, including all preferred shares convertible into common stock, to San Diego Regenerative Medicine Institute as investment in research and development. Of these options, an aggregate of 2,500,000 shares of common stock, including 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock, has been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer. In addition, milestone payments will occur pursuant to the exclusive license agreement upon first achievement of the following milestones: (1) first regulatory approval for clinical development or an investigational new drug (IND) of first Licensed Product; and (2) first commercial sale or first market approval for clinical uses of a Licensed Product for each disease indication.

3. Convertible Preferred Stock and Stockholder Equity

The authorized, issued and outstanding shares of convertible preferred stock by series as of October 31, 2013 are as follows:

	Shares Authorized	Shares Outstanding	Liquidation Preference
Series A	3,000,000	500,000	$ 6,400
Undesignated	7,000,000	-	-
Total	10,000,000	500,000	6,400

Convertible Preferred Stock

Dividend provisions: Dividends shall be payable pro rata on the Preferred Stock based on the number of shares of Common Stock into which they are convertible, but only if and when declared by the Company Board of Directors; dividends are not cumulative. No dividends shall be paid on any Common Shares unless comparable dividends are paid on all of the Preferred Stock based on the number of Common Shares into which they are convertible. For any other dividends or distributions, Preferred Stock participates with Common Stock on an as-converted basis.

Conversion: One share of the Series A Preferred Stock shall be convertible into 10 shares of the Company Common Stock. The conversion rate of each series of preferred stock issuable pursuant to stock option in future, if any, will be determined by our board of Directors.

Liquidation preference: In the event of any liquidation or winding up of the Company, the holders of the Preferred Stock shall be entitled to receive in preference to the holders of Common Stock the amount based on the number of Common Shares into which they are convertible. The remaining balance of the proceeds from the liquidation will then be allocated the Common Stock holders on an as-converted basis. At the option of the holders of the Preferred Stock, a merger, sale of all or substantially all of the assets of the Company, reorganization or other transaction in which control of the Company is transferred may be treated as a liquidation, dissolution or winding up for purposes of the liquidation preference.

Redemption: The Preferred Stock will not be redeemable.

Anti-dilution provisions: The conversion price of the Preferred Stock shall be subject to appropriate adjustment in the event of a stock split, stock dividend or similar event; and shall be adjusted on a weighted average basis to prevent dilution, in the event that the Company sells additional shares of Common Stock, preferred stock or convertible debt convertible into Common Stock or preferred stock at a purchase price less than the applicable conversion price of the Preferred Stock. No adjustment shall be made for the sale of Common Stock to employees, directors or consultants. Proportional adjustments will be made for stock splits and stock dividends.

Voting rights: Except as set forth herein, each holder of Preferred Stock shall have the right to that number of votes equal to the number of shares of Common Stock issuable upon conversion of the Preferred Stock held by such holder and shall vote with the Common Stock.

Right of first refusal: In the event that any of the existing shareholders, managers, employees or other shareholders propose to sell to a third party or parties a number of shares of their preferred stock, then the stock to be sold will be offered first to the Company to purchase the shares on the same terms as the third-party offer. If the Company does not purchase any, or all, of the available shares, then the Preferred Stock shareholders have the right to purchase the remaining portion at the same terms. If the Preferred Stock shareholders and/or the Company do not purchase all of the shares, then they may be offered to the third party. These rights of refusal shall terminate upon the Company initial public offering or upon sale of the Company through merger, sale of stock or assets or otherwise.

Preemptive rights: Holders of Preferred Stock shall have the right to participate in any future sales of securities by the Company (other than (a) options and shares granted or sold to employees, directors and consultants, (b) issuance of stock in connection with corporate acquisitions or joint ventures) on the basis of maintaining their pro rata share of all outstanding common and preferred shares of the company. Such right shall expire upon and shall not apply to an initial public offering of Common Stock, and shall not apply to: (i) shares issued under stock options plans approved by the Board of Directors in an amount not to exceed shares; or (ii) shares exchanged for assets or securities of another corporation in any acquisition of assets, merger, or other reorganization.

Co-sale rights: Each holder of Preferred Stock will have a co-sale right to sell shares in the event that any of the existing shareholders propose to sell to a third party or parties a number of shares of their Common Stock or securities convertible into Common Stock. This clause does not apply to any holders of less than 10,000 shares of stock or any manager, board member, employee selling less than 10,000 shares of stock in any 12 month period. This number of shares will be adjusted for any stock splits, combinations, etc. authorized by the Company. The co-sale rights shall terminate upon the Company initial public offering or upon sale of the Company through merger, sale of stock or assets or otherwise.

Board representation: The holders of Preferred Stock shall have the right to designate one director. The remaining directors will be designated by holders of the Common Stock. One director shall be jointly elected by a majority of common stock and a majority of the Preferred stock, voting as separate classes; and the holders of preferred stock and common stock voting together as a single class shall be entitled to elect any additional directors.

Information rights: Each holder of the Preferred Stock shall receive standard information rights including financial reports and, subject to minimum holdings requirements, annual budget and business plan, as well as standard inspection rights. This right to financial information and plans shall terminate upon a public offering.

Restrictions on stock transfers or sales: No transfers or sales of the Preferred Stock are allowed prior to 3 years after the Closing of the issuance or the Company initial public offering, whichever is the earliest. No transfers or sales are permitted during lock-up period of up to 180 days in connection with stock offerings by the Company.

Issuances of Stock Options and Restricted Stock Awards to Our Founders

In May 2013, we have issued 800,000 shares of our restricted common stock, at a par value of $0.0001 per share, and 300,000 shares of series A preferred convertible stock, at a par value of $0.001 per share, to San Diego Regenerative Medicine Institute under an exclusive license agreement, with a term of 10 years. Of these options, 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock have been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer. In addition, we have issued 150,000 shares of our series A preferred convertible stock to our founders pursuant to outstanding stock options, with a term of 2 years. Of these options, 100,000 shares of series A preferred convertible stock have been exercised as of filing date of this offer, with exercise prices ranging from $0.01 to $3 per share, average $0.06 per share. All of the foregoing securities consisting of an aggregate 3,500,000 shares of common stock awarded upon the exercise of outstanding options, including all preferred shares convertible into common stock, are deemed restricted securities under the Securities Act.

Stock Option Awards and Restricted and Control Stock Awards to Our Affiliates

In May 2013, we have issued 9,200,000 shares of our restricted common stock, at a par value of $0.0001 per share, and 2,550,000 shares of series A preferred convertible stock, at a par value of $0.001 per share, to our affiliates pursuant to outstanding stock options, with a term of 10 years. Of these options, 2,500,000 shares of common stock and 200,000 shares of series A preferred convertible stock have been exercised at its par value in September 2013. The aggregate 4,500,000 shares of common stock awarded upon the exercise of outstanding options, including all preferred shares convertible into common stock, are deemed to be restricted and control securities subject to holding period and volume limitation requirements under Rule 144 of the Securities Act.

4. Subsequent Events

Amended and Restated Articles of Incorporation

In December 2013, in connection with the filing of this registrant, the Company filed an amended and restated articles of incorporation. Effective upon the filing of the amended and restated articles of incorporation, the Company authorized shares consisted of the following:

	Shares Authorized
Convertible preferred stock:	
Series A	3,000,000
Undesignated	7,000,000
Total	10,000,000
Common stock:	
Issued	10,000,000
Fully Diluted	40,000,000
Undesignated	60,000,000
Total	100,000,000

Part II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all expenses to be paid by the Registrant, other than estimated underwriting discounts and commissions, in connection with our initial public offering. All amounts shown are estimates.

		Amount
SEC registration fee	$	5,456
FINRA filing fee	$	*
NASDAQ Global Market initial listing fee		*
Printing and engraving expenses		*
Accounting fees and expenses		*
Blue sky fees and expenses		*
Legal fees and expenses		*
Transfer agent and registrar fees and expenses		*
Miscellaneous		*
TOTAL	$	*

*To be completed by amendment

Item 14. Indemnification of Directors and Officers

The General Corporation Law of California require a corporation to indemnify any director or officer who is a party to any threatened, pending or completed civil, criminal, administrative or investigative action, suit arbitration or other proceeding, whether formal or informal, which involves foreign, federal, state or local law and that is brought by or in the right of the corporation or by any other person. A corporation obligation to indemnify any such person includes the obligation to pay any judgment, settlement, penalty, assessment, forfeiture or fine, including any excise tax assessed with respect to an employee benefit plan, and all reasonable expenses, including fees, costs, charges, disbursements, attorney and other expenses except in those cases in which liability was incurred as a result of the breach or failure to perform a duty that the director or officer owes to the corporation and the breach or failure to perform constitutes: (i) a willful failure to deal fairly with the corporation or its shareholders in connection with a matter in which the director or officer has a material conflict of interest; (ii) a violation of criminal law, unless the person has reasonable cause to believe his conduct was lawful or had no reasonable cause to believe his conduct was unlawful; (iii) a transaction from which the person derived an improper personal profit; or (iv) willful misconduct.

An officer or director seeking indemnification is entitled to indemnification if approved in any of the following manners: (a) a majority vote of the Disinterested Directors, even though less than a quorum of the Board of Directors; (b) a committee comprised of Disinterested Directors, such committee having been designated by a majority vote of the Disinterested Directors (even though less than a quorum); (c) if there are no such Disinterested Directors, or if a majority of Disinterested Directors so directs, by independent legal counsel; (d) by a panel of three arbitrators; (e) by an affirmative vote of disinterested shareholders; or (e) with respect to any additional right to indemnification granted, by any other method permitted in the General Corporation Law of California.

Reasonable expenses incurred by a director or officer who is a party to a proceeding may be reimbursed by a corporation at such time as the director or officer furnishes to the corporation written affirmation of his good faith belief that he has not breached or failed to perform his duties and a written undertaking to repay any amounts advanced if it is determined that indemnification by the corporation is not required.

The indemnification provisions of the General Corporation Law of California are not exclusive. A corporation may expand an officer or director right to indemnification (i) in its articles of incorporation or bylaws; (ii) by written agreement between the director or officer and the corporation; (iii) by resolution of its board of directors; or (iv) by resolution of a majority of all of the corporation voting shares then issued and outstanding. As permitted by the General Corporation Law of California, the Company has adopted indemnification provisions in its bylaws that closely track the statutory indemnification provisions with a limited exception. The Company may choose to further indemnify its officers, directors and employees by purchasing liability insurance and additional insurance on their behalf or by entering into individual or group indemnification agreements with such officer, director, or employee.

Item 15. Recent Sales of Unregistered Securities.

As of filing date of this offer, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Stock Options and Restricted Stock Awards to Our Founders

In May 2013, we have issued 800,000 shares of our restricted common stock, at a par value of $0.0001 per share, and 300,000 shares of series A preferred convertible stock, at a par value of $0.001 per share, to San Diego Regenerative Medicine Institute under an exclusive license agreement, with a term of 10 years. Of these options, 500,000 shares of common stock and 200,000 shares of series A preferred convertible stock have been exercised at its par value pursuant to the exclusive license agreement as of filing date of this offer. In addition, we have issued 150,000 shares of our series A preferred convertible stock to our founders pursuant to outstanding stock options, with a term of 2 years. Of these options, 100,000 shares of series A preferred convertible stock have been

exercised as of filing date of this offer, with exercise prices ranging from $0.01 to $3 per share, average $0.06 per share. All of the foregoing securities consisting of an aggregate 3,500,000 shares of common stock awarded upon the exercise of outstanding options, including all preferred shares convertible into common stock, are deemed restricted securities under the Securities Act.

(b) Stock Option Awards and Restricted and Control Stock Awards to Our Affiliates

In May 2013, we have issued 9,200,000 shares of our restricted common stock, at a par value of $0.0001 per share, and 2,550,000 shares of series A preferred convertible stock, at a par value of $0.001 per share, to our affiliates pursuant to outstanding stock options, with a term of 10 years. Of these options, 2,500,000 shares of common stock and 200,000 shares of series A preferred convertible stock have been exercised at its par value in September 2013. The aggregate 4,500,000 shares of common stock awarded upon the exercise of outstanding options, including all preferred shares convertible into common stock, are deemed to be restricted and control securities subject to holding period and volume limitation requirements under Rule 144 of the Securities Act.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering, and the Registrant believes that each transaction was exempt from the registration requirements of the Securities Act in reliance on the following exemptions:

(1) With respect to the transactions described in paragraphs (a) and (b), Section 4(2) of the Securities Act, or Rule 506 of Regulation D promulgated thereunder, as transactions by an issuer not involving a public offering. Each recipient of the securities in this transaction represented his or her intention to acquire the securities for investment only and not with a view to, or for resale in connection with, any distribution thereof, and appropriate legends were affixed to the share certificates issued in each such transaction. In each case, the recipient received adequate information about the registrant or had adequate access, through his or her relationship with the registrant, to information about the registrant.

(2) With respect to the transactions described in paragraph (b), Rule 701 promulgated under the Securities Act as transactions pursuant to a compensatory benefit plan approved by the Registrant's board of directors.

Item 16. Exhibits and financial statement schedules

(a) Exhibits.

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

(b) Financial Statement Schedules.

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act 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 Securities 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 Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus 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) For the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. 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 first use, 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 date of first use.

(4) 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.

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of San Diego, State of California, on the 5th day of March, 2014.

Xcelthera, INC.

By: /s/ /Xuejun H. Parsons/

Xuejun H. Parsons, PhD

Chief Executive Officer, President, and Chairman of the Board

/s/ /Dennis A. Moore/

Dennis A. Moore

Vice Chairman of the Board

Exhibit Index

Exhibit Number	Description of Exhibit
1.1#	Form of Underwriting Agreement
3.1	Article of Incorporation, as currently in effect
3.2	Form of Amended and Restated Articles of Incorporation of Registrant, to be effective upon the closing of Registrant initial public offering
3.3	Bylaws of Registrant
4.1	Form of Registrant Common Stock Certificate
5.1#	Legal Opinion
10.1*	Exclusive License Agreement by and between Registrant and San Diego Regenerative Medicine Institute
10.2	Form of Indemnification Agreement for Directors and Officers
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Original Report of 2013 North American Technology Innovation Award in Stem Cell Technologies Provided by Frost & Sullivan
23.3	Announcement or Consent of Frost and Sullivan 2013 North American Technology Innovation Award in Stem Cell Technologies to Xcelthera, INC.-part 1
23.4	Announcement or Consent of Frost and Sullivan 2013 North American Technology Innovation Award in Stem Cell Technologies to Xcelthera, INC.-part 2

* Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment is requested has been filed separately with the Securities and Exchange Commission.

To be included by amendment.