Zacks Small-Cap Research

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# Cytrx Corp (CYTR-NASDAQ)

**CYTR: continues to make progress in advancing its pipeline--Outperform**

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | Neutral |
| Date of Last Change | 02/23/2012 |
| Current Price (03/09/12) | $0.33 |
| **Twelve-Month Target Price** | **$1.35** |

## OUTLOOK

CytRx is a biopharmaceutical company with a focus on oncology. The Company has three candidates in middle to late stage development targeting various cancer indications. The most advanced candidate is tamibarotene which is in a pivotal clinical trial for acute promyelocytic leukemia (APL). The combined market opportunity for CytRx's pipeline is huge. The Company's strategy is to develop drugs with known mechanisms of action which will minimize operational risks. CytRx is well capitalized with a strong balance sheet which sets it apart from its peers. Current valuation is low based on the Company's fundamentals. Therefore, we assign a market Outperform rating on CytRx.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.99** |
| **52-Week Low** | **$0.26** |
| **One-Year Return (%)** | **-61.64** |
| **Beta** | **1.43** |
| **Average Daily Volume (sh)** | **1,088,023** |
| **Shares Outstanding (mil)** | **148** |
| **Market Capitalization ($mil)** | **$49** |
| **Short Interest Ratio (days)** | **0.55** |
| **Institutional Ownership (%)** | **12** |
| **Insider Ownership (%)** | **8** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2011 Estimate** | **N/A** |
| **P/E using 2012 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Avg.,** |
| **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) |
|---|---|---|---|---|---|
| 2010 | 0.00 A | 0.00 A | 0.00 A | 0.10 A | 0.10 A |
| 2011 | 0.00 A | 0.15 A | 0.00 A | 0.00 E | 0.15 E |
| 2012 | | | | | 0.00 E |
| 2013 | | | | | 2.73 E |

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2010 | -$0.04 A | -$0.05 A | -$0.04 A | -$0.02 A | -$0.14 A |
| 2011 | -$0.06 A | -$0.03 A | -$0.04 A | -$0.04 E | -$0.17 E |
| 2012 | | | | | -$0.19 E |
| 2013 | | | | | -$0.19 E |

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

## WHAT'S NEW

### *CytRx is Making Progress in Advancing its Pipeline*

#### *An international Phase IIb trial of INNO-206 initiated for soft tissue sarcoma*

On December 22, 2011, CytRx announced that it has initiated an international **Phase IIb** clinical trial to evaluate the preliminary efficacy and safety of its tumor-targeting doxorubicin conjugate **INNO-206** in patients with late-stage **soft tissue sarcoma**.

The Phase IIb clinical trial will provide the first direct clinical trial comparison of INNO-206 with native doxorubicin, which is dose-limited due to toxicity, as a first-line therapy.

The Phase IIb clinical trial with INNO-206 in patients with soft tissue sarcomas is an international trial under the direction of Sant P. Chawla, M.D., F.R.A.C.P., Director of the Sarcoma Oncology Center in Santa Monica, Calif. Dr. Chawla also is acting as principal investigator for the Company's ongoing Phase Ib/II clinical trial with INNO-206.

The Phase IIb clinical trial's primary objectives are to measure the progression-free survival, tumor response and overall survival of patients with advanced soft tissue sarcomas treated with INNO-206. This clinical trial also will assess the safety of INNO-206 compared to doxorubicin in this patient population through a number of indicators, including the frequency and severity of adverse events.

The open-label trial will enroll 105 patients with metastatic, locally advanced or unresectable soft tissue sarcoma at approximately 30 study centers in the U.S., Hungary, Romania, Ukraine, Russia, India and Australia. Patients will be randomized into two groups with twice as many receiving INNO-206 as doxorubicin. Patients will be treated intravenously once every 21 days for up to eight consecutive cycles with INNO-206 administered drug at 350 mg/m2 (260 mg/m2 doxorubicin equivalents) and doxorubicin administered at 75 mg/m2.

Doxorubicin is currently the only FDA-approved drug on the market as a treatment for soft tissue sarcoma and is a standard chemotherapy for a variety of other cancers. It is used either alone or in combination with other chemotherapy agents. Dose levels of doxorubicin are limited due to its toxicity. INNO-206 is a novel conjugate of doxorubicin that binds covalently to albumin, and is circulated throughout the body. INNO-206 is designed with a linker that releases doxorubicin in the low pH environment of tumors, concentrating the chemotherapeutic agent where it preferentially damages the tumor while minimizing the effect on healthy tissues.

#### *Favorable results reported from initial Phase Ib/II trial of INNO-206*

The international Phase IIb trial is based on favorable Phase Ib/II trial.

In October 2011, CytRx announced positive results from the Company's ongoing **Phase Ib/II** clinical trial with **INNO-206** from a group of patients with advanced solid tumors, principally **soft tissue sarcomas**. The patients from the early portion of the trial were evaluated for tumor response after **four cycles** of INNO-206. Total of 24 patients will be enrolled in the Phase Ib/II trial.

Of five patients who have completed four cycles with INNO-206 at the maximum tolerated dose, one patient has exhibited a partial tumor response (greater than 30% tumor shrinkage) and four patients have stable disease. A large, painful oral sarcoma that caused difficulty eating in one patient was greatly reduced following a single INNO-206 treatment. Common side effects reported to date from the Phase Ib/II trial include low neutrophil and platelet counts, minor mouth ulcers and mild nausea, which are expected side effects of doxorubicin.

CytRx is currently enrolling additional patients who will be treated at that dose to gather further response data in parallel with the newly initiated **international Phase IIb** clinical trial.

We think the initial data for INNO-206 are impressive. Although these initial results are from a limited number of patients, the individuals treated were very advanced in their disease and had previously received multiple different chemotherapy agents, including doxorubicin. These early indications may bode well for the potential success of the international Phase IIb clinical trial in patients who have advanced disease but were not previously administered chemotherapy.

***Positive Phase II Clinical Results with Bafetinib Presented at ASH Conference***

CytRx presented positive results from the open-label, single-agent **Phase II ENABLE** proof-of-concept clinical trial, which demonstrates **bafetinib**'s clinical activity and preliminary safety in patients with relapsed or refractory B-cell chronic lymphocytic leukemia **(B-CLL)**, on December 12 at the 2011 ASH meeting.

The results were presented by Tapan Kadia, M.D., Department of Leukemia at the University of Texas, M.D. Anderson Cancer Center, in a poster session. CytRx also announced that the ENABLE abstract has been selected for inclusion in the Highlights of ASH® program for presentation in 2012 in ASH meetings in Austin, Orlando, Atlanta, Las Vegas, New York and San Francisco.

As a reminder, in May 2010, CytRx initiated a **Phase II** proof-of-concept clinical trial (ENABLE) with bafetinib as a **second line** treatment for B-CLL due to the potent and specific inhibitory properties of bafetinib against Lyn and Fyn kinases, which are overexpressed in B-CLL cancers.

In this clinical trial, high-risk B-CLL patients who have failed treatment with first-line agents will self-administer oral doses of bafetinib twice daily. The bafetinib dose used in this trial is based on the highest dose that was best tolerated in the Phase I study. Patients will be monitored for clinical response, time to disease progression and cancer progression-free survival. Total of 30 patients will be enrolled. The dose of bafetinib may be escalated to 360 mg twice daily if relatively few side effects are observed at the 240 mg twice daily dose. The endpoint of this Phase II trial is objective response rate (30% ORR is target). MD Anderson is the primary US site.

Each of the 18 late-stage B-CLL patients enrolled in the ENABLE trial had been treated with and failed between one and six therapies, with a median of three, and 14 of the 18 patients (87%) having unfavorable cytogenetics(del 17p; 13) . Patients were treated with orally administered bafetinib twice daily. Six of 12 (50%) of the evaluable patients achieved 30% or greater shrinkage of the lymph node and spleen, and four of 12 (33%) patients had stable disease.

Lymph node softening also was noted in these patients. Only one grade 3 or 4 adverse event (grade 3 elevated liver enzymes) was noted, which resolved when bafetinib administration was ceased. Grade 1 and 2 adverse events included elevated liver enzymes with normal bilirubin, fatigue and gastrointestinal symptoms. No serious adverse events (SAEs) were observed at the dose of 240 mg twice daily, which is the dose that would likely be used in any future clinical trials in chronic lymphocytic leukemia. Two patients remain in the trial, which is being conducted at the M.D. Anderson Cancer Center and City of Hope Medical Center.

CytRx is currently in discussions with potential partners to further advance bafetinib's clinical development as the Company focuses its clinical efforts on other two promising drug candidates, INNO-206 and tamibarotene.

The initial results are encouraging. The Phase II study demonstrated that bafetinib is clinically active in a group of patients with relapsed B-CLL who have failed several other treatments for their cancer. Based on this indication of clinical activity and the low incidence of adverse events, additional patients enrolled

in the ENABLE Phase II clinical trial will receive bafetinib as a single agent at a higher dose. This increased dosage could increase the potential for greater efficacy.

B-CLL is the most common form of leukemia in adults in Western countries. More than 17,000 new cases of B-CLL are reported in the United States alone each year; however up to an estimated 40% of cases may not be reported due to under-diagnosis and lack of placement in cancer registries. Virtually all patients are older than 55 years at presentation, with an average age of 70 years. Patients in the high-risk B-CLL classification have a median overall survival period of one to five years.

The progress CytRx has made so far to advance its pipeline is impressive and encouraging. We think the Company is heading in the right direction. With positive data for its lead candidates Bafetinib and INNO-206, the Company plans to expedite the development of these therapeutic programs. The preliminary positive data may also help the Company to land lucrative partnership deals in 2012.

In addition to a relatively strong pipeline, CytRx also has a relatively strong balance sheet which sets it apart from most small cap biotech companies in the industry. As of September 30, 2011, CytRx held cash, cash equivalents and marketable securities of $41.4 million. There was no debt on the balance sheet. Current liquidity source will be sufficient to fund operations for the foreseeable future, probably to the end of 2012 according to our financial model.

Based on the relatively strong fundamentals, we have an Outperform rating on CYTR. Of course, risk is also high for CYTR as for most other small biotech companies. Investors should balance their return expectations and risks in the context of portfolio.

## KEY POINTS

- We maintain our market Outperform rating on CytRx Corp and reiterate our 12-month price target of $1.35.
- CytRx is a biopharmaceutical company focused on cancer. The Company's pipeline consists of three candidates under middle to late stage development: tamibarotene, bafetinib and INNO-206, targeting various cancer indications.
- Tamibarotene is under a pivotal Phase II trial for acute promyelocytic leukemia (APL) and another Phase II trial for non-small cell lung cancer. Bafetinib is under a Phase II trial for B-cell CLL and a Phase II trial for prostate cancer and a Phase I trial for brain cancer.
- INNO-206 is currently under a Phase Ib/II trial, but the Company plans to initiate a Phase IIB trial for soft tissue sarcoma in December 2011. In addition, the Tumor Biology Center in Freiburg, Germany, plans to initiate a Phase II trial in advanced pancreatic cancer in 2H11. More importantly, the acid sensitive linker used by INNO-206 represents a platform technology which can be used by many different anticancer agents.
- All three oncology candidates have known mechanisms of action which minimize its clinical risks. More rapid indication of efficacy can be shown because clinical trials will treat patients with advanced cancers.
- Diversified oncology portfolio offers substantial market opportunities. The Company's combined portfolio targets multi-billion dollar cancer markets.
- CytRx is well capitalized with a strong balance sheet which sets it apart from most small cap biotech companies in the industry. As of September 30, 2011, CytRx had $41 million in cash/cash equivalents and marketable securities. There was no debt on the balance sheet as of September

30, 2011. Current liquidity source will be sufficient to fund operations for the foreseeable future, probably to the end of 2012 according to our financial model.

- Valuation is low for CytRx at its current market price based on the Company's fundamentals. Therefore we rate the Company's shares a market Outperform with a twelve-month price target of $1.35. Risks include clinical and regulatory uncertainties and potential competition for each of the Company's three cancer candidates.

## OVERVIEW

CytRx Corporation (NASDAQE: CYTR) is a biopharmaceutical company focused on the development and commercialization of human therapeutics for the treatment of **cancers**.

In September, 2008, CytRx completed its acquisition of Innovive Pharmaceuticals, Inc. Prior to the acquisition of Innovive, CytRx was focused on developing human therapeutics based primarily upon its small-molecule molecular chaperone amplification technology, including **arimoclomol** for ALS and stroke recovery and **iroxanadine** for diabetic foot ulcers and other potential indications. After the acquisition, CytRx redirected its focus from central nervous system disorders to oncology.

**Tamibarotene** is currently in a pivotal Phase II clinical trial for the treatment of acute promyelocytic leukemia (APL) and a Phase IIb trial for the treatment of non-small cell lung cancer (NSCLC). A Phase I/II combination trial with Trisenox is also underway for APL.

**Bafetinib** is currently in Phase II trials for refractory B-cell chronic lymphocytic leukemia (B-CLL) and advanced prostate cancer. Bafetinib is also in a Phase I clinical trial for brain cancer.

An abbreviated Phase Ib clinical trial is on-going with **INNO-206** for patients with advanced cancers including soft tissue sarcoma. Two Phase II clinical trials for INNO-206 are planned as a treatment for soft tissue sarcomas and pancreatic cancer following the abbreviated safety trial.

In addition to its core oncology programs, CytRx owns rights to drug candidates based on its molecular **chaperone regulation technology**, which are designed to repair or degrade mis-folded proteins associated with disease. The Company's current business strategy is to seek one or more strategic partnerships to pursue the development of this technology.

CytRx and four researchers in the field of RNAi founded RXi Pharmaceuticals Corporation (NASDAQ: RXII) in April 2006. In January 2007, CytRx transferred to RXi substantially all of its RNAi-related technologies and assets, and RXi began operating on a stand-alone basis for the purpose of accelerating the discovery of RNAi therapeutics. RXi's initial focus is on developing RNAi-based product candidates for treating neurological and metabolic disorders and cancer. It has since expanded into cancer vaccines.

Before early 2008, CytRx owned approximately 85% of the outstanding shares of common stock of RXi Pharmaceuticals. Since then, the Company has been reducing its ownership in RXi and sold its remaining number of shares of RXi common stock in December 2010 for approximately $6.9 million.

CytRx is a Delaware corporation, incorporated in 1985. The Company is headquartered in Los Angeles, California. As of March 11, 2011, CytRx had 15 employees, six of whom were engaged in clinical, regulatory and development activities and nine of whom were involved in management and administrative operations.

***Table 1: Development Pipeline***

| Technology | Product Candidate | Indication(s) | Stage of Development |
|---|---|---|---|
| **Synthetic retinoid** | Tamibarotene | Non-small-cell lung cancer | Phase IIb |
| | | APL (acute promyelocytic leukemia) | Pivotal Phase II |
| | Tamibarotene/Trisenox | APL | Phase I/II |
| **Tyrosine kinase inhibitor** | Bafetinib | B-CLL | Phase II |
| | | Advanced prostate cancer | Phase II |
| | | Brain cancer | Phase I |
| **Doxorubicin prodrug** | INNO-206 | Soft tissue sarcomas | Phase IIb |
| | | Pancreatic cancer | Phase II (2H11) |

*Source: Company filings*

## INVESTMENT THESES

***CytRx Reports Third Quarter 2011 Financial Results***

On Nov 08, 2011, CytRx Corporation (CYTR) reported financial results for the three months ended September 30, 2011.

There was no revenue for the third quarter of 2012.

Research and development (R&D) expenses were $3.2 million for the third quarter of 2011 and included development expenses for the Company's programs of $2.1 million for INNO-206, $0.3 million for bafetinib and $0.2 million for tamibarotene. R&D expenses were $2.8 million for third quarter of 2010.

General and administrative (G&A) expenses remained relatively unchanged at $1.7 million and $1.8 million for the third quarters of 2011 and 2010, respectively. G&A expenses included $0.2 million of employee stock option expense in both quarters.

CytRx reported a GAAP net loss of $0.6 million, or $0 per share, for the third quarter of 2011, which included a $4.3 million gain on warrant derivative liability related to warrants associated with past equity financings. For the third quarter of 2010, the net loss was $4.4 million, or $0.04 per share.

Non-GAAP net loss was $4.9 million or $0.04 per share.

CytRx reported cash, cash equivalents and marketable securities of $41.4 million as of September 30, 2011.

We believe investors are not concerned about the earnings release for CytRx. Right now all eyes are on the Company’s balance sheet and pipeline development. In this regard, we think CytRx has made great progress so far.

### *Tamibarotene for NSCLC and APL*

Tamibarotene is an orally available, synthetic retinoid rationally designed to overcome resistance and avoid toxic side effects of differentiation therapy with all-trans retinoic acid (ATRA), a component of the current first-line treatment for acute promyelocytic leukemia (APL).

CytRx has agreements with **TMRC Co. Ltd** of Japan for the license of patent rights held by TMRC for North American and European development and commercialization of tamibarotene. The license is exclusive, applies to all products that may be subject to the licensed intellectual property and may be used in the treatment of APL and non-small cell lung cancer (NSCLC). Under the agreement, CytRx must pay TMRC royalties based on net sales and make payments to TMRC in the aggregate of $4.165 million upon meeting clinical, regulatory, and sales milestones up to and including the first commercial sale of the product for the treatment of APL.

### *Tamibarotene for the treatment of NSCLC*

The true value for tamibarotene may rest on non-small cell lung cancer (NSCLC), a multi-billion dollar market opportunity. The rationale for developing tamibarotene for NSCLC is based on the following evidence.

A recent Phase II clinical trial published in the peer-reviewed Journal of Clinical Oncology (2010; 28: 3463-3471) compared ATRA added to a regimen of paclitaxel plus cisplatin to a regimen of paclitaxel plus cisplatin alone as a treatment for patients with advanced NSCLC. The group administered ATRA plus the chemotherapy agents showed improved response rates of 55.8% versus 25.4%, and increased progression-free survival of 8.9 months versus 6.0 months. Median overall survival was increased from 9.5 months to 23.5 months when ATRA was added to the above chemotherapy regimen, representing a 14-month median extension of life.

Tamibarotene was designed to overcome resistance to ATRA. In vitro, tamibarotene is approximately ten times more potent than ATRA, and tamibarotene has a lower affinity for cellular retinoic acid binding protein (CRABP). This should allow for sustained plasma levels during administration. This may enhance tamibarotene's potential efficacy, because patients may be able to experience benefits from the drug over a longer period of time. Tamibarotene does not bind the RAR-$\gamma$ receptor, the major retinoic acid receptor in the dermal epithelium, which should lessen the occurrence of skin toxicities.

Based on the above published results, in December 2010, CytRx initiated a randomized **Phase IIb** clinical trial, in which patients with stage IIIB (with pleural effusions) or stage IV **NSCLC** will be treated with up to six cycles of paclitaxel plus carboplatin and either tamibarotene or placebo (**first line**). The primary objective of the clinical trial is to determine the objective response rate (complete and partial responses) and progression-free survival. Secondarily, the study will evaluate overall survival, quality-of-life and the pharmacokinetics of tamibarotene in this population. The clinical trial, which is expected to enroll approximately 140 patients, is being conducted in 15 clinical sites in the U.S. and Mexico.

More than 220,000 new cases of lung cancer occur in the U.S. each year, and more than 1.5 million occur annually worldwide. Deaths due to lung cancer account for the majority of cancer-related deaths (180,000 in the U.S., 1.35 million worldwide) and the five-year survival ranges between 8%-15%. Non-small cell-lung cancer (NSCLC) accounts for 85%-90% of all lung cancers, with subsets adenocarcinoma representing 35%-40%, squamous cell carcinoma accounting for 25%-30% and large cell carcinoma accounting for 10%-15%.

The NSCLC is a mega-billion dollar market. Worldwide sales of anti lung cancer drugs will grow to $13.3 billion by 2015 according to Global Industry Analysts. 60% of NSCLC patients have stage IIIb/IV disease at diagnosis. In 2010, approximately 113,485 patients were diagnosed in the US with stage IIIb/IV. Therefore, market potential is huge for tamibarotene if it's successfully developed for the combination treatment of NSCLC.

***Tamibarotene for the treatment of APL***

Acute promyelocytic leukemia (APL) is a specific type of acute myeloid leukemia (AML) characterized by the t (15; 17) translocation, which fuses the promyelocytic leukemia (PML) gene on chromosome 15 to the retinoic acid receptor (RAR) $\alpha$ gene on chromosome 17. This fusion causes abnormal cell growth.

Differentiation therapy with ATRA is the basis for the treatment of APL. Differentiation therapy causes leukemic promyelocytes to mature and undergo cell death. Patients typically receive ATRA in combination with chemotherapy as the initial therapy, followed by anthracycline-based consolidation therapy designed to produce complete remission. The majority of patients treated this way generally experience a complete remission of disease. Current National Comprehensive Cancer Network guidelines recommend that patients then undergo one to two years of maintenance therapy with ATRA to prevent a recurrence. However, ATRA therapy is associated with several toxicities, the most serious of which, is **retinoic acid syndrome (RAS).** RAS, which occurs in up to 25% of patients treated with ATRA, is a serious and potentially fatal complication characterized by fever, dyspnea (breathing difficulties), weight gain, pulmonary infiltrates (abnormal accumulation in the lungs), and pleural or pericardial effusions (excess fluid around the lungs or heart).

Patients that initially respond to front-line therapy with ATRA plus chemotherapy sometimes relapse, and some of these patients fail to respond to a second course of treatment with ATRA. Currently, patients who fail ATRA-based therapy are treated with **Trisenox (arsenic trioxide)**, a compound administered intravenously and associated with significant toxicity, including irregular heartbeat. There currently is no standard of care for patients who do not respond to ATRA and arsenic trioxide, or who respond but subsequently relapse.

Tamibarotene was approved in Japan in 2005 under the brand name **Amnolake** for use in relapsed or refractory APL. The approval was based on data from two Phase II studies in Japanese patients. In the pivotal studies, tamibarotene was administered to 63 Japanese subjects with APL. Patients included individuals who had never received treatment for APL and patients who had been previously treated with ATRA. Tamibarotene was administered orally at a dose of 6 mg/m$^2$ /day for eight weeks. The overall complete response rate in these patients was 60%. In patients who had a recurrence of APL following ATRA therapy, the response rate was 81%. RAS was reported in three patients (7.3% of the patient group), much lower compared to 15-25% for ATRA.

Based on the Japan results, at the end of 2007, CytRx initiated a **pivotal Phase II** registration clinical trial of Tamibarotene for **APL** under a Special Protocol Assessment (SPA) with the FDA. The pivotal trial is called STAR-1, which is evaluating the efficacy and safety of tamibarotene as a **third-line treatment** for APL after ATRA and Trisenox. The STAR-1 trial is ongoing and currently includes six clinical sites in the U.S. The Company recently reported interim results at ASH 2009. Of the 11 patients enrolled in the STAR-1 trial then, three (27%) achieved a hematologic complete response, and five (45%) achieved a morphologic leukemia-free state.

Enrollment has been slow due to the rarity of this type of leukemia and the fact that the trial is treating patients that have failed other treatments. But CytRx has seen several patients respond dramatically to tamibarotene after failing multiple standard treatments for their APL. The total elimination of APL from a patient was reported in the peer-reviewed Journal of Clinical Oncology in April 2011. This report was astounding which support the ongoing APL clinical trial and Phase IIb NSCLC trial.

In addition, in September 2009, the Company initiated a **Phase I/II** dose escalation clinical trial with tamibarotene **combined with Trisenox** (arsenic trioxide) injection (marketed by Cephalon, Inc.) in patients with relapsed APL. This trial is sponsored by both CytRx and Cephalon. The objectives are to examine whether the combination of the two drugs is safe and a possible efficacy profile. This trial will also determine the appropriate doses for future trials testing the tamibarotene/Trisenox combination as a first-line treatment for patients not wanting exposure to anthracyclines. This is a multi-center Phase I/II

dose escalation trial that will enroll about 20 patients with relapse in three dose groups. The patients will be treated with either two or three six-week cycles of IV arsenic trioxide and self-administered oral tamibarotene tablets with 2-6 weeks between cycles. A total of 10 patients will be enrolled at the MTD, for one or two additional cycles of therapy, and the dose for the subsequent Phase II trial will be the dose at which at least 50-60% of the patients tolerate the treatment or the maximum dose used in this trial.

The FDA has granted Orphan Drug Designation for APL and Fast Track Designation for the use of tamibarotene with relapsed or refractory APL following treatment with ATRA and arsenic trioxide. In addition, tamibarotene has been granted orphan medicinal product status by the European Medicines Agency for the treatment of APL.

Currently, treatment of APL is based on induction and maintenance therapy with ATRA and chemotherapy (typically idarubicin). ATRA and idarubicin are both generic compounds. Arsenic trioxide, currently marketed by Cephalon, is approved for use in patients who have relapsed after ATRA-based therapy in APL. There are no FDA-approved therapies for patients who have failed arsenic trioxide. In practice, it appears that patients who fail arsenic trioxide are retreated with ATRA. Tamibarotene is the only candidate in clinical development for refractory APL so far.

Peak sales of tamibarotene could reach $150 million in the US.

### *Bafetinib for Various Cancers*

**Bafetinib** (formerly INNO-406) is an oral novel drug developed by the Japanese pharmaceutical company Nippon Shinyaku, to overcome some of the limitations of Gleevec and other tyrosine kinase inhibitors in resistant chronic myelogenous leukemia (CML). Bafetinib is a rationally designed inhibitor of **Bcr-Abl, Lyn and Fyn kinases.** The key differentiator for bafetinib is its potent inhibition of Lyn kinase, which is overexpressed in many cancers, including B-cell CLL, prostate cancer and glioblastoma multiforme.

CytRx entered into an exclusive, worldwide (with the exception of Japan) royalty-bearing license agreement with **Nippon Shinyaku**, including the right to grant sublicenses, for the intellectual property relating to bafetinib in all fields. Under the agreement, CytRx is obliged to pay Nippon Shinyaku an aggregate of $13.35 million (including $5 million upon the product's initial final marketing approval) upon the achievement of clinical and regulatory milestones up to and including approvals in the U.S. and Europe. CytRx is also obligated to pay commercially reasonable royalties and a percentage of sub-licensing income.

### *Bafetinib for B-CLL*

In November 2008, CytRx completed a **Phase I** clinical trial in patients with CML and other leukemias. In this trial, bafetinib demonstrated clinical responses in patients with CML that have a certain mutation called the Philadelphia Chromosome (Ph+) and are intolerant of or resistant to Gleevec (Novartis) and, in some cases, second-line tyrosine kinase inhibitors such as dasatinib (Sprycel from BMS ) and nilotinib (Tasigna from Novartis). The Phase I clinical trial was designed to identify the optimal dose for possible future studies by escalating doses from 30 mg once per day to up to 480 mg twice per day in a total of 56 patients with Ph+ leukemias. Of the patients, 31 had CML in chronic phase (CML-CP), nine were in accelerated phase (CML-AP), seven were in blast phase (CML-BP), and nine had Ph+ acute lymphocytic leukemia. The clinical trial was conducted at seven clinical sites in the US, Germany, and Israel. A positive, dramatic decrease in the number of leukemia cells in the bone marrow was seen in 35% of the patients that were randomly chosen to begin their treatment with the optimal bafetinib dose of 240 mg twice per day.

The maximum tolerated dose (MTD) was determined to be 240-360 mg given twice per day, based on evidence of increasing potential liver toxicity at higher doses. Common adverse events (observed in greater than 20% of patients in the 240 mg twice per day dose group) were gastrointestinal toxicity,

swelling, and fatigue. There was no evidence of fluid accumulating around the lungs, or significant changes in a certain heart rhythm called QTc prolongation, which are serious side effects known to occur in patients treated with approved drugs for this indication. Approximately 13% of patients across all dose groups discontinued dosing due to unacceptable toxicity.

Based on the Phase I results, in May 2010, CytRx initiated a **Phase II** proof-of-concept clinical trials with bafetinib as a **second line** treatment for B-cell chronic lymphocytic leukemia **(B-CLL)** due to the potent and specific inhibitory properties of bafetinib against Lyn and Fyn kinases, which are overexpressed in B-CLL cancers.

In this clinical trial, high-risk B-CLL patients who have failed treatment with first-line agents will self-administer oral doses of bafetinib twice daily. The bafetinib dose used in this trial is based on the highest dose that was best tolerated in the Phase I study. Patients will be monitored for clinical response, time to disease progression and cancer progression-free survival. Total of 30 patients will be enrolled and enrollment is expected to be completed 12 to 14 months following initiation of the trial, with potential interim data announcements. The dose of bafetinib may be escalated to 360 mg twice daily if relatively few side effects are observed at the 240 mg twice daily dose. The endpoint of this Phase II trial is objective response rate (30% ORR is target). The Phase II clinical trial is being performed at M.D. Anderson Cancer Center, City of Hope Medical Center and Cancer Care Centers of Texas with MD Anderson as the primary US site.

B-CLL is the most common form of leukemia in adults in Western countries. More than 17,000 new cases of B-CLL are reported in the United States alone each year; however up to an estimated 40% of cases may not be reported due to under-diagnosis and lack of placement in cancer registries. Virtually all patients are older than 55 years at presentation, with an average age of 70 years. Patients in the high-risk B-CLL classification have a median overall survival period of one to five years.

***Bafetinib for Prostate Cancer***

In September 2010, the Company initiated the Prostate Advanced Cancer Treatment (PROACT) **Phase II** proof-of-concept clinical trial to evaluate the efficacy and safety of bafetinib in patients with **advanced prostate cancer**. The open-label PROACT trial is being conducted at City of Hope Cancer Center. In the trial, up to 50 patients with metastatic hormone-refractory prostate cancer who have failed first-line chemotherapy could receive orally available bafetinib at 240 mg twice daily. The trial endpoints are reduction in prostate-specific antibodies and increases in progression-free survival compared to baseline and historical data. An assessment of response to bafetinib (tumor shrinkage, prostate-specific antigen (PSA) reduction and stabilization of disease) will occur after the first 21 patients have been treated with bafetinib for three months. The dose of bafetinib may be escalated to 360 mg twice daily if relatively few side effects are observed at the 240 mg twice daily dose.

Prostate cancer is the second most common malignancy and second-leading cause of cancer death among American men, according to the American Cancer Society. Of those diagnosed, one in 35 men will die of prostate cancer. The National Cancer Institute estimates that more than 217,000 new cases and more than 32,000 deaths will be attributed to prostate cancer in the U.S. this year. Treatment of the disease can vary significantly from watchful waiting to surgery, radiation or both, followed by hormonal treatment. Hormonal treatment can shrink the cancer, delay its growth and reduce symptoms. However, patients with metastatic prostate cancer usually stop responding to this therapy within two years. The disease at this stage, called metastatic hormone-refractory prostate cancer, is typically treated with chemotherapeutic agents, and patients have a median survival period of less than two years, according to the National Cancer Institute.

***Bafetinib for Brain Cancer***

In November 2010, CytRx initiated a **pharmacokinetic** clinical trial with bafetinib in patients with recurrent **brain tumors**. Results from this trial are expected in the second quarter of 2011 and will be

used in evaluating potential further clinical development of bafetinib in patients with brain cancer. Six to eight patients with recurrent primary brain cancer or recurrent brain metastases who have undergone brain surgery will be evaluated in the trial, which is being conducted at City of Hope Cancer Center. The trial's primary objective is to provide neuropharmacokinetic information, such as the ability of bafetinib to cross the blood brain barrier and, if so, the percentage that enters the brain compared to the amount in systemic blood.

The rationale for brain tumor is that Lyn and Fyn kinase activities are significantly elevated in glioblastoma and these activities promote malignancy. Lyn kinase activity accounts for more than 90% of pan-Src kinase activity in glioblastoma samples. Bafetinib has been shown to selectively inhibit Lyn kinase. In vivo studies, orally administered bafetinib can penetrate the blood-brain barrier (BBB). The key to this trial is **blood-brain barrier** penetration. Although good potency was seen in the clinical trials for other oncology indications, brain cancer poses a unique challenge because of the blood-brain barrier. The clinical trial has been designed to show the drug's blood-brain barrier pharmacokinetics.

If the pharmacokinetic trial results demonstrate that bafetinib can penetrate BBB in brain cancer patients, CytRx plans to initiate a **Phase II** proof-of-concept clinical trial in glioblastoma patients that have failed first line therapy (surgery, radiation or temozolomide).

Brain tumors can be benign, with no cancer cells, or malignant, with cancer cells that grow quickly. There are two main types of brain cancer. Primary brain cancer (gliomas) starts in the brain and metastatic brain cancer starts somewhere else in the body and moves to the brain. Gliomas represent approximately 70% of the 22,500 malignant primary brain tumors diagnosed annually in American adults. Glioblastoma, the most common type of glioma in adults, is incurable with a median overall survival period of 12-15 months.

It is very difficult to treat glioblastoma due to several complicating factors

- The tumor cells are very resistant to conventional therapies
- The brain is susceptible to damage due to conventional therapy
- The brain has a very limited capacity to repair itself
- Many drugs cannot cross the blood-brain barrier to act on the tumor

Current treatment regimes include surgery, radiation and chemotherapy. Currently, two chemotherapeutic agents (including one targeted therapy) approved by the FDA are frequently used for the treatment of glioblastoma in combination with radiation therapy. They are **Temodar** (temozolomide) from Merck/Schering Plough for newly diagnosed GBM and **Avastin** from Roche for recurred GBM. A third chemotherapeutic agent on the market for glioblastoma is Bristol Myers Squibb's **Carmustine** injection and Eisai's **Carmustine wafer**, which are less frequently used.

Clearly, there is an unmet medical need for the treatment of glioblastoma. The glioblastoma market is a multibillion dollar business. Worldwide sales of Temodar reached $1.1 billion in 2010.

We believe that brain cancer would be an excellent additional indication for the bafetinib program.

***Bafetinib for Other Cancers***

In addition to the above three clinical programs, results from a series of **preclinical studies** demonstrating bafetinib's ability to inhibit bone destruction in model systems were presented on April 2, 2011 at the American Academy for Cancer Research (AACR) 102nd Annual Meeting in Orlando, Florida.

Research has shown that bafetinib, even in low concentrations, significantly inhibits the cells that cause bone destruction that can lead to devastating consequences in cancer patients such as fractures, bone pain and hypercalcemia. The rationale for these preclinical studies lies in bafetinib's ability to inhibit Lyn/Fyn kinases. Prior studies indicated that Lyn and Fyn kinases have negative impacts on osteoclasts,

thus potentially reducing bone resorption. Bafetinib is an inhibitor of Bcr-Abl, Fyn and Lyn kinases, which prompted these initial studies in bone loss and bone resorption.

To evaluate the effects of bafetinib on osteoclast formation and bone resorption, monocytes derived from multiple myeloma patients and normal subjects were stimulated to form osteoclasts and at the same time were treated with bafetinib. As a parallel, the same type of cells were treated with zoledronic acid (Zometa), an inhibitor of osteoclast formation and bone resorption currently used to prevent skeletal complications for patients with multiple myeloma, metastatic bone diseases or osteoporosis. Bafetinib and zoledronic acid both markedly inhibited osteoclast cell formation at similar concentrations in both multiple myeloma and normal monocytes. An additional in vitro study demonstrated that bafetinib reduced osteoclast formation by blocking the pathway leading to monocyte transformation. In other experiments, bafetinib, even at low concentrations, significantly inhibited bone resorption in a concentration-dependent fashion.

This may be a significant opportunity for bafetinib with its ability to block several of the kinases involved in bone resorption as well as cancer cell growth. Several cancers have a high incidence of bone metastases, and bafetinib may be an important therapy, either alone or in combination with other agents, to treat theses types of tumors.

### *INNO-206 for the Treatment of Soft Tissue Sarcoma and Pancreatic Cancer*

INNO-206 (formerly DOXO-EMCH) is a **prodrug** of the commonly prescribed chemotherapeutic agent **doxorubicin**. Specifically, it is the (6-Maleimidocaproyl) hydrazone of doxorubicin. Essentially, this chemical is doxorubicin (DOXO) attached to an acid sensitive **linker** (EMCH).

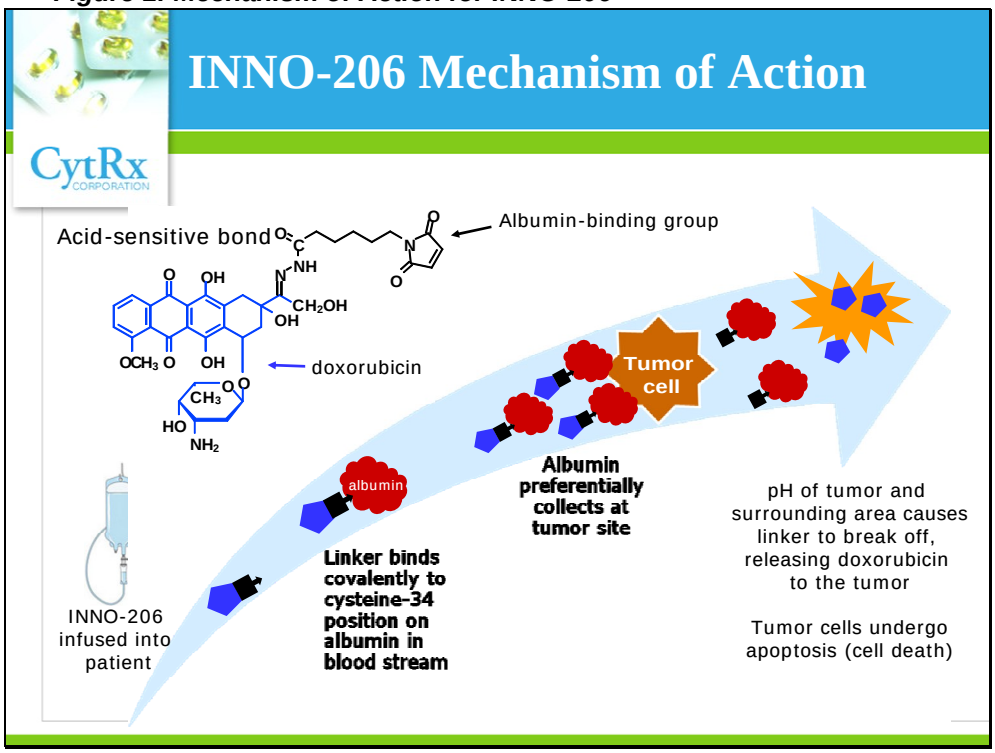
CytRx licensed the patent rights to INNO-206 from **KTB Tumorforschungs GmbH (KTB)** for the worldwide development and commercialization of INNO-206. The license is exclusive and worldwide, applies to all products that may be subject to the licensed intellectual property and may be used in all fields of use. Under the agreement, CytRx must make payments to KTB in the aggregate of $7.5 million upon meeting clinical and regulatory milestones up to and including the product's second final marketing approval. The Company also agreed to pay commercially reasonable royalties based on a percentage of net sales, sub-license income and milestones of $1 million for each additional final marketing approval.

Doxorubicin belongs to a class of anticancer antibiotics: anthracyclines. Anthracylines are among the most commonly used agents in the treatment of cancer. Doxorubicin, the first anthracycline to gain FDA approval, has demonstrated efficacy in a wide variety of cancers including breast cancer, lung cancer, sarcomas, and lymphomas. **Doxorubicin is currently the only FDA-approved drug on the market for soft tissue sarcoma,** and is a standard chemotherapeutic treatment for a variety of other cancers. However, due to the uptake of doxorubicin by various parts of the body, it is associated with many side effects such as cumulative cardiotoxicity, myelosuppression (decreased production of blood cells by bone marrow), gastrointestinal disorders, mucositis, stomatitis (inflammation of the mouth's soft tissue), and extravasation (the leakage of intravenous drugs from the vein into the surrounding tissue).

INNO-206 is designed to improve on native doxorubicin, including reduction of adverse events, improvement in efficacy and the ability to reach the tumor more quickly. These improvements can be achieved by the following mechanisms of action:

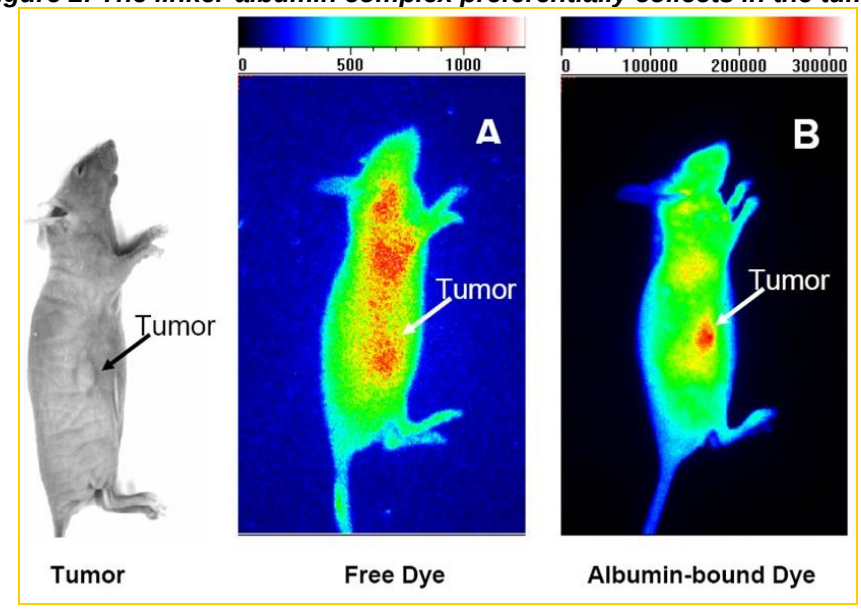
- After administration, INNO-206 rapidly binds circulating albumin through the EMCH linker;
- Circulating albumin preferentially accumulates in tumors, bypassing uptake by other non-tumor sites, including the heart, liver and the gastrointestinal tract;
- Once albumin-bound INNO-206 reaches the tumor, the acidic environment of the tumor causes cleavage of the acid sensitive linker; and
- Free doxorubicin is released at the site of the tumor and is taken up by the cancer cells.

***Figure 1: Mechanism of Action for INNO-206***




*Source: Company presentation*

***Figure 2: The linker-albumin complex preferentially collects in the tumor***




*Source: Company presentation*

The attributes of the linker make it a true **platform technology** which has potential use for various anti-cancer drugs.

In a variety of **preclinical models**, INNO-206 was superior to doxorubicin in its ability to increase the total doxorubicin dose, antitumor efficacy, and safety, including a reduction in cardiotoxicity. Animal studies demonstrated statistically significant efficacy against breast, ovarian, pancreatic and small cell lung cancers growing in immunodeficient mice.

A **Phase I** study of INNO-206 that demonstrated safety and objective clinical responses in several tumor types was completed in 2005. In this study, single doses were administered every 3 weeks at up to six times the standard dosing of doxorubicin without an increase in side effects over those historically observed with doxorubicin. Twenty-three of 35 evaluable patients had either an objective clinical (partial) response or stable disease. Objective clinical responses were observed in patients with sarcoma, breast, and small cell lung cancers.

On Mar 17, 2011, CytRx initiated an open-label **Phase Ib/II** safety and dose escalation clinical trial with INNO-206 at the Sarcoma Oncology Center in Santa Monica, California. The clinical trial will include up to 24 patients with advanced solid tumors who have failed standard therapies. This trial is to determine the maximum tolerated dose (MTD) of INNO-206.

On October 31, 2011, CytRx announced favorable initial response and safety indications from the ongoing **Phase Ib/II** clinical trial with **INNO-206**. Patients in this portion of the Phase Ib/II clinical trial received three different dose levels of INNO-206 to determine its maximum tolerated dose.

Based upon preclinical data, the completed Phase I trial results and the interim positive results of the Phase Ib/II trial, CytRx plans to initiate a **Phase IIb** trial of INNO-206 in patients with **advanced soft tissue sarcomas** in the US, Latin America and Europe in December 2012. INNO-206 vs doxorubicin will be administered in the enrolled patients who are ineligible for surgery. The Phase IIb trial is slated to start by year end. It will be a randomized trial comparing INNO-206 versus doxorubicin in a 99 patient study with a 2:1 randomization.

Sarcomas are a diverse and relatively rare group of malignant tumors that develop in soft tissue and bone. Soft tissue sarcomas form in fat, muscles, nerves, joints, blood vessels, and deep skin tissues. Osteosarcomas and Ewing sarcomas form in bone and cartilage. Soft tissue sarcoma accounts for majority of sarcomas. According to the American Cancer society, about 10,520 new soft tissue sarcomas will be diagnosed. 3,920 Americans are expected to die of soft tissue sarcomas annually. There are about 25,000 new cases of soft tissue sarcoma and 10,000 deaths worldwide annually.

Doxorubicin is the backbone of soft tissue sarcoma treatment. With increased efficacy and reduced toxicity compared to doxorubicin, INNO-206 should be able to command a major market share of the soft tissue sarcoma market or even replace doxorubicin as the leading drug if it is successfully developed.

In 2H11, investigators at the KTB Tumor Biology Center in Freiburg, Germany, plan to start a **Phase II,** open label clinical trial of INNO-206 in patients with **pancreatic cancer.** Patients will be administered with either INNO-206 plus gemcitabine or gemcitabine alone. Pancreatic cancer is the fourth leading cause of cancer death in the US. According to National Cancer Institute (NCI), there are approximately 43,140 new cases and 36,800 deaths each year in the US. The survival rate of patients with any stage of pancreatic cancer is poor. Therefore there is a unmet medical needs for these patients. This Phase II clinical trial will be initiated upon the completion of the Phase Ib trial, which probably will occur in 2H2011.

Market potential for INNO-206 is also huge especially when we consider its broad applications in other cancer indications. Even considering the soft tissue sarcoma and pancreatic cancer alone, INN)-206 could have the potential of a blockbuster.

### *Other Technologies and Programs*

CytRx owns the rights to drug candidates that are based on the Company's **molecular chaperone regulation technology** and are designed to repair or degrade mis-folded proteins associated with disease.

On May 17, 2011, CytRx sold the worldwide rights to its molecular chaperone assets to privately-held, Copenhagen, Denmark-based Orphazyme ApS.

If all of the development and commercialization milestones in the transaction agreement are met, in addition to an up-front payment, CytRx could receive total payments of up to $120 million, in addition to royalties on sales of products developed by Orphazyme from its molecular chaperone technology. This transaction represents the completion of CytRx's previously announced, **non-dilutive monetization strategy** for its non-core assets.

The CytRx molecular chaperone portfolio includes three drug candidates, **arimoclomol, iroxanadine** and **bimoclomol**, which are orally administered molecular chaperone amplifiers. The compounds collectively have proven to be safe and well tolerated in more than 680 human subjects tested in 13 Phase I and six Phase II clinical trials. By targeting the underlying cause of many diseases, this novel approach has the potential to be developed for a broad variety of indications, including genetic diseases.

The Company's other technologies include **TranzFect**, a delivery technology for DNA-based vaccines, which is licensed to Vical, Inc. (NASDAQ: VICL). Vical is preparing to enter a Phase III clinical trial with its product that utilized the TranzFect technology.

### *CytRx is well Capitalized with a Strong Balance Sheet*

Currently, CytRx has no meaningful revenue to fund its business and operations, but the Company is well capitalized with a strong balance sheet, which sets it apart from most other small cap biotech companies.

CytRx reported cash, cash equivalents and marketable securities of $41.4 million as of September 30, 2011.

In July 2011, the Company raised net proceeds of approximately $19.1 million by issuing 39.2 million shares of common stocks and warrants to purchase up to 39,200,000 shares of common stock at a combined public offering price of $0.52 per share. The warrants are exercisable immediately upon issuance at an exercise price of $0.64 per share and, unless exercised, will expire on the fifth anniversary of the date of issuance.

We noticed that following the share offering, the company's share price declined dramatically at about 38%. We think investors are over reacted to the event. We admit that equity offering always dilute existing shareholder base, but for a small cap biotech company like CytRx, it's necessary to raise money for its operations, especially for advancing its clinical programs.

On the other hand, the funds raised from the common stock offering have greatly boosted the Company's balance sheet. Although share price suffered in the short run, we think this offering is positive for the company in the long term.

Balance sheet may be further boosted if CytRx can find partners for one or more of its three core cancer programs when data are available late this year or in 2012.

Further, in early April, CytRx received approximately 163,000 shares of common stock in Adventrx Pharmaceuticals, Inc. (NYSE Amex: ANX) in exchange for its 19.1% ownership position in SynthRx, Inc., following the completion of the acquisition of SynthRx by Adventrx. If all milestones under this agreement are achieved, CytRx could receive up to 2.9 million additional shares for a total ownership stake of 7.8% in Adventrx. SynthRx was formed in 2004 and licensed the rights to several of CytRx's copolymer technologies. CytRx will still be able to receive a royalty on products developed and commercialized by Adventrx.

### *Experienced Management Team and Scientific Advisors*

**Steven A. Kriegsman** - President and Chief Executive Officer

Mr. Kriegsman has been CytRx Corporation's President and Chief Executive Officer and a director since July 2002. He also serves as a director of RXi Pharmaceuticals Corporation (Nasdaq: RXII) and Chairman of RXi's Compensation and Transaction Committees. He previously served as Director and Chairman of Global Genomics from June 2000. Mr. Kriegsman is an inactive Chairman and Founder of Kriegsman Capital Group LLC, a financial advisory firm specializing in the development of alternative sources of equity capital for emerging growth companies in the healthcare industry. Mr. Kriegsman has a BS degree with honors from New York University in Accounting and completed the Executive Program in Mergers and Acquisitions at New York University, The Management Institute. Mr. Kriegsman is a graduate of the Stanford Law School Directors' College. Mr. Kriegsman was formerly a Certified Public Accountant with KPMG in New York City. He served as a Director and is the former Chairman of the Audit Committee of Bradley Pharmaceuticals, Inc. Mr. Kriegsman has been a guest speaker and lecturer at various universities including California Institute of Technology (Caltech), Brown University and New York University. He was also an instructor at York College in its entrepreneurship program. Mr. Kriegsman has been active in various charitable organizations including the Biotechnology Industry Organization, the ALS Association, the Los Angeles Venture Association, the Southern California Biomedical Council, the California Health Initiative, the American Association of Dance Companies, and the Palisades-Malibu YMCA.

**Daniel Levitt, M.D., Ph.D.** – Chief Medical Officer
Dr. Levitt brings more than 24 years of senior management experience, spearheading numerous drug development programs to commercialization at leading biotechnology and pharmaceutical companies. Prior to joining CytRx, Dr. Levitt served as Executive Vice President, Research and Development at Cerimon Pharmaceuticals, Inc., where he implemented three Phase III pivotal trials. Prior to that, he was Chief Medical Officer and Head of Clinical and Regulatory Affairs at Dynavax Technologies Corporation, managing clinical trials for four programs and overseeing multi-country regulatory strategies. Dr. Levitt was also Chief Operating Officer and Head of Research and Development at Affymax, Inc., where he spearheaded all aspects of that company’s research, development, and commercialization operations, and he spent six years at Protein Design Labs, Inc., completing his tenure as that firm’s President and Head of Research and Development. Dr. Levitt’s past experience includes a position as Head of Drug Development at Geron Corporation, and Head of the Cytokine Development Unit and Global Clinical Oncology at Sandoz Pharmaceuticals Ltd., and as Director, Clinical Oncology and Immunology at Hoffmann-LaRoche, Inc. Dr. Levitt graduated Magna Cum Laude and Phi Beta Kappa with a Bachelor of Arts degree from Brandeis University. He earned both his M.D. and his Ph.D. in Biology from the University of Chicago Pritzker School of Medicine. Dr. Levitt has received 10 major research awards and authored or co-authored nearly 200 papers and abstracts.

**John Y. Caloz** - Chief Financial Officer
Mr. Caloz has an accomplished history of providing senior financial leadership in the life sciences sector, including as Chief Financial Officer of Occulogix, Inc, a NASDAQ listed, a medical therapy company. Prior to that, Mr. Caloz served as Chief Financial Officer of IRIS International Inc., a Chatsworth, CA based medical device manufacturer. He served as Chief Financial Officer of San Francisco-based Synarc, Inc., a medical imaging company, and from 1993 to 1999 he was Senior Vice President, Finance and Chief Financial Officer of Phoenix International Life Sciences Inc. of Montreal, Canada, which was acquired by MDS Inc. in 1999. Mr. Caloz was a partner at Rooney, Greig, Whitrod, Filion & Associates of Saint Laurent, Quebec, Canada, a firm of Chartered Accountants specializing in research and development and high tech companies, from 1983 to 1993. Mr. Caloz, a Chartered Accountant, holds a degree in Accounting from York University, Toronto, Canada.

**Benjamin S. Levin** - General Counsel, Vice President of Legal Affairs and Corporate Secretary
Until 2004, Mr. Levin practiced at O'Melveny & Myers LLP in Los Angeles as a transactional attorney. He worked in a wide variety of disciplines including mergers and acquisitions, public and private securities offerings, corporate governance and SEC reporting and disclosure. Mr. Levin graduated from Stanford Law School with distinction, and graduated Phi Beta Kappa from the Massachusetts Institute of Technology with a S.B. in Economics.

**Scott Wieland, Ph.D**. - Senior Vice President of Drug Development
Prior to joining CytRx, Dr. Wieland was Vice President of Drug Development and Regulatory Affairs, with clinical and regulatory oversight of a Alzheimer's disease development program. His fifteen years of experience in the biopharmaceutical industry has provided Scott a balanced approached to developing products for the market place. His experience ranges across all aspects of drug development with a focus on neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease, and stroke. Scott received a M.A. and Ph.D. in biopsychology from the University of Arizona and a M.B.A. from Webster University.

**Scott Geyer** - Senior Vice President of Manufacturing
Mr. Geyer brings more than 28 years of manufacturing and technical operations knowledge overseeing all aspects of product manufacturing in oncology and other fields, including direct experience with small molecules, biologics and topicals. He most recently served as Vice President, Technical Operations at Cerimon Pharmaceuticals, Inc., where he was responsible for developing FDA-compliant quality systems manufacturing processes, led the contract manufacturing function and evaluated in-licensing opportunities. In this position, he established state-of-the-art bioanalytical methods and developed formulations to support clinical advancement of several lead programs. He previously served as Senior Vice President, Technical Operations & Product Development at TRF Pharma, Inc.; Vice President, Technical Operation at Xencor, Inc.; and Vice President, Manufacturing and Process Development at BioMarin Pharmaceuticals Inc. Mr. Geyer's past experience includes holding senior positions at Onyx Pharmaceuticals and Protein Design Labs, Inc., as well as positions at Ares-Sorono Group and SmithKline Beckman, among others. Mr. Geyer has co-authored numerous publications in peer-reviewed journals. He holds an M.S. in veterinary microbiology from Texas A&M University and a B.S. in microbiology from the University of Southwestern Louisiana.

**David J. Haen** - Vice President, Business Development
Graduated Cum Laude from Loyola Marymount University in Business and Communications. Mr. Haen is responsible for negotiating strategic alliances, mergers and acquisitions, and in-licensing and out-licensing of product opportunities.

**Max Link, Ph.D.** – Chairman
Dr. Link has been Chairman of the Board and a director since 1996. Dr. Link has been retired from business since 2003. From March 2002 until its acquisition by Zimmer Holdings, Dr. Link served as Chairman and CEO of Centerpulse, Ltd. From May 1993 to June 1994, Dr. Link served as the Chief Executive Officer of Corange Ltd. (the holding company for Boehringer Mannheim Therapeutics, Boehringer Mannheim Diagnostics and DePuy International). From 1992 to 1993, Dr. Link was Chairman of Sandoz Pharma, Ltd. From 1987 to 1992, Dr. Link was the Chief Executive Officer of Sandoz Pharma and a member of the Executive Board of Sandoz, Ltd., Basel. Prior to 1987, Dr. Link served in various capacities with the United States operations of Sandoz, including President and Chief Executive Officer. Dr. Link also serves as a director of Alexion Pharmaceuticals, Inc., Celsion Corporation, Inc. and Discovery Laboratories, Inc.

**Louis Ignarro, Ph.D** - Chief Scientific Spokesman
Dr. Ignarro is a Nobel Laureate in Medicine and also serves as the Jerome J. Bezler, M.D. Distinguished Professor of Pharmacology in the Department of Molecular and Medical Pharmacology at the UCLA School of Medicine. He received the Nobel Prize for Medicine or Physiology in 1998. Dr. Ignarro has been at the UCLA School of Medicine since 1985 as a Professor, Acting Chairman and Assistant Dean. Dr. Ignarro has received countless awards for his work in medicine and as a professor. He is also an active participant in numerous scientific and medical associations.

**Joseph Rubinfeld, Ph.D**. - Chief Scientific Advisor-Oncology
Dr. Rubinfeld was one of the four initial founders of Amgen in 1980 and served as Vice President and Chief of Operations until 1983. From 1987 to 1990, he was a Senior Director at Cetus Corporation. From 1968 to 1980, Dr. Rubinfeld was employed at Bristol-Myers Company International Division in a variety of positions, most recently as Vice President and Director of Research and DevelopmentDr.

Rubinfeld co-founded SuperGen (Nasdaq:SUPG) in 1991. He has served as CEO, President and director of the Company since inception and was Chief Scientific Officer from inception until September 1997.

## INDUSTRY OUTLOOK

***Our Outlook for the Biotech Industry is Positive in General***

We think there are a number of strong secular growth drivers that still power the biotech industry-namely, an aging population and an enormous research and development (R&D) effort to bring new, better drugs to market. People are living longer, and many have prescription pharmaceuticals to thank for it. Recent breakthroughs in oncology, neurology, and cardiology offer sizable market opportunities. Biotechnology research is finally starting to deliver. Expanded knowledge of genomics and proteomics is attracting significant attention from some of the industry's larger players. Drug companies are finding ways to reformulate and enhance current products. This is clearly a positive for the biotech industry. Demand for innovative medicines remains strong and biotechnology should deliver the next wave of pharmaceutical products to the market. This should allow the group to outperform the broader sector.

Licensing/partnership remain the lifeline of biotech industry. We expect to see continued partnership and in-licensing/out-licensing activities for biotech companies in the next few years.

We also expect further consolidation throughout the industry because we believe that current market environment in the Pharma/Biotech industry is favorable for M&A activities. The big pharmaceutical companies have long been faced with big challenges such as patent expiration for blockbusters, low research and development productivity, and generic competition. Platform technology and efficient R&D efforts in smaller biotech companies may be part of the solution to the challenges faced by big Pharma companies. As long as the challenges still exist in the pharmaceutical industry, the buyout of smaller biotech companies by big Pharma/giant biotech companies will continue to make sense.

For individual biotech companies, we think companies with one or more of the following fundamentals will be attractive.

- With approved products on the market which can generate cash for the company;
- With a strong balance sheet and low cash burn rate; huge amount of cash will be needed to provide funds for drug development before it can reach the market;
- With platform technologies with deep, diversified pipeline (from early to late stage drug candidates); platform technology can produce series drug candidates, and is usually worth more than a single drug candidate program. When a drug candidate is moving closer to market, it usually reduces development risks.

Investors should pay attention to those large profitable biotechnology stocks, as well as small-cap biotechnology stocks with promising pipelines.

## VALUATION AND RECOMMENDATION

We maintain our market outperform rating on CytRx Inc. (CYTR) and reiterate our 12-month price target of $1.35 per share.

CytRx is a late stage clinical development biotech company with a focus on cancer indications. The Company has three cancer candidates in middle to late stage development with a multi-billion dollar market opportunity. The linker technology for the INNO-206 program is a really a platform technology with potential to target other cancer indications in addition to current soft tissue sarcoma and pancreatic cancer.

CytRx is well capitalized with a strong balance sheet. Unlike most small cap biotech companies which are haunted by cash burn concerns, CytRx is in a strong position. Current cash in hand will last through the end of 2012.

Based on the Company's strong fundamentals, we believe CytRx shares are undervalued compared to its peers. Currently, the Company's shares are trading at about $0.30 per share which values the Company at about $49 million in market cap based on about 148.5 million shares outstanding. We believe this is a discount compared to its peers. Most small biotech companies of development stage are valued from $50 million to $500 million in market cap depending on how advanced the pipeline is and which indications the company is targeting. CytRx is a late stage development biotech company, and its lead candidate tamibarotene is under two Phase II clinical trials with one as a pivotal trial for APL. Tamibarotene could reach the market in 2014 for APL and the Company will become profitable in fiscal 2016 with earnings per share of $0.06 on total revenue of $58 million.

Our price target of $1.35 values CytRx at about $200 million in market cap which we think is appropriate based on the Company's fundamentals.

## RISKS

### *Clinical and Regulatory Risks*

Although CytRx is a late stage development company with one program in pivotal clinical trial, all its other programs are still in middle or early stage of development. We remind investors drug candidates, even in their late stage of development, are always exposed to both clinical and regulatory risks.

We have seen many clinical trial failures in the past, and will continue to see a lot in the future. Besides the long process of drug development, regulatory hurdle for drug development is also big at present. Drug companies must face a more conservative health authority nowadays more than ever before. We have seen many cases in which drug candidates with positive clinical data are still denied by the FDA.

With these in mind, we can not rule out completely the possible failure of any of CytRx's clinical programs, even for the late stage programs.

### *Competition is Fierce in the Cancer Market*

Although cancer market is a multi-billion dollar business, the market is also crowded with various drugs. Competition is fierce with many big players like Pfizer, Roche, Novartis and Merck. All of CytRx's three cancer candidates face strong competition from existing therapies and candidates under development.

Although **tamibarotene** faces little or no competition for **APL,** it has to meet great challenges for **NSCLC**. NSCLC is a competitive indication in which patients are treated with a variety of agents. The standard regimen for first-line locally advanced or metastatic NSCLC is a doublet comprised of a platinum agent combined with a taxane, vinka alkaloid or antimetabolite. The addition of Genentech/Roche's Avastin to the standard treatment doublet has resulted significant improvements in survival and rates of remission. Tarceva by OSI and Genentech/Roche and Iressa by AstraZeneca have shown benefit in second-line regimens for specific patients but have not conferred survival benefit. In addition, there are several drugs

in late-stage development including Eisai's eribulin, Eli Lilly & Co.'s necitumumab and Pfizer's axitinib and crizotinib.

Due to tough competition in the CML market including three approved drugs: Gleevec and Tasigna from Novartis, and Sprycel from BMS and multiple candidates under development, CytRx plans to develop **bafetinib** initially for B-CLL, prostate cancer and brain cancer. But bafetinib still faces competition in these three selected markets.

There are several drugs approved for the treatment of **CLL**. First-line therapy for CLL includes a variety of combination therapies including fludarabine, cyclophosphamide, Rituxan and Campath. Treatment for relapsed or refractory CLL includes several chemotherapy regimens including CHOP, CFAR, hyperCFAD and OFAR in addition to single agents including GlaxoSmithKline's Arzerra and Sanofi-Aventis' Oforta. Arzerra was approved in October 2009 for CLL patients who are refractory to treatment with fludarabine and Campath. Oforta, an oral tablet formulation of fludarabine, was approved in December 2008 as a second-line treatment for CLL.

Bafetinib also faces several competitors in the **prostate cancer** market. Sanofi-Aventis' Taxotere (docetaxel) Injection Concentrate was approved by the FDA in 2004 for the therapeutic treatment of metastatic, androgen-independent prostate cancer. In 2010, the FDA approved Dendreon's Provenge for hormone refractory prostate cancer. In addition, bafetinib may compete with late-stage oral therapies in development such as Johnson and Johnson's abiraterone and Medivation's MDV3100.

Current standard of care for **glioblastoma,** the primary brain cancer, is surgery followed by radiation therapy and chemotherapy. Merck's Temodar is approved for treating newly diagnosed GBM concomitantly with radiotherapy and then as a maintenance treatment. Roche's Avastin was approved in May 2009 for treatment of recurrent GBM. Other drugs in development for glioblastoma include Merck Serono's cilengitide, Myrexis' MPC-6827, ImmunoCellular's ICT-107 and Arno Therapeutics' AR-67.

**INNO-206** apparently has advantages over doxorubicin by adding an acid sensitive linker to it. Doxorubicin is the only approved drug for treating **soft tissue sarcoma** and is often used in combination with radiation. The National Comprehensive Cancer Network also includes the use of ifosfamide, epirubicin, Eli Lilly's Gemzar, dacarbazine and liposomal doxorubicin marketed in the U.S. as Doxil by Johnson & Johnson. For patients ineligible for surgery, radiation and/or chemotherapy is the only option. Other approaches to treating soft tissue sarcoma are in late stage clinical development. These include ridaforolimus being developed by Ariad Pharmaceuticals and Merck & Co., Cell Therapeutics' brostallicin, GlaxoSmithKline's pazopanib, Sanofi-Aventis' AVE8062, Threshhold Pharmaceuticals' TH-302, trabectedin being co-developed by Johnson and Johnson and PharmaMar and Ziopharm Oncology's palifosfamide.

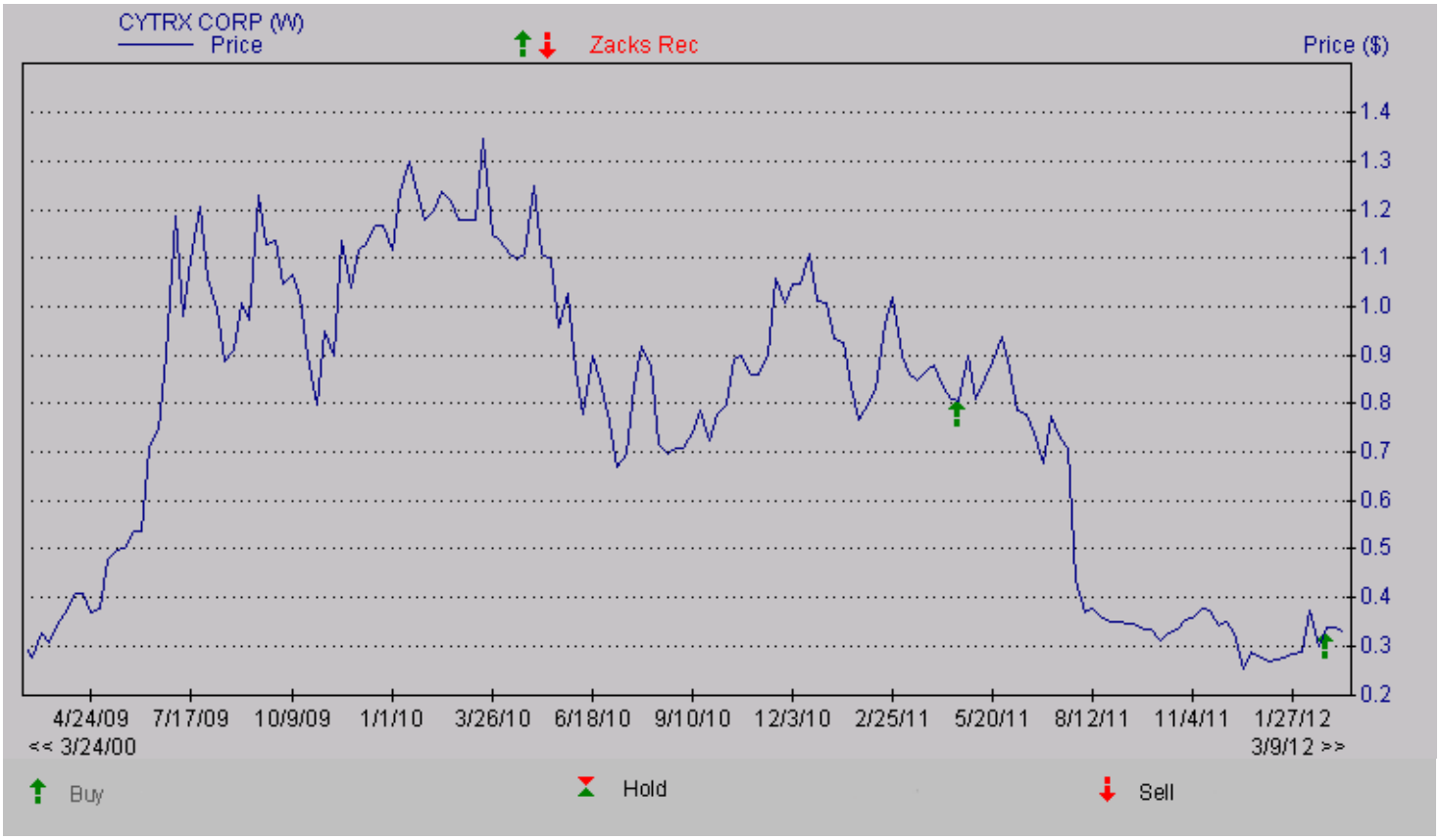
In the **pancreatic cancer** market, INNO-206 faces competition from Eli Lilly's Gemzar, which is currently approved for the first line treatment of locally advanced or metastatic pancreatic cancer. It is also indicated for the use in patients who have received prior treatment with 5-FU. OSI Pharmaceuticals' Tarceva was approved in 2005 for the use in combination with Gemzar. Late stage drugs in clinical trials for pancreatic cancer include Abraxane by Abraxis BioScience, AGS-1C4D4 by Astellas Pharma Inc., and TS-1 by Taiho Pharmaceutical Co.

## PROJECTED INCOME STATEMENT

| | 2010A (Dec) | | | | | 2011E (Dec) | | | | | 2012E (Dec) | 2013E (Dec) | 2014E (Dec) | 2015E (Dec) | 2016E (Dec) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| $ in million except per share data | Q1A | Q2A | Q3A | Q4A | FYA | Q1A | Q2A | Q3A | Q4E | FYE | FYE | FYE | FYE | FYE | FYE |
| *Product revenue* | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $4.80 | $21.43 | $57.45 |
| *Service revenue* | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| *Licensing revenue* | $0.00 | $0.00 | $0.00 | $0.10 | $0.10 | $0.00 | $0.15 | $0.00 | $0.00 | $0.15 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| **Total Revenues** | **$0.00** | **$0.00** | **$0.00** | **$0.10** | **$0.10** | **$0.00** | **$0.15** | **$0.00** | **$0.00** | **$0.15** | **$0.00** | **$0.00** | **$4.80** | **$21.43** | **$57.45** |
| *YOY Growth* | *-100.0%* | *-100.0%* | *-100.0%* | *0.0%* | *-98.9%* | - | - | - | - | - | - | - | *#DIV/0!* | *346.4%* | *168.1%* |
| *CoGS* | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.72 | 3.21 | 8.62 |
| **Gross Income** | **$0.00** | **$0.00** | **$0.00** | **$0.10** | **$0.10** | **$0.00** | **$0.15** | **$0.00** | **$0.00** | **$0.15** | **$0.00** | **$0.00** | **$4.08** | **$18.21** | **$48.83** |
| *Gross Margin* | - | - | - | *100.0%* | *100.0%* | - | - | - | - | - | - | *#DIV/0!* | *85.0%* | *85.0%* | *85.0%* |
| R&D | $2.05 | $3.07 | $2.85 | $0.54 | $8.51 | $4.82 | $1.89 | $3.22 | $4.00 | $13.93 | $20.50 | $22.00 | $23.50 | $20.00 | $15.00 |
| *% R&D* | - | - | - | - | - | - | - | - | - | - | - | - | - | - | |
| SG&A | $2.65 | $2.06 | $1.85 | $1.68 | $8.24 | $2.05 | $2.03 | $1.74 | $2.35 | $8.17 | $10.50 | $12.50 | $15.00 | $17.50 | $22.50 |
| *%SG&A* | - | - | - | - | - | - | - | - | - | - | - | - | - | - | |
| Other | $0.00 | $0.00 | $0.00 | $0.11 | $0.11 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| *% Other* | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| **Operating Income** | **($4.7)** | **($5.1)** | **($4.7)** | **($2.2)** | **($16.8)** | **($6.9)** | **($3.8)** | **($5.0)** | **($6.4)** | **($21.9)** | **($31.0)** | **($34.5)** | **($34.4)** | **($19.3)** | **$11.3** |
| *Operating Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - | - | *19.7%* |
| Other Net | $4.1 | $6.4 | $0.28 | $6.4 | $17.2 | $0.7 | $0.6 | $4.4 | $0.2 | $5.9 | $0.8 | $0.8 | $0.8 | $0.8 | $0.8 |
| **Pre-Tax Income** | **($0.6)** | **$1.3** | **($4.4)** | **$4.1** | **$0.4** | **($6.2)** | **($3.1)** | **($0.6)** | **($6.2)** | **($16.0)** | **($30.2)** | **($33.7)** | **($33.6)** | **($18.5)** | **$12.1** |
| Income taxes(benefit) | $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 | $0.0 |
| *Tax Rate* | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| **Reported Net Income** | **($0.6)** | **$1.3** | **($4.4)** | **$4.1** | **$0.4** | **($6.2)** | **($3.1)** | **($0.6)** | **($6.2)** | **($16.0)** | **($30.2)** | **($33.7)** | **($33.6)** | **($18.5)** | **$12.1** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Shares Out* | *108.9* | *111.6* | *109.1* | *116.1* | *111.4* | *109.2* | *109.2* | *134.8* | *148.5* | *125.4* | *155.0* | *165.0* | *175.0* | *185.0* | *195.0* |
| **Reported EPS** | **($0.01)** | **$0.01** | **($0.04)** | **$0.04** | **$0.00** | **($0.06)** | **($0.03)** | **($0.00)** | **($0.04)** | **($0.13)** | **($0.19)** | **($0.20)** | **($0.19)** | **($0.10)** | **$0.06** |
| *YOY Growth* | - | - | - | - | - | | | | | - | - | - | - | - | - |
| One time charge | *($3.85)* | *($6.32)* | *$0.00* | *($6.40)* | *($16.57)* | *($0.60)* | *($0.58)* | *($4.32)* | *$0.00* | *-$5.49* | *$0.00* | *$0.00* | *$0.00* | *$0.00* | *$0.00* |
| **Non GAAP Net Income** | **($4.5)** | **($5.0)** | **($4.4)** | **($2.3)** | **($16.2)** | **($6.8)** | **($3.7)** | **($4.9)** | **($6.2)** | **($21.5)** | **($30.2)** | **($33.7)** | **($33.6)** | **($18.5)** | **$12.1** |
| **Non GAAP EPS** | **($0.04)** | **($0.05)** | **($0.04)** | **($0.02)** | **($0.14)** | **($0.06)** | **($0.03)** | **($0.04)** | **($0.04)** | **($0.17)** | **($0.19)** | **($0.20)** | **($0.19)** | **($0.10)** | **$0.06** |

*Source: Company filings and Zacks estimates*

## HISTORICAL ZACKS RECOMMENDATIONS

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