PrimeGen BIOTECH LLC

PrimeCell Therapeutics LLC
a PrimeGen Biotech company

NEWSTEM BIOSCIENCES LLC

PrimeGen BIOTECH, LLC
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Company Overview:

- **Founded in 2002; incorporation Delaware**
- **Privately held**
- **10 pending (or issued) US patents**
- **32 pending International patents**

Current Funding:

- **Private equity investment**

First Pharmaceutical Products:

Tissue Regenerative Products:

- **PrimeCell®**, pluripotent autologous (self) cells for regeneration, restoration and rejuvenation
- **SCell™**, pluripotent allogeneic cells for tissue regeneration
- **DrmCell™** , for skin regeneration, wound healing, fine line wrinkles, psoriasis, scleroderma
- **OsteoCell™**, for bone regeneration
- **ChondroCell™**, for cartilage regeneration
- **RetinalCell™**, for age-related macular degeneration and damage from glaucoma
- **VascCell™,** for peripheral vascular disease
- **CardioCell™**, for cardiac indications
- **NervoCell™**, for spinal cord repair
- **IsletCell™**, for diabetes

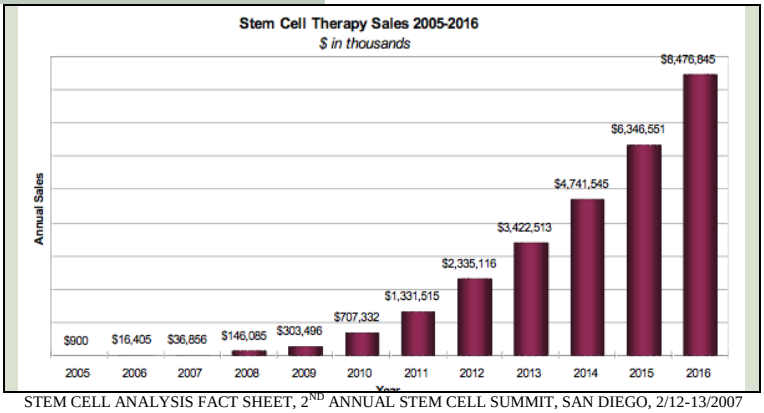
Management Team:

- **Tom Yuen, CEO and Chairman**
- **Chauncey Sayre –** Co-Founder & GM, PrimeCell Therapeutics, LLC
- **Francisco Silva –** GM, NewStem Biosciences, LLC
- **Cyril Sirk** – Co-Founder & GM, Core Operations
- **Steve Gershick** – CFO

Company: **PrimeGen Biotech, LLC** is a Delaware corporation founded to develop and manufacture novel classes of therapeutic stem cells for regenerative, restorative and rejuvenative medical uses. **PrimeGen** has two operating companies: **PrimeCell® Therapeutics, LLC**; and, **NEWSTEM BIOSCIENCES, LLC**. The Company's proprietary technology platform, referred to as "***Therapeutic Reprogramming***", allows an adult germ cell to be converted into a totipotent stem cell. Only three laboratories in the world have succeeded in reprogramming mouse cells. The Company is the only one (worldwide) to translate it's successful mouse reprogramming to humans. The Company's stem cell technology is the only one offering future customized patient treatments with autologous cells, i.e., derived from the patients' own body and reprogrammed in the laboratory.

BioPharmaceutical Markets: Five decades of use have established the clinical benefits of stem cells in bone marrow transplantation and cancer treatment. Including bone marrow and hematopoietic uses, market reports give revenue projections of $30Bn US by 2015 ("*Cell Therapy Commercialization*", D&MD Publications, 2006. Stem cells now hold great promise in many other novel clinical indications. Emerging stem cell therapy markets have been estimated at $200-500M US and >$300M EU; increasing at about 5%/annum US and 7%/annum EU; to a projected $8Bn by 2016 (*Stem Cell Summit, San Diego, Feb. 12-13, 2007*).

U.S. Stem Cell Market- Size in $Bn



STEM CELL ANALYSIS FACT SHEET, 2ND ANNUAL STEM CELL SUMMIT, SAN DIEGO, 2/12-13/2007

The Problem: Tissue destruction in disease and traumatic injury is at present irreversible. The human body has stem cells in many tissues that are capable of repairing the damage, but the extent of the damage, the disease condition and aging may overwhelm the ability of the body to respond effectively. No drug is presently able to restore damaged tissue. Existing therapies are mostly palliative, i.e., inhibiting inflammation but not restoring damaged tissue. In critical tissues like the heart the damage may be life-threatening. In non-critical tissues the accumulated damage may result in lowered quality of life and reduced life expectancy. Regenerative, restorative and rejuvenative treatment options are needed.

Technologies:

***Therapeutic Reprogramming* by**

"***Intrinsic Reprogramming***" – micro- and nano-injection of reprogramming signals into cells

"***Extrinsic Reprogramming***" – media-based reprogramming in tissue culture

First Clinical Indications:

- **Peripheral arterial disease (PAD)**
  - Patients at risk of amputation
- **Aging-related cosmetic reconstructive surgery**
  - Stem cells for bone, cartilage and tendon regeneration
  - Dermal repair and regeneration, e.g., fine line wrinkles, scars, surgical incisions
- **Vitreoretinal ophthalmic surgery**
  - Age-related macular degeneration
  - Glaucoma

Competitive Advantages:

- No products are currently available to regenerate diseased and damaged vascular or ophthalmic tissues
- Existing products for cosmetic and reconstructive surgery are fillers and sealers and are not capable of generating new tissue
- Existing products for treating the "Wet" form of Age-Related Macular Degeneration (ARMD) or diabetic retinopathy do not slow disease progression
- There are no products for the "Dry" form of ARMD

Revenue Sources:

- **Research Reagents**
- **Clinical Grade Cells**
- **Corporate Partnerships**

Projected Revenues:

-Projected Licensing Revenue 2008: $xx-xxM

Proforma: ($M)

YR	Net Income	Income Milestones (P1 + P2)	Product Income Royalty*	Product Market Share
1		-	0	-
2		15	0	-
3		-	0	-
4			0	-
5			0	-

Assumptions: Product 1: ™, license yr.2, launch yr.6, 15% royalty, xxM patients/yr., revenue/patient/yr =$2000; Product 2: **™**, license yr.4, launch yr. 8, xxM patients/yr, revenue/patient/yr = $xxx. ***Royalty Income is only ™**** Model Assumes Sale of $xxxM Equity

The Solution: Stem cell therapies offer an opportunity for tissue regeneration, restoration of normal functions and rejuvenation to a more healthy state. Stem cells have two important characteristics that distinguish them from other cells, namely, (1) the capacity for self-renewal indefinitely; and, (2) the ability to make any cell in the body (referred to as pluripotency or totipotency). No other class of biopharmaceutical products has these properties.

Core Technologies: Proprietary "***Therapeutic Reprogramming***" of germ cells and somatic cells has been accomplished using extracellular matrix and tissue culture media containing exact mixtures of growth factors, i.e., referred to as "*extrinsic reprogramming*". Alternatively, reprogramming is accomplished by injecting signaling factors directly into cells, i.e., referred to as "*intrinsic reprogramming*". Technology refinement for *intrinsic* reprogramming and product development optimization of *extrinsic* reprogramming is ongoing in **PrimeCell® Therapeutics, LLC.** **PrimeCells®** are precursor for production of all other cellular products. On a rapid path to patient therapies, **NEWSTEM BIOSCIENCES, LLC** is focused toward scale-up and cGMP production of minimally manipulated fetal-derived non-programmed human stem cells (**FetalCells™**). Like **PrimeCells®**, **FetalCells™** are a precursor for manufacturing of all other cellular products. The lessons learned with **FetalCells™** will be directly applicable to scale-up and cGMP production of **PrimeCells®**.

Business Model: Pharmaceutical companies are increasingly relying on biotechnology innovation to offset expiring patents and stagnant drug development. Pharmaceutical licensing has, in turn, supplied early revenue to fuel growth of many successful biotechnology companies. To cut costs and expedite development of revenue generating products, **PrimeGen** plans to pursue a policy of "**Leveraged Growth**", i.e., by generating early operating revenue from allowable reimbursement for costs incurred in producing regenerative therapeutics for clinical trials in international markets (**NEWSTEM BIOSCIENCES, LLC**); conducting certain fee-for-service contract R&D for corporate partners (**PrimeCell® Therapeutics, LLC**); and, sales of research reagents (**NewCo**). Pursuing a strategy of early academic and biopharmaceutical partnering and licensing, the Company seeks to minimize the equity capital required to achieving profitability while bringing forward multiple related products through FDA and EU compliant preclinical and clinical development. Cell-based biopharmaceuticals are currently entering a Renaissance because of attractive and relatively short routes to clinical trials, particularly in foreign countries.

Initial Clinical Indications: The Company plans initially to focus development toward three significant medical markets: namely, peripheral arterial disease, aging-related cosmetic and reconstructive surgery and ophthalmic indications.

Peripheral arterial disease (PAD) is "*..a major cause of acute and chronic illness,*" and "*are associated with decrements in functional capacity and quality of life, cause limb amputation, and increase the risk of death*" (American Heart Association). PAD affects about 8-12M Americans and while most cases can be managed by lifestyle changes, a significant subset cannot. PAD encompasses acute and chronic diseases that affect the extremities, kidneys, reproductive organs and gastrointestinal tracts resulting in decreased life expectancy and increased risk of amputation and death. Existing medications are by in large palliative and damage to peripheral arteries and vessels has been largely viewed as irreversible. Now, stem cell transplants offer the opportunity for regeneration of damaged tissues.

As a class, aging-related cosmetic reconstructive surgical and ophthalmic products are the fastest growing segments in the pharmaceutical industry with estimated market sizes of $1.6Bn and $3.5Bn, respectively, and growth at 12-15% as the US population ages. Needs have only partially been addressed by existing products. In this market improved treatments could be offered with the availability of autologous (self) skin, bone and cartilage products. Similarly, there exist significant deficiencies in ophthalmic treatments for age-related macular degeneration and glaucoma.

Competitors:

- **Osiris Therapeutics, Inc.**
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- **Cytori**
- **GamidaCell**
- **Geron**
- **Stem Cells Innovations**
- **Stem Cell Therapy**

Comparative Valuations:

Competition: **PrimeGen** is aware of companies that have intellectual property relating to uses of embryonic and certain adult stem cells for patient treatments in certain countries. These types of stem cell are, in general, NOT reprogrammed adult or fetal cells, NOT autologous (self-derived) and NOT **PrimeCells®.** The Company believes its cellular products have significant advantages over those of competitors. In many international jurisdictions there are few pending or issued patents and market competition will prevail. The Company's business development strategy incorporates intellectual property considerations which have been addressed, and will be addressed, e.g. by a combination of in- and out-licensing and corporate partnering.

Regulatory Strategy: **PrimeCell® Therapeutics, LLC** is embarking on an established FDA path to uses of autologous patient cells in biotherapies, i.e., a path pursued by companies like Genzyme Biosurgery with Chondricell® for cartilage repair. Reprogrammed autologous stem cells find uses in cosmetic and reconstructive surgery (**DrmCell™**, **OsteoCell™**, **ChondroCell™**) and vitreoretinal ophthalmology (**RetinCell™**). **NEWSTEM BIOSCIENCES, LLC** is pursuing an international path to first use in humans, i.e., first in treatments for Peripheral Arterial Diseases (**VascCell™**), then in cardiomyopathy (**CardioCell™**), spinal cord injury (**NervoCell™**) and Type 1 Insulin Dependent Diabetes Mellitus (IDDM; **IsletCell™**). Discussions are ongoing with possible clinical sites in Asia for regulated and EU/FDA compliant cGCP (current good clinical practices) phase I/II trials. Advantage and cost-savings are achieved in product development by virtue of: common precursor cells (PrimeCells® or FetalCells™); and, common and/or closely related cGMP preparatory, expansion and formulation methods. Similarly, lessons learned with **FetalCells™** in regulatory affairs and clinical trials are transferable to **PrimeCells®**.

Manufacturing:

- **Germany – *ICH compliant cGMP***
- **Asia**

Manufacturing: **PrimeGen**, through its **NEWSTEM** subsidiary, is in discussions for acquisition of controlling rights in a regulated biopharmaceutical manufacturing facility in Germany. The facility has an existing DE site license and is compliant with current ICH regulations for manufacture of cell-based biopharmaceuticals. Discussions are also ongoing with alternative Asian biopharmaceutical manufacturers.

Published Patent Applications:

- **PCT/US2003/001570**
- **WO2003/062,384 A3**
- **PCT/US2005/002487**
- **WO2005/123,901**
- **PCT/US2005/005,052**
- **WO2005/123,123**
- **PCT/US2006/004,077**
- **WO2006/084,229**
- **PCT/US2005/047,437**
- **WO2006/074,075**
- **PCT/US2006/028,043**
- **PCT/US2006/062,522**

PCT/US2007/065,709

Intellectual Property Strategy: **PrimeGen** is aggressively pursuing patent protection in US and international jurisdictions for its proprietary "***Therapeutic Reprogramming***". As a forefront early leader in development of this technology the company is pursuing a broad scope of patent protection for its products. The Company plans to monitor intellectual property issues on a routine basis and has retained senior intellectual property management and patent counsel to advise to this end. The Company believes that its patent positions will provide the exclusive rights guaranteed under the U.S. and International patent statutes. Freedom to operate analyses have been conducted on a case-by-case basis by the Company and by its counsel. The latter corporate intelligence has been used to advantage in licensing certain select patent opportunities related to the company's core business.