Zacks Small-Cap Research

June 28 2011
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International Stem Cell Corp. (ISCO-OTC)

ISCO: Unique Platform With Commercial Drivers. Initiating Coverage of ISCO.

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (06/28/11)	$1.10
Target Price	**$1.50**

INITIATION

We are initiating coverage of International Stem Cell Corp. (ISCO) with a Neutral rating and $1.50 price target. Although we are intrigued by company's technology and development of human parthenogenetic stem cells (hpSC), we have yet to see any of these programs enter human clinical development. We believe that ISC is on track to enter the clinic with its first programs later this year in corneal transplant. ISC is also progressing toward entering the clinic with programs for corneal-tissue healing, age-related macular degeneration (AMD), liver disease, and neurodegenerative diseases.

We see $1.50 as fair value for the company based on a sum-of-parts valuation incorporating the development pipeline, and the two subsidiary businesses, Lifeline Cell Technology and Lifeline Skin Care.

SUMMARY DATA

52-Week High	**$2.29**
52-Week Low	**$0.83**
One-Year Return (%)	**-4.35**
Beta	**0.05**
Average Daily Volume (sh)	**174,071**
Shares Outstanding (mil)	**76**
Market Capitalization ($mil)	**$83**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**44**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**2**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0.3 A	0.4 A	0.3 A	0.5 A	1.6 A
2011	1.5 A	0.8 E	1.8 E	2.2 E	6.3 E
2012					10.1 E
2013					14.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.20 A	$0.06 A	-$0.04 A	-$0.05 A	-$0.21 A
2011	-$0.02 A	-$0.03 E	-$0.03 E	-$0.02 E	-$0.10 E
2012					-$0.10 E
2013					-$0.08 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Initiating Coverage International Stem Cell Corp.

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…Significant Market Opportunity…

Human parthenogenetic stem cells (hpSC) offer key advantages over stem cell therapeutics that utilize embryonic stem cells, adult stem cells, or induced pluripotent stem cells (iPSC). We see several reasons why ISC's hpSC could become the standard for which stem cell therapeutics are developed in the future. These include:

- ✓ No ethical issues related to the destruction of a human embryo.
- ✓ No immune-matching issues associated with adult stem cells or induced pluripotent stem cells.
- ✓ Pluripotency on par with embryonic stem cells or induced pluripotent stem cells.
- ✓ Strong proliferation on par with embryonic stem cells.
- ✓ No genetic manipulation associated with induced pluripotent stem cells (iPSC).

Over the near-term, focus is on the Lifeline Skin Care division. Sales in the first quarter of $1.1 million far exceeded expectations. We are expecting a snap-back in the second quarter as management revamped supply, and then a steady rising trajectory in the third when "normal operations" ensue. Revenues from skin care sales provide non-dilutive cash and build brand awareness for ISC. Strong sales from skin care products could change our recommendation on the stock.

…Target is $1.50…

We think the entire company is worth around $125 million based on the sum-of-parts. Using the current 80 million shares outstanding, we arrive at a target price of $1.50 per share. Our rating is Neutral, but we would be buyers of the stock on weakness below $1. We think there is good support there, with upside later in the year on positive clinical and cosmeceutical developments.

OVERVIEW

International Stem Cell Corporation (ISC) is developing a powerful new stem cell technology, called parthenogenesis, which aims to significantly advance the field of regenerative medicine by addressing the serious medical problem of immune-rejection and the ethical questions associated with embryonic stem cells. Parthenogenesis utilizes unfertilized human eggs to create parthenogenetic stem cells (hpSC) that can be immune-matched to millions of persons of differing sexes and racial backgrounds. In theory, a relatively small number of hpSC lines could provide sufficient immune-matched cells to cover large parts of the world's population, making stem cell therapies potentially more cost-effective and widely available. ISC has begun to create a bank of these valuable hpSC lines, which the company markets as the UniStemCell Bank, to serve populations across the world. In our view, human parthenogenetic stem cells (hpSC) have great therapeutic potential without the ethical issues associated with traditional embryonic stem cells. ISC's scientists are focused on using hpSC to treat severe diseases of the eye, the nervous system and the liver where cell therapy has been proven clinically yet is limited by the availability of safe immune-matched human cells. ISC has also developed two related business that generate cash flow to offset the costs of its research operations, one in retail skin care and the other in research products.

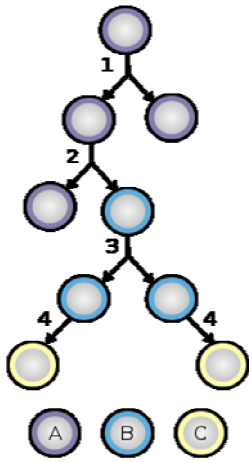


Stem Cell Backgrounder

Stem cells are a class of biological undifferentiated cells with the potential to divide and differentiate into diverse range of specialized cell types in the body, including additional stem cells. Stem cells have two important characteristics that distinguish them from other cells:

- Firstly, they are not specialized to do specific jobs. Instead, they are pluripotent and, under certain conditions, can be differentiated to assume the various functions needed in the body.
- Secondly, they can reproduce in large numbers while still remaining undifferentiated.

It is the combination of these two above characteristics that provide stem cells with their tremendous therapeutic promise for a wide range of degenerative diseases. Adult stem cells can be taken from a variety of sources, including umbilical cord blood, bone marrow, and adipose tissue. Embryonic cell lines and adult cells that have been reprogrammed into stem cells have been proposed as promising candidates for future therapies.



A = Stem cell
B = Progenitor Cell
C = Differentiated Cell

Stem cells can be artificially grown in the laboratory and transformed into specialized cell types with characteristics consistent with cells of various tissues and systems. There are several types of stem cells found naturally in the body.

These include, among others, hematopoietic stem cells that are found in bone marrow and give rise to all blood cell types, mammary stem cells that provide the source for growth of the mammary gland during puberty and gestation, endothelial stem cells which give rise to new blood vessels, and mesenchymal stem cells (MSCs) that may differentiate into a variety of tissues. MSCs have the potential to develop or differentiate into many cell types in the body. Lineage differentiation includes adipogenic (fat), cardiomyogenic (heart muscle), leiomygenic (smooth muscle), myogenic (skeletal muscle), chondrogenic (cartilage), osteogenic (bone), neurogenic (nerve), angiogenic (blood vessel), and hematopoietic (blood) cells.

Stem cells are also capable of secreting a large number of growth factors including: hepatocyte (HGF), placental (PGF), transforming factor-β (TGFβ), fibroblast (FGF), vascular endothelial (VEGF), and granulocyte / macrophage colony stimulating factors (GM-CSF). Analysis of these growth factors and proteins suggest a strong active role in neovascularization and angiogenesis (the growth of new vessels). The underlying hypothesis for using stem cells is that they have the potential to regrow or repair almost any type of damaged tissue found inside the body. This has enormous potential for applications in the medical community.

…All About Potency…

Potency specifies the differentiation potential (the potential to differentiate into different cell types) of the stem cell. There are a number of different cell potency types:

- Totipotent (also known as “omnipotent”) stem cells can differentiate into embryonic and extra-embryonic cell types. Such cells can construct a complete, viable organism. These cells are produced from the fusion of an egg and sperm cell (zygote). The cells produced by the first few divisions of a zygote are totipotent.
- Pluripotent stem cells are the descendants of totipotent cells and can differentiate into nearly all cells, i.e. cells derived from any of the three germ layers.
- Multipotent stem cells can differentiate into a number of cells, but only of a closely related family of cells.
- Oligopotent stem cells can differentiate into only a few cells, such as lymphoid or myeloid stem cells.
- Unipotent cells can produce only one cell type, their own, but have the property of self-renewal which distinguishes them from non-stem cells (e.g. muscle stem cells).

…Adult vs. Embryonic…

In mammals, there are two broad types of stem cells: embryonic stem cells that are isolated from the inner cell mass of blastocysts (day 5 of fertilization), and adult stem cells that are found in various tissues such as bone marrow or adipose fat. Embryonic stem cells (eSCs) are pluripotent, but do require the use (destruction) of a fertilized egg that, under the right circumstances, has potential to develop into a human. This creates a significant ethical dilemma in the use of eSCs.

Adult stem cells (aSCs) are rare cells in an adult that have a limited ability to differentiate into cells with specific functions. While these stem cells do not require use or destruction of a fertilized egg or extensive manipulation of gene expression, they are hard to extract and generally proliferate poorly compared to eSCs. Still however, several companies are pursuing late-stage development programs using aSCs.

One type of stem cells created by scientists in an attempt to navigate the key issues holding back development of embryonic and adult stem cell therapeutics are induced pluripotent stem cells (iPSC). Induced pluripotent stem cells (iPSC) are differentiated adult somatic cells that are chemically or otherwise "reprogrammed" or forced back to earlier developmental stages. While creation of such cells does not involve the use or destruction of an embryo, it requires dramatic changes in gene expression that may have unknown biological impact and likely will be subject to substantial scrutiny by regulatory authorities before any approval for therapeutic use. Also, autologous induced pluripotent stem cells cannot be used for hereditary diseases therapy because of bearing the same genetic defects. The major concern with the potential clinical application of iPSCs is their propensity to form tumors.

ISC Technology – Human Parthenogenetic Stem Cells

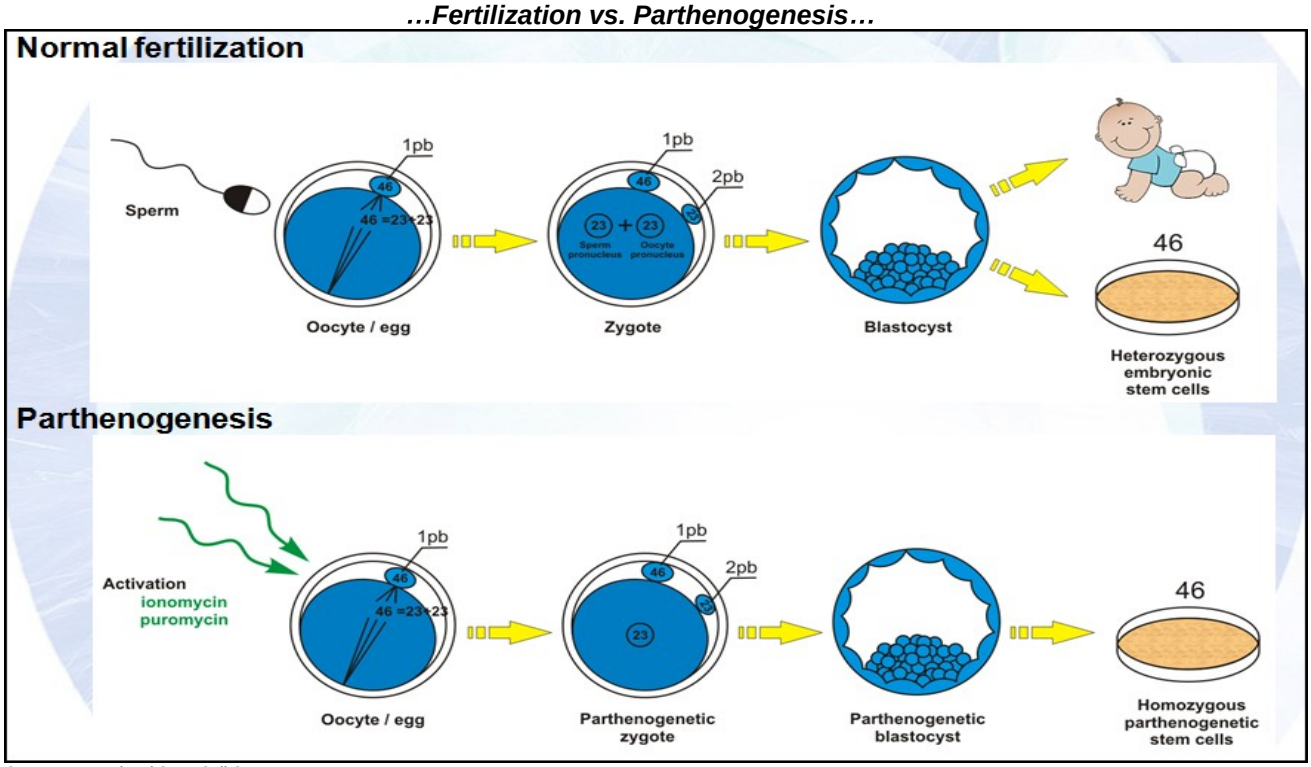
International Stem Cell has developed human parthenogenetic stem cells (hpSC) as an alternative to the three aforementioned stem cell types. Management believes this new type of stem cell line has the best characteristics of each of the previous three classes of stem cells.

…No Ethical Issues…

Human parthenogenetic stem cells are derived from parthenogenetically activated human oocytes (eggs). Parthenogenesis is a form of asexual reproduction in which females produce eggs that develop without fertilization, in other words - without sperm. The process can occur naturally in some animals, such as amphibians or insects, but does not occur in humans. Parthenogenetically activated oocytes cannot become a living person. This eliminates a number of the ethical or religious objections to embryonic stem cell research. Additionally, there is no NIH or other government funding currently available for hpSC, so there is no risk of a federal funding ban.

The beginning of the process of parthenogenesis in oocytes can be induced by different electrical or chemical stimuli that simulate sperm penetration. Activated oocytes have the ability to develop into pluripotent parthenogenetic stem cells that can proliferate as embryonic and induced pluripotent stem cells.

…Fertilization vs. Parthenogenesis…



Source: International Stem Cell Corp.

…Limited Immune-Matching Issues…

Risk of rejection for stem cell therapeutics is proportional to the degree of difference between the immune system proteins present on the donated cells and the immune system proteins present on the cells of the recipient (the patient). Normally donor tissue is screened for these immune system proteins (antigens) in order to determine the degree of compatibility with the recipient. The human leukocyte antigen (HLA) system is the term used for antigens important for transplantation. Matching donor and recipient tissue for HLA antigens greatly increases the likelihood of transplant survival. Different activation techniques applied to human oocytes create two types of human parthenogenetic stem cell lines relative to the HLA antigens. These are:

- HLA heterozygous cell lines: Are exactly HLA-matched and totally compatible with the donors
- HLA homozygous cell lines: May be compatible with significant segments of the human population.

Parthenogenetic activation of human oocytes may be one way to produce compatible/HLA matched cells for cell-based therapy. The stem cells derived are genetically matched. Therefore, heterozygous parthenogenetic stem cells are a perfect solution for someone looking to bank their own cells because the therapeutic derived will be a perfect match. However, homozygous parthenogenetic stem cells are different because they have a simple genetic code. If the HLA antigens in a homozygous parthenogenetic stem cell are found commonly in the population, then these cells can be genetically matched to millions of potential recipients.

ISC has successfully derived and characterized 10 hpSC lines, including both HLA homozygous and HLA heterozygous lines. One of these lines homozygous parthenogenetic lines (hpSC-Hhom-4) carries the most common set of HLA antigens found across racial groups within the U.S. population. In fact, management estimates that this hpSC line alone will target 75 million people worldwide. ISC has the potential to target more of the population as new cell lines are commercialized. And since there is no forced change of gene expression patterns, hpSCs are not likely to face the same safety and regulatory hurdle as induced pluripotent stem cells (iPSCs).

…Highly Pluripotent Cell Lines…

ISC's has demonstrated that hpSCs can be successfully differentiated into functional cells with the same degree of differentiation and viability to embryonic stem cells. The company's *in vitro* data shows hpSC cell differentiation follows the same differentiation program that occurs in the course of normal organism development. HpSCs are highly pluripotent, making them a promising potential development platform for therapeutic products.

	hpSCs	Embryonic	iPS	Adult SCs
Ethics (Relative to destruction of viable human embryos)	No viable embryo	Destroys viable embryo	No embryo	No embryo
Immune matching and cell banking (practical source of cells)	Population groups & individuals (♀)	Impractical (each line is unique)	Matched to individual only	Matched to individual only
Pluripotency (Become cells from all parts of body)	Yes	Yes	Yes	No
Proliferation (Ease of expansion in culture)	Strong	Strong	Strong	Weak
Genetic Manipulation (Restructuring of gene expression patterns)	Minimal	Minimal	Substantial	Minimal
Application for diseases with genetic component	Superior	Superior	Deficient (carry damaged gene)	Deficient (carry damaged gene)

Source: International Stem Cell Corp.

Collaborative Business Model

ISC is taking a unique approach to advancing its pipeline and creating shareholder value. Their business model is focused on creating partnerships, collaborations, and joint ventures to push the pipeline forward, rather than engage in large-scale, expensive and risky, clinical trial programs. We believe that hpSC have a wide therapeutic application potential, but management at ISC understand that they are most likely not going to be able to fund multiple clinical programs in several therapeutic areas without going down the route of massive shareholder dilution. Instead, the company is looking to partner with academic and research institutions, both inside and outside the U.S., and concentrating on a narrow focus for their commercial efforts with hpSC. We note that beside forming collaborations, ISC has two subsidiaries, Likfeline Skin Care and Lifeline Cell Technology, each which contribute revenue to offset the costs of therapeutic research and reduce the need for outside capital.

…U.S. Strategy…

In the U.S., ISC is working with academic institutions such as the University of California Irvine, and private laboratories such as Cedars-Sinai Medical Center, to advance their technology. Management's goal is to continue to expand their collaboration network with additional academic institutions in the coming quarters. We believe this is a wise move, because the hpSC platform is early-stage, and academic institutions are more likely to receive federal and stage research funding grants to advance in this area than ISC acting alone as a for-profit company.

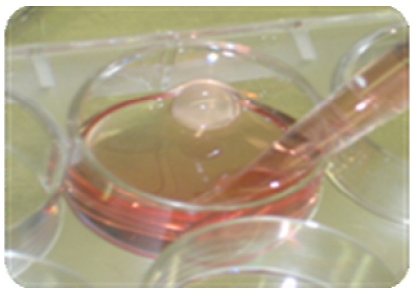
…India / China Opportunity…

The company is actively in negotiations for collaborative partnerships in India and China. These include talking with academic and research labs in these parts of the world, looking to strike symbiotic strategy relationships where ISC obtains entry into the market, as well as use of high quality research facilities and funding, in return for licensing their technology. We see both India and China as significant market opportunities for stem cells. Programs in these countries are often cheaper, shorter, and present a more near-term opportunity than the U.S. or EU.

ISC's Therapeutic Pipeline

Given the company's prudent business model and limited funding, ISC has decided to focus on creating prioritized therapeutic areas where management believes its technology can show a meaningful improvement in the treatment paradigm. This includes the creation of therapeutic cells for use in proven areas where cell therapy has shown to be efficacious, but limited supply of cells has inhibited use. ISC has developed the platform and is partnering with other organizations to develop the therapeutic applications that can be derived from the platform. These areas include retinal degeneration, diabetes, liver diseases, neurodegenerative diseases, and spinal traumas and other related central nervous system injuries. The company is utilizing its significant manufacturing experience to build the additional capacity and new facilities suitable for producing cells to meet or exceed all relevant FDA and HHS regulations for these key areas.

…Cornea Transplant…



ISC has development laboratory-grown "cornea-like tissue" that can mimic the human cornea. These corneal-like structures grow to clear, hollow spheres containing cells and three-dimensional structure similar to those found in normal human corneal tissue. Portions or all of these structures may be suitable for cornea transplantation in humans. There are approximately 10 million corneally blind people in the U.S., many of which are candidates for corneal transplant. There are an estimated 50,000 corneal transplant surgeries each year in the U.S. The corneas are taken from human cadavers. Europe breaks down in similar fashion, with human cadaver corneal transplant as the standard of care.

ISC is not looking to compete with or replace corneal transplant from human cadavers. The market is too well established and rejection rates are already low. Instead, the opportunity exists in areas of the world where corneal transplant from human cadavers does not occur. These areas include India and China, where for various reasons, including lack of adequate medical facilities, inability to harvest corneas from cadavers in adequate time, and cultural or spiritual limitations, human cadaver corneas are not commonly used. ISC is currently doing form and function testing on its cornea-like tissue. The company is also standardizing the procedure for which the tissue is transplanted in animal studies.

In October 2010, ISC formed an Indian affiliate, ISCO India, along with partner Insight Bioventures India Private Ltd. (IBVI). The goal of the joint-venture between ISC and IBVI is to facilitate the development of the company's corneal-like tissue, to be called CytoCor, and retinal cells, CytoRet, for the treatment of blindness and severe vision impairments throughout Asia. Between India and China, we estimate there are 2.5 million corneally blind people that are potential candidates for corneal transplant. A corneal transplant in the U.S. is approximately $3,000 per eye. ISC's CytoCor has the potential to greatly improve access to corneal transplant through lower cost and overcoming several culture or logistical hurdles in Asia.

ISC is also testing two additional applications for its corneal-like tissue. Corneal can be applied to contact lens for the purpose of accelerating corneal healing when the cornea has been damaged due to injury or infection. The concept is almost like a Band-Aid for the eye, with the contact lens holding the corneal-tissue in place until it can successful be incorporated in the eye. We also see the possibility to test cosmetics, perfumes, eye drops, pesticides, herbicides, and potentially other harsh chemicals on these structures in an attempt to reduce or even eliminate live animal testing.

…Retinal Pigment Epithelium (RPE)…

ISC has developed RPE cells from its parthenogenetic stem cells. These cells have potential to treat age-related macular degeneration (AMD), one of the leading causes of blindness. According to a 2004 study on *Blindness and Blinding Diseases in the US* published by the University of Washington, approximately 13 million Americans have signs of AMD, over 10 million suffer visual loss and over 200,000 are legally blind from the disease. The occurrence of AMD increases with age. In China, close to 20 million people suffer from AMD and 1.8 million from RPE.

Retinal cell transplantation has been shown to benefit patients and has the potential to become one of the first successful medical uses of ISC's cells therapy. ISC, in collaboration with the University of California at Irvine, is currently testing RPE in animals for functionality in their ability to treat AMD. ISC's goal is to help facilitate UC Irvine or another corporate or academic partner to enter human clinical testing in 2012.

…Liver Disease…

ISC has successfully produced liver cells (called "hepatocyte-like cells") from its parthenogenetic stem cells that may have application in treating human liver diseases. These cells have been shown to engraft and grow into animal livers, a first important step towards clinical testing. ISC is working with scientists and liver transplant surgeons at Cedars Siani Hospital on this exciting project. The collaboration is currently focusing on animal testing with a goal of entering the clinic in 2012.

In June 2011, the company announced it had discovered a novel, patent-pending technology to produce unlimited numbers of liver cells (hepatocytes) that are free of contamination from potentially dangerous undifferentiated cells. The starting materials for the production are pluripotent stem cells, either ISC's proprietary human parthenogenetic stem cells (hpSCs) or human embryonic stem cells (hESCs), with the final product requiring no additional purification steps or long differentiation protocols. Instead, the method uses a differentiation device that incorporates a three-dimensional extracellular matrix, combined with a porous membrane where undifferentiated cells are migrated through the membrane matrix via differentiation-directed proteins. ISC believes the process is universal, and can be tailored to isolate other cell types, such as pancreatic or heart cells.

ISC has publish the technology in an article called, "Derivation of High-Purity Definitive Endoderm from Human Parthenogenetic Stem Cells using an in vitro Analog of the Primitive Streak" online, and in print form in *Cell Transplantation, the Regenerative Medicine Journal* in the next several months.

Chronic liver disease, including hepatitis B and C, is a major cause of mortality around the world. HCV and HBV represent approximately 75% of all cases of liver disease around the world. Globally, there are an estimated 200 million individuals infected with Hep-C, with 3-5 million cases noted in the U.S. It's an estimated $100 billion burden on the U.S. healthcare market. Hepatocyte transplantation has been used successfully to treat patients with acute or chronic liver disease and in patients with genetic defects that lead to liver disease. Hepatocyte transplantation involves supplementing a patient's liver function by injecting a suspension of hepatocytes obtained from donated livers that are not used for whole organ transplantation. Unfortunately, as with retinal cells and islets, hepatocytes can be subject to immune rejection and the demand for hepatocytes far exceeds the number of cells available. ISC's scientists are developing their own differentiation protocol based of existing technologies.

…Diabetes…

Diabetes is another potential area where ISC's hepatocyte-like cells may show therapeutic utility. Diabetes is the inability to produce, regulate or use insulin. The disease is a major health care problem worldwide. In the U.S., approximately 25 million people, around 8% of the population, has diabetes. However, according to the NIH and diabetes.org, an astonishing 80 million Americans are "pre-diabetic" and are at high risk of developing diabetes in their lifetime. It is a $200+ billion burden on the U.S. healthcare system.

Islet transplantation has been shown to relieve the suffering caused by diabetes and the serious side effects caused by current insulin therapy. Islet transplantation has been used in more than seventy people with poorly controlled diabetes and has improved the condition of nearly all those studied. However the therapy is severely hampered by a lack of sufficient islets and by the complications caused by immune rejection. Scientists at ISC, together with Novocell, the word leader in derivation islet cells from stem cells, are developing methods to produce islet cells from hpSC. ISC is implementing existing technologies in a unique way to develop efficient protocols differentiate hpSC into cells to treat diabetes.

…Neurodegenerative Diseases…

ISC scientists have successfully derived neural stem cells (NSC) that may be valuable for the treatment of neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease, and Lou Gehrig's disease (amyotrophic lateral sclerosis). Alzheimer's and Parkinson's affect 5.5 million and 1.5 million American's. ALS affects another 30,000. These are clearly large unmet medical needs. Animal studies have already convincingly shown the possibility that NSC could provide a useful treatment for Parkinson's disease. ISC is preparing to begin animal studies to confirm and advance development in this area.

Universal Stem Cell Banking

ISC has established a cGMP facility and has passed the necessary ethical and regulatory hurdles to build the world's first universal immune-matched parthenogenetic stem cell bank. Branded as the UniStemCell, the bank will be the first of its kind to offer non-embryonic histocompatible human stem cells available for research and therapeutic use. ISC currently has ten research-grade lines. The first clinical-grade line has stem cells with common immune types (haplotypes) that occur with high-frequency in the U.S. population. For example, every person has an immune type. There are roughly 200 common types in the U.S. population. As such, only five parthenogenetic cell lines with these common haplotypes could be matched to approximately 42 million people in the U.S., and provide immune-matched cells at an affordable cost.

The company will offer its intellectual property, process technology and business franchise to other companies for development and commercialization of similar universal stem cell banks for other ethnic groups such as Asians and Hispanics. The strategy is to enable academic and corporate researchers around the world to use hpSCs for development of therapeutic solutions knowing that matching most patients immunologically will become available.

Management has referred to their business model resembling the "Intel Inside" where ISC would provide a general cell therapy "engine" for a range of therapeutic applications rather than the therapy itself. In the medium term, ISC hopes to generate revenue from the UniStemCell franchises across populations and scientists accessing these lines. In the future, once therapeutic applications have been developed, ISC would collect royalties from sales of each successful, hpSC-derived cellular therapeutic.

Lifeline Cell Technology

Lifeline Cell Technology (LCT) is a wholly-owned subsidiary of International Stem Cell Corporation (ISC). Lifeline develops, manufactures, and markets high-quality, purified human primary cells, stem cells, and optimized media and reagents for sale to pharmaceutical, academic and government laboratories. Lifeline's products are distributed in the U.S., Europe, and Asia. In the U.S., Lifeline employs an internal sales force and direct sales model with. The company partners with OEM arrangements with American Type Culture Collection (ATCC), Millipore, and Life Technologies for International distribution.



ISC management has extensive experience in the human cell culture market, including research and development, manufacturing, quality control, marketing and sales of human cell culture products. The company is building out its product portfolio, which currently includes over 130 products such as growth factors, media, and human cells, all cGMP with significant capacity. The company's human cell culture products consist of frozen human cells and optimized media. Lifeline's products include human cells from the skin, cardiovascular system (including smooth muscle) and specific organs including kidney, prostate and lungs. The company also provides skin models for toxicity testing. Serum-free, low-serum or animal-free cell systems are available that eliminate the need for scientists to create their own media or try to adapt "off the shelf" products to match the nutritional needs of specific cell types.

LCT also develops and manufactures custom cells and media, under strict quality control with a high level of consistency and standardization. For example, the company is collaborating with Absorption Systems of Exton, PA on a human corneal tissue product that shows excellent correlation between the rates at which drugs pass through rabbit corneal tissue compared with ISC's human corneal tissue derived from parthenogenetic stem cells. This product has potential therapeutic use for the over 10 million people who suffer blindness due to corneal opacification from disease or trauma and for use in the eye safety and drug toxicity testing markets.

Sales were $1.6 million in 2010, up 40%. Sales in the first quarter 2011 were $0.4 million. Key products include:

- DermaLife: Human skin cells for the study of skin disease, toxicology, or wound healing.
- VascuLife: Human skin cells from the heart and blood vessels used by researchers to study cardiovascular disease and cancer.
- A line of neural stem cells and reagents, including a product with the ability to produce neurons that can survive in low-oxygen and low glucose conditions for the study and treatment of stroke.
- Adult stem cells (mesenchymal stem cells) and the reagents necessary to differentiate them into various tissues, including bone, cartilage and fat. These products are valuable for researchers in the emerging field of regenerative medicine.
- ProstaLife: Human prostate cells and specialized medium to study prostate disease including cancer.
- RenaLife: Human renal and bladder cells and associated media to study renal and bladder diseases.
- OccuLife: Human corneal cells and associated media for the study of corneal disease and as a model of toxicology for consumer product testing.
- An assortment of many other cell culture reagents and supplements for the growth, staining and freezing of human cells.

The goal is to get the company's products in use for early-stage research and discovery programs at pharmaceutical and biotechnology companies. Once regulatory product submissions are made to the FDA and similar authorities, the media and reagents used during development cannot be changed easily after approval. So if Lifeline can get its products in early, the opportunity exists to see significant scale up for commercialization activities at its customer. Once a specific component or reagent is used for development and commercialization of a pharmaceutical product, it becomes difficult to change source or supply without getting the FDA involved. In simplest terms, once the recipe is approved, the FDA does not like to see it changed. LCT makes the ingredients that other companies are using for their recipe. Such is the case with Lifeline's Fibrolife media, which CytoGraft (Novato, CA) is using as part of the process of creating their tissue engineered vascular grafts. It's a potential billion dollar opportunity. CytoGraft is currently entering phase 3 clinical trials. If successful, this application could open a therapeutic market for LCT's products.

Lifeline Skin Care

Lifeline Skin Care (LSC) is another wholly owned subsidiary of ISC. LSC develops and manufactures high-end cosmetic products designed specifically to help individuals improve the look and feel of their skin by combining the latest discoveries in the fields of stem cell biology, nanotechnology, and skin cream formulation technology. The company currently markets two core products:

Recovery Night Moisture Serum



Retail Price: $190 / bottle.

Defensive Day Moisture Serum SPF-15



Retail Price: $160 / bottle

These anti-aging products were developed by ISC in collaboration with internationally recognized cosmetics experts. Both products, the Recovery Night Serum and the Defensive Day Serum, use ISC's patented parthenogenetic stem cell extract which, in combination with vitamin complexes, provides major rejuvenating effects, including improvement in skin tone and elasticity, and improvement in the appearance of fine lines and wrinkles. These effects have been substantiated by clinical studies performed at industry-leading independent testing organizations.

The Night Serum provides a number of important factors that help defend against damaging free radicals and promote firmer, smoother, younger and healthier-looking skin. The Day Serum targets collagen and fibroblasts, leaving skin feeling smoother and looking more radiant. The Day Serum also includes a Sun Protection Factor (SPF 15) and can be worn daily under makeup to help prevent sun damage. LSC is planning to launch more advanced skin care products later in the year.

…Impressive Results…



LSC sells these products online at www.lifelineskincare.com and through select luxury spas and dermatologists offices in the U.S. A combination Night / Day pack retails online for $340. Management is focusing its marketing on direct-to-consumer channels to highly targeted audiences with traditional print and media promotions. LSC utilizes a direct response marketing approach through the use of a newsletter written by John Mauldin. LSC and John Mauldin did a preliminary launch in December 2010 resulting in the sale of over 7,000 bottles. Sales in the first quarter 2011 were $1.1 million. We are impressed with the initial sales figures for Lifeline Skin Care. This was above management's expectations, and actually limited by the initial launch supply. The initial newsletter written by John Mauldin targeted about 350,000 people. Mr. Mauldin covers all the costs, including advertising and promotion, or the newsletter. The response rate of 2% is impressive, as most direct mail campaigns like this struggle to achieve even 1% response. LSC and John Mauldin are expecting to launch another direct mail campaign targeting around 1,000,000 people in July 2011.

The current distribution business model allows management to slowly roll out its product before it aggressively begins to expand supply. Current supply is around 10,000 units per month, but can be scaled to meet demand in the coming months. In the future, we expect management to expand the distribution channels to plastic surgeons, and into more dermatology clinics and spas. If successful, management will need to expand the supply to 20,000 units per month. We think, in time, Lifeline Skin Care can achieve sales over $10 million if the distribution channel is expanded and the company steps-up active promotion of the product. Revenues generated by LSC help to fund and to support ISC's internal therapeutic development efforts.

MANAGEMENT

Kenneth C. Aldrich, Chairman and Co-Founder. Mr. Aldrich has been active in venture capital investing and private equity since 1975. He is Co-founder and Chairman of International Stem Cell Corporation (ISCO), a Managing Director of Convergent Ventures, an early-stage life sciences investment company, and an active member of Tech Coast Angels. Through those entities and predecessor companies, he has provided early-stage funding and management assistance for a variety of biomedical and other start-ups, including WaveTec Vision Systems, a VC backed ophthalmic device company (as a Director and co-founder), Neurion Pharmaceuticals, Inc., a drug discovery and evaluation company (as a Director and co-founder), and Orfid Corporation, a developer of organic transistors (as a founder and financial advisor). He is also a director of Green Dot Corporation, the world's largest issuer of prepaid debit cards now listed on the NYSE (as a Director and Investor). Mr. Aldrich holds degrees, with honors, from both Harvard University and Harvard Law School.

Andrey Semechkin, Ph.D., Director and Chief Executive Officer (CEO). Dr. Semechkin is a specialist in system analysis, strategic planning and corporate management. He is a member of the Russian Academy of Sciences and has been Deputy Director of Institute of System Analysis since 2004. Professor Semechkin was awarded the Russian Government Award in Science and Technology in 2006 and has written several scientific books. He has over 20 years experience creating and managing businesses across different industries and scientific sectors. He was CEO of X-Master Inc., a private U.S. company with real estate and other investments.

Jeffrey Janus, Senior Vice President of Operations and President of Lifeline Cell Technology. Mr. Janus is trained in biochemistry and business management and has over 20 years experience focused on cell-based businesses. He is a member of the team that discovered parthenogenesis and is published in the stem cell field. After a career at Hybritech, he led the development and commercialization of Clonetics Corporation's brand of human-cell based products well known for quality and innovation. After growing over 20% annually for ten consecutive years, the company was sold successfully in 1995. Mr. Janus subsequently founded Lifeline to meet a growing need for media and human cells in pharmaceutical drug screening, consumer product testing and basic research at universities and government laboratories. A number of highly experienced ex-Clonetics staff followed Mr. Janus to Lifeline.

Ray Wood, CPA, Chief Financial Officer (CFO) Mr. Wood has over 20 years of experience in the accounting and corporate finance arenas. Mr. Wood began his career working for Coopers and Lybrand, CPA's. From there, Mr. Wood has held various positions working from small start up companies, one of which went from a private to a public company, to large International public corporations. He has extensive knowledge and experience working with public companies and in the implementation of the Sarbanes-Oxley Act of 2002. Mr. Wood holds B.S. degree in Accounting from San Diego State University and is a CPA of the state of California.

Ruslan Semechkin, PhD, Director, President of Lifeline Skin Care. Dr. Semechkin is a specialist in analysis of biological processes and mathematical modeling in biology. He is an honors graduate from the Moscow State University and a member of the Society of Cosmetic Chemists. Dr. Semechkin became a Director in October 2008 and bring to International Stem Cell Corp both scientific expertise and experience in international relationships. He has been the CEO and President of Lifeline Skin Care since July 2009, and from December 2008 to July 2009 he served as Senior Research Scientist of ISC. Dr. Semechkin's also brings extensive experience in medical science and business management to ISC.

Simon Craw, PhD, Vice President, UniStemCell. Dr. Craw is trained in chemistry and molecular modeling in Europe and the US. He has a total of over eighteen years experience in program, research and development management as well as operations and information technology at Merck, AstraZeneca and Novartis and most recently head of research, development and financial informatics and regulatory operations at publicly traded ACADIA Pharmaceuticals. Dr. Craw's experience includes guiding world-class internal and external scientists to facilitate development programs, contract negotiations, systems validation and regulatory compliance.

VALUATION & RECOMMENDATION

Initiating Coverage

We are initiating coverage of International Stem Cell Corp. (ISCO) with a Neutral rating and $1.50 price target. Although we are intrigued by company's technology and development of human parthenogenetic stem cells (hpSC), we have yet to see any of these programs enter human clinical development. We believe that ISC is on track to enter the clinic with its first programs later this year in corneal transplant. ISC is also progressing toward entering the clinic with programs for corneal-tissue healing, age-related macular degeneration (AMD), liver disease, and neurodegenerative diseases.

…Significant Market Opportunity…

Human parthenogenetic stem cells (hpSC) offer key advantages over stem cell therapeutics that utilize embryonic stem cells, adult stem cells, or induced pluripotent stem cells (iPSC). We see several reasons why ISC's hpSC could become the standard for which stem cell therapeutics are developed in the future. These include:

- ✓ No ethical issues related to the destruction of a human embryo.
- ✓ No immune-matching issues associated with adult stem cells or induced pluripotent stem cells.
- ✓ Pluripotency on par with embryonic stem cells or induced pluripotent stem cells.
- ✓ Strong proliferation on par with embryonic stem cells.
- ✓ No genetic manipulation associated with induced pluripotent stem cells (iPSC).

With respect to corneal transplant, the market represents a very attractive opportunity in Asia where access to human corneas for transplant is limited, or in most cases, impractical. We estimate there are 2.5 million individuals in China and India that are corneally blind and could be a candidate for ISC's CytoCor product. Another 20+ million people in Asia suffer from age-related macular degeneration. Similar to the corneal transplant market, current treatment options are limited for the majority of these individuals.

Liver disease is a major cause of mortality around the world. HCV and HBV represent approximately 75% of all cases of liver disease around the world. Globally, there are an estimated 200 million individuals infected with Hep-C, with 3-5 million cases noted in the U.S. It's an estimated $100 billion burden on the U.S. healthcare market. Hepatocyte transplantation has been used successfully to treat patients with acute or chronic liver disease and in patients with genetic defects that lead to liver disease. Hepatocyte transplantation involves supplementing a patient's liver function by injecting a suspension of hepatocytes obtained from donated livers that are not used for whole organ transplantation. Unfortunately, hepatocytes can be subject to immune rejection and the demand for hepatocytes far exceeds the number of cells available. The use of ISC's hpSC could be a major step forward for the treatment of liver diseases.

A similar large market opportunity exists for ISC in the treatment of neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease, and Lou Gehrig's disease (amyotrophic lateral sclerosis). Alzheimer's and Parkinson's affect 5.5 million and 1.5 million American's. ALS affects another 30,000. ISC scientists have successfully derived neural stem cells (NSC) that may be valuable for treating this large unmet medical need.

ISC's goal is to establish the world's first universal immune-matched parthenogenetic stem cell bank, called UniStemCell, to position itself as the sole supplier of hpSC for the above therapeutic applications. The company is modeling itself after semiconductor chip-market Intel. ISC's goal is to supply the cells and allow other companies to develop the therapeutic applications and handle the commercialization.

…Lifeline Kicking In Upside…

ISC's two subsidiaries, Lifeline Cell Technology (LCT) and Lifeline Skin Care (LSC) are both generating revenues that help reduce operating burn and fund the internal development of the hpSC platform. Upside to both franchises is sizable in our view. LCTs goal is to provide products in use for early-stage research and discovery programs at pharmaceutical and biotechnology companies. Once regulatory product submissions are made to the FDA and similar authorities, the media and reagents used during development cannot be changed. So if Lifeline can get its products in early, the opportunity exists to see significant scale up for commercialization activities at its customer. LCT posted revenues of $1.6 million in 2010, up 40% from 2009.

The initial launch of LSC's Recovery Night Serum and the Defensive Day Serum has been impressive. In the first full quarter on the market, LSC sold approximately 7,000 bottles to generate revenue of approximately $1.1 million. The majority of these sales came from a newsletter written by John Mauldin targeting 350,000 readers. The response rate of 2% is impressive, as most direct mail campaigns like this struggle to achieve even 1% response. Mr. Mauldin covers all the costs, including advertising and promotion, or the newsletter. LSC and John Mauldin are expecting to launch another direct mail campaign targeting around 1,000,000 people in July 2011. We think, in time, LSC can achieve sales over $10 million if the distribution channel is expanded and the company steps-up active promotion of the product.

Valuation

The Stem Cell industry remains in its infancy, with no meaningfully successful stem cell products launched today. Many companies are in phase 3 trials with potential blockbuster therapeutics for cardiovascular or metabolic disease. Names such as Cytori Therapeutics are taking a medical device route, seeking to commercialize a stem cell processing system, leaving the therapeutic applications to the end-user. Others such as NeoStem are supporting development of their stem cell products with active pharmaceutical ingredients (API) operations.

ISC currently trades with a market value of $82 million. If we look at a basket of a dozen stem cell companies, we see the average market value is $169 million, with ISC towards the bottom of the group. However, the entire industry is made up of small-cap stocks with unproven technology. Our basket to the right has a total market value of only $2.2 billion. By comparison, the market values of Cubist Pharmaceuticals (CBST) and Amarin Corp (AMRN) are both roughly $2.2 billion. It is clear that the market has yet to assign a winner in the stem cell horserace due to the fact that no company has commercialized a big winner.

Stem Cell Basket

Company	Market Cap
Geron Corp. - GERN	$511
Advanced Cell Technology - ACTC	$290
Cytori Therapeutics - CYTX	$248
Osiris Therapeutics, Inc. - OSIR	$238
BioTime, Inc. - BTX	$222
Pluristem Therapeutics. - PSTI	$122
NeoStem, Inc. - NBS	$112
Aastrom Biosciences - ASTM	$102
Neuralstem Inc. - CUR	$87
International Stem Cell Corp. - ISCO	$86
StemCells, Inc. - STEM	$80
Athersys, Inc. - ATHX	$62
Fibrocell Science - FCSC	$32
Total Market Capitalization	$2,192
Average Market Capitalization	$169

We think ISC is trading about where it should within our basket. Companies like ACT, Aastrom and Osiris are in phase 3 development, BioTime and Cytori are beginning to generate revenues from their approved products, and Geron has a number of cancer therapeutics under development the market is assigning value to separate from its stem cell / regenerative medicine platform.

Based on the potential for hpSC, we believe International Stem Cell Corp. is fairly valued with a market capitalization of around $75 million. This number should grow over the next several quarters as candidates enter the clinic using ISC's technology. This is roughly the value of the entire firm today. That means investors can buy ISC and get Lifeline Cell Technology and Lifeline Skin Care for free.

Based on an estimated $2.0 million in revenues in 2011 for LCT, growing at around 35% CAGR over the next several years, we see the LCT subsidiary worth $15 million (7X 2011 sales). Lifeline Skin Care is the wildcard in the valuation. Sales of $1.1 million from skin care products in the first quarter exceeded expectations. The response rate has been excellent and management is preparing for another wave of the rollout in July 2011. New products should come online by the end of the year. By 2014, we think Lifeline Skin Care can generate revenues of over $10 million. We think LSC is worth $35 million based on our projections. We admit this may be optimistic given the early-stage nature of the product launch, but we see a big opportunity here. The cosmeceutical market is around $2.6 billion in size growing mid-single digits year-over-year. The company's products are niche, backed up by impressive science and results, and are aggressively priced. Significant traction with Lifeline Skin Care is the biggest near-term drive for the shares.

Company	Value
hpSC Discovery Platform	$75
Lifeline Cell Technology	$15
Lifeline Skin Care	$35
International Stem Cell Corp.	$125

We think the entire company is worth around $125 million based on the sum-of-parts. Using the current 80 million shares outstanding, we arrive at a target price of $1.50 per share. Our rating is Neutral, but we would be buyers of the stock on weakness below $1. We think there is good support there, with upside later in the year on positive clinical and cosmeceutical developments.

PROJECTED FINANCIALS

International Stem Cell Corp.
Income Statement

Intl. Stem Cell Corp.	2009 A	2010 E	Q1 A	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Lifeline Cell Technology	**$1.1**	**$1.6**	**$0.4**	**$0.5**	**$0.5**	**$0.6**	**$2.0**	**$2.6**	**$3.5**	**$5.0**
YOY Growth	-	*39.8%*	*39.8%*	*13.3%*	*43.3%*	*18.6%*	*26.3%*	*31.2%*	*34.6%*	*42.9%*
Lifeline Skin Care	**$0**	**$0**	**$1.1**	**$0.3**	**$1.3**	**$1.6**	**$4.3**	**$7.5**	**$10.5**	**$15.0**
YOY Growth	-	-	-	-	-	-	-	*73.1%*	*40.0%*	*42.9%*
hpSC Royalties & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$1.1**	**$1.6**	**$1.5**	**$0.8**	**$1.8**	**$2.2**	**$6.3**	**$10.1**	**$14.0**	**$20.0**
YOY Growth	-	*39.8%*	*455.7%*	*81.4%*	*415.8%*	*335.0%*	*100.0%*	*59.9%*	*38.6%*	*42.9%*
CoGS	$0.8	$0.7	$0.4	$0.2	$0.5	$0.6	$1.7	$2.8	$3.8	$5.0
Product Gross Margin	*29.6%*	*53.8%*	*71.7%*	*75.0%*	*71.1%*	*72.7%*	*72.3%*	*72.3%*	*72.9%*	*75.0%*
R&D	$2.2	$3.4	$1.0	$1.1	$1.1	$1.2	$4.4	$5.0	$5.5	$6.0
% R&D	-	-	-	-	-	-	-	*49.5%*	*39.3%*	*30.0%*
SG&A	$5.4	$7.9	$2.4	$2.0	$2.2	$2.4	$9.0	$11.5	$12.5	$13.5
% SG&A	-	-	-	-	-	-	*142.5%*	*113.9%*	*89.3%*	*67.5%*
Operating Income	($7.2)	($10.5)	($2.3)	($2.5)	($2.0)	($2.0)	($8.8)	($9.2)	($7.8)	($4.5)
Operating Margin	*0%*	*0.0%*	-	-	-	-	*-139.9%*	*-91.1%*	*-55.7%*	*-22.5%*
Total Other Income	($1.3)	($2.3)	$0.9	$0.1	$0.1	$0.1	$1.2	$0.4	$0.3	$0.3
Pre-Tax Income	($8.5)	($12.7)	($1.4)	($2.4)	($1.9)	($1.9)	($7.7)	($8.8)	($7.5)	($4.2)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Divs. Of Preferred	$4.4	$1.6	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.5	$0.5
Net Income	($12.9)	($14.3)	($1.5)	($2.5)	($2.0)	($2.0)	($8.1)	($9.3)	($8.0)	($4.7)
Net Margin	*0%*	*0.0%*	-	-	-	-	*-127.7%*	*-92.1%*	*-57.1%*	*-23.5%*
Reported EPS	**($0.28)**	**($0.21)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.02)**	**($0.10)**	**($0.10)**	**($0.08)**	**($0.05)**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Shares Outstanding	46.4	68.8	75.3	78.0	80.0	82.0	78.8	90.0	95.0	100.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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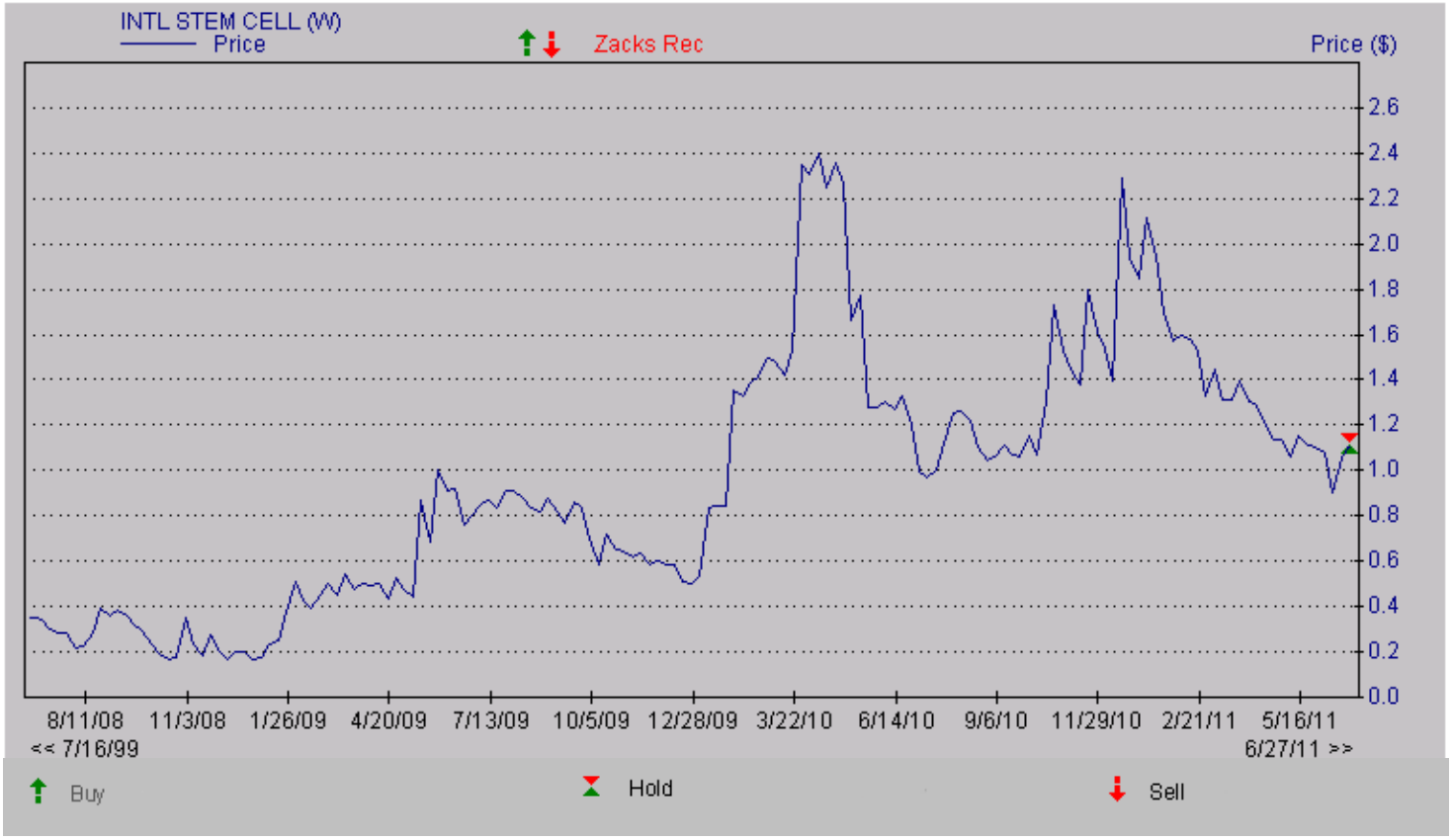

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