



Sector Research Report

Regenerative Medicine

The issue of regenerative medicine and 'stem cells' is an emotive and volatile debate. The perfection and subsequent implementation of replacing damaged, lost or aging tissues and organs through replacement or autologous stimulation will have profound effects on modern medicine and treatment.

OneMedResearch reports on the **Emerging Trends in Regenerative Medicine** will look at the major areas in this sector and insights as to how best to identify the most promising investment opportunities.

- **Part I: Mesenchymal Stem Cells** (July 12th, 2012)
- Part II: iPSC as a Drug and Biologics Screening Platform
- Part III: Stem Cells as a Cure for Baldness
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About OneMedResearch:

OneMedResearch delivers information on investment opportunities to serious investors in healthcare and life sciences. The team produces monthly research reports exploring the emerging growth companies developing disruptive technology in life sciences. In addition, OneMedResearch produces investor guides and directories to various life sciences sectors, updated quarterly.

Investor Guides aggregate critical information, contacts and resources in one place, thereby delivering a time-saving, risk-reducing tool for anyone with a significant investment in the sector.

- A near comprehensive list of companies and short descriptions of both public and private companies, to include contact information important to deal-makers.
- Interviews with thought leaders, company executives, and investors
- Directory of resources including major investors, associations, research institutions, conferences.
- Market analysis from leading industry researchers and publications, including developments, technology advances, economics and political impact

Accompanying this printed, abridged version of the Investor Guide is an electronic version, which provides hyperlinks to interviews, news stories, and database profiles scattered throughout the guide.

To view the electronic Investor Guide to Regenerative Medicine, visit www.onemedplace.com/investor-guide-regenerative-medicine.pdf

Investors can also subscribe to the full investor guide, updated quarterly. The full electronic investor guide subscription will include:

- Quarterly updates of interviews and market analysis
- Expanded companies profiles with executive contact information
- Directory of investors and additional resources

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Emerging Trends in Regenerative Medicine

Part I: Mesenchymal Stem Cells

The approvals of *Prochymal* (Osiris Therapeutics) in Canada (May 2012) and New Zealand (June 2012) for the treatment of steroid refractory Graft versus Host Disease (GVHD), and *Hearticellgram* (FBC-Pharmicell) in South Korea last year for acute myocardial infarction (AMI) represent milestones for the regenerative medicine field. These developments help legitimize Mesenchymal Stem Cells (MSCs) as viable cell based therapies for unmet medical conditions.

Equally important, several promising companies operating in the same space are not too far behind Osiris and FBC-Pharmicell. It is now imperative that the investor community understand key factors that help distinguish clinical phase products for similar conditions, as well as comprehend up-to-date issues surrounding MSCs. The promise of stem cell based therapies has had a long and tumultuous history, but the day of redemption may finally be near. This review will provide a brief introduction to MSC and highlight several biotech companies operating in this space.

Stem cells come in different flavors

Stem cells can be broadly divided into embryonic (human embryonic stem cells - hESC) and non-embryonic (adult) stem cells. Adult stem cells exist in various forms throughout the body and function as reservoirs for continuous cell replacement during the life of an organism. Skin, blood and intestinal stem cells are some of the better studied examples of adult stem cells, and serve as prototypes.

Mesenchymal stem cells (or, what some prefer to call multipotent stem cells, multipotent stromal cells or somatic stem cells) refer to a group of as yet incompletely characterized cells with unique therapeutic properties. Mesenchymal stem cells are classified based on a handful of unifying traits:

- The ability to home to sites of inflammation following tissue injury.
- Secretion of bioactive molecules capable of stimulating recovery of injured cells.
- The ability to perform immunomodulatory functions.
- The ability to self-renew as well as differentiate into various cell types.

These characteristics make this stem cell class very attractive as therapeutic agents. Further, MSCs avoid the political and moral-ethical quandaries associated with the use of hESCs.

Numerous pre-clinical and early-to-late stage clinical studies have demonstrated MSC efficacy for the treatment of conditions with unmet medical needs. These include: inflammatory bowel disease (IBD); acute and chronic myocardial infarction/ischemia (AMI, CMI); ischemic stroke; critical limb ischemia (CLI); peripheral artery disease (PAD); dilated cardiomyopathy (DCM); Graft vs Host Disease (GVHD); degenerative bone diseases; and type I diabetes mellitus (T1DM), to list a few.

With this enormous market potential, several companies currently operate in the MSC space with recently approved products or products in early to late phase trials. But no two products are alike, and several key features help distinguish them.

Non-autologous (allogeneic donor-derived) MSCs vs. Autologous (self-derived) MSCs

Many peer-reviewed studies support the use of non-autologous MSCs with minimal concern for rejection. This is due to the lack of MHC II surface antigen expression, leading to the MSC's hypo-immunogenicity. In addition, MSCs exhibit immuno-modulatory and immuno-suppressive properties, which help MSCs avoid host immune-surveillance. However, cells constantly monitor and adapt to their environments through changes in gene expression. Specifically, part of MSC's therapeutic effect is a direct result of their ability to undergo differentiation once they're inside the patient. Thus, it is unclear whether MSCs – as they undergo changes in the patient – would continue to maintain long-term immune-privileged status and raises the concern of rejection.

In order to circumvent the issue of rejection, several products based on patient-derived autologous MSCs have been developed. This strategy avoids the issue of rejection, however the financial costs associated with individualized harvesting and expansion of autologous MSCs may be significant. More importantly, in contrast to ready-made "off the shelf" allogeneic MSCs, generating autologous MSCs from scratch is a time-consuming process. Critically ill patients who recently suffered AMI or stroke may not have the luxury of time to wait several days before patient specific MSCs are ready for use. On the other hand, a patient suffering from a chronic inflammatory condition such as IBD may be willing to wait a few days for autologous, patient derived MSCs.

Thus, the medical community's decision to pursue therapies based on autologous vs non-autologous MSCs will be impacted by target patient populations, medical indications and willingness of payors to cover costs.

Expanding varieties of MSCs

Bone marrow derived MSC is the first MSC to be identified, and therefore has been characterized most extensively. As a consequence, most MSC based products are bone marrow derived. However, as several additional types of MSCs have been discovered throughout the body with different properties, companies have started to explore non-bone marrow derived sources. Currently, sources of MSCs being explored or marketed include skin, fat, umbilical cord blood and the placenta. But this list is expected to grow as MSCs from different sources have been shown to exhibit different characteristics.

Different attributes of MSCs include:

- Innate proclivity to home to particular target organs.
- Differentiation into specific tissue types.
- Extent to which they can self-renew before undergoing differentiation.
- Ability to avoid host-immune surveillance.

In addition to differences in cellular properties, accessibility to the cells is a consideration. For example, harvesting MSC from bone marrow is a more involved process than harvesting MSCs from the placenta, which is readily available and considered medical waste by most people.

Variations on the same theme: from cell harvest to administration

Within the subcategory of MSC based therapy, products can be further differentiated based on the company propriety methods of cell processing. Of the steps involved from cell harvesting to final administration of cell based products, cell enrichment/expansion, manipulation, and administration deserve special attention, as they are thought to have the greatest impact on the product's therapeutic index.

- Cell enrichment/expansion is an obligatory step that leads to purified and expanded population of MSC from the limited starting mixture of harvested cells.
- Companies may decide to introduce proprietary small molecules or genetic alterations in order to enhance the product's therapeutic index and minimize potential side effects, although it is not an obligatory step in cell processing.
- Last but not least, administration of therapeutic cells is not as straightforward as it may seem. Unlike systemic (blood stream) injection of small molecule based drugs, empirical evidence has shown that a major complication of systemic injection of MSCs is their sequestration in major draining organs such as the liver, spleen and the lungs. To circumvent this issue, companies have devised proprietary methods of delivering MSCs locally to target organs using proprietary catheters or by intramuscular injections. In situations where local injection is not possible due to diffuse nature of the disease or inaccessibility of the target organ, MSCs can be manipulated in vitro to minimize adherence to draining organs.

Upcoming Investor Guide Editions: Emerging Trends in Regenerative Medicine

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Mesenchymal Stem Cell Companies

The following is an exploration of two companies operating in the Mesenchymal Stem Cell space. Each edition, we select relevant companies to audit their technology clinical phase success.

Aastrom Biosciences [NASDAQ:ASTM 86M]

Products: Ixmyelocel-T, patientbone marrow derived expanded multicellular therapy, is being developed for critical limb ischemia (CLI) and dilated cardiomyopathy (DCM). In addition to MSCs, ixmyelocel-T contains a mixed population of monocytes and activated macrophages, which the company claims enhances the therapeutic effects of their product.

Indications: CLI is the most severe form of peripheral artery disease (PAD), and according to Aastrom represents a market potential of over \$2B. Patients with CLI require re-vascularization surgeries to improve blood flow to affected limbs. However, up to 40% of patients with CLI do not qualify for surgical intervention due to underlying medical conditions. These "no-option" patients have to resort to amputations, and represent an unmet medical need. Approximately 1 million people suffer from CLI in the United States, a figure expected to rise with aging population and increasing incidence of underlying medical conditions, including diabetes and coronary artery diseases.

Several risk factors including alcohol abuse, viral infection, autoimmune conditions and genetic conditions contribute to DCM, which is the leading cause of heart failure and heart transplant in the US. Approximately 5 million American suffer from heart failure, and according to Aastrom represent a market potential of approximately \$1B. Current medical interventions include angiotensin-converting enzyme inhibitors, diuretics, anticoagulants and artificial pacemakers. Treatment modality depends on the underlying etiology of DCM and currently, there is no cure for DCM.

Clinical Trials:

- REVIVE-CLI, a phase 3 study designed to assess the efficacy and safety of ixmyelocel-T treatment for CLI, is currently enrolling "no-option" patients. The study sets amputation free survival at 12 months post-injection of ixmyelocel-T as the threshold for positive outcome. The company's phase 2 study, RESTORE-CLI, also assessed safety and efficacy of ixmyelocel-T, albeit on a smaller scale. Results of Phase 2 study are published in peer-reviewed journals and seem generally positive. It is anticipated that the Phase 3 study will have similar success as Phase 2.
- IMPACT-DCM, a phase 2a study designed to assess the safety and tolerability of ixmyelocel-T treatment compared to standard of care in patients with DCM, is completed and pending publication of results.
- CATHETER, a Phase 2a study to assess the safety of catheter and transendocardial delivery of ixmyelocel-T, is currently underway.

Pluristem [NASDAQ:PSTI 113M]

Products: PLX cells (PLacentalXpanded cells) are mesenchymal-like adherent stromal cells derived from the placenta. PLX cells, although derived from donor sources, are claimed to be immune-privileged with minimal risk of rejection. Therefore, Pluristem claims that tissue matching is not required. Pluristem expands the cells in a proprietary 3 dimensional bioreactor, PluriX, which mimics the microenvironment of bone marrow substrates and does not require addition of cytokines or growth factors. PluriX is claimed to offer larger-scale expansion of cells and a superior batch to batch consistency compared to the traditional 2 dimensional approach. Furthermore, this proprietary cell expansion method can be applied to the expansion of embryonic or induced pluripotent stem cells (iPSC) should the need arise. PLX-PAD is being developed for the treatment of CLI and intermittent claudication.

Indications: CLI is the most advanced form of PAD and represents an unmet medical need. Intermittent claudication is a variant of PAD and is thought to ultimately lead to CLI. Etiologies for Intermittent claudication includes underlying atherosclerosis of the peripheral arteries, which causes narrowing of the blood vessels and reduced blood flow to affected limbs. Intermittent claudication can also result from underlying inflammation of the arterial walls (arteritis). Symptoms of pain and cyanosis manifest during varying degrees of physical exertion, or in severe cases even during rest, when oxygen demand of the muscles is not satisfied due to vascular insufficiency. Different versions of PLX are currently in exploration for the treatment of other medical conditions including skeletal, pulmonary, autoimmune and CNS diseases, as well as for the improved engraftment of bone marrow transplants.

Clinical Trials: PLX-PAD passed phase I and II trials for CI and CLI respectively and is expected start phase II and phase III studies in 2012.

Of note, PLX is in pre-clinical stage development for the enhanced engraftment of hematopoietic stem cell (HSC) transplant. In May, PLX received compassionate care use approval in Israel and cells were administered to a 7 year old patient with aplastic bone marrow who failed two prior attempts at bone marrow transplants. Within 10 days following two doses of PLX cell administration, the patient started showing signs of bone marrow engraftment demonstrating the feasibility of using PLX as an adjunct treatment for enhanced engraftment of bone marrow transplant. The 7 year old patient is reported to be showing continued signs of recovery.

Listen to Dr. William Prather, Senior VP Corporate Development, discuss this milestone on [OneMedRadio](#).

[OneMedRadio](#) interviewed Jason Napodano, Senior Biotech Analysis at Zacks Investment Research, about these and other particularly intriguing regenerative medicine companies.



AF Cell Medical
Parsippany, NJ.

Early Stage
Wound Healing

Robin Young, Founder, CEO

AF Cell produces AmnioClear, human allograft derived from the amniotic membrane. Allografts (human derived) represent alternatives to xenografts (non-human animal derived) in surgical applications. AmnioClear can be applied to damaged lining of the tissues to enhance healing, minimize pain and restore normal function of tissues such as the periosteum, synovium, deep and superficial fascia and the meninges. AmnioClear is harvested from human placentas and each product is rigorously screened by CLIA-certified lab for major infectious agents and produced in accordance with the FDA regulation 21CFR1271 (GTP). All allografts are processed aseptically, sterilized and packaged to maintain the integrity of the product.

[Private]



Amarantus BioSciences
Sunnyvale, CA.

Early Stage
Regenerative Medicine

Gerald E Commissiong, CEO

Amarantus BioSciences focuses on developing biologics based on the intellectual property rights to a therapeutic protein, Mesencephalic-Astrocyte-derived Neurotrophic Factor ("MANF"), that has anti-apoptotic properties. The company is developing treatments for brain-related disorders including traumatic brain injury (TBI) based on MANF. On June 7, 2012, Amarantus and Banyan Biomarkers, a leader in developing in vitro diagnostics for the detection of TBI, announced a collaboration agreement to evaluate MANF's potential as a disease-modifying agent for the treatment of TBI. While the data is early in development, in-vitro cell culture experiments showed neuroprotective properties of MANF in various cell death-related assays. The data raise the possibility of modulating MANF in patients suffering from TBI and in patients who have suffered multiple concussions over an extended period, to promote recovery of neurologic function after TBI.

[Amarantus](#) presents at the 2012 New York Biotechnology Association annual meeting.

[OTC BB: AMBS]



IntelliCell BioSciences
New York, NY.

Early Stage
Regenerative Medicine

Steven Victor, Chairman,
CEO

IntelliCell BioSciences is developing autologous stromal vascular cells (SVC's) derived from the blood vessels of the adipose tissue for the treatment of osteoarthritis, gingival gum degeneration, sports medicine injuries and multiple sclerosis to list a few. Clinical trials for some of these conditions are planned for 2012 and 2013. At the core of the company's technology platform is a proprietary ultrasound based method of separating the capillary network from the adipocytes that bypasses the need for any enzymatic treatments and is thought to yield superior products. Patients undergoing the procedure receive a mini-liposuction followed by cell purification process and quality test which takes about an hour before the patient is ready to receive the processed therapeutic cells. In May 2012, IntelliCell entered a sponsored research agreement with the Institute for Cell Engineering and Regenerative Medicine (ICERM) at the University of Florida to explore the physiological characteristics of the adult autologous vascular cells the company is developing as product.

[OTC:SVFSC 7M]



InVivo Therapeutics
Cambridge, MA.

Early Stage
Regenerative Medicine

Frank Reynolds, CEO

InVivo Therapeutics is focused on utilizing polymers as a platform technology to develop and commercialize groundbreaking treatments for spinal cord injuries (SCI). SCI represents an unmet medical need with symptom relief as the mainstay of treatment. InVivo's approach is focused on neuroprotection to minimize bleeding, inflammation, and cell death in order to support the body's own ability repair and recover through a process called neuroplasticity. To this end, InVivo is developing biocompatible polymer scaffolding device and hydrogel for local controlled release of steroids for acute SCI and biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic SCI. InVivo's proprietary technology was developed by professors at MIT and MGH and has been shown in preclinical studies to promote functional recovery following traumatic SCI in several animal models.

[OneMedRadio](#) interviews Frank Reynolds, CEO and CFO of InVivo Therapeutics

[OTC:NVIV 159M]



ISTO Technologies
St Louis, MO.

Late Clinical Stage
Regenerative Medicine

Mitchell Seyedin, President,
CEO

ISTO Technologies is an orthobiologics company focused on developing biologic products for orthopedic and spinal conditions such as osteoarthritis and degenerative spinal discs. In collaboration with Zimmer Inc., ISTO Technologies offers various allograft tissue products for bone graft extension and knee cartilage injuries. The company is also developing formulations of living cartilage implants to repair and regenerate damaged knee cartilage based on patented juvenile cell-based technology which has been shown to have superior regenerative properties compared to adult cells. DeNovo ET, in clinical stage III, is designed as off-the-shelf living cartilage implant to repair and regenerate damaged knee cartilage. NuQu, in clinical stage I, is being developed as injectable live cell product for the treatment of back pain associated with degenerative disc diseases. Both conditions represent unmet medical needs with large market potential.

[Private]



NeoStem
New York, NY.

Clinical Stage
Regenerative Medicine

Robin Smith, Chairman, CEO

NeoStem is an international biopharmaceutical company with global research and development capabilities and operations in three business units: U.S. adult stem cells, China adult stem cells and China pharmaceuticals, primarily antibiotics. In the United States the Company is a provider of adult stem cell collection, processing and storage services enabling healthy individuals to donate and store their stem cells for personal therapeutic use. NeoStem is engaged in research and development of new therapies based on very small embryonic-like stem cells (VSEL) technology, with the University of Louisville Research Foundation (ULRF). On January 2011, NeoStem completed acquisition of Progenitor Cell Therapy, LLC (PTC) which provides NeoStem with expertise in both manufacturing and regulatory affairs and positions NeoStem as a premeir cell therapy company. NeoStem also acquired Amorcyte, LLC in October 2011 along with it's lead product AMR-001 which is currently in phase II trial for cardiovascular indications.

[NYSEAMEX: NBS 65M]



Pluristem Therapeutics
Haifa, Israel

Late Clinical Stage
Regenerative Medicine

Zami Aberman, Chairman, CEO

Pluristem is developing PLX cells (PLacental eXpanded cells) derived from the placenta for the treatment of chronic limb ischemia (CLI), which is the most severe form of peripheral vascular disease (PVD). Variations of PLX cells are also under investigation for other medical conditions including skeletal, pulmonary, autoimmune and CNS diseases as well as for improved engraftment of bone marrow transplants. Of note, PLX was administered as part of compassionate care to a 7 year old patient with aplastic anemia who failed bone marrow transplant twice. Within days of PLX cell administration, the patient responded with signs of improved engraftment. At the core of Pluristem's technology platform is their proprietary 3 dimensional bioreactor, PluriX, which mimics the microenvironment of bone marrow substrates and does not require the addition of cytokines or growth factors for cell expansion. PluriX is claimed to offer larger-scale expansion of cells and superior batch to batch consistency compared to traditional 2 dimensional approach to cell expansion.

[OneMedRadio](#) interviews Dr. William Prather of Pluristem Therapeutics, about PLX Stem Cells and how they save the life of a child after a bone marrow transplantation failure.

[NASDAQ:PSTI 113M]



Wound Management Technologies
Fort Worth, Texas.

Commercial Stage
Wound Healing

Bob Lutz, President, CEO

Wound Management Technologies is an emerging commercial stage company with its primary products in the \$5B worldwide advanced wound care market. Wound Management's primary focus is the distribution of its unique, patented collagen product, CellerateRX®, which is FDA cleared and reimbursable under Medicare Part B. CellerateRX has a competitive proprietary feature and performance advantages over other collagen-based products. It is available in powder (95% collagen) and gel (65%) forms that don't need special handling (like refrigeration) and is active in all 4 phases of wound healing. Manufacturing of its products is conducted by Applied Nutritionals, LLC which owns the CellerateRX trademark. Wound Management has other advanced biotech products in development including a patented resorbable bone wax line that is in late stages of development. In May 2012, newly named CEO, Robert Lutz, released a letter highlighting anticipated increase in sales through existing and expanding distribution channels as well as anticipated positive cash flow by the end of 2012 given current trajectory of the firm.

[OneMedRadio](#) interviews Deborah Jenkins Hutchinson of Wound Management Technologies.

[PINK:WNDM 6M]

Regenerative Medicine Company Directory

The following is an extensive list and brief description of companies operating in regenerative medicine. Public companies will include ticker symbol and market cap (in USD unless otherwise noted). More expanded information on each company is available in the full guide.

AderansResearch | Private | Developing cell based therapy to reverse hairloss using a proprietary method, JiGamid
Advanced BioHealing | Private | Produces Dermagraft®, a bio-engineered skin substitute for restoring damaged tissue
Advanced Cell Technology | [ACTC] 146 M | Developing human embryonic and adult stem cell technology
AF Cell | Private | Produces AmnioClear, human allograft derived from the amniotic membrane for surgical applications
Alseres Pharmaceutical | [ALSE] 6M | Developing diagnostic and therapeutic products for CNS disorders
Amarantus | [ALSE] 6M | Developing biologics with anti-apoptotic properties for CNS disorders
America Stem Cell Inc. | Private | Developing products to improve the homing and engraftment of stem cells to target organs
Arterioocyte | Private | Developer of NANEX™ Hematopoietic Stem/Progenitor Cell (HSPC) Expansion Kit for research use
AxoGen, Inc | [AXGN] 31M | Provides surgeons with solutions to repair and protect peripheral nerves
BD Biosciences | [BDX] 15B | Major supplier of devices and reagents for biopharmaceutical firms in stem cell field
Beike Biotechnology | Private | Involved in stem cell R&D, iPS research, drug screening and stem cell evaluation
Bellicum Pharmaceuticals | Private | Cell based vaccines for prostate cancer and methods to reduce GVHD
Bio-Matrix Scientific Group, Inc. | [BMSN] 0.2M | Devices and disposable instruments for stem cell extraction and storage
BioE, Inc. | Private | Products to enable umbilical cord blood processing
Bioheart, Inc | [BHRT] 3M | Autologous cell therapies for the treatment of chronic and acute heart damage and PVD
BioLife Solutions, Inc. | [BLFS] 6M | Preservation media for cells, tissues and organs
BioParadox | Private | Platelet Cell Therapy (PCT) for the treatment of cardiovascular disease
BioSperix | Private | cell incubation and processing system
BioTime, Inc. | [BTX] 200M | Developer of blood plasma volume expanders and therapies based on hESC technology
Bluebird bio inc. | Private | In vitro alteration of autologous bone marrow derived stem cells for the treatment of genetic diseases
Brainstorm Cell Therapeutics Inc | [BCLI] 33M | Autologous stem cells for the treatment of neurodegenerative diseases
Celgene Cellular Therapeutics | [CELG] 30B | Developing cell based therapies for a variety of inflammatory diseases
Cell and Tissue Systems, Inc. | Private | Long term storage and distribution of cell based therapies, tissues and organs
Cell Line Genetics | Private | Characterization and multispecies QA services for adult and pluripotent stem cell lines
Collectis | [ALCLS] 120M Euro | R&D of robust reproducible means of controlling stem cell production and differentiation
Cellerant Therapeutics | Private | Cell-based medicine as a treatment for chemotherapy and radiation induced neutropenia
Cellular Dynamics | Private | iPSC for drug screening and disease modeling of cardiac, nervous and hepatic systems
Celsense | Private | Real-time MRI detection of inflammation and cellular therapeutics
Cognate BioServices | Private | Contract manufacturer of cell-based products
Cook MyoSite | Private | Provider of human skeletal muscle derived cells for research and treatment of muscle related disorders
Cytomedix, Inc. | [CMXI] 140M | Autologous platelet rich plasma based products for enhanced wound healing
Cytori | [CYTX] 130M | Autologous Adipose-Derived Stem and Regenerative Cells (ADRCs) for regenerative medicine
Fate Therapeutics | Private | Develop biologic and small molecules to guide cell fate and methods to characterize stem cells
Fibralign | Private | Develop and market 3D matrices to enable cell and tissue engineering
Fibrocell Science | [FCSC] 21M | Fibroblast based products for treatment of skin conditions from burns, acne and UV exposure
FollicInc | Private | Novel therapies for treatment of hair loss or long-term removal of unwanted hair
Gamida Cell Ltd | Private | Developer of StemEx (Phase 3), a cell expansion method, for treatment of hematopoietic malignancies
Genzyme | Subsidiary of Sanofi | Provider of therapies for genetic diseases as well as products that enable regenerative medicine
HealthpointBiotherapeutics | Private | R&D of various wound care, incontinent care and skin care products
Histogen | Private | Human fibroblast derived products for hair growth, oncology and wound healing applications
Humacyte | Private | Human extracellular matrix based products for treatment of vascular diseases and wound healing
ImmunoCellular Therapeutics Ltd | [IMUC] 120M | Cell based vaccine to treat glioblastomamultiforme
Inception Biosciences, Inc. | Private | Provider of cord blood banking services
IntelliCell Biosciences, Inc. | [SVFC] 7M | Adipose stromal vascular fraction for orthopedic, gastrointestinal, age related diseases
Intercytex Ltd | Private | Human skin fibroblasts for the treatment of epidermolysisbullosa, scar contractures and acne scarring
International Stem Cell Corp. | [ISCO] 30M | Owns Lifeline Cell Technology and Lifeline Skin Care for cell based cosmetics
InVivo Therapeutics | [NVIV] 147M | Developing platform technology to deliver therapeutics for spinal cord injury
iPierian | Private | iPSC based small molecule and biologics screening platform for neurodegenerative diseases
ISTO Technologies | Private | Orthobiologics company developing products for spinal therapy, sports medicine, and trauma.
Juventas Therapeutics | Private | Developing Stromal-cell Derived Factor 1 for tissue repair tissue following organ-damage
Life Technologies | [LIFE] 7.8B | Developing cancer therapies, regenerative medicine and sequencing technologies
MaxCyte | Private | Developer of stem cell transfection methods in regenerative medicine
MedCell Bioscience | Private | Technologies for the treatment of tendon and ligament injuries in animal healthcare markets
Medipost | Private | Develops products related to a human Umbilical Cord Blood derived Mesenchymal Stem Cells (hUCB-MSCs)
MediStem | [MEDS] 5M | Develops Endometrial Regenerative Cell (ERC), for critical limb ischemia and ischemic heart disease
Mesoblast | [MSB] 1.8B | Develops adult bone marrow derived mesenchymal stem cells for unmet medical needs
Moraga Biotechnology | Private | Developer of blastomere-like stem cells from adult tissue for regenerative medicine

MultiCell Technologies | [MCET] 2.5M | Developing therapeutics for neurological disorders, hepatic disease and cancer
Mytogen | Private | Develops myoblasts/stem cells to treat patients with cardiac indications, such as congestive heart failure
Neostem | [NBS] 55M | provider of adult stem cell collection, processing and storage services
Neuralstem | [CUR] 50M | Develops neural stem cells for the treatment of CNS diseases
Opexa Therapeutics | [OPXA] 7M | Autologous T-cell immunotherapy for the treatment of autoimmune diseases (MS)
Organogenesis | Private | Develops Apligraf, a human skin substitute, to treat diabetic foot ulcers and venous leg ulcers
Organovo | [ONVO] 390M | Develops bioprinting technology to produce 3-D cellular constructs
Osiris Therapeutics | [OSIR] 350M | Develops mesenchymal stem cell based therapies for GVHD and other unmet needs
Pathfinder Cell Therapy | [PFND] 20M | Cell-based therapy for treatment of diabetes, renal disease and myocardial infarction
Pervasis Therapeutics | Private | Methods to enhance the body's ability to recover from trauma of vascular procedures
PharmaCell | Private | Cell line development, cell banking, cell line characterization and custom cGMP manufacturing services
Plureon | Private | Develops pluripotent stem cell isolated from placental tissue for therapeutic purposes
Pluristem Therapeutics | [PSTI] 100M | Therapies based on novel 3D culture method and stem cells harvested from placenta
Primorigen Biosciences | Private | Develops media for cell growth and stem cell based compound and toxicity screening platform
Progenitor Cell Therapy | Private | Provider of cell manufacturing, process development, cell storage and consultation services
Proteonomix | [PROT] 6M | Develops stem cell therapeutics, tissue banking services and cosmeceutical products
Proxy Biomedical | Private | Produces biomaterials products and solutions for optimal tissue regeneration
Q Therapeutics | Private | Develops cell-based therapies for the treatment of degenerative diseases of the brain and spinal cord
RegeneRx | [RGRX] 12M | R&D of molecules to promote tissue and organ protection, repair and regeneration
Regenesis Biomedical | Private | Develops and markets noninvasive tissue regenerative medicine products
Regenicin | Private | Tissue-engineered skin substitutes for treatment of burns, chronic wounds and cosmetic purposes
RegenoCELL Therapeutics | [RCLL 0.5M] | Cell therapy for treatment of congestive heart failure and peripheral artery disease
ReNeuron Group | Private | "Off-the-shelf" stem cell therapy for the treatment stroke and peripheral arterial disease
Revivicor | Private | Develops genetically engineered pigs for human compatible tissues and organs for clinical applications
RhinoCyte | Private | Develops nasal stem cells for spinal cord injuries
RTI Biologics | [RTIX] 200M | Processes allo and xenografts for transplants using proprietary sterilization methods
SanBio | Private | Develops regenerative therapies for neurological disorders
Sangamo Biosciences | [SGMO] 270M | Develops zinc finger DNA binding proteins (ZFPs) for human therapeutics
Shire | [SHPGY] 18B | Develops therapeutics for ADHD, gastrointestinal (GI) diseases, and regenerative medicine
Sistemic | Private | Develops micro-RNA based products to enhance drug development, cell therapy and bioprocessing
SLL Sciences | Private | R&D of therapeutics that modulate stem cell fate to facilitate use of human embryonic stem (hES) cells
Stem Cell Authority | [SCAL] 0.9M | Collection and preservation of the Hematopoietic stem cells from the umbilical cord blood
Stem Cell for Life | Private | Company in Thailand providing umbilical cord blood and peripheral blood stem cell banking services
Stem Cells | [STEM] 21M | Clinical stage company developing HuCNS-SC, human neural stem cells for CNS disorders
Stem Cell Therapeutics | [SSS] 6.5M | Clinical stage firm developing therapeutics for ischemic stroke, brain trauma and MS
StemBioSys | Private | Manufactures 3D matrix for efficient expansion of mesenchymal stem cells from several sources
Stemedica | Private | Provides several well characterized stem cell lines for pre-clinical studies
Stemlogix | Private | Veterinary stem cell company providing autologous adipose derived stem cells for joint and heart diseases
Stemnion | Private | Focuses on R&D of stem cells derived from the placenta for clinical uses
Stratatech | Private | Develops NIKS cells, human keratinocytes, for therapeutic uses in severe burns and non-healing ulcers
TAP Biosystems | Private | Provides automation systems and consumables to improve productivity in R&D and production
Tarix Pharmaceuticals | Private | Clinical stage firm developing TXA127 for enhanced engraftment of stem cell transplant
Tengion | [TNGN] 7.5M | Developing use of autologous cells for generation human tissues and organs
Theradigm | Private | Develops cell-based therapies for stroke, spinal cord injury, and Amyotrophic Lateral Sclerosis
Theragen | Private | Develops Anginera, cell based tissue patch, for cardiovascular applications
ThermoGenesis | [KOOL] 15M | Products that enable the collection, processing and cryopreservation of stem cells
TiGenix NV | [TIG] 41M | Belgium-based company that focuses on local treatments for damaged and osteoarthritic joints
Tissue Genesis | Private | Developing autologous stem cell coated vascular grafts for peripheral vascular disease
VentriNova | Private | Involved in R&D of gene therapy for the regeneration of heart tissue in patients with heart failure
Vet-Stem | Private | Developing stem cell based therapies for arthritic conditions in cats, dogs and horses
ViaCord | Private | Subsidiary of PerkinElmer involved in umbilical cord blood banking
ViaCyte | Private | R&D of human embryonic stem cells and encapsulation technologies to treat type I diabetes
Vistagen Therapeutics | [VSTA] 16M | Stem cell based bioassay system to screen for drug safety and toxicity
Wound Management Technologies | [WNDM] 6M | Markets FDA approved CellerateRX for wound management

The following regenerative medicine companies are scheduled to present at OneMedForum NY on July, 12th 2012.



Advanced Cell Technology
Santa Monica, CA

Gary Rabin, Chairman, CEO
*****@advancedcell.com

Stephen Price, Senior VP,
Corporate Development
*****@advancedcell.com

Advanced Cell Technology, Inc. is a biotechnology company specializing in the development of cell therapies, applying stem cell-based technologies (both adult and human embryonic) and other proprietary methods in the field of regenerative medicine. ACT has developed the “single-cell blastomere” technique, the first-ever proven alternative method for successful hESC generation without harm to the embryo. The company’s lead platform is retinal pigment epithelium program, with Phase I trials underway for Stargardt’s Macular Dystrophy and dry AMD. In addition the company is developing three preclinical therapeutic platforms, for indications: disease and disorders of circulatory vascular system; corneal blindness and glaucoma; migration to injury site in eye and damaged tissue repair.

[OTC BB: ACTC 131M]
310.576.0611



Opexa Therapeutics
The Woodlands, TX.

Neil Warma, CEO
*****@opexatherapeutics.com

Donna Rill, Senior VP,
Operations
****@opexatherapeutics.com

Opexa Therapeutics develops patient-specific cellular therapies for the treatment of autoimmune diseases such as multiple sclerosis (MS) and diabetes. Opexa’s lead product, Tcelna™, (formerly Tovaxin), is a novel T-cell immunotherapy positioned to enter Phase IIb clinical development for the treatment of patients with Secondary Progressive MS (SPMS). In November 2011, Tcelna was granted Fast Track Designation by the US FDA for the SPMS indication, and Opexa hopes to initiate a Phase IIb clinical trial in SPMS patients in 2012 subject to securing the necessary resources. Approximately 200,000 cases of SPMS are diagnosed each year in the United States. Current therapies generate almost \$9B sales annually, and the market is expected to reach \$15B by 2015.

[Nasdaq: OPXA 7M]
281.775.0600



Organovo
Fort Worth, Texas.

Keith Murphy, CEO
*****@organovo.com

Michael Renard, EVP,
Commercial Operations
*****@organovo.com

Organovo is involved in bioprinting of 3-D tissues from human cells to enable more rigorous drug testing and research by pharmaceutical firms. This technology will also enable generation of human organs and tissues in order to meet the demands of transplants. Organovo’s NovoGen MMX Bioprinter™ is a novel hardware and software platform that allows placement of cells in any pattern desired. After printing, the cell aggregates retain enough cellular mobility for them to flow into one another, creating a fused tissue construct. The principles of developmental biology, including cellular self-assembly, allow the final construct to mature into the desired shape and properties.

[OTC: 156M]
858-550-9994



Osiris Therapeutics
Columbia, MD.

C. Randal Mills, President, CEO
*****@osiristherapeutics.com

Stephen Potter, SVP, Operations
*****@osiristherapeutics.com

Osiris Therapeutics, Inc. commercializes bone marrow derived autologous adult stem cells, Prochymal, for off the shelf treatments of unmet medical needs including Graft versus Host Disease (GVHD), inflammatory bowel diseases, ischemic heart diseases and type I diabetes to list a few. Prochymal is approved for steroid refractory GVHD in Canada and New Zealand. It is also available in seven other countries including the United States under Expanded Access Program (EAP). Prochymal is in early to late clinical phases for other medical indications. Osiris also markets Grafix, wound-care matrix containing stem cells for diabetic foot ulcers, which is eligible for medicare reimbursement. Chondrogen for arthritis is in phase 2 and Osteocel for focal bone regeneration is in phase 1.

[Nasdaq: OSIR 7M]
443-545-1800

Resource Directory

The following is a list of resources active in regenerative medicine. In this list we have identified: foundations and associations; research institutions; events; and publications. Below is an example of the expanded resource profile found in the full guide.



**California Institute for
Regenerative Medicine**
San Francisco, CA

(415) 396-9100

Established in 2004 after Californians passed Proposition 71, the California Institute for Regenerative Medicine accelerates the development of new therapies for chronic disease and injury by funding stem cell research programs throughout California. The statewide ballot measure provided \$3 billion in funding for stem cell research at California universities and research institutions. The mission of CIRM is to support and advance stem cell research and regenerative medicine under the highest ethical and medical standards for discovery and development.

Alan Trounson, President
*****@cirm.ca.gov

Ellen Feigal, SVP, Research and Development
*****@cirm.ca.gov

Foundations/Associations

ALS Association
Americans for Cures Foundation
Association of Clinical Research Organizations (ACRO)
Bedford Stem Cell Research Foundation
California Institute for Regenerative Medicine
Californians for Cures
Canadian Association for Research in Regenerative Medicine (CARRM)
Cell Society
Christopher & Dana Reeve Foundation
Coalition for the Advancement of Medical Research
Foundation for Regenerative Medicine
Genetics Policy Institute
Interdisciplinary Stem Cell Institute
Irish Stem Cell Foundation
Juvenile Diabetes Research Foundation
Michael J. Fox Foundation

Muscular Dystrophy Association
New York Biotechnology Association
New York City Economic Development Corporation
New York State Stem Cell Science
New York Stem Cell Foundation
Parkinson's Action Network
Pittsburgh Tissue Engineering Initiative
Regenerative Medicine Foundation
Stem Cell Technology Foundation
Student Society for Stem Cell Research
The American Society of Gene & Cell Therapy (ASGCT)
The Cell Therapy Foundation
The Massachusetts Life Sciences Center (MLSC)
The Sabrina Cohen Foundation for Stem Cell Research
The UK Stem Cell Foundation
Unite 2 Fight Paralysis

Research Institutions

California Center for Reproductive Medicine
Cardiovascular Innovation Institute
Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research at UCLA
EuroStemCell
Harvard Stem Cell Institute
Howard Hughes Medical Institute
Institute for Stem Cell Research, University of Edinburgh

International Society for Stem Cell Research (ISSCR)
MRC Center for Regenerative Medicine
Neural Stem Cell Institute
Sanford Consortium for Regenerative Medicine
Stanford-Burnham Institute for Medical Research
The Harvard Stem Cell Institute
UK Stem Cell Bank
Wake Forest Institute for Regenerative Medicine

Publications

AlphaMed Press
American Journal of Stem Cell Research
Cell Therapy News
International Journal of Regenerative Medicine
Journal of Stem Cells and Regenerative Medicine
Journal of Tissue Engineering and Regenerative Medicine
New York Academy of Sciences Journal
Regenerative Medicine Journal
Stem Cell Research
Stem Cells Translational Medicine (SCTM)

Events

BIRAX Regenerative Medicine Initiative
EMBL Conference
Hydra VIII
Translational Stem Cell Research Conference, NYSCF
Stem Cell Meeting on the Mesa
Stem Cell Research and Therapeutics Conference
Stem Cell Summit
The London Regenerative Medicine Event
Translational Regenerative Medicine Forum
World Stem Cells and Regenerative Medicine Congress

To view the electronic Investor Guide to Regenerative Medicine, visit www.onemedplace.com/investor-guide-regenerative-medicine.pdf

To learn more about the full Investor Guide subscription, which provides access to quarterly updates of interviews and directories, visit www.onemedresearch.com.