# Zacks Small-Cap Research

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111 North Canal Street, Chicago, IL 60606

## **Corgenix Medical**

(CONX-OTC)

CONX: Attractive Entry Point. Initiating At Outperform.

Current Recommendation Prior Recommendation Date of Last Change	Outperform N/A 10/18/11
Current Price (10/18/11)  Target Price	\$0.13 <b>\$0.50</b>

#### **OUTLOOK**

Corgenix is on the front-end of a transition away from reliance on certain legacy products to a more determined focus on growing higher potential areas of their business. Highlighted by the recent transfer of their international business and related joint product development agreements, the transition is expected to help jump-start revenue growth in the current fiscal year and form the basis for continued double-digit growth over the next several years. Based on comparable valuations, Corgenix's shares trade significantly cheaper than warranted. We are initiating coverage of the company with a \$0.50 per share price target and an Outperform rating.

#### **SUMMARY DATA**

52-Week High	\$0.14
52-Week Low	\$0.06
One-Year Return (%)	4.81
Beta	0.98
Average Daily Volume (sh)	150,144
Shares Outstanding (mil)	41
Market Capitalization (\$mil)	\$6
Short Interest Ratio (days)	N/A
Institutional Ownership (%)	0
Insider Ownership (%)	17
Annual Cash Dividend	\$0.00
Dividend Yield (%)	0.00
5-Yr. Historical Growth Rates	
Sales (%)	2.5
Earnings Per Share (%)	N/A
Dividend (%)	N/A
P/E using TTM EPS	N/A
P/E using 2012 Estimate	14.0
P/E using 2013 Estimate	14.0
Zacks Rank	N/A

Risk Level	High,
Type of Stock	Small-Value
Industry	Med Products

ZACK	S ESTIMA	ATES			
Reven	ue				
(in '000)	Q1	Q2	Q3	Q4	Year
	(Sep)	(Dec)	(Mar)	(Jun)	(Jun)
2011		\$1,786 A	\$1,829 A	\$2,349 A	\$7,942 A
2012	\$2,423 E	\$2,464 E	\$2,570 E	\$2,616 E	\$10,073 E
2013					\$11,705 E
2014					\$13,255 E
Earnin	gs per Sh	are			
Earnin	gs per Sh Q1	are Q2	Q3	Q4	Year
Earnin	<b>.</b>		<b>Q3</b> (Mar)	<b>Q4</b> (Jun)	<b>Year</b> (Jun)
Earnin 2011	Q1	Q2			. • • • • • • • • • • • • • • • • • • •
	Q1 (Sep)	Q2 (Dec)	(Mar)	(Jun)	(Jun)
2011	<b>Q1</b> (Sep) -\$0.01 A	<b>Q2</b> (Dec) \$0.00 A	(Mar) \$0.00 A	(Jun) \$0.00 A	(Jun) -\$0.01 A
2011 2012	<b>Q1</b> (Sep) -\$0.01 A	<b>Q2</b> (Dec) \$0.00 A	(Mar) \$0.00 A	(Jun) \$0.00 A	(Jun) -\$0.01 A \$0.01 E

#### **KEY POINTS**

- Offering an array of in vitro diagnostic (IVD) testing products in the areas of liver diseases (fibrosis and cirrhosis), autoimmune disease (bone and joint disorders) and vascular disease, Corgenix has become a renowned expert in the diagnosis and measurement of blood coagulation, vascular occlusion and thrombosis
- Corgenix's considerable R&D, manufacturing and production capabilities have also afforded the award of several U.S. government contracts and grants as well as facilitated the consummation of partnerships with several leading IVD companies
- ➤ The company is in the midst of a transition away from reliance on certain legacy tests to a greater focus on faster-growth products and segments. This includes leveraging key partnerships in the development of novel high-potential products and in the expansion of their sales and distribution reach
- ➤ Revenue growth, which has been stagnant over the last several years, is expected to turnaround in short-order. Recent restructurings, highlighted by the transfer of their international sales operation and consummation of a related amended co-development agreement, along with key additions to the U.S. sales force, new product launches and additional product development contracts are expected to help jump-start revenue growth in 2012
- Management's most recent guidance is for revenue of approximately \$10 million in fiscal 2012, implying growth of 26% from 2011, with positive net income and cash flow
- Despite very positive recent developments including completion of two new products under a recently consummated joint product development agreement, double-digit revenue growth in the most recent quarter (Q4 2011), a cleaned-up balance sheet, completion of the transfer of their international operations, meaningful progress towards new product launches, and a plan to deliver on management's robust financial guidance, the stock barely trades higher than book value
- ➤ We model revenue grow at a four-year CAGR of 17% from 2011 to 2015 and EPS to increase from (\$0.01) to \$0.03 over that same period
- ➤ Based on comparable valuations, Corgenix trades significantly below fair value. We recommend accumulating the shares towards our \$0.50 / share target price. We are initiating coverage of Corgenix with an Outperform rating

#### **BUSINESS**

A pioneer in the field of antiphospholipid antibody detection, Corgenix Medical Corporation is credited with development of the first FDA-cleared assay for measuring anticardiolipin antibodies. The association of antiphospholipid antibodies with thrombosis (antiphospholipid syndrome is a coagulation disorder) encouraged the company to develop assays for other bleeding and clotting disorders. Corgenix has quickly become a renowned expert in the diagnosis and measurement of blood coagulation, vascular occlusion and thrombosis. They offer an array of in vitro diagnostic (IVD) testing products in the areas of **liver diseases** (fibrosis and cirrhosis), **autoimmune disease** (bone and joint disorders) and **vascular disease**, including the only non-blood based test for determining the effectiveness of aspirin, and have sold over 12 million tests to-date.

Most of the company's diagnostic products are developed on an **ELISA** testing format, a method widely used in clinical testing laboratories. As a result of recent R&D collaborations, Corgenix has also implemented additional immunoassay platforms including **lateral flow** (a rapid test format similar to that commonly used for home pregnancy tests) and **immunoturbidimetry** (a liquid-based system for use on automated chemistry analyzers). Although revenue from these additional formats has been immaterial to-date, the immunoturbidimetry format in particular represents an integral portion of the company's growth strategy.

The company has remained competitive in an industry that has experienced substantial consolidation over the recent past by delivering high quality products and service in niche areas such as antiphospholipid syndrome and hemophilia. Over the course of history, sales and distribution have largely been handled in-house. Corgenix's considerable R&D, manufacturing and production capabilities have also afforded the award of several U.S. government contracts and grants as well as facilitated the consummation of partnerships with several leading IVD companies. And while certain products are experiencing rapid growth (i.e. - AspirinWorks), due to increased competition, some of Corgenix's initial areas of expertise now offer less upside opportunity. As a result, the company has begun a measured transition away from reliance on certain legacy tests to a greater focus on faster-growth products and segments. This includes leveraging key partnerships in the development of novel high-potential products and in the expansion of their sales and distribution reach. Corgenix will continue to leverage their R&D/manufacturing capabilities to facilitate product development as well as to attract valuable government grants and manufacturing contracts, all of which are expected to hold outsized opportunities for revenue growth.

Corgenix generates revenue from four main business segments; manufactured products, OEM (private label) products, contract manufacturing, and contract development. Approximately 18% of Corgenix's revenue comes from overseas (i.e. - ex-North America). International revenues fell 36% from 2010 to \$1.46 million in fiscal 2011 while sales in North America increased by 8% over the same period to \$6.48 million in 2011.

- Manufactured Products: CONX currently manufactures and sells 52 diagnostic products worldwide to hospitals, clinical testing laboratories, universities, biotechnology and pharmaceutical companies and research institutions. In North America, Corgenix's labeled products are sold through a small internal sales force as well as through a number of independent sales representatives. Corgenix, through a wholly-owned subsidiary located in the U.K., had also been handling sales of these products overseas but in October 2010 transferred that responsibility to the ELITech Group, who now serves as the company's international master distributor and is Corgenix's largest shareholder. Revenue from Corgenix's manufactured products fell about 7% from 2010 to \$6.03 million in fiscal 2011 and accounted for approximately 76% of Corgenix's total revenue.
- **OEM Products:** CONX sells some of their manufactured IVD products (mainly antiphospholipid and coagulation products) to other diagnostic companies for resale under their own brand names.
- Contract Manufacturing: CONX provides contract manufacturing services to other medical diagnostic companies. Contract manufacturing revenue fell almost 21% from 2010 to \$356k in fiscal 2011 and accounted for approximately 4% of Corgenix's total revenue.
- Contract Development: CONX provides contract development services to strategic partners including ELITech, Tulane University and the National Institutes of Health (NIH). Contract development revenue grew 87% from 2010 to \$1.15 million in fiscal 2011 and accounted for approximately 14% of Corgenix's total revenue.

Corgenix's total revenue fell about 4% from 2010 to \$7.94 million in fiscal 2011 with EPS decreasing from (\$0.00) to (\$0.01) over the same period. This trend is not expected to repeat itself in 2012, however. Corgenix's recent restructurings, highlighted by the transfer of their international sales operation and consummation of a related amended co-development agreement with ELITech, along with key additions to the U.S. sales force, new product launches and additional product development contracts are expected to help jump-start revenue growth in 2012. Management's most recent guidance (provided on the Q4 earnings call on September 23, 2011) is for revenue of approximately \$10 million in 2012, implying growth of 26% from 2011, with positive net income and cash flow.

Despite recent positive momentum in revenue and earnings growth (Q4 2011 revenue grew 14% y-o-y, income grew from \$12k in Q4 2010 to \$182k in Q4 2011), an apparent plan to deliver on the robust financial guidance for 2012 (and beyond), a recently cleaned up and reasonably healthy balance sheet with historically only moderate cash burn (along with 2012 guidance of positive cash flow) and an expectation that revenue will continue to grow for the foreseeable future, CONX's share price continues to flounder at around book value (in our opinion, unfairly so).

#### **FACILITIES**

Corgenix is headquartered near Denver, CO where, along with its corporate offices, it maintains its research and development, manufacturing and distribution facilities in a 32k square foot building. Corgenix is ISO certified and all of the products are CE marked for sale in Europe.

#### **Headquarters**



**R&D** and Production



#### **Product Development**



**Automated Filling Line** 



#### **ELISA Instrumentation**

#### SOURCE: Corgenix Medical Corporation

#### **Bulk Reagent Production**



### **PRODUCTS**

The majority of Corgenix's product lines are developed on an ELISA testing format which are used by trained technicians in clinical labs for the diagnosis of autoimmune disorders, vascular disease and liver diseases. Testing is done with a standard 96-sample well microplate, allowing for automated high-throughput processing with quantitative (i.e. - accurate, non-subjective) results. (The following product and contract descriptions are per Corgenix's most recent 10-K).

- Autoimmune Disease Products: sales of autoimmune products fell about 25% from 2010 to \$127k in fiscal 2011, representing approximately 2% of the company's total revenue. The products are used for the diagnosis and monitoring of autoimmune diseases, including rheumatoid arthritis, systemic lupus erythematosus, mixed connective tissue disease, Sjogren's Syndrome, dermatopolymyositis and scleroderma. The company's autoimmune product line includes tests for antinuclear antibodies (ANA) screening, dsDNA, Sm, SM/RNP, SSA, SSB, Jo-1, Scl-70, Histones, Centromere, Mitochondria, MPO, PR3, Thyroglobulin, LKM-1, anti Ribosomal P, BP-180, DSG-1, DSG-3, anti-polymer antibodies and thyroid peroxidase. Of Corgenix's 21 autoimmune products, two are manufactured in-house, with the remainder produced by other companies and sold through Corgenix's distribution network.
- Vascular Disease Products: Corgenix's vascular disease business, which includes antiphospholipid and coagulation products, is Corgenix's single largest source of revenue, accounting for almost 60% of the company's total sales in fiscal 2011. The vascular disease products are sold both as labeled (i.e. "manufactured products") as well as OEM. OEM-related revenue accounts for approximately 18% of total coagulation and antiphospholipid sales. Corgenix expects OEM-related revenue to show a consistent decline as a percentage of total sales as the company shifts its focus towards higher growth products and segments.
  - Antiphospholipid antibody testing: sales of antiphospholipid products fell about 7% from 2010 to \$3.39 million in fiscal 2011, representing approximately 43% of Corgenix's total revenue.

Antiphospholipid antibodies are associated with the presence of both venous and arterial thrombosis (clotting), thrombocytopenia (low platelet count that can result in bleeding), and recurrent miscarriage. These antibodies are frequently found in patients with systemic lupus erythematosis (SLE), and other autoimmune diseases, as well as in some individuals with no apparent previous underlying disease. They are also found in patients with antiphospholipid syndrome, an important medical condition with serious clinical manifestations such as chronic and recurrent venous (deep vein) thrombosis, as well as arterial

thromboembolic disease, including heart attacks, strokes and pulmonary embolism. Thrombocytopenia has been attributed to the temporary removal of platelets from circulation during a thrombotic episode (clot formation). Corgenix manufactures and sells 11 antiphospholipid antibody testing products including aCL IgG, IgA, and IgM; anti-phosphatidylserine ("aPS") IgG, aPS IgA, aPS IgM; anti-B2-Glycoprotein I ("aB2GPI") IgG, aB2GPI IgA, and aB2GPI IgM; and anti-Prothrombin ("aPT") IgG and IgM.

A potential significant bright spot for Corgenix's vascular disease business is with its "AtherOx" technology. AtherOx is being developed as a novel technology utilizing oxidized low density lipoprotein (oxLDL) in the assessment of cardiovascular disease, the nations number one killer. AtherOx is currently in clinical trials with a potential FDA submission coming during calendar 2012. As there is only limited information related to development and potential for eventual FDA approval we do not currently include any contribution from AtherOx in our financial model.

o **Bleeding / Clotting risk tests (coagulation):** sales of bleeding / clotting tests fell almost 15% from 2010 to \$1.33 million in fiscal 2011, representing approximately 17% of Corgenix's total revenue.

In people that suffer from excessive clotting or bleeding, Corgenix's tests are used to help find the source of the disorder such as von Willebrand's Disease (Hemophilia B). Corgenix's portfolio of bleeding / clotting risks tests include Protein C Antigen ELISA, Protein S Antigen ELISA, Monoclonal Free Protein S ELISA, von Willebrand Factor Antigen ELISA, von Willebrand Factor Activity Test; abp Ristocetin, and Collagen Binding Assay. Corgenix manufactures 5 of the 20 bleeding / clotting tests and markets the other 15 which are manufactured by other companies.

We expect coagulation may be another area that holds future promise for Corgenix, especially as it relates to expansion into tests for other biological markers on ELITech's immunoturbidimetry testing platform.

AspirinWorks: sales of the AspirinWorks test were \$406k in fiscal 2011, representing approximately 5% of Corgenix's total revenue. The test is sold almost exclusively in North America. Sales of the test doubled from the \$202k posted in fiscal 2010 and are expected (per management's recent guidance) to double again in fiscal 2012 (to about \$800k) as additional customers adopt the test and existing customers place more orders. A 28% increase in reimbursement under existing CPT codes, which became effective in 2011, should also be a catalyst in driving demand for the test.

Approximately 25% of people are resistant to the benefits of aspirin, a daily dose of which is often recommended to reduce the risk of heart attack or stroke. AspirinWorks is a urine test and the only FDA-cleared test to help doctors accurately determine aspirin's effectiveness by measuring the levels of thromboxane in urine. The test can be administered at the point of care (i.e. - doctor's office) with results available within minutes, a significant advantage over blood sample tests that must be evaluated in a clinical lab. The test allows physicians to adjust aspirin dosage or prescribe different therapy for those individuals that show aspirin resistance. The AspirinWorks test was developed in conjunction with

AspirinWorks kit



SOURCE: www.aspirinworks.com

biotechnology company Creative Clinical Concepts and biochemical research products manufacturer Cayman Chemical Company. Certain technology patents covering the test are owned by McMaster University which granted Co

patents covering the test are owned by McMaster University which granted Corgenix exclusive rights to them.

Corgenix, in collaboration with Randox Laboratories, is also working on an automated version of the test which would run on clinical lab analyzers, affording high volume throughput. Corgenix expects to release further details on the progress of development of the automated test in the near future. We think the automated version could be commercialized before fiscal 2012 year-end and, in the future, provide a strong complement in growing the AspirinWorks franchise.

Liver Disease test: sales of the company's hyaluronic acid (HA), liver disease tests fell almost 19% from 2010 to \$783k in fiscal 2011, representing approximately 10% of Corgenix's total revenue. The test is used to measure the levels of hyaluronic acid in the blood to help assess the degree of liver fibrosis and cirrhosis in chronic liver disease. We expect revenue from this business to turn around and show positive growth in fiscal 2012 as a result of new product launches. Liver disease is another area where we think there is significant

upside potential from new products via the ELITech development agreement and a segment which we model to grow at a 20%+ annual rate over the next several years.

#### **R&D CONTRACTS / GRANTS**

Corgenix's contract development business currently covers two main areas; government contracts and grants which are mainly involved in infectious diseases, and a joint-development agreement with ELITech. Revenue from this segment increased 87% in fiscal 2011 to \$1.15 million. As R&D and grant revenue started to become more meaningful, during fiscal 2011 Corgenix began reclassifying related expenses from R&D expense to cost of goods sold (2011 10-K reflects this reclassification for 2011 as well as for 2010). R&D contracts / grants gross margin was 32% in 2011, compared to approximately 52% for the remainder of Corgenix's combined businesses.

■ Government Contracts / Grants: These are typically one to three year contracts. Corgenix serves as a sub-contractor to Tulane University for several NIH funded grants and contracts related to development of diagnostics, vaccines and therapeutics for hemorrhagic fever viruses. Corgenix serves as the principal investigator for a \$600k NIH funded two-year contract to develop recombinant diagnostic tests for the filoviruses (Ebola and Marburg), and has engaged three subcontractors (Tulane University, Autoimmune Technologies and the Scripps Research Institute) to assist in the development. Ebola and Marburg viruses are indigenous to Africa, cause hemorrhagic fever and can be fatal. Development of these tests are still in the early stages.

The company, along with Tulane and other collaboration partners, are also working on development of Lassa virus test kits as part of an NIH grant. Lassa virus, spread by rodents and potentially fatal, is endemic in parts of Africa. The Lassa kits are currently being used in clinical trials in Africa, which could wrap up by calendar year-end 2012, followed by regulatory submissions. The regulatory process is expected to be relatively simple and commercial sales in Africa could potentially commence by early 2013. Corgenix has rights to manufacture and market these infectious disease tests upon gaining all the requisite approvals - upon commercialization, sales will flow through ELITech (international distributor). While sales of tests for infectious diseases related to developing countries may not offer much in the way of significant revenue for Corgenix, the company's capabilities in developing these tests should bode well for procuring additional government grants.

In an effort to continue to grow this business, Corgenix regularly submits for additional government grants (related to both infectious diseases and bio-terrorism) and recently indicated that they are in discussions with a number of other potential R&D contract partners that could materialize in the future (no timeline was offered). We model this segment to grow at a low double-digit to mid-teens annual rate over the next several years as a result of new government contracts and the ELITech deal (described below).

■ ELITech Joint Product Development Agreement: The ELITech Group (ELITech) is a worldwide manufacturer and distributor of IVD equipment, chemical analyzers and reagents. ELITech distributes diagnostic products for clinical chemistry, microbiology, immunology, and molecular biology through its own sales force as well as a distribution network to over 100 countries.

ELITech also serves as Corgenix's international master distributor and is the company's largest shareholder. In 2010 Corgenix entered into a product co-development agreement with ELITech called the Joint Product Development Agreement. In July 2011 the agreement was amended and extended until July 2014 (with options to extend it further). The current agreement has two phases; Phase I entails modification of Corgenix's existing assay technology for use in ELITech's analyzers (testing instruments) while Phase II is focused on the development of new Corgenix Immunoturbidimetry (IT) assays for use in ELITech analyzers.

Corgenix recently began beefing up their manufacturing capabilities to support production of these new assays. When commercialized, Corgenix will manufacture and sell the assays to ELITech (for sales overseas) and will also have the option of selling derivatives of the assays in North America. Corgenix expects to begin selling new assays developed under this agreement in the very near-term and noted on the Q4 2011 call that the ELITech product development agreement will be a catalyst to growing the R&D contracts segment's revenue in 2012 and should provide in excess of \$1.5 million (over the next few years).

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In conjunction with the original (2010) joint development agreement, Corgenix and ELITech (along with Wescor, a wholly owned subsidiary of ELITech) entered into a Common Stock Purchase agreement. Among other terms (which we detail later) Wescor is required to purchase 3.33 million shares of CONX's common stock for an aggregate \$500k (\$0.15 / share) upon the successful completion of two new Corgenix assays (related to the joint development agreement). Wescor will also receive a warrant to purchase 1.67 million CONX shares at \$0.15 / share. Wescor bought the 3.33 million shares on September 15, 2011. Management noted on the Q4 call (9/23/2011) that development of the two products has been completed and that they are now preparing for the launch - when that time comes they will announce exactly what these two products are.

Corgenix expects to continue pumping out new products on a regular basis through their partnership with ELITech and has indicated several tests are under development and could reach commercialization in the not-too-distant future. We expect new products through this deal, coupled with ELITech's significant international distribution reach, to be a significant driver of Corgenix's revenue (including reviving sales of the vascular disease segment) over the next several years.

#### **CONTRACT MANUFACTURING**

CONX provides contract manufacturing services to other medical diagnostic companies. Their most significant contract manufacturing customer is BG Medicine, a Boston, MA based biotechnology company. While revenue from this segment can be somewhat irregular from period-to-period (i.e. - quarter-to-quarter as well as year-to-year) as a result of contracts churn, as this business has historically accounted for only a small portion of total revenue (~5% - 7%), this volatility has only a relatively minor impact on Corgenix's financial performance.

Earlier in fiscal 2011 management had projected revenue from this business to come in at about \$350k in Q4 2011. This fell short by \$129k (actual Q4 contract manufacturing revenue was \$221k) as a result of unexpected shortages of certain raw materials which was the major reason behind the 21% drop in revenue for the full year through 2011. Corgenix expects contract manufacturing revenue to significantly rebound in 2012, however, as a result of an increase in business under existing accounts and commencement of activity under recently signed contracts. Corgenix is also in the midst of expanding their testing platforms (from almost exclusively ELISA to also focusing on immunoturbidimetry and lateral flow) which not only broadens their potential customer base, it also allows them to hold onto existing clients that switch between testing platforms.

#### **ELITECH AGREEMENTS / INTERNATIONAL TRANSITION**

In July 2010 Corgenix and ELITech / Wescor entered into an agreement calling for Wescor to purchase a stated value of CONX common stock on three separate occasions. Two of the three stock purchases were contingent on Corgenix meeting pre-specified milestones.

The first purchase came in July 2010 in the amount of \$1.25 million for 8.33 million shares of common (\$0.15 / share). Wescor also received warrants to purchase 4.17 million shares at a \$0.15 strike. In conjunction with closing of this first tranche, the companies entered into a Master Distribution Agreement and the aforementioned Joint Product Development Agreement (the latter which we explained previously) - terms of the Master Distribution Agreement stated that closing of the second tranche was contingent on ELITech becoming Corgenix's exclusive international distributor.

The second tranche, an investment of \$250k for 1.67 million shares (also included warrants for 833k shares @ \$0.15 strike), closed in October 2010, commensurate with the transfer of Corgenix's international distribution activity

(handled by Corgenix UK) over to ELITech. Corgenix took a \$486k charge in fiscal 2011 related to the shuttering of Corgenix UK.

The third and final tranche, as discussed earlier, was for an investment of \$500k for 3.33 million shares (along with warrants to purchase 1.67 million shares @ \$0.15) and contingent upon the successful completion of two new Corgenix assays (per terms of the First Amended Joint Product Development Agreement). Wescor bought the 3.33 million shares on September 15, 2011. Management noted on the Q4 call (9/23/2011) that development of the two products has been completed and that they are now preparing for the launch - when that time comes (expected to be imminent) they will announce exactly what these two products are.

#### FINANCIAL CONDITION

Corgenix recently paid off debt, repurchased preferred shares, received the third tranche investment from ELITech and brought on a revolving credit facility which, in aggregate, has significantly cleaned up their balance sheet, reduced interest expense, and strengthened cash and liquidity positions. This, coupled with (expected) positive cash generation from here on out, bodes well for increasing CONX's book value (as well as market value) which should, at the very least, offer investors in CONX's common stock even greater downside protection (shares currently trade barely above book value as it is now).

#### Cash

As of their most recent reporting period (6/30/2011) Corgenix had \$1.1 million in cash and equivalents. Pro forma for the \$500k received (on 9/16/2011) from Wescor related to the third tranche investment, cash balance was \$1.6 million. Additional liquidity is provided by a two-year, \$1.5 million revolver which Corgenix secured in July 2011 (a portion of which was used to pay off a receivables loan). Cash used in operations was \$402k through the twelve months ending 6/30/2011. Management's financial guidance includes an expectation that the company will generate positive cash flow for the fiscal year ending 6/30/2012.

#### Debt

Total debt at 6/30/2011 was relatively minor at \$164k (\$98k short-term, \$66k long term) and consisted of a prime+2.0% note maturing August 2012 (\$57k balance), a prime+2.75% note maturing September 2012 (\$25k balance) and a 8.63% installment loan (to finance the upgrade of CONX's accounting software) maturing February 2014 (\$82k balance).

Corgenix also had a \$791k liability related to borrowings against certain of its accounts receivable through a Summit Financing Agreement and carries a balance of \$164k on an inventory loan, representing additional borrowings from Summit, the maximum borrowing amount which is determined by Corgenix's inventory value. The accounts receivable-related borrowings were subsequently repaid through a draw on the revolver - described below.

In July 2011 Corgenix secured a two-year revolving credit facility through LSQ Funding Group. Terms of the loan allow Corgenix to draw up to the lesser of \$1.5 million or 85% of "eligible accounts plus 50% of eligible inventory". Interest accrues at 0.043% per day (16.99% annualized) and any balance on the loan is due in full July 2013.

#### **Preferred Stock**

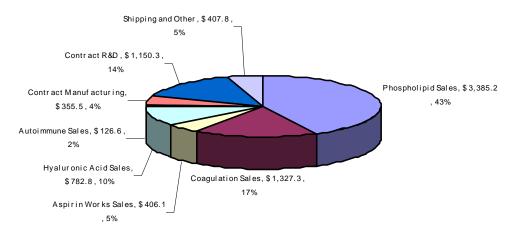
Corgenix repurchased 200k preferred shares for \$50k during fiscal 2011 (October 2010). At 6/30/2011 37k shares of preferred stock valued at \$10.5k was outstanding. The 37k shares are convertible into 146k shares of common stock (\$0.25 strike price).

#### 2011 FINANCIAL RESULTS

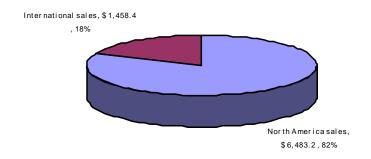
Corgenix breaks out revenue by geography (North America and International) as well as by source (phospholipid, coagulation, contract R&D, etc.). North America and International accounted for 82% and 18% of total revenue in 2011, respectively. The company also references OEM products (sold to other companies who then resell them under their own brand names), sales of which account for approximately 18% of phospholipid and coagulation

product revenue. While management has indicated that they expect OEM product sales to decline as a percentage of total revenue going forward, we think the phospholipid and coagulation categories (i.e. - vascular business), which combined account for ~ 60% of Corgenix's revenue, will return to (moderate) growth in fiscal 2012.

## 2011 Revenue By Source



## **2011 Revenue By Geography**



#### Revenue

Revenue was \$7.94 million in 2011, down 3.8% from the \$8.26 million posted in 2010. While North America revenue increased 8.1% (from \$6.0MM to \$6.48MM), international sales fell 35.5% (from \$2.26MM to \$1.46MM).

Of the eight revenue source categories, only two posted positive growth. While Corgenix does not itemize North America and International sales by revenue source (i.e. - phospholipid international revenue versus phospholipid North America revenue, etc.), it can be inferred that the relative strength in North America revenue was mostly due to a combination of the two categories that did show positive growth; AspirinWorks (101% growth, +\$204k) and R&D Contract revenue (87% growth, +\$535k), partially offset by softness in some of the older product lines - most notably, phospholipid and coagulation which combined fell 9% (-\$466k).

Meanwhile, weakness in International was attributed to the transfer of operations from Corgenix UK to ELITech, which happened in October 2010 (~ 9 months prior to fiscal 2011 year-end). Corgenix indicated that while the changeover caused an approximate \$700k hiccup in sales in fiscal 2011 (just prior to the transfer, International sales were at an annualized run-rate of about \$2.1MM), there were no significant customer defections and International revenue should begin to rebound in fiscal 2012 and grow at double-digit rates thereafter. We think it's safe to assume that a reduction in OM (captured in the "Shipping and Other" category) revenue due to discontinuation of some products resulting from the international reorganization along with a decline in sales of OEM phospholipid and coagulation products represented the bulk of the decrease in International revenue in 2011.

Noteworthy is that while total revenue fell for the full year, Q4 2011 revenue increased by 14.1% over the same period 2010, reflecting a very strong rebound in Contract Manufacturing revenue and continued robust growth from AspirinWorks and Contract R&D - all of which we expect will be a continuing trend in 2012.

	<b>FY 2010</b>	<b>FY 2011</b>	<b>Change</b>	<u>Q4 '10</u>	<u>Q4 '11</u>	<b>Change</b>
Phospholipid Sales	\$3,621.4	\$3,385.2	-6.5%	\$890.2	\$851.8	-4.3%
Coagulation Sales	\$1,556.7	\$1,327.3	-14.7%	\$378.6	\$340.7	-10.0%
Aspirin Works Sales	\$202.4	\$406.1	100.7%	\$63.4	\$134.5	112.2%
Hyaluronic Acid Sales	\$965.4	\$782.8	-18.9%	\$276.0	\$207.5	-24.8%
Autoimmune Sales	\$169.8	\$126.6	-25.4%	\$31.7	\$25.5	-19.5%
Contract Manufacturing	\$448.3	\$355.5	-20.7%	\$102.4	\$220.9	115.8%
Contract R&D	\$614.5	\$1,150.3	87.2%	\$188.3	\$466.0	147.5%
Shipping and Other	\$679.7	\$407.8	-40.0%	\$127.3	\$101.7	-20.2%
North America sales	\$5,996.3	\$6,483.2	8.1%	\$1,502.1	\$2,044.3	36.1%
International sales	\$2,261.8	\$1,458.4	-35.5%	\$555.7	\$304.1	-45.3%
<b>Total Revenue</b>	\$8,258.2	\$7,941.6	-3.8%	\$2,057.7	\$2,348.5	14.1%

#### **Gross Margin**

Gross margin was 49.5% in 2011, down 170 basis points from the 51.2% posted in 2010. As R&D Contract revenue started to become more meaningful, during fiscal 2011 Corgenix began reclassifying related expenses from R&D expense to cost of goods sold (2011 10-K reflects this reclassification for 2011 as well as for 2010). The company also began breaking out gross margin related to this business versus that for their "core" business (i.e. - everything other than R&D Contract). 2011 core margin was 52.4% with R&D Contract margin at 32%. Corgenix did not disclose what these two components of gross margin were in fiscal 2010, although it appears the 87% growth in lower margin Contract R&D revenue likely had the most influential impact on overall gross margin falling year-over-year. Core margin may have also contracted some due to international sales being handled 100% by an outside distributor (ELITech), resulting in less at the margin for Corgenix. However, narrowing in gross margin was at least somewhat offset by a reduction in operating expenses related to shedding ongoing costs related to Corgenix UK. While we think gross margin may slightly contract again in fiscal 2012, we look for this to stabilize in 2013.

Fiscal 2011	Core	<b>R&amp;D Contract</b>	TOTAL
Revenue	\$6,791.3	\$1,150.3	\$7,941.6
Related COGS	<u>\$3,230.5</u>	<u>\$781.9</u>	<u>\$4,012.4</u>
Related Gross Profit	\$3,560.8	\$368.4	\$3,929.2
<b>Related Gross Margin</b>	52.4%	32.0%	49.5%

#### **Operating Expenses**

Corgenix took a \$486k charge in 2011 related to the shuttering of Corgenix UK. Excluding this one-time expense, operating expenses were \$3.58 million, equal to 45% of revenue. This compares to \$3.90 million in 2010, equal to 47% of revenue. The majority of the year-over-year decline is a result of shedding costs related to Corgenix UK (which management noted were running at about \$750k annually).

Operating income was (\$136k), down slightly from \$329k in 2010. Management expects this to come back to positive territory in 2012 from a combination of a very significant ramp in revenue and slightly greater leverage in operating expenses (which we think may be partially offset by lower gross margin).

Corgenix also recently cleaned up their balance sheet and eliminated borrowings against their A/R which dropped interest expense from \$321k in 2010 to \$258k in 2011. We model interest expense to come down further in 2012 which, by itself, should result in another ~ \$100k flowing to the bottom line.

#### **OUTLOOK**

Corgenix is in the midst of what we believe to be the front-end of a transition away from reliance on certain legacy vascular disease tests to a greater focus on faster-growth segments and products. The recent transfer of their international sales operation and consummation of the related amended co-development agreement with ELITech offers Corgenix additional opportunity to develop novel high-potential products and significantly expands their sales and distribution reach. While the domestic business will likely be the greatest initial beneficiary (via Contract R&D revenue), the ELITech partnerships should provide especially strong support for international sales growth over the longer-term (via new product launches and ELITech's sales network).

In addition, segments that have been productive and growing (such as AspirinWorks and Contract R&D) or at least have reasonable potential to make meaningful contributions in the future (such as Contract Manufacturing), will continue to be nurtured and expanded. The company has already begun adding headcount to its R&D and domestic sales teams in anticipation of new business and increased demand.

#### **North America**

We model North America sales of \$8.35 million in fiscal 2012, implying growth of almost 29% (+\$1.87MM) from 2011. The major drivers being AspirinWorks (+\$394k), Contract Manufacturing (+\$944k) and Contract R&D (+\$250k). AspirinWorks sales, which doubled in fiscal 2011, are (based on management's guidance) expected to (approximately) double again in 2012 as a result of additional customers adopting the test and existing customers placing more orders. While the automated version of the test could possibly make it to market during 2012, as the test may not launch until later in the year, we think little of the ~\$800k sales guidance is related to sales of this test. Meanwhile Contract R&D revenue should get a very meaningful boost from products being developed under the ELITech joint product development agreement as well as ongoing government sponsored infectious disease contracts. We expect Contract Manufacturing, which saw revenue dive 21% in fiscal 2011, to do an about-face in 2012 from increased business from current customers (BG Medicine) as well as contracts from new customers.

Going into 2013 through 2015 (the furthest out that we model), AspirinWorks should remain a significant catalyst to North America-related sales growth. Corgenix views AspirinWorks as a very high potential product and clearly believes that the tests (including the automated version) can become a major contributor to overall revenue over the next several years. We also look for consistent revenue growth from Contract R&D and Contract Manufacturing, both of which should directly benefit from Corgenix expanding their testing platforms (from almost exclusively ELISA to also focusing on immunoturbidimetry and lateral flow). The ELITech development agreement will continue to provide at least a base amount of Contract R&D revenue throughout the next few years. Corgenix will also hopefully be able to leverage their capabilities in infectious disease-related test development to secure additional government contracts (in areas such as infectious disease and bio-terrorism) to facilitate further growth of their Contract R&D business.

#### International

We model International sales of \$1.73 million in fiscal 2012, implying growth of approximately 18% (+\$267k) from 2011. This growth is mostly a function of a lack of disruption (that occurred in 2011) from the international business transition than it is from any fundamental growth in product demand. We do expect to see some contribution in 2012 from the two new products developed under the ELITech agreement that have been completed but not yet launched. These two tests, along with what we expect to be a fairly regular flow of new products coming out of the ELITech development agreement, is what we expect to be a major impetus for growth of international revenue over the next several years. ELITech's distribution network provides greater reach than did Corgenix UK, which should afford a steeper sales ramp of new products and increase potential peak revenue. We think the ELITech partnership could end up being a big winner for Corgenix and revive sales in the vascular disease and HA businesses as well as play a key role in building their budding infectious disease area - including sales of these tests as well as helping secure new R&D contracts.

Despite what we expect to be very robust sales growth in North America, we model international revenue growth to outpace that of domestic sales beginning in 2013, which largely reflects our expectation that new product launches begin to gain significant sales traction towards the back half of 2012 or early 2013.

#### Revenue

We model \$10.1 million in revenue in fiscal 2012 which is very much in-line with management's financial guidance ("sales approaching or exceeding \$10 million, along with a positive bottom line, increased EBITDA and internally generated cash flow") which was provided on the Q4 earnings call (September 23, 2011).

Looking forward from 2012 we model revenue to grow at a CAGR of almost 14% through 2015, reflecting North America and International annual revenue growth of approximately 12% and 19%, respectively.

#### **Gross Margin**

We think gross margin will continue to narrow during the current fiscal year due to a combination of continued strong growth in lower margin Contract R&D revenue and a full year of ELITech handling international sales (where as this was only about 9 months in fiscal 2011, following the October 2010 transition). We look for gross margin of 46% in 2012, down from 49.5% in 2011.

We look for gross margin to stabilize in 2013 at 46% and to continue to incrementally widen through 2015, mostly reflecting a reduced rate of growth of Contract R&D and Corgenix beginning to realize much more meaningful economies of scale from higher production volumes.

#### Income / EPS

We model net income of approximately \$300k (\$0.01 EPS) in 2012, an increase of over \$700k from the ~ -\$400k (-\$0.01) posted in fiscal 2011. This reflects our ~27% estimated growth in revenue and incremental operating expense leverage, slightly offset by a 350 basis point contraction in gross margin.

We expect Corgenix to continue to gain leverage in operating expenses going forward and, coupled with strong revenue growth and incremental widening of gross margin, to result in EPS showing consistent year-over-year improvement. We look for EPS of \$0.03 in 2015.

### **VALUATION**

Our comparable cohort used to value CONX consists of several companies in the medical diagnostic testing space, some of which are considered direct competitors to Corgenix. Our valuation methodology uses the average of four metrics; price-to-2015 estimated EPS, price-to-book value, price-to-sales (trailing 12 months), and enterprise value-to-sales (trailing 12 months).

Based on these four metrics, Corgenix is valued between \$0.36/share (based on an average 3.4x book value multiple) and \$0.61/share (based on an average 3.1x sales multiple). Our other two metrics value the company at \$0.46/share (based on average 2015 P/E multiple of 15.5x) and \$0.55/share (based on average EV/sales multiple of 2.8x). Average valuation based on these four metrics is almost exactly \$0.50/share which, based on CONX's current market price of approximately \$0.13/share, indicates the stock is significantly undervalued. As such we recommend accumulating the stock and are initiating coverage of Corgenix with an Outperform rating.

Ticker	Est Long-term EPS growth	Implied 2015 P/E	Price / Book Value	Price / Sales (ttm)	EV / Sales (ttm)
IVD	NA	NA	1.6	1.2	0.9
DIA.MI	14.9%	8.1	NA	NA	3.4
OSUR	NA	NA	4.1	5.6	4.7
TRIB	14.7%	8.3	1.4	2.8	1.8
CEMI	18.9%	26.2	4.4	1.6	1.5
SRLS	18.2%	8.2	1.4	1.2	0.8
IDXX	13.2%	16.2	6.7	3.5	3.5
VIVO	14.9%	12.7	5.0	4.5	4.3
QDEL	9.0%	25.2	3.0	3.7	3.6
ABAX	11.2%	19.2	3.2	3.8	3.3
Average	14.3%	15.5	3.4	3.1	2.8

	Value using	Value using	Value using	EV using	Value using	
	2015 Comp	Comp	Comp			
	<u>P/E</u>	Price/Book	<u>Price/Sales</u>	Comp EV/Sales	Comp EV/Sales	AVG
CONX	\$0.46	\$0.36	\$0.61	\$22.08	\$0.55	<b>\$0.50</b>

#### **KEY PERSONNEL**

#### **Douglass Simpson, President/CEO**

Douglass T. Simpson has been the President of Corgenix since May 1998 and was elected a director in May 1998. Mr. Simpson joined Corgenix's operating subsidiary as Vice President of Business Development in 1992, was promoted to Vice President, General Manager in 1995, to Executive Vice President in 1996, to President in February 1998 and then to Chief Executive Officer in April 2006. Prior to joining Corgenix's operating subsidiary, he was a Managing Partner at Venture Marketing Group in Austin, Texas, a health care and biotechnology marketing firm, and in that capacity, served as a consultant to REAADS from 1990 until 1992. From 1984 to 1990 Mr. Simpson was employed by Kallestad Diagnostics, Inc. (now part of BioRad Laboratories, Inc.), one of the largest diagnostic companies in the world, where he served as Vice President of Marketing, in charge of all marketing and business development. Mr. Simpson holds B.S. and M.S. degrees in Biology and Chemistry from Lamar University in Beaumont, Texas.

#### William Critchfield, SVP Operations & Finance/CFO

William H. Critchfield has been Senior Vice President Operations and Finance and Chief Financial officer since April 2011, was the Senior Vice President Finance and Administration and Chief Financial Officer of the Company since April 2006, and was Vice President and Chief Financial Officer from December 2000 to April 2006. Prior to joining Corgenix, Mr. Critchfield was Executive Vice President and Chief Financial Officer of U.S. Medical, Inc., a Denver, Colorado based privately held distributor of new and used capital medical equipment. From May of 1994 through July of 1999, he served as President and Chief Financial Officer of W.L.C. Enterprises, Inc., a retail business holding company. From November 1991 to May 1994, Mr. Critchfield served as Executive Vice President and Chief Financial Officer of Air Methods Corporation, a publicly traded company which is the leading U.S. company in the air medical transportation industry and is the successor company to Cell Technology, Inc., a publicly traded biotechnology company, where he served in a similar capacity from 1987-1991. From 1986 through September 1987 he served as Vice President of Finance and Administration for Biostar Medical Products, Inc., a developer and manufacturer of diagnostic immunoassays. In the past, Mr. Critchfield also served as Vice President of Finance for Nuclear Pharmacy, Inc., formerly a publicly traded company and the world's largest chain of centralized radiopharmacies. Mr. Critchfield is a certified public accountant in Colorado. He graduated magna cum laude from California State University-Northridge with a Bachelor of Science degree in Business Administration and Accounting.

#### Luis Lopez, M.D.

Luis R. Lopez, M.D., served as the Chief Executive Officer and Chairman of the Board of Directors of Corgenix from May 1998 until April 2006 when his title was changed to Chairman of the Board of Directors and Chief Medical Officer. In July 2009, Dr. Lopez stepped down from his role as Chairman. From 1987 to 1990, Dr. Lopez was Vice President of Clinical Affairs at BioStar Medical Products, Inc., a Boulder, Colorado diagnostic firm. From 1986 to 1987 he served as Research Associate with the Rheumatology Division of the University of Colorado Health Sciences Center, Denver, Colorado. From 1980 to 1986 he was Professor of Immunology at Cayetano Heredia University School of Medicine in Lima, Peru, during which time he also maintained a medical practice with the Allergy and Clinical Immunology group at Clinica Ricardo Palma in Lima. From 1978 to 1980 Dr. Lopez held a fellowship in Clinical Immunology at the University of Colorado Health Sciences Center. He received his M.D. degree in 1974 from Cayetano Heredia University School of Medicine in Lima, Peru. He is a clinical member of the American College of Rheumatology, and a corresponding member of the American Academy of Allergy, Asthma and Immunology. Dr. Lopez is licensed to practice medicine in Colorado, and is widely published in the areas of immunology and autoimmune disease.

#### Ann Steinbarger, SVP Sales & Marketing

Ann L. Steinbarger has been the Senior Vice President of Sales & Marketing since April 2011, was the Senior Vice President of Operations from April 2006 to April 2011 and was the Vice President of Sales and Marketing from May 1998 to April 2006. Ms. Steinbarger joined Corgenix's operating subsidiary in January 1996 as Vice President, Sales and Marketing with responsibility for its worldwide marketing and distribution strategies. Prior to joining Corgenix, Ms. Steinbarger was with Boehringer Mannheim Corporation, Indianapolis, Indiana, a \$200 million IVD company. At Boehringer from 1976 to 1996, she served in a series of increasingly important sales management positions. Ms. Steinbarger holds a B.S. degree in Microbiology from Purdue University in West Lafayette, Indiana.

#### Taryn G. Reynolds, VP Facilities and IT

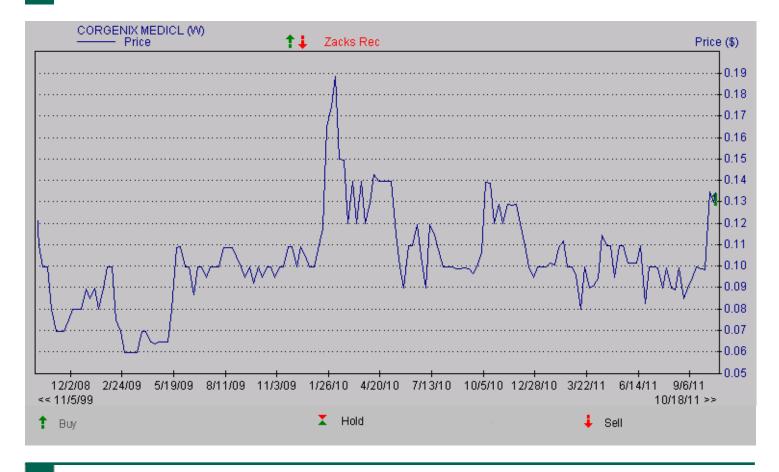
Taryn Reynolds has been a Vice President of Corgenix since May 1998. Mr. Reynolds joined Corgenix's operating subsidiary in 1992, serving first as Director of Administration, then as Managing Director, U.S. Operations. He has served as Vice President, Operations and in 1999, became Vice President, Facilities and Information Technology. Prior to joining Corgenix, Mr. Reynolds held executive positions at Brinker International, MJAR Corporation and M&S Incorporated, all property, operational and financial management firms.

## FINANCIAL MODEL

## **Corgenix Medical Corporation**

	2011 A	Q1E	Q2E	Q3E	Q4E	2012 E	2013 E	2014 E	2015 E
North America sales	\$6,483.2	\$2,028.0	\$2,064.0	\$2,125.0	\$2,131.0	\$8,348.0	\$9,655.0	\$10,780.0	\$11,858.0
y-o-y growth	8.1%	38.5%	45.4%	36.7%	4.2%	28.8%	15.7%	11.7%	10.0%
International sales	\$1,458.4 -35.5%	\$395.0 -23.1%	\$400.0 9.1%	\$445.0 62.4%	\$485.0 59.5%	\$1,725.0 18.3%	\$2,050.0 18.8%	\$2,475.0 20.7%	\$2,922.0 18.1%
y-o-y growth Revenue	\$7,941.6	\$2,423.0	\$2,464.0	\$2,570.0	\$2,616.0	\$10,073.0	\$11,705.0	\$13,255.0	\$14,780.0
YOY Growth	-3.8%	22.5%	38.0%	40.5%	11.4%	26.8%	16.2%	13.2%	11.5%
Cost of Goods Sold	\$4,012.4	\$1,314.9	\$1,332.9	\$1,385.8	\$1,408.3	\$5,441.8	\$6,317.1	\$7,018.6	\$7,508.5
Gross Income	\$3,929.2	\$1,108.1	\$1,131.1						
Gross Margin	49.5%	<b>\$1,100.1</b> 45.7%	<b>\$1,131.1</b> 45.9%	\$1,184.2 46.1%	\$1,207.7 46.2%	\$4,631.2 46.0%	\$5,387.9 46.0%	\$6,236.4 47.0%	\$7,271.5 49.2%
Sales / Mktg	\$1,536.9	\$450.7	\$460.8	\$467.7	\$486.6	\$1,865.8	\$2,106.9	\$2,332.9	\$2,512.6
Sales / Wiking	19.4%	18.6%	18.7%	18.2%	18.6%	18.5%	18.0%	17.6%	17.0%
R&D	\$194.5	\$68.0	\$74.0	\$82.0	\$90.0	\$314.0	\$355.0	\$388.0	\$410.0
% R&D	2.4%	2.8%	3.0%	3.2%	3.4%	3.1%	3.0%	2.9%	2.8%
G&A	\$1,847.7	\$499.0	\$488.0	\$502.0	\$498.0	\$1,987.0	\$2,110.0	\$2,217.0	\$2,340.0
% G&A	23.3%	20.6%	19.8%	19.5%	19.0%	19.7%	18.0%	16.7%	15.8%
Disposal of assets	\$486.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$136.0)	\$90.5	\$108.4	\$132.5	\$133.1	\$464.4	\$816.0	\$1,298.5	\$2,008.9
Operating Margin	-1.7%	3.7%	4.4%	5.2%	5.1%	4.6%	7.0%	9.8%	13.6%
Other income (net)	\$0.9	\$0.8	\$0.8	\$0.8	\$0.8	\$3.2	\$4.0	\$7.0	\$10.0
Loss on extinguishment of debt	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Interest expense	(\$258.0)	(\$45.0)	(\$39.0)	(\$37.0)	(\$36.0)	(\$157.0)	(\$100.0)	(\$50.0)	\$0.0
Total other income	(\$257.1)	(\$44.2)	(\$38.2)	(\$36.2)	(\$35.2)	(\$153.8)	(\$96.0)	(\$43.0)	\$10.0
Pre-Tax Income	(\$393.1)	\$46.3	\$70.2	\$96.3	\$97.9	\$310.6	\$720.0	\$1,255.5	\$2,018.9
Taxes (benefit)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Preferred dividends	\$21.5	\$2.8	\$2.8	\$2.8	\$2.8	\$11.2	\$0.0	\$0.0	\$0.0
Income to common	(\$414.6)	\$43.5	\$67.4	\$93.5	\$95.1	\$299.4	\$720.0	\$1,255.5	\$2,018.9
Net Margin	-5.2%	1.8%	2.7%	3.6%	3.6%	3.0%	6.2%	9.5%	13.7%
EPS	(\$0.01)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.01	\$0.01	\$0.02	\$0.03
YOY Growth	674.1%	NA	NA	NA	NA	NA	84.6%	74.4%	60.8%
Diluted Shares O/S	40,153	50,000	55,000	55,000	58,000	54,500	71,000	71,000	71,000
				rckx, CFA					

#### HISTORICAL ZACKS RECOMMENDATIONS



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