Zacks Small-Cap Research

August 12, 2013
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Soligenix Inc. (SNGX-OTCBB)

SNGX: Balance sheet remains strong, on track to move clinical programs---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/15/2013
Current Price (08/09/13)	$1.43
Twelve- Month Target Price	**$4.50**

OUTLOOK

SNGX is a development stage biopharmaceutical company focused on cancer supportive care, GI disorders and biodefense. Based on three platform technologies, SNGX has built a diversified pipeline targeting multiple indications. We are optimistic about its lead candidate SGX942 for the treatment of oral mucositis. SGX942 will enter into Phase II studies soon serving as a major short term catalyst. The Company's oral BDP is in various development stages for a variety of indications, most notably, in pediatric Crohn's disease, where they will be initiating a Phase II/III study in 2H13. SNGX also is developing vaccines using its ThermoVax technology for biodefense.

Valuation is attractive at this time based on the fundamentals. We rate the shares Outperform.

SUMMARY DATA

52-Week High	**$2.05**
52-Week Low	**$0.30**
One-Year Return (%)	**266.67**
Beta	**1.02**
Average Daily Volume (sh)	**87,239**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$27**
Short Interest Ratio (days)	**0.43**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**23.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.8 A	0.4 A	5.8 A	0.7 A	7.7 A
2012	0.6 A	0.8 A	0.9 A	0.8 A	3.1 A
2013	0.9 A	0.6 A	0.8 E	0.8 E	3.1 E
2014					3.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.16 A	-$0.18 A	$0.20 A	-$0.08 A	-$0.22 A
2012	-$0.13 A	-$0.09 A	-$0.07 A	-$0.09 A	-$0.37 A
2013	-$0.10 A	-$0.22 A	-$0.09 E	-$0.09 E	-$0.47 E
2014					-$0.31 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

WHAT'S NEW

Soligenix Reports Second Quarter 2013 Financial Results

On August 12, 2013, Soligenix, Inc. (SNGX) reported its financial results for the quarter ended June 30, 2013.

Revenues for the second quarter ended June 30, 2013 were $0.6 million as compared to $0.8 million for the quarter of 2012.

Research and development expenses for the second quarter of 2013 were $2.1 million as compared to $0.5 million for the quarter ended June 30, 2012. Included in the current quarter is a $1.5 million non-cash charge related to the collaboration with Intrexon.

General and administrative expenses for the second quarter of 2013 were $0.7 million as compared to $0.6 million for the quarter ended June 30, 2012.

Net loss for 2Q13 was $3.4 million, or $0.28 per share as compared to $1.0 million, or $0.09 per share for 2Q12. Included in the net loss for the quarter ended June 30, 2013 are non-cash charges of $2.1 million which include a $1.5 million expense related to the exclusive worldwide collaboration with Intrexon Corporation and a $0.6 million charge due to the change in fair value of liability related to warrants issued in the Company's June 25, 2013 registered public offering.

Excluding the $1.5 million non-cash charge, operating expenses for the quarter ended June 30, 2013 increased by $0.2 million related primarily to the pediatric Crohn's disease Phase I clinical study.

Other net income/expense include a $0.6 million charge for the quarter ended June 30, 2013, related to the change in fair value of the liability for warrants issued in the Company's June 25, 2013 registered public offering.

Balance Sheet Remains Strong

As of June 30, 2013, the Company's cash position was $8.1 million.

On June 21, 2013, Soligenix announced the pricing of a registered public offering of shares of common stock and warrants to purchase common stock.

In connection with the public offering, the Company has entered into definitive agreements with institutional investors and certain members of the Company's management and Board of Directors to sell approximately $7.0 million of the Company's securities, consisting of an aggregate of approximately 6.7 million shares of common stock at a price per share of $1.05 and 5-year warrants to purchase up to approximately 5.0 million shares of common stock with an exercise price of $1.65 per share.

Institutional investors in the offering include, among others, an affiliated fund of Third Security, LLC, a venture capital firm founded by R.J. Kirk. In connection with Third Security's investment in the Company, the Company intends to appoint a Third Security designee to the Board of Soligenix.

The Company plans to use the net proceeds from the offering to further develop its product candidates and for general working capital purposes.

Current cash balance will last through the end of 2014 according to our financial model. The

strengthened cash runway allows the Company to initiate a **Phase II** clinical study in oral mucositis as well as a **Phase II/III** study in pediatric Crohn's disease by the end of this year.

Soligenix also remains active and opportunistic in pursuing non-dilutive capital through government grants and contracts. Most notably, the company is awaiting response from the Biomedical Advanced Research and Development Authority (BARDA) on its contract proposal to support the development of OrbeShield™ for the treatment of gastrointestinal acute radiation syndrome (GI ARS), which if awarded, has the potential to be a multi-million dollar contract.

Soligenix is on track to advance SGX203 for pediatric Crohn's disease

Phase I Clinical Study with SGX203 for the Treatment of Pediatric Crohn's Disease has been completed

On June 28, 2013, Soligenix (SNGX) announced that it has enrolled and treated all patients in the **Phase I Study** BDP-PCD-01; the first clinical study for development of SGX203 (oral beclomethasone 17,21-dipropionate or oral BDP) for the treatment of **pediatric Crohn's disease**.

SGX203 has received Fast Track and Orphan Drug designations from the US FDA for the treatment of pediatric Crohn's disease.

As a reminder, Soligenix initiated the **Phase I clinical study** on May 15, 2013. The objective of the Phase I study BDP-PCD-01 is to determine the pharmacokinetic (PK) and pharmacodynamic (PD) profile of SGX203 in healthy young male and female adolescents and adults.

This study enrolled 24 subjects between the ages of 18-22, with all assessments completed in May 2013. Preliminary PK results indicate that the PK profile in this population is consistent with the profile established in previous studies in a broader population and supports a convenient twice a day dosing regimen. SGX203 administration (6 mg BDP twice daily over 7 days) was found to be safe and well-tolerated.

The study in healthy male and female adolescents and young adults provided important complementary data to that previously obtained, to enable the refinement of the PK model that is fundamental to the pediatric Crohn's disease development program. In addition, the study confirmed the safety profile observed in all previous clinical studies with oral BDP.

Phase II/III trial is planned

Soligenix plans to start **Phase II/III** trial of SGX203 in 2H 2013. Primary endpoint data are expected in 2H 2014.

The PK data generated from the Phase I study will be used to refine the PK model previously established with Dr. Jeffrey S. Barrett, PhD, FCP, from The Children's Hospital of Philadelphia. The refined model will provide the justification for limited PK sampling in the planned Phase II/III pediatric clinical study and will help inform the dose selection for the Phase III component of the study.

There is currently no cure for Crohn's disease, and there is no one treatment that works for everyone. Drug therapies usually include anti-inflammatory drugs, immune system suppressors and antibiotics. There are currently no FDA approved corticosteroid therapies for pediatric Crohn's disease. 80% of patients with Crohn's disease are treated with **steroids off-label** as first-line therapy, which may suppress adrenal function and result in growth retardation. **Remicade** is the only approved product in pediatric Crohn's disease in the US, which is used in 30% of patients within first year of diagnosis. However, Remicade carries a black box warning for potential malignancy (T cell lymphoma). Two biologics, Cimzia and Tysabri and one corticosteroid Entocort (budesonide) are on the market to treat Crohn's disease in adult patients, and are currently in trials in pediatric patients.

SGX203 is designed to block inflammation of Crohn's disease throughout the GI tract and is positioned as a corticosteroid option with less toxicity than the current standard systemic steroid therapy – **prednisone.**

We believe SGX203 has the potential to meet an important medical need in children with this serious illness.

Commercial Collaboration with SciClone Pharmaceuticals in China for SGX942

On July 8, 2013, Soligenix announced a personalized medicine collaboration with **SciClone** Pharmaceuticals of China in the Company's **oral mucositis (OM)** clinical program with SGX942. As part of this collaboration, Soligenix will receive access to SciClone's oral mucositis clinical and regulatory data library in exchange for commercialization rights in the People's Republic of China, including Hong Kong and Macau. Specific deal terms have not been disclosed at this time.

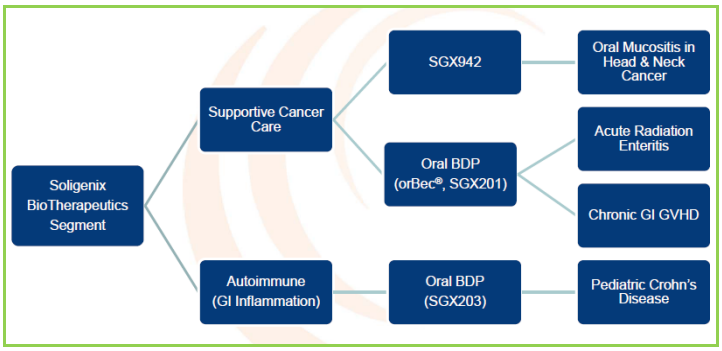
SciClone completed two sequential **Phase II clinical studies** in 2010 and 2012 evaluating its drug, **SCV-07,** for the treatment of OM caused by chemoradiation therapy in head and neck cancer patients, before terminating its program. As this is the same population that Soligenix is pursuing for its OM program, this information has the potential to increase the probability of success of its upcoming Phase II clinical study. By analyzing data available from the placebo subjects in the SciClone trials, Soligenix will acquire essential insight into disease progression, along with quantitative understanding of its incidence and severity in this patient population. This has the potential to enable the design of the SGX942 clinical trials to be optimized and may allow for novel and more robust response criteria to be defined. In addition, analysis of blood samples from these subjects has the potential to identify key biomarkers that could enable development of a prognostic enrichment tool capable of predicting patients expected to develop severe OM on the basis of their deoxyribonucleic acid (DNA) signature. The ability to identify the patient population most likely to develop severe disease increases the likelihood of observing a treatment response.

This collaboration is unique in that it is the first time that a personalized medicine approach has been comprehensively integrated with an oral mucositis development program. The extension of these biomarker approaches in the SGX942 clinical trials also has the potential to form the basis of a predictive enrichment tool and companion diagnostic to identify patients more likely to respond to SGX942 treatment, thereby increasing the likelihood of program success.

We think the collaboration with SciClone is an ideal match for Soligenix. SciClone has a significant commercial presence and expertise in China, and their clinical and regulatory contribution to the SGX942 OM program has the potential to accelerate development while dramatically improving clinical response.

The SGX94 IDR Platform Has Potential To Targets Multiple Indications

Soligenix's BioTherapeutics segment targets two areas of inflammation: supportive cancer care and GI inflammation.



Soligenix is developing **SGX94**, which belongs to a new class of compounds called **Innate Defense Regulators (IDRs),** to treat infections and tissue damages. The **SGX94 IDR platform** represents a novel and innovative approach to therapeutically modulating the immune system by targeting the innate immune system and has the potential to target multiple indications.

IDRs provide a novel approach to the control of **infection** and **tissue damage** via highly selective binding to an intracellular adaptor protein, **sequestosome-1**, also known as **p62**, which has a pivotal function in signal transduction during activation and control of the innate defense system. Sequestosome is a recently identified target for modulation of innate defenses and is expressed in most cell types.

IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy.

Since IDRs target the host (and not the pathogen), IDRs do not engender resistance and are active against resistant pathogens. In vitro data indicate that the endothelium plays a significant role in SGX94 activity and animal studies show that IDRs selectively promote monocyte and macrophage recruitment to disease sites and accelerate resolution of disease. Though IDR action depends on monocytes and macrophages, there is no dependence on either the adaptive immune system (e.g., T cells and B cells) or neutrophils. This suggests that IDRs may be effective in immunosuppressed patients. Moreover, p62 functions downstream of signaling receptors (TLRs, NODs) responsible for sensing both infection and tissue damage, which gives it a role in innate immune modulation relevant to **a wide range of diseases** from infection (pathogen sensing) to colitis and mucositis (damage sensing).

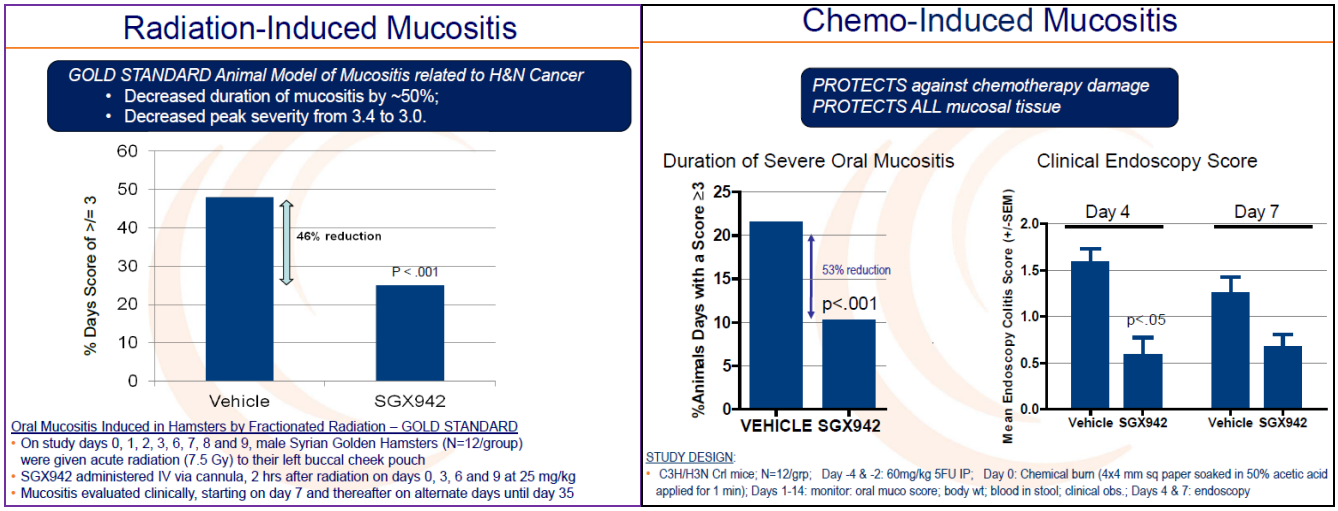
Soligenix acquired **SGX942** (formerly IMX942) in December 2012 from **Inimex Pharmaceuticals** of Canada. Soligenix is developing SGX942 for the treatment of **oral mucositis in head and neck cancer patients** following chemo- or radiation therapy. **SGX94** is the research name for the active ingredient in SGX942, which is the research name for the finished drug product being studied in oral mucositis.

SGX94 is a fully synthetic, 5-amino acid peptide with high aqueous solubility and stability. Extensive in vivo **preclinical studies** have shown that SGX94 reduces tissue damage associated with chemotherapy, radiation, trauma and inflammation. Although SGX94 is not directly antimicrobial, it accelerates pathogen clearance and increases host survival in a broad spectrum of bacterial infections including Gram positive and negative bacteria, and both drug sensitive and resistant strains, by directly targeting the host innate immune system.

Extensive **animal data** set points to high potential for development of a broad spectrum of SGX94 products based on the following attributes:

- ameliorate injury;
- reduce inflammation;
- fight both antibiotic sensitive and resistant infections;
- complement antibiotics; and
- protect immune-compromised animals.

More specifically, SGX94 ameliorates tissue damage in models of chemotherapy- or radiation-induced mucositis as well as DSS-induced colitis and has shown accelerated healing in a murine model of skin infection and injury. SGX94 is not a growth factor and does not promote tumor growth or protect tumors against treatment in a breast cancer xenograft model using the MCF-7 cell line.



Studies in murine models of bacterial infection have shown activity against a broad range of pathogens including methicillin-resistant S. aureus (MRSA), K. pneumoniae, E.coli, P. aeruginosa, and B. pseudomallei. SGX94 enhances the activity of antibiotics administered at sub-optimal doses. Studies in a model of MRSA bacteremia indicate that SGX94 is effective both therapeutically and prophylactically. SGX94 is most effective when administered by IV injection and has a very short plasma half-life (~10 minutes). When administered prophylactically in the MRSA model, a single dose of SGX94 is protective when injected up to 5 days before bacterial challenge, indicating a prolonged pharmacodynamic effect despite rapid plasma clearance.

Inimex has completed a double-blind, placebo-controlled **Phase I** clinical trial of SGX942 in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. SGX942 showed a strong safety profile when administered IV over 7 days and was consistent with safety results seen in pre-clinical studies. Drug clearance in humans is rapid and similar to results seen in pre-clinical studies.

Soligenix plans to start a **Phase II** proof-of-concept multi-center, double-blind, placebo-controlled trial in approximately 75 patients in the **second half of 2013.** This Phase II trial is designed to evaluate the efficacy of SGX942 (research name for oral mucositis indication) in reduction of the severity of **oral mucositis** in head and neck cancer patients undergoing fractionated radiation therapy and/or chemotherapy. The cGMP manufacture of drug product to initiate the Phase II studies is complete. Results are expected to be available in **2H14**.

In addition to oral mucositis, SGX942 has the potential for multiple other indications as listed below.

Target Indication	Potential Application (s)	External Funding	Summary and Potential Next Steps
Vaccine Adjuvant	Biodefense; infectious disease	NIH, DoD, BARDA, Gates	Potential for immediate application with our existing vaccines under current $9.4M ThermoVax™ NIH Grant
Acute Bacterial Skin and Skin Structure Infection (ABSSSI)	Infectious disease	NIH, FDA	Data generated in animal model; Phase 2 protocol cleared by FDA
Acinetobacter	Infectious disease	NIH, FDA, Gates	Established animal model
Melioidosis	Biodefense – Category B; infectious disease	NIH, DoD, FDA, BARDA	Established animal model – NIH grant filed; common in Thailand – 20% of all community acquired septicemia; potential collaboration with Thai partner
GI Acute Radiation Syndrome	Biodefense – Category A; GI inflammation	NIH, DoD, FDA, BARDA	Established animal model

Market Opportunity For SGX94 Is Huge

The SGX94 platform offers a new way to address serious infections and injury by enhancing the host response without increasing inflammation. Positive clinical activity in the planned Phase II will provide an important proof of concept for the IDRs. Soligenix' technology has the potential to provide adjunctive or stand-alone therapies for the broader antimicrobial/antibiotic, antiviral, anti-inflammatory, and anti-cancer markets. Each of the above mentioned market is a multi- billion dollar market.

More narrowly, the tissue damage (mucositis) opportunity alone represents a $1B+ market.

Mucositis is a debilitating condition involving extensive ulceration of the oral cavity that frequently affects cancer patients undergoing radiation and chemotherapy treatment. Roughly 90% of patients on radiation (43% severe) and 40% of patients receiving chemotherapy get mucositis. There is an estimated 500,000 cancer patients getting mucositis annually in the United States alone. World-wide, the potential market for mucositis will exceed $1 billion in the next few years.

Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The gastrointestinal damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes. We believe any treatment that accelerates healing and/or diminishes the rate of appearance of mucositis would have a significant beneficial impact on the quality of life of these patients and may allow for more aggressive chemotherapy.

The **mechanisms of mucositis** have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is now regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions. As a modulator of the innate immune system, SGX942 has the potential to target both **primary** and **secondary** causes of mucositis.

Oral mucositis is an area of unmet medical need where there are only limited treatment options. Ccurrently, no drug has been approved for oral mucositis in head and neck cancer. We noticed that there are a few products already on the market for oral mucositis. But the competitive landscape favors SGX942 in our view.

Amgen's **Kepivance (Palifermin)** is the only approved drug for oral mucositis in transplantation; but is contra-indicated for solid tumor patients. Kepivance is a recombinant form of human keratinocyte growth factor (KGF), a protein that is naturally produced by the body. Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support. The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Kepivance must be IV injected for 3 consecutive days before and 3 consecutive days after treatment for a total of 6 injections. Also, Kepivance is expensive at about $10,000 per patient.

Access Pharma's **MuGard** is approved as a medical device and is dispensed in a ready to use mouth rinse. MuGard is indicated for the management of oral mucositis/stomatitis that may be caused by radiotherapy and/or chemotherapy.

Three other medical devices on the market are EKR Therapeutics' Gelclair, GeoPharma's Mucotrol, and EUSA Pharma's Caphosol. **Gelclair** is a prescription mouth gel that is designed and approved for the management and relief of pain caused by mouth sores. Gelclair is established by mixing the powder in a glass of water to form the rinse and patients gargle and spit out. **Mucotrol** is concentrated oral gel wafer which is indicated for the management and relief of pain from oral lesions associated with oral

mucositis/stomatitis. **Caphosol** is similar to Gelclair. Patients must mix the contents of two ampoules to form a rinse and then swish/spit out. These devices attempt to create a protective barrier around the oral ulceration; however, none of these devices are biologically based.

Apparently, most of the above treatment options for mucositis only address the symptoms and do not address the cause of mucositis, while Soligenix's SGX942 has a new mechanism of action which can address both the primary and the secondary causes of mucositis. We believe that, if approved, SGX942 will command a significant market share of the mucositis market, which could reach $1 billion in the next few years.

We believe SGX942 will have peak sales of $300 million and that the potential worldwide market for SGX942 is in excess of $500 million for all applications, including oral mucositis.

SGX201 for Preventing Acute Radiation Enteritis

SGX201 is a **delayed-release** formulation of BDP specifically designed for oral use and is designed to block inflammatory component of **radiation enteritis** in GI tract of cancer patients receiving pelvic radiation therapy.

Soligenix completed a 16-subject **Phase I/II** clinical trial testing SGX201 in prevention of **acute radiation enteritis**. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study were to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. The study demonstrated that

- oral administration of SGX201 was safe and well tolerated across all four dose groups.
- There was also evidence of a potential dose response with respect to diarrhea, nausea and vomiting and the assessment of enteritis.
- In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population.

This program was supported in part by a $500,000 two-year Small Business Innovation and Research (SBIR) grant awarded by the National Institutes of Health (NIH).

Soligenix plans to initiate a **Phase II** randomized, double-blind, placebo-controlled trial in 1H2014. Data are expected in 1H2015, assuming continued financial support from NIH. The Company has received **Fast Track** designation from the FDA for SGX201 for radiation enteritis. It's possible for continued government funding for the Phase IIa trial.

External radiation therapy is used to treat most types of cancer. During delivery of treatment, some level of radiation will also be delivered to healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very sensitive to radiation and the larger the dose of radiation the greater the damage to normal bowel tissue. **Radiation enteritis** is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiation therapy to the abdomen, pelvis, or rectum. Most tumors in the abdomen and pelvis need large doses, and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization.

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of

chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

Based upon published studies and reports, there are over 100,000 patients annually in the U.S. and over 200,000 patients worldwide, who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis. Currently there are no approved therapies for this indication. Based on current preclinical and Phase I/II clinical data, SGX201 has the potential to make a meaningful difference in this indication.

orBec® –for Treating Chronic GVHD

orBec ® is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP to treat the gastrointestinal manifestation of **chronic GVHD**, the organ system where GVHD is most frequently encountered and highly problematic.

orBec® is intended to reduce the need for systemic immunosuppressive drugs such as prednisone to treat chronic GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue.

orBec® has been awarded **orphan drug** designations in the U.S. and in Europe for the treatment of GI GVHD. In September 2012, Soligenix received a $300,000 two-year SBIR grant awarded by the NIH to support a **Phase II** study for the treatment of chronic GI GVHD. Soligenix plans to initiate a Phase II trial in 2013 with **data expected in 2H14**.

GVHD is a major complication of allogeneic hematopoietic cell transplantation. GVHD is an inflammatory disease initiated by T cells in the donor graft that recognize histocompatibility and other tissue antigens of the host, and is mediated by a variety of effector cells and inflammatory cytokines. GVHD presents in both acute and chronic forms. The symptoms of chronic GVHD typically present at between 100 days and three years post-transplant.

Chronic GVHD has features resembling autoimmune and other immunologic disorders such as scleroderma, Sjögren syndrome, primary biliary cirrhosis, wasting syndrome, bronchiolitis obliterans, immune cytopenias and chronic immunodeficiency. The manifestations of chronic GVHD may be restricted to a single organ or tissue or may be widespread. Chronic GVHD can lead to debilitating consequences, e.g., joint contractures, loss of sight, end-stage lung disease, or mortality resulting from profound chronic immune suppression leading to recurrent or life-threatening infections.

Treatment of chronic GVHD is a challenge because it can be refractory to frontline immunosuppression. High-dose systemic corticosteroids are used with some success but carry significant toxicity. The risks of prolonged immunosuppression include local and disseminated infections; Epstein-Barr virus associated lymphoproliferative disease, hypothalamic-pituitary-adrenal (“HPA”) axis suppression, myopathy, glucose intolerance, neuropsychiatric disease and bone demineralization.

There are about 6,000 patients annually in the U.S., with a comparable number in Europe that suffer from chronic GVHD.

RiVax™ - Ricin Toxin Vaccine

RiVax™ is Soligenix’s proprietary **aluminum-adsorbed** vaccine developed to protect against exposure to **ricin toxin**, and is the first ricin vaccine. With RiVax, Soligenix is a world leader in ricin toxin vaccine research.

The development of RiVax™ has been sponsored through a series of overlapping challenge grants. The immunogen in RiVax™ induces a protective immune response **in animal models** of ricin exposure and

functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin.

Two **Phase I** human clinical trials have been completed. Results of the first Phase I human trial of RiVax™ established that the immunogen was safe and induced antibodies anticipated to protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The second trial (Phase Ib) evaluated a more potent formulation of RiVax™ that contained an **aluminum adjuvant** (Alum), was completed in September 2012. The results of the **Phase Ib** study indicated that Alum adjuvanted RiVax™ was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax™.

RiVax™ has been granted Orphan Drug designation by the FDA for the prevention of ricin intoxication. Assuming development efforts are successful for RiVax™; potential government procurement contract(s) could reach $200 million.

Soligenix plans to evaluate additional adjuvants for more rapid onset immunity in 1H2013 and establish multivalent or combination vaccine POC (e.g., combination ricin-anthrax vaccine) in 2H2013. The Company expects to initiate a **Phase II** study in 1H2014.

RiVax has FDA Orphan Drug designation. Soligenix plans to submit NIH SBIR and Orphan grants to support clinical development of RiVax in 2014.

In January of 2012, a Request for Information (RFI) was issued by the Chemical Biological Medical Systems – Joint Vaccine Acquisition Program (CBMS-JVAP) of the Department of Defense (DoD). This RFI was entitled “Development of a Ricin Toxin Vaccine to FDA Approval”, and marks the first time any agency of the U.S. government has specifically indicated an interest in development of a vaccine against ricin toxin. Soligenix intends to pursue this avenue of funding to the fullest extent.

VeloThrax™ – Anthrax Vaccine

VeloThrax™ is Soligenix’s proprietary vaccine based on a recombinant Protective Antigen (rPA) derivative intended for use against **anthrax**. Soligenix has entered into an exclusive license option with Harvard College to license VeloThrax™ (also known as DNI for dominant negative inhibitor) for a vaccine directed at the prevention of anthrax infection of humans.

VeloThrax™ is a translocation-deficient mutant of PA with double mutations of K397D and D425K that impede the conformational changes necessary for endosomal membrane translocation into the cell cytoplasm. In the absence of that PA translocation step, anthrax toxin trafficking and function cease. VeloThrax™ is also considered a more immunogenic candidate than native rPA. This apparent increase in immunogenicity suggests that the DNI rPA is processed and presented to the immune system more efficiently by cellular antigen processing pathways, which is consistent with known properties of the molecule.

DNI versions of rPA such as VeloThrax™ are also capable of inducing antibodies that neutralize the activity of the anthrax toxin complex. Unlike fully-functional rPA, VeloThrax™ might be given to a patient post-exposure without risk of enhancing intoxication during an infection, although clinical tests involving intravenous administration of potentially therapeutic levels of DNI rPA resulted in serious adverse events and so further development of this product as a therapeutic biological for blocking the effects of infection by B. anthracis was discontinued. Soligenix intends to test VeloThrax™ at a 1,000 fold lower dose than previously tested for an **intramuscular or intradermal** vaccine.

VeloThrax™’s greater immunogenicity could lead to a vaccine that can be administered in the fewest possible doses to induce the highest level of toxin neutralizing antibodies. Utilizing ThermoVax™, Soligenix will be able to develop VeloThrax™ into a vaccine with an improved stability profile, an issue

that has proven challenging in the development of other anthrax vaccines. Extended stability at ambient temperatures would be a significant improvement for stockpiled vaccines and one which is not expected from conventional vaccines. Further, a large-scale, Good Manufacturing Practice (cGMP) production methodology has already been completed. Assuming long-term stability can be met; VeloThrax™ could be stockpiled for general prophylactic as well as a post exposure use.

The overall objective of the VeloThrax™ program is to rapidly and efficiently develop a next generation anthrax vaccine which combines a well-established, safe and relatively low risk vaccine development and dosing approach with targeted, proven innovative strategies. VeloThrax™ will potentially be a combination of a stable, readily manufactured mutant rPA subunit antigen with next generation, clinically compatible adjuvants which have been demonstrated to enhance potency and reduce the time and number of vaccine doses required to achieve protective titer using a variety of vaccine antigens. This blend of proven yet innovative technologies will provide a safe and stable alternative to the existing licensed anthrax vaccine product. Soligenix also proposes to adapt newly developed glassification technology to enable a thermostable, dried, single vial, pre-formulated adjuvanted rPA vaccine which is suitable for both long term storage and field use without typical cold chain constraints.
Soligenix plans to complete preclinical animal studies of VeloThrax in 2H13 and initiate Phase I study in 2H14. Potential government procurement contracts could reach $500 million assuming development efforts are successful for VeloThrax™.

OrbeShield™ – For Treating GI ARS

OrbeShield™ is an oral immediate and delayed release BDP formulation that is being developed for the treatment of **GI ARS** (gastrointestinal acute radiation syndrome).

In **preclinical studies**, OrbeShield™ has demonstrated positive results in a canine GI ARS model which indicate that dogs treated with OrbeShield™ demonstrated statistically significant (p=0.04) improvement in survival with dosing at either 2 hours or 24 hours after exposure to lethal doses of total body irradiation (TBI) when compared to control dogs. The median survival was 100 days (p=0.04) when canines were treated 2 hours post exposure, 87 days (p=0.048) when canines were treated 24 hours post exposure. OrbeShield™ appears to significantly mitigate the damage to the GI epithelium caused by exposure to high doses of radiation.

Soligenix plans to conduct **a follow-on replication dog study** in 1H14 with results available also in 1H14.

The FDA has cleared the **IND application** for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS.

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. This is the same type of toxicity that occurs in Soligenix's acute radiation enteritis clinical program with SGX201. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a "dual use" compound, a desirable characteristic which is a specific priority of Biomedical Advanced Research and Development Authority (BARDA) for ARS and other medical countermeasure indications.

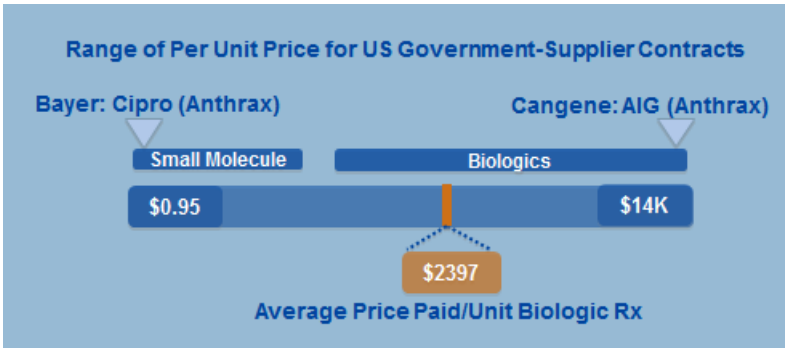
BARDA recently invited Soligenix to submit a full contract proposal for a potential multi-year, multi-million dollar contract to develop OrbeShield™ from its current level of technical readiness to potential FDA approval. In response, Soligenix submitted its contract proposal **in February 2013**. The Company expects a response in the second half of 2013.

Soligenix has had and is having strategic discussions with a number of pharmaceutical companies regarding the partnering or sale of its biodefense/vaccine products. The Company may market its biodefense vaccine products directly to government agencies. It's our belief that both military and civilian health authorities of the U.S. and other countries will increase their stockpiling of therapeutics and vaccines to treat and prevent diseases and conditions that could ensue following a bioterrorism attack.

The Animal Rule Advantages

Soligenix's vaccines and OrbeShield are being developed under specific FDA regulatory guidelines called the "**Animal Rule**." The Animal Rule provides that under certain circumstances, where it is unethical or not feasible to conduct human efficacy studies, the FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans. Demonstration of the product's safety in humans is still required.

We think the "Animal Rule" means a lot for Soligenix, because this can accelerate the development of the ricin and anthrax vaccines. Once approved by the FDA, Soligenix will have the opportunity to negotiate a stock-pile contract with the US government. These stock-pile or procurement contracts have been very lucrative for other companies supplying similar drugs to the US government.



VALUATION AND RECOMMENDATION

We maintain an **Outperform rating** for Soligenix and reiterate our 12-month price target of $4.50 per share.

Soligenix is a mid-stage development biopharmaceutical company focused on cancer supportive care and GI disorders, two large pharmaceutical markets both in the US and around the world. Soligenix also develops vaccines/oral therapeutics for biodefense.

Soligenix has built a diversified pipeline using three proprietary platform technologies. We are especially optimistic about its lead drug candidate SGX942 for the treatment of mucositis. SGX942 will enter into Phase II study in 2H13, which may serve as a major short term catalyst. Results will be available in 2H14, which, if positive, would be a significant de-risking event for Soligenix. SGX942 has a new mechanism of action and will command a significant market share of the oral mucositis market if approved in our view.

The Company's oral BDP has the potential to target multiple GI disorders such as Crohn's disease, radiation enteritis and GVHD as well as ARS.

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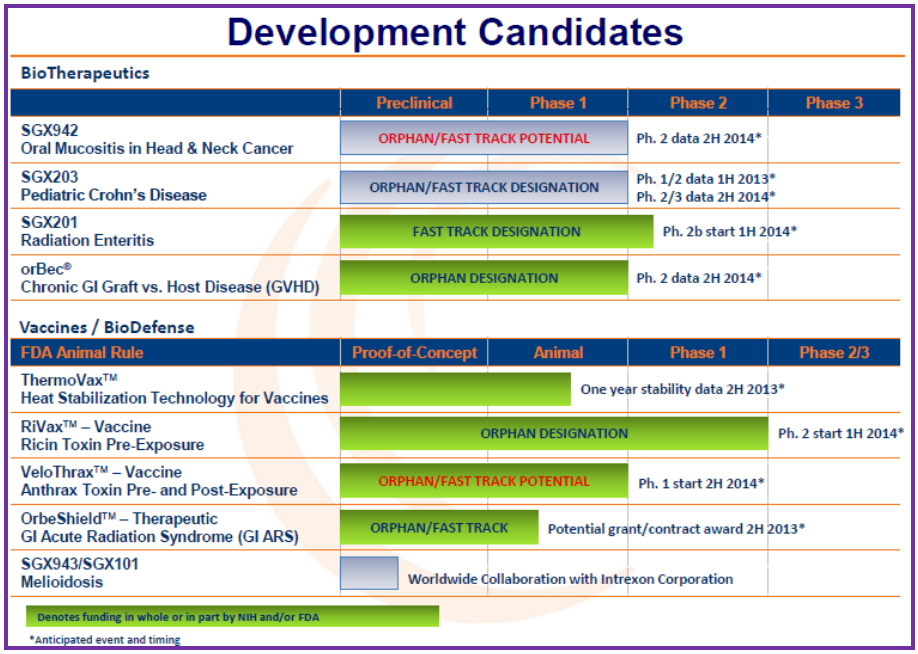
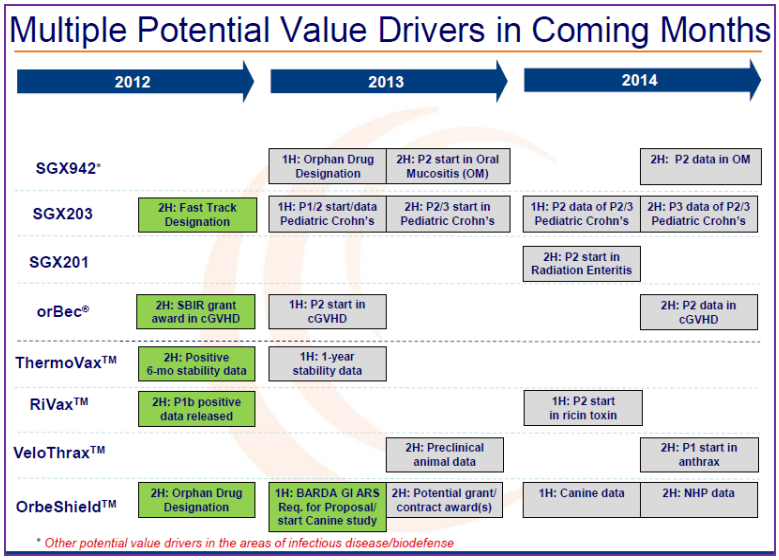


We think the “Animal Rule” means a lot for Soligenix, because this can accelerate the development of the ricin and anthrax vaccines as well as OrbeShield. Once approved by the FDA, Soligenix will have the opportunity to negotiate a stock-pile contract with the US government. These stock-pile or procurement contracts have been very lucrative for other companies supplying similar drugs to the US government and will provide significant cash flow to Soligenix.

Based on our analysis, we think Soligenix shares are undervalued at this time. Currently, shares of Soligenix are trading at around $1.50 per share, which values the Company at $27 million in market cap. We admit that it’s always difficult to value a development stage biotech company. Soligenix is no exception. However, we do think that current market value of Soligenix is a deep discount compared to its peers in the same industry.

Most small biotech companies of development stage are valued from $50 million to $500 million depending on how advanced the pipeline is and which indications the company is targeting. Soligenix’s SGX942 for oral mucositis will enter a **Phase II** clinical study later this year, and the Company’s SGX203 for pediatric Crohn’s disease will also move to Phase II/III study later this year. Soligenix has multiple catalysts in the next 12 month or so.



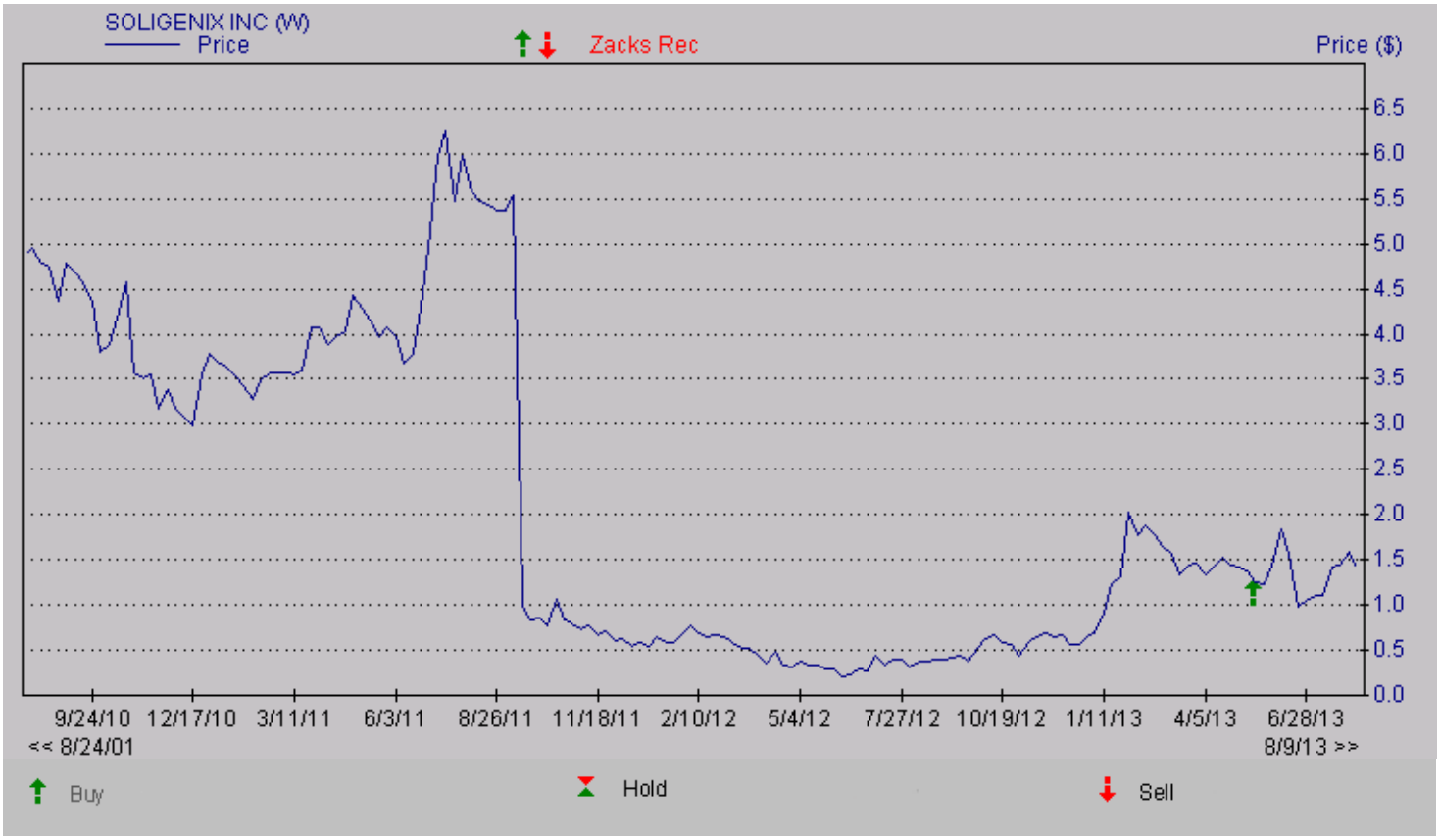
Our price target of $4.50 per share values Soligenix at $86 million in market cap which we think is very conservative.

PROJECTED INCOME STATEMENT

		2012					2013					2014	2015	2016
$ in millions except per share data	FY	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE
License Revenue	$5.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-100.0%*	*#DIV/0!*	*-100.0%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Grant Revenue	$2.7	$0.6	$0.8	$0.9	$0.8	$3.1	$0.9	$0.8	$0.8	$0.8	$3.3	$3.5	$4.0	$4.5
YOY Growth	*36.7%*	-	-	*17.1%*	*22.9%*	*18.1%*	-	*4.9%*	*-14.1%*	*-0.3%*	*5.0%*	*6.0%*	*14.3%*	*12.5%*
Product Sales	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth			-	-										*#DIV/0!*
Total Revenues	**$7.7**	**$0.6**	**$0.8**	**$0.9**	**$0.8**	**$3.1**	**$0.9**	**$0.8**	**$0.8**	**$0.8**	**$3.3**	**$3.5**	**$4.0**	**$4.5**
YOY Growth	*293.4%*	*-19.9%*	*88.0%*	*-83.9%*	*22.9%*	*-59.0%*	*39.1%*	*4.9%*	*-14.1%*	*-0.3%*	*5.0%*	*6.0%*	*14.3%*	*12.5%*
Cost of Revenue	$2.1	$0.6	$0.6	$0.8	$0.7	$2.6	$0.7	$0.7	$0.7	$0.7	$2.7	$2.9	$3.3	$3.7
Gross Income	**$5.6**	**$0.1**	**$0.1**	**$0.2**	**$0.1**	**$0.6**	**$0.2**	**$0.1**	**$0.1**	**$0.1**	**$0.6**	**$0.6**	**$0.7**	**$0.8**
Gross Margin	*72.5%*	*14.0%*	*19.2%*	*18.2%*	*18.0%*	*17.5%*	*17.4%*	*18.0%*	*18.0%*	*18.0%*	*17.8%*	*18.0%*	*18.0%*	*18.0%*
R&D	$6.3	$0.9	$0.5	$0.4	$0.9	$2.6	$0.8	$1.0	$1.1	$1.2	$4.0	$5.5	$7.5	$10.0
% R&D	*81.9%*	*135.4%*	*65.7%*	*39.9%*	*107.2%*	*83.0%*	*84.0%*	*118.8%*	*137.5%*	*150.0%*	*121.4%*	*157.1%*	*187.5%*	*222.2%*
SG&A	$2.2	$0.7	$0.6	$0.6	$0.8	$2.6	$0.5	$0.7	$0.7	$0.7	$2.6	$3.0	$3.6	$4.3
% SG&A	*29.3%*	*101.2%*	*82.2%*	*60.0%*	*98.6%*	*83.7%*	*54.2%*	*87.5%*	*87.5%*	*87.5%*	*78.4%*	*85.7%*	*90.0%*	*96.0%*
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
% Other	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($3.0)**	**($1.4)**	**($1.0)**	**($0.8)**	**($1.5)**	**($4.7)**	**($1.1)**	**($1.5)**	**($1.7)**	**($1.8)**	**($6.0)**	**($7.9)**	**($10.4)**	**($13.5)**
Operating Margin	-	-	-	-	-	-	-	-	*-207.0%*	*-219.5%*	-	-	-	-
Other Income (Net)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($3.0)**	**($1.4)**	**($1.0)**	**($0.8)**	**($1.5)**	**($4.7)**	**($1.1)**	**($1.5)**	**($1.7)**	**($1.8)**	**($6.0)**	**($7.9)**	**($10.4)**	**($13.5)**
Net Taxes (benefit)	($0.6)	$0.0	$0.0	$0.0	($0.5)	($0.5)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*19.4%*	*0.0%*	*0.0%*	*0.0%*	*34.6%*	*11.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($2.4)**	**($1.4)**	**($1.0)**	**($0.8)**	**($1.0)**	**($4.2)**	**($1.1)**	**($1.5)**	**($1.7)**	**($1.8)**	**($6.0)**	**($7.9)**	**($10.4)**	**($13.5)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*11.0*	*11.1*	*11.1*	*11.1*	*11.2*	*11.1*	*11.2*	*11.9*	*17.9*	*18.0*	*14.7*	*25.0*	*35.0*	*45.0*
Reported EPS	**($0.22)**	**($0.13)**	**($0.09)**	**($0.07)**	**($0.09)**	**($0.37)**	**($0.10)**	**($0.13)**	**($0.09)**	**($0.10)**	**($0.41)**	**($0.31)**	**($0.30)**	**($0.30)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$0.0	$0.00	$0.0	$0.00	$0.0	$0.0	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($2.4)**	**($1.4)**	**($1.0)**	**($0.8)**	**($1.0)**	**($4.2)**	**($1.1)**	**($1.5)**	**($1.7)**	**($1.8)**	**($6.0)**	**($7.9)**	**($10.4)**	**($13.5)**
Non GAAP EPS	**($0.22)**	**($0.13)**	**($0.09)**	**($0.07)**	**($0.09)**	**($0.37)**	**($0.10)**	**($0.13)**	**($0.09)**	**($0.10)**	**($0.41)**	**($0.31)**	**($0.30)**	**($0.30)**

Source: Company filings and Zacks estimates

HISTORICAL ZACKS RECOMMENDATIONS



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