Zacks Small-Cap Research

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Access Pharma (ACCP-OTC)

ACCP: MuGard sales could accelerate in 2012-Outperform

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	02/23/2012
Current Price (02/24/12)	$1.30
12-month Target Price	**$7.00**

OUTLOOK

Access is a biopharmaceutical company focused on cancer and cancer supportive care based upon the Company's three drug delivery technologies. Access currently has one approved product **MuGard** for the management of oral mucositis. Two cancer drug candidates **ProLindac** and **Thiarabine** are in phase II studies. We are also impressed with the Company's Cobalamin-based oral drug delivery system which has great potential for monetization. Both oral insulin and human growth hormone have achieved unprecedented oral bioavailability in animal models. Current share price is undervalued. We encourage investors accumulate the Company's shares. Our price target is $7.

SUMMARY DATA

52-Week High	**$2.45**
52-Week Low	**$1.25**
One-Year Return (%)	**-41.70**
Beta	**0.93**
Average Daily Volume (sh)	**43,387**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$34**
Short Interest Ratio (days)	**0.35**
Institutional Ownership (%)	**68**
Insider Ownership (%)	**6**
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 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**N/A**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0.10 A	0.11 A	0.13 A	0.14 A	0.48 A
2011	0.15 A	0.15 A	1.04 A	1.14 E	2.48 E
2012					17.65 E
2013					38.75 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.13 A	-$0.07 A	-$0.18 A	-$0.20 E	-$0.53 E
2011	-$0.14 A	-$0.16 A	-$0.13 A	-$0.11 E	-$0.53 E
2012					-$0.24 E
2013					$0.01 E

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

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WHAT'S NEW

MuGard Sales Expected to Accelerate in 2012

MuGard sales ramp has been certainly slower than expected, disappointing but somewhat understandable. With all the groundwork done in 2011, we think MuGard sales could start to accelerate in 2012.

Our call is based on the following facts and assumptions:

In the international markets

- Access' MuGard partner in China Rhei Pharmaceuticals HK Ltd received regulatory and marketing approval for MuGard in China on Feb 24, 2012. Manufacturing of MuGard will commence shortly in the United States to meet the demand created by Jian An, Rhei's sales and marketing partner in China.

- In 2011, Access and Rhei signed a $30 million supply agreement for MuGard to ensure manufacturing capacity of up to a minimum of $30 million of product in the licensed territories. In addition, Access also approved a sub-license agreement between Rhei Pharmaceuticals and Jian An Pharmaceuticals Limited in Shenzhen, China to leverage Jian An's extensive sales, marketing and regulatory infrastructure for the launch of MuGard in China and Taiwan. Jian An is headquartered in Shenzhen, China and has a 25-year history of selling pharmaceutical and other medical products in the China market. Jian An has 1400 sales representatives covering all majors centers in China through 169 sales offices.

- China represents a key target market for MuGard. China is one of the fastest growing oncology markets and cancer supportive care has been improving throughout recent years. We believe revenue from China MuGard sales will make a meaningful contribution to total revenue in 2012.

In the US market

- **MuGard prescriptions** continued to increase through the third quarter and into the 4Q11. Clinicians prescribing MuGard continue to provide feedback and anecdotal evidence of positive clinical experiences. Over 700 clinicians have prescribed MuGard for their patients and over 75% of these doctors are recurring prescribers.

- Throughout the third quarter and into 4Q11, Access made significant progress in increasing **reimbursement** for MuGard. MuGard continued receiving reimbursement from many networks of leading insurance companies and pharmacy benefit managers including Group Health Incorporated (GHI), TRICARE, Harvard Pilgrim, Humana and ExpressScripts. Reimbursement has more than doubled and now includes payers such as several state Anthem plans, various Aetna and Cigna plans, Assurant Health, Keystone, Premera and additional BlueCross Blue Shield (BCBS) and United Healthcare state plans. Over the past few months, Access has more than doubled the amount of payers providing coverage for MuGard in the U.S.; growing from approximately 30 payers to over 70 payers and pharmacy benefit managers (PBM's).

- Since its launch last quarter, Access' MuGard Patient Reimbursement and Support Center (**PRSC**), also known as the MuGard HUB, has improved patient access to MuGard by enhancing product distribution and facilitating payment for MuGard by insurance carriers. In addition to the MuGard HUB, in the third quarter, Access also brought on several specialty pharmacies including CSPN (Community Specialty Pharmacy Network) and CuraScript, the specialty division of Express Scripts, to further expand its specialty pharmacy and third party logistics networks. CSPN

and CuraScript began providing MuGard to the patients within their expansive network. CuraScript Specialty Distribution, its third party logistics division, warehouses MuGard and serves as its specialty distributor and wholesaler for specialty pharmacy providers.

- Some hospitals purchase products, drugs, devices through large Group Purchasing Organizations **(GPOs).** Access is currently negotiating a Preferred Product/Rebate agreement with the largest GPO in the US that represents approximately 2,000 of the 5,000-5,500 hospitals in the US.

- Access has spent significant resources on **creating and building demand** throughout the U.S. Part of the effort included an extensive sampling to reach patients, caregivers, and the oncology community. The formulary process in local hospitals and large institutions are well underway with many decisions already made by the end of 2011.

- Access' **contracted sales reps** continue their broad-scale marketing push for MuGard. Access has identified under-resourced geographic areas and allocated additional coverage in these underserved areas and in new territories as it solidifies reimbursement activities and gains additional payer acceptance.

- MuGard clinical trial: Access has been running what it believes is the "gold-standard" oral mucositis trial in the US which is double-blinded, randomized, controlled, multi-center trial. The trial is targeted to be 80 patients, roughly 65 has been enrolled and randomized right now. The successful outcome of this trial will make MuGard the standard of care in the treatment of oral mucositis.

At the front of partnership

- Access continues to have active discussions with potential **co-promotion partners** in the US. If this can materialize in the first half of 2012, it will have a significant impact on MuGard sales for the year of 2012 and beyond. With a decent product and all the infrastructure in place, a co-promotion partner with much stronger marketing muscle will help Access better reach the oncology community.

We noticed the dramatic percentage increase of MuGard US sales in the third quarter compared to that in the first quarter and second quarter of 2011. We expect a meaningful sales number for MuGard in 4Q11. We have pointed out in our previous reports that sales ramp-up of MuGard is important for Access since MuGard is the Company's only marketed product.

For the reasons mentioned above, we think sales could accelerate from 2012 onwards. We will closely watch MuGard sales ramp in the coming quarters. Investors may need some patience

Access Pharma Reports Third Quarter Financial Results

On November 15, 2011, Access Pharma reported its fiscal third quarter financial results ended September 30, 2011.

Licensing revenue for the third quarter of 2011 was $936,000 as compared to $107,000 for 2010. In the third quarter 2011, Access regained licenses from its former Korean partner for ProLindac and MuGard and recognized all of the previously received license fees ($849,000) that were recorded in deferred revenue.

Royalty revenue for MuGard in Europe was $23,000 for the third quarter of 2011 as compared to $20,000 for 2010, an increase of $3,000.

Product sales of MuGard in the United States totaled $82,000 for the third quarter of 2011 with no revenues for the same period of 2010. Sales of MuGard in 2Q11 were $43,000.

Product costs for MuGard in the United States were $454,000 for the third quarter of 2011 with no product costs for the same period in 2010. MuGard was launched in the fourth quarter of 2010.

Total research and development spending for the third quarter of 2011 was $1,063,000, as compared to $1,199,000 for 2010, a decrease of $136,000.

Total general and administrative expenses were $1,252,000 for the third quarter of 2011, an increase of $87,000 compared to the same period in 2010 of $1,165,000.

Total operating expenses for the third quarter of 2011 were $2,825,000 as compared to total operating expenses of $2,423,000 for 2010, an increase of $402,000.

Net loss allocable to common stockholders for the third quarter of 2011 was $97,000, or a $0.00 basic and diluted loss per common share, compared with net loss of $13,171,000, or a $0.83 basic and diluted loss per common share for the same period in 2010.

On an adjusted basis, non-GAAP net loss for the third quarter of 2011 was $2.5 million, or $0.13 per share compared net loss of $2.9 million or $0.18 per share for the third quarter of 2010.

Balance Sheet has been Boosted

As of September 30, 2011, Access had cash and cash equivalents of $1.3 million. Management believes that current cash and expected license fees should fund expected burn rate into the first quarter of 2012.

However, in November 2011, Access has entered into definitive agreements for the purchase of $5.2 million of units, consisting of common stock and warrants in a private placement financing with a select group of institutional and accredited investors. Each unit consists of the one share of common stock at $1.45 share price, with 50% warrant coverage with an exercise price of $1.67 per share and a term of two and half years and 50% warrant coverage with an exercise price of $2.00 per share and a term of five years.

With this financing, the Company's liquidity could fund the operations into the end of 2012.

EXECUTIVE SUMMARY

- We maintain our Outperform rating on Access Pharmaceuticals Inc. and our price target is $7.
- Access' MuGard has already been approved by US, EU and South Korea health authorities. The Company's EU partner **SpePharm Holding, B.V** is marketing MuGard in some European countries and expansion into other EU countries is under way. Access officially launched MuGard in early August 2010 in the US. Korean partner **JCOM Co., Ltd**. also plans to launch MuGard in Korea soon.
- Access' MuGard partner in China **RHEI** Pharmaceuticals HK Ltd received regulatory and marketing approval for MuGard in China on Feb 24, 2012. Manufacturing of MuGard will commence shortly in the United States to meet the demand created by Jian An, Rhei's sales and marketing partner in China. We believe revenue from China MuGard sales will make a meaningful contribution to total revenue in 2012.
- **MuGard** is indicated for the management of oral mucositis which is a frequent side effect for cancer patients under radiation and chemotherapy. MuGard boasts competitive advantages over its competitors already on the market. We believe MuGard will strongly boost the company's top line in the coming quarters. Peak sales of MuGard could reach $300 million in the US alone.

- Both **ProLindac** and **Thiarabine** target the multi-billion dollar cancer market. The two candidates are in middle stage of development. ProLindac is in phase II study for relapsed ovarian cancer patients and Access already initiated a Phase I/II studies of Thiarabine in adult AML, ALL and other indications.

- We are optimistic with the Company's **three proprietary drug delivery technologies** which create multiple product opportunities and mitigate single product exposure. We are especially impressed with the Cobalamin-based drug delivery system (CobaCyte and CobOral). Both oral insulin and oral human growth hormone have achieved unprecedented oral bioavailability in animal models. Clinical studies have been planned for the two candidates. The Company is also making progress in monetizing its technologies.

- Current price is undervalued compared to its peers. We encourage investors to accumulate Access's shares at current level. Risks related to our call include cash burn concern, competition in the cancer market and clinical and regulatory failures.

OVERVIEW

Access Pharmaceuticals, Inc. (Access) is an emerging biopharmaceutical company focused on developing a range of pharmaceutical products for the treatment of cancer and cancer supportive care primarily based upon the company's **three key drug delivery technologies:** Synthetic Polymer Targeted Drug Delivery System; Cobalamin Mediated Oral Drug Delivery System (CobOral) and Cobalamin Mediated Targeted Drug Delivery System (CobaCyte).

Table 1: Pipeline under development

Compound	Originator	Technology	Indication	Clinical Stage
MuGard	Access	Mucoadhesive, liquid	Mucositis	(510k) Marketing clearance received
ProLindac	Access /Univ of London	Synthetic Polymer	Cancer	Phase II
Thiarabine	Southern Research Institute	Small molecule	Cancer	Phase I/II
CobOral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
Other CobOral Therapeutics	Access	Cobalamin	Various	Pre-clinical
CobaCyte Therapeutics	Access	Cobalamin	Anti-tumor	Pre-clinical

Source: Company filing and Zacks Investment Research, Inc.

The Company currently has one approved product **MuGard** for the management of oral mucositis, a frequent side-effect of cancer. Pipeline includes two products at Phase II of clinical development and several products in pre-clinical development. **ProLindac** is a replacement for Sanofi-Aventis' Eloxatin using the company's Synthetic Polymer technologies. ProLindac, representing a $3 billion plus market opportunity, is currently under phase II clinical studies for ovarian cancer. Another phase II candidate is **Thiarabine**, a novel nucleoside analogue for the treatment of blood cancers and solid cancers. Other

product candidates include Cobalamin-based oral therapeutics and Cobalamin targeted therapeutics, which are in preclinical studies. The following table summarizes the company's major pipeline under development.

Part of Access' growth strategy is to form alliances with major pharmaceutical and biotech companies to support its in-house development of drug candidates.

Access Pharmaceuticals, Inc. was founded in 1988 and is based in Dallas, Texas. The Company has about 10 employees.

INVESTMENT THESES

MuGard will Boost Top Line Growth in the Coming Quarters

MuGard has been approved by both the EU and the US health authorities as a medical device. MuGard is a proprietary nanopolymer formulation of mucoadhesive liquid, indicated for the management of **oral mucositis**, a frequent side-effect of cancer radiotherapy and chemotherapy for which there is no established treatment.

Mucositis is a debilitating condition involving extensive ulceration of the oral cavity that frequently affects cancer patients undergoing radiation and chemotherapy treatment. Roughly 90% of patients on radiation (43% severe) and 40% of patients receiving chemotherapy get mucositis. There is an estimated 400,000 cancer patients getting mucositis annually in the United States alone. World-wide, the potential market for mucositis could exceed $1 billion in the next few years. We believe any treatment that accelerates healing and/or diminishes the rate of appearance of mucositis would have a significant beneficial impact on the quality of life of these patients and may allow for more aggressive chemotherapy.

MuGard is a viscous polymer solution which provides a coating for the oral cavity. A multi-site, randomized clinical study was performed in the United States testing MuGard and MuGard containing an anti-inflammatory drug to determine the effect of these products on the prevention and treatment of mucositis. The data from this trial indicated that the patients using MuGard displayed a lower incidence of mucositis than is typically seen in the studied population with no additional benefit from the drug. The data were retrospectively compared with two historical patient databases to evaluate the potential advantages MuGard may provide in the prevention, treatment and management of mucositis. The patient evaluation was conducted using the oral mucositis assessment scale (OMAS), which qualifies the disease severity on a scale of 0-5. In both cases, it was shown that mean mucositis score were lower for patients using MuGard than for similar patients on standard care. The average severity of the disease was reduced by approximately 40%. The maximum intensity of the mucositis was approximately 35% lower; and the median peak intensity was approximately 50% lower. One of the most striking features of the comparison is that 43% of patients on MuGard experienced no mucositis (OMAS score never exceeded 0.5) compared with only 7% in the historical control group. These data confirmed the fact that MuGard could represent an important advancement in the management and prevention of mucositis.

In December, 2006, Access received 510(k) marketing clearance for MuGard from the FDA for the indication of the **management of oral wounds** including mucositis, stomatitis, aphthous ulcers and traumatic ulcers.

In the US, launch of MuGard has been delayed due to partnership problem. On July 29, 2009, Access took control of the North American rights to MuGard from a previous partner which had not received required funding to launch the product in the U.S. In addition, Access is evaluating strategic options for the commercialization of MuGard in North America. The company has hired Mr. Frank Jacobucci, formerly President & COO of Milestone Biosciences, as Vice President, Sales and Marketing, to assist with ongoing reimbursement, manufacturing and commercial launch activities of MuGard, while

discussions with potential licensee and co-promotion partners is ongoing. Access has appointed Accupac, Inc. as the US manufacturer for MuGard. The Company officially launched MuGard in the US on August 3, 2010.

Internationally, Access has been making good progress in registering and promoting MuGard. In August 2007 Access signed a definitive licensing agreement with **SpePharm Holding, B.V.** under which SpePharm will market MuGard in **Europe**. MuGard sales started in part of Europe in the second quarter of 2009, and rolling launch in more EU countries is underway. In January 2008, Access signed a definitive licensing agreement with **RHEI Pharmaceuticals**, Inc. under which RHEI will market MuGard in **China** and other Southeast Asian countries. **JCOM Co., Ltd**., the company's **Korean** licensee for MuGard, has received approval of MuGard in Korea. As soon as JCOM has completed the additional steps required to import MuGard from the United States, marketing will commence.

The official US launch of MuGard coupled with the Company's international commercialization efforts will greatly boost its top line in the coming quarters in our view.

MuGard Holds Competitive Advantages Over Its Competitors

We noticed that there are a few products already on the market for oral mucositis. But the competitive landscape favors MuGard in our view.

MuGard is dispensed in a ready to use mouth rinse. The rinse may be expelled or swallowed (safe to swallow). MuGard has a very broad range of usage for the management of oral mucositis/stomatitis that may be caused by radiotherapy and/or chemotherapy and for all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

Amgen's **Kepivance (Palifermin),** bought by Swedish pharmaceutical company Biovitrium AB in December 2008, is a recombinant form of human keratinocyte growth factor (KGF), a protein that is naturally produced by the body. Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support. The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Kepivance must be IV injected for 3 consecutive days before and 3 consecutive days after treatment for a total of 6 injections. Also, Kepivance is expensive at about $10,000 per patient compared to the cost of about **$1200 per patient for MuGard (6 bottles, $200/bottle)**. Access recently increased MuGard price to $250/bottle, resulting in $1500 per patient.

Three other medical devices on the market are EKR Therapeutics' Gelclair, GeoPharma's Mucotrol, and EUSA Pharma's Caphosol. **Gelclair** is a prescription mouth gel that is designed and approved for the management and relief of pain caused by mouth sores. Gelclair is established by mixing the powder in a glass of water to form the rinse and patients gargle and spit out. **Mucotrol** is concentrated oral gel wafer which is indicated for the management and relief of pain from oral lesions associated with oral mucositis/stomatitis. **Caphosol** is similar to Gelclair. Patients must mix the contents of two ampoules to form a rinse and then swish/spit out. However, one study has shown that Caphosol seems to have no influence on the frequency, duration and severity of oral mucositis during (chemo) radiation in head and neck cancer patients.

Apparently, MuGard is a more user-friendly ready-to-use rinse which can either be expelled or swallowed. We believe MuGard will eventually capture about 25% market share of the mucositis market with peak sales about $300 million.

Deep Pipeline Provides Sustainable Long Term Growth

Besides MuGard, Access has a relatively decent pipeline under various stage of development based on its three proprietary drug delivery platform technologies: Synthetic Polymer Targeted Drug Delivery

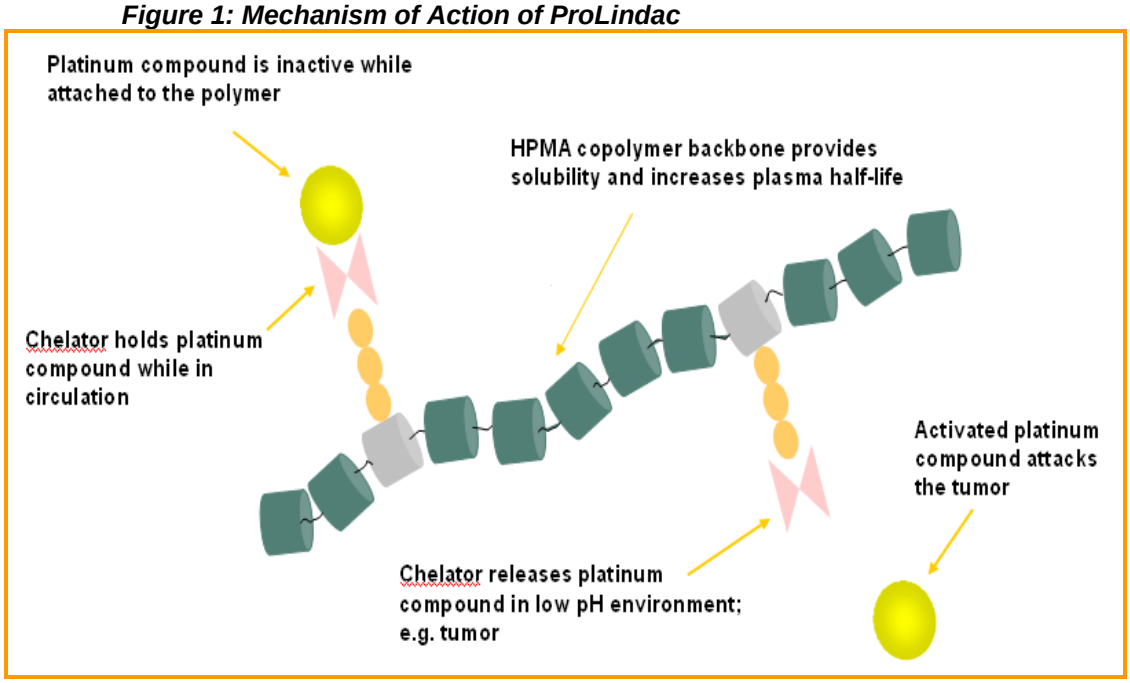
System; Cobalamin Mediated Oral Drug Delivery System and Cobalamin Mediated Targeted Drug Delivery System. This is important for a biotech company because platform technologies create multiple product opportunities, mitigate operational risks.

ProLindac represents a multi-billion dollar market opportunity

In collaboration with The School of Pharmacy, University of London, Access has developed a **synthetic polymer targeted drug delivery technology**, which utilizes a hydroxypropylmethacrylamide (**HPMA**) polymer as the drug carrier, designed to exploit enhanced permeability and retention effect (EPR), at tumor sites to selectively accumulate drug and control drug release. Many solid tumors possess vasculature that is hyperpermeable, or leaky, to macromolecules. In addition to this enhanced permeability, tumors usually lack effective lymphatic and/or capillary drainage. Consequently, tumors selectively accumulate circulating macromolecules, including, for example, up to 10% of an intravenous dose in mice. These polymers take advantage of endothelial permeability as the drug carrying polymers are trapped in tumors and then taken up by tumor cells. Linkages between the polymer and drug can be designed to be cleaved extracellularly or intracellularly. Utilizing the principles of prodrugs, the drug is essentially inert while attached to the polymer, but is released inside the tumor mass while polymer/drug not delivered to tumors is cleared from the body via the kidneys.

Based on the HPMA technology, Access has designed ProLindac. **ProLindac** is the conjugate of HPMA and DACH platinum. DACH platinum is the active ingredient of **Eloxatin** (**oxaliplatin**) marketed by Sanofi-Aventis. Platinum-based chemotherapies are one of the most clinically and commercially successful classes of chemotherapeutic cancer drugs. Total sales of Eloxatin in 2008 were €1.35 billion ($2.0 billion). Either alone or in combination, platinum-based therapies are used in a broad range of solid tumors such as lung cancer, colon cancer or breast cancer. However, platinum-based chemotherapies have serious systemic side effects such as neurotoxicity, nephrotoxicity, ototoxicity and nausea/vomiting among other things, which limit its usage especially at large doses.

Figure 1: Mechanism of Action of ProLindac



Source: Access Pharmaceuticals Inc.

ProLindac is attached to a pH-sensitive linker which releases the platinum cytotoxic agent much faster in the low pH environments found typically outside of hypoxic tumor cells and within specific compartments inside of tumor cells. Data generated in animal studies have shown that the polymer/drug complexes are far less toxic than free drug alone and that greater efficacy can be achieved. Thus, these polymer

complexes have demonstrated significant improvement in the therapeutic index of anti-cancer drugs. The following chart illustrates the mechanism of action for ProLindac.

Access completed a **phase I** multi-center clinical study of ProLindac conducted in Europe In 2005. The trial was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible anti-tumor activity of ProLindac. Of the 16 evaluable patients, 2 demonstrated a partial response, 1 experienced a partial response based on a biomarker and 4 experienced stable disease. ProLindac has demonstrated superior safety profile to oxaliplatin. No unanticipated toxicities were observed. There is no sign of oxaliplatin-like neurotoxicity, no signs of nephrotoxicity, no hematotoxicity. Emesis is comparable to that seen in oxaliplatin. At least 5x more platinum can be dosed compared to oxaliplatin before onset of toxicity.

Access completed a **phase II** clinical trial of ProLindac in late 2008 in **ovarian cancer** patients who relapsed after first line platinum therapy and second line therapies. The primary aim of the study was to determine the response rate of ProLindac monotherapy in this patient population. The response rates for other platinum compounds in this indication are reported, and were used for comparison. Patients were dosed either once every 2 weeks or once every three weeks. As the phase I study involved weekly dosing, the initial phase of the ovarian cancer monotherapy study involved some dose escalation to determine recommended doses using these dosing regimens.

This 26 patient Phase II study explored 3 different dose levels and 2 dosing regimens of ProLindac as a monotherapy treatment for advanced ovarian cancer, to provide data on the monotherapy anticancer activity and safety of ProLindac. Of patients eligible for evaluation, clinically-meaningful disease stabilization was achieved in 42% of all patients, and 66% of all patients in the higher dose groups. Sustained and significant reductions in Ca125, the established specific serum marker for ovarian cancer, were also observed in several patients. No patient in any dose group exhibited any signs of acute neurotoxicity, and ProLindac was well tolerated overall. The maximum tolerated dose of ProLindac was established as well as the recommended dose levels for future combination studies.

The above phase II clinical trial was extended to enroll additional cohort of 8 patients in France and the company completed the study in January 2010. The additional cohort of 8 patients received the ProLindac batch made by an improved scalable process, which will be used on a larger scale for future clinical and commercial supplies. None of the 8 patients experienced any acute significant adverse events, while treatment had the same beneficial pharmacodynamic effect seen in the first 26 patients treated with the former ProLindac production batch. Clinically relevant sustained biomarker decrease and disease stabilization were seen in several patients.

The significant efficacy data of ProLindac in patients at the highest dose levels is very encouraging given that this study involved monotherapy in a heavily pretreated patient population that typically only respond to aggressive drug combinations. The DACH platinum activity level was seen benchmarked favorably with published studies of monotherapy oxaliplatin in similar but less heavily pre-treated patient populations.

Based on the above monotherapy of ProLindac phase I and phase II study results, Access initiated a new **phase II** study of ProLindac **in combination with Paclitaxel** in second line treatment of platinum pretreated advanced **ovarian cancer** patients in November 2010. This study is the first to look at the safety and efficacy of ProLindac in combination with other oncology agents. The efficacy of Diamino Cyclohexane (DACH) Platinum, the active principle in ProLindac, is evidenced mainly through their synergic association with multiple anticancer agents. The choice of Paclitaxel and ovarian cancer as the potential first NDA strategic choice to be explored is based on the positive results of the Paclitaxel/Oxaliplatin combination in the same clinical setting. This multi-center study of up to 25 evaluable patients will be conducted in Europe. The efficacy endpoint goal is to achieve a minimum of 63% response rate in the total of 25 evaluable patients the study is planning to accrue on a two step design. The results of this combination study will lead to registrational trial in our view.

Access previously submitted an IND application to the US Food and Drug Administration, and received clearance from the agency to proceed with a **phase I** clinical study of ProLindac in combination with fluorouracil and leucovorin. The study is designed to evaluate the safety of ProLindac in combination with two standard drugs used to treat colorectal cancer and to establish a safe dose for Phase II clinical studies of this combination in **colorectal cancer**. The Company is currently evaluating various options for combination trials to be conducted, in the US or other countries.

Access has licensed ProLindac to **Jiangsu Aosaikang Pharmaceutical Co., Ltd**. for the Greater China Region and to **JCOM, Ltd** for South Korea. Under these agreements both of these partners will be conducting combination studies with ProLindac in specific tumor types at their expense based on these results.

Thiarabine---next generation of nucleoside analogue chemotherapeutic agent

Nucleoside analogue is another important class of chemotherapeutic agents. Cytarabine (ara-C), fluorouracil (5-FU), gemcitabine are benchmarks in this class of highly effective cytotoxic drugs for cancers. Gemcitabine (Gemzar, Lilly) is the market leader with world wide sales of $1.7 billion and $1.4 billion in 2008 and 2009 respectively.

Thiarabine (4-thio Ara-C) is a next generation nucleoside analog licensed from Southern Research Institute. Thiarabine exhibited significant activity, including regressions or cures, in six tested leukemia or lymphoma cell lines. The compound produced better activity than ara-C or a fatty acid-modified ara-C (depot) analog in four of six tested models. Thiarabine also performed as well or better than clofarabine and gemcitabine in each of the models.

Unlike ara-C, Thiarabine was found to be active in a wide variety of solid tumor xenograft models (14 different cell lines), including colorectal, lung, renal, prostate, breast and pancreatic tumors. Thiarabine produced regressions or tumor-free survivors in about half of the models and exhibited better activity than gemcitabine or clofarabine in many models. Thiarabine activity was also better than that of paclitaxel or cisplatin in certain lung models. An increase in regression or cure rate over either compound alone was observed with combinations of Thiarabine and cisplatin in lung tumors, Thiarabine and irinotecan or clofarabine in colorectal tumors, and Thiarabine plus clofarabine in a leukemia model.

Based on the excellent anticancer activity, **two phase I** studies were conducted of Thiarabine monotherapy in patients with solid tumors.

In the **first phase I** study, 26 patients with incurable advanced and/or metastatic solid tumors were enrolled. Out of 21 evaluable patients, 9 experienced stable disease (median duration 4.3 months, range 1.8-6.4 months). Dose-limiting toxicities (DLTs) were observed at 400-600 mg/m^2. Unlike previous observations with gemcitabine and ara-C (where the DLT is myelosupression, leucopenia and thrombocytopenia), there were no grade four toxicities and no hematological toxicities other than reversible lymphopenia. Investigators concluded that the (Grade 3) dose-limiting toxicities were fatigue, rash, fever, seizure and lymphopenia.

A second solid tumor **phase I** trial was carried out to explore other schedules. Of the 27 evaluable patients, 7 patients (including bladder cancer and mesothelioma) achieved disease stabilization (median 3.7 months, range 1.9-5.4). The main toxicity was fatigue, which appeared to be schedule independent.

Based on the positive phase I results, Access initiated a **Phase I/II** clinical trials of Thiarabine in patients with hematologic malignancies in early August 2010.

The primary objective of the study is to determine the maximum tolerated dose (MTD) in two different dosing schedules with various leukemias and lymphomas and recommended Phase II dose.

The clinical development program follows previously conducted Phase I and Phase II trials of Thiarabine in solid tumors, where myelosuppression (decrease in the production of blood cells), particularly lymphopenia (abnormally low white blood cell levels) was dose limiting. Theoretically, an agent that produces significant lymphopenia can be a strong active against lymphoproliferative disorders like acute lymphoblastic leukemia (ALL), chronic myelogenous leukemia (CML), myeloma and lymphoma.

Lymphopenia observed in previous studies coupled with the excellent preclinical results in leukemia models indicate that Thiarabine is an excellent candidate for treating advanced hematologic malignancies. Access has signed an agreement to conduct a clinical study in this indication at MD Anderson, and the study is expected to start enrolling in August 2010.

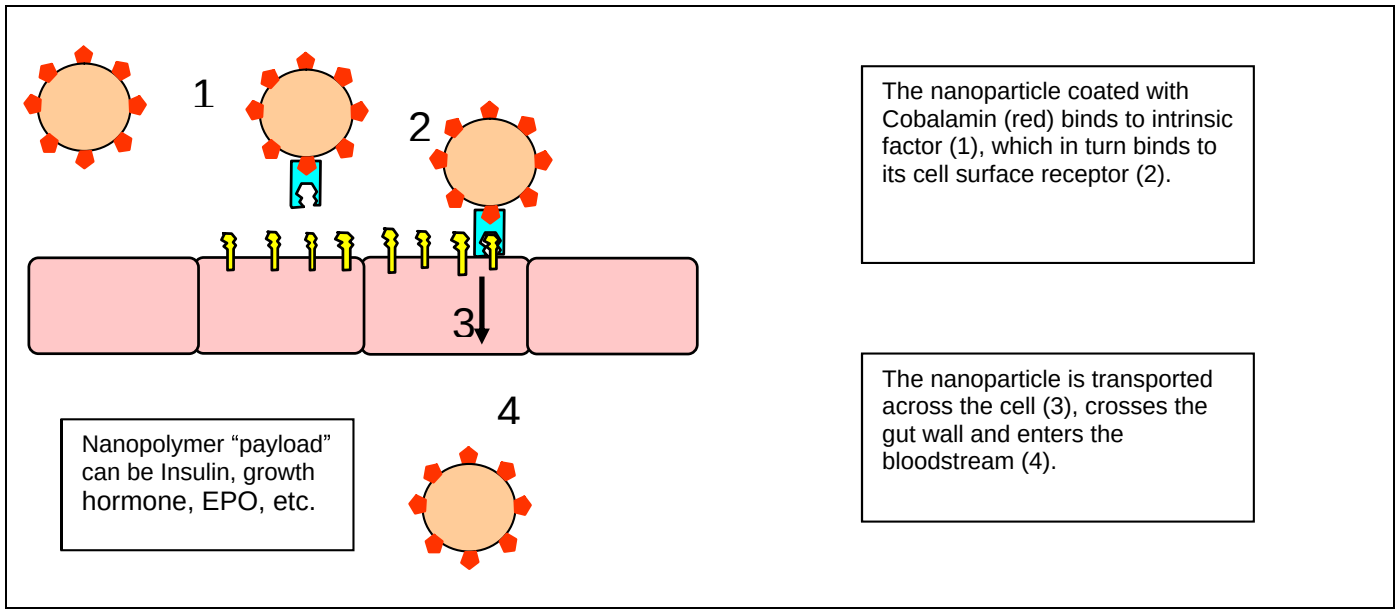
CobOral Technology has Great Potential

Access has developed Cobalamin based oral drug delivery technology **(CobOral)** based on the natural vitamin B12 oral uptake mechanism.

The difficulty in administering proteins orally is their susceptibility to degradation by digestive enzymes, their inability to cross the intestinal wall and their rapid excretion by the body. The field of oral drug delivery of proteins and peptides has yet to achieve successful commercialization of a product although positive results have been achieved in early clinical trials for some products under development.

Many pharmaceutically active compounds such as proteins, peptides and cytotoxic agents cannot be administered orally due to their instability in the gastrointestinal tract or their inability to be absorbed and transferred to the bloodstream. A technology that would allow many of these actives to be taken orally would greatly enhance their acceptance and value. Several technologies for the protection of sensitive actives in the gastro-intestinal tract and/or enhancement of gastro-intestinal absorption have been explored and many have failed.

Figure 2: Cobalamin-based drug delivery system



Sources: Access Pharmaceuticals, Inc.

Access’ Cobalamin (analogue of VB12) oral drug delivery **(CobOral)** utilizes the body’s natural vitamin B12 (VB12) transport system in the gut. The absorption of VB12 in the intestine occurs by way of a receptor-mediated endocytosis. Initially, VB12 binds to naturally-produced intrinsic factor (IF) in the small intestine, and the VB12-IF complex then binds to the IF receptor on the surface of the intestine.

Receptor-mediated endocytosis then allows the transport of VB12 across the gut wall. After binding to another VB12-binding protein, transcobalamin II (TcII), VB12 is transferred to the bloodstream.

In preclinical studies, Cobalamin-based **oral insulin** has achieved unprecedented level of oral bioavailability (>80%) of insulin in two animal models.

In March 2010, Access signed a collaborative development agreement with **bioRASI, LLC**, a full-service global CRO specializing in the accelerated development of novel therapeutics, to facilitate clinical development for its Cobalamin-based oral insulin and other Cobalamin-based products. A major focus of this program will be a first-in-man study for Access' oral insulin product.

bioRASI will utilize its Translational Clinical Development Process which has demonstrated the ability to generate high quality human proof-of-principle data very quickly and cost-effectively, particularly in the Russian Federation. Under the agreement, bioRASI will implement the development program necessary to initiate the first-in-man study in Russia and satisfy all regulatory requirements through approval. Preclinical and clinical studies will be conducted at highly-respected research facilities within Russian Federation and will follow the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines to support regulatory submissions in Europe, Japan and the United States. While facilitating the studies and satisfying all necessary regulatory requirements for the program, bioRASI will also assist Access in finding partners for oral insulin and other Cobalamin-based products in Russia and other Eastern European and CIS countries. Access has the option to extend the agreement to additional Cobalamin-based products following a similar development pathway. At a future time the Parties may agree for bioRASI to take an equity position in Access for some or all of the expenses associated with this project.

We believe a **phase I** trial of Cobalamin-based oral insulin will be initiated soon.

In addition to oral insulin program, the company has also other Cobalamin-based oral therapeutics under pre-clinical development, such as Cobalamin-based oral **human growth hormone.** Together, these Cobalamin-based oral drug delivery therapeutics will provide the company great potential to grow.

Access Continues to Make Progress to Monetize its CobOral Drug Delivery Technology

On the drug delivery technologies front, Access has been making efforts to monetize its programs and has made great progress.

For the CobOral technology, the Company has co-operations with big pharma or biotech companies in oral insulin program, diabetes and prostate cancer.

On April 13, 2011, Access entered into an agreement with a major global pharmaceutical company to exploit its CobaCyte and CobOral technology for the targeted delivery of RNAi therapeutics.

Access will provide the pharmaceutical company with CobOral and CobaCyte siRNA formulations for evaluation of gene knockdown following oral and intravenous administration. Though the terms of the agreement have not been disclosed, Access indicated that any successful formulation developed will be jointly owned by the Parties and subject to a subsequent full licensing agreement.

These pre-licensing programs are progressing very well and full license deals could be closed any time soon.

In July and October, 2010, Access entered into pre-licensing feasibility agreement with two leading biotechnology companies to develop an oral formulation of its currently-marketed, proprietary injectable drugs (diabetes) and prostate cancer compound respectively.

Access will utilize its proprietary **CobOral Drug Delivery Technology** to develop oral formulations of the drugs for pre-clinical testing. Although the name and the terms of the agreements have not been disclosed due to competitive reasons, management indicated that any successful formulation developed will be subject to a subsequent full-licensing agreement.

We are impressed with the progress Access has made in the last few months about its CobOral drug delivery technology. In addition to applications for oral insulin, human growth hormone and siRNA developed in house, the Company has made great efforts to expand the application to other areas and great progress has been made so far.

We believe the alliance further validates Access's drug delivery technology. It will also strengthen the company's balance sheet in the event of any upfront and milestone payments. As part of the deals, Access filed new patent applications on formulations, and has covered probably 50 of the top selling injectable drugs. This may have strategic implications for the company. Management has indicated that there are a few other big pharma companies which are interested in the alliance to use Access' Cobalamin Oral Drug Delivery System.

Cobalamin-mediated Targeted Delivery Technology further Expands Platform Technologies

While Access' Cobalamin-based oral drug delivery system tries to enhance bioavailability of macromolecules systematically, its Cobalamin-mediated targeted drug delivery system **(CobaCyte)** tries to increase concentration of drugs into diseased cells.

Most drugs are effective only when they reach a certain minimum concentration in the region of disease, yet are well distributed throughout the body following delivery to the bloodstream contributing to undesirable side effects. It is therefore advantageous to alter the natural biodistribution of a drug to have it more localized where it is needed.

Access' Cobalamin-mediated targeted delivery technology **(CobaCyte)** utilizes the fact that in many diseases where there is rapid growth and/or cell division, the demand for certain vitamins increases. By coupling the drug to a vitamin analog, the analog serves as a carrier to increase the amount of drug at the disease site relative to its normal distribution.

One application of this technology is in **tumor targeting**. The use of cytotoxic chemotherapeutic drugs is one of the most common methods for treating a variety of malignancies including solid and non-solid tumors. The drawbacks of chemotherapeutic treatments, which include tumor resistance, cancer relapse and toxicity from severe damage to healthy tissues, have fuelled a scientific quest for novel treatments that are specifically targeted to malignant cells thus reducing damage to collateral tissues.

The design of targeted therapies involves exploitation of the difference between the structure and function of normal cells compared with malignant cells. Differences include the increased levels of surface receptors on cancer cells, which makes them more sensitive to treatment regimes that target these cell surface receptors and differences in blood supply within and around tumor cells compared with normal cells.

It has been known for some time that vitamin B12 and folic acid are essential for tumor growth, and as a result, receptors for these vitamins are up-regulated in certain tumors. Vitamin B12 receptor over-expression occurs in breast, lung, leukemic cells, lymphoma cells, bone, thyroid, colon, prostate and brain cancers and some other tumor lines, while folate receptor over-expression occurs in breast, lung, ovarian, endometrial, renal, colon, brain and cancers of myeloid hemotopoietic cells and methotrexate-sensitive tumors.

The Cobalamin-mediated tumor targeting programs are still in preclinical development. We believe Access is going to accelerate the programs once the company finds appropriate partners.

Another important application area for CobaCyte is **siRNA** program, in which the Company has received much interest from big pharma or biotech companies.

We believe the above discussed three proprietary platform technologies, Synthetic Polymer Targeted Drug Delivery System; Cobalamin Mediated Oral Drug Delivery System and Cobalamin Mediated Targeted Drug Delivery System, will create multiple product opportunities and mitigate single product exposure. Therefore, these technologies provide sustainable growth for the company in the years to come.

VALUATION

We continue to maintain our Outperform rating on Access Pharma and reiterate our price target of $7 per share.

We believe MuGard will strongly boost the Company's top line in the coming quarters. MuGard has competitive advantages over its competitors for the management of oral mucositis. World-wide sales could exceed $200 million in 2015. We have a high confidence in the successful launch of MuGard. Our confidence is based upon factors including the strong clinical data, unmet medical needs in the mucositis market and the Company's focused marketing strategy. Although initial sales ramp is expected to be slow, sales of MuGard in the US should pick up steam when more and more doctors/nurses are convinced by MuGard's clinical benefits. Sales of MuGard will grow at a tremendous CRGR of 370% from 2011 to 2015 according to our long term model.

We are optimistic with the company's pipeline which will provide sustainable growth for the company in the years to come. Both ProLindac and Thiarabine are in middle stage of development and both target the multi-billion dollar cancer market.

We see great potential for the Company's three key platform technologies which create multiple product opportunities. We are especially impressed with the Company's CobOral delivery system. The oral insulin and oral human growth hormone have already achieved unprecedented oral bioavailability in preclinical studies. The Company has signed agreements with two major biotech companies to develop oral drugs with its CobOral delivery system. We believe Access will continue to monetize its platform technology in the coming years.

We believe Access is undervalued at current share price compared to its peers. The Company will be profitable in fiscal 2013 with EPS of $0.01 per share. From 2011 to 2015, top line will grow at a CAGR of 300%. At current price of $1.30, Access trades at 4.1 x our estimated 2014 EPS of $0.33 and 1.4 x our estimated 2015 EPS of $1.00 which is at huge discount compared to its peers. We believe Access should be trading at a P/E multiple of 15x which is only half of the biotech industry mean P/E multiple of 30x which translate into per share price of $7 based on our estimated EPS of $1.00 in fiscal 2015, discounted at 30% for three years.

RISKS

Cash Position is our Chief Concern

As of September 30, 2011, Access had cash and cash equivalents of $1.3 million. This current cash and expected license fees can only fund expected burn rate into the first quarter of 2012.

However, in November 2011, Access entered into definitive agreements for the purchase of $5.2 million of units, consisting of common stock and warrants in a private placement financing with a select group of

institutional and accredited investors. Each unit consists of the one share of common stock at $1.45 share price, with 50% warrant coverage with an exercise price of $1.67 per share and a term of two and half years and 50% warrant coverage with an exercise price of $2.00 per share and a term of five years.

With this financing, the Company's liquidity could fund the operations into the end of 2012. The Company may need to tap the capital market in late 2012. Equity financing will dilute shareholder base and share price will suffer.

Competition Remains Fierce in the Cancer Market

Access's current marketed product MuGard and late stage candidates ProLindac and Thiarabine target the same cancer market which becomes extremely competitive in recent years. Each product faces fierce competition in its own market. Although MuGard holds competitive advantages over its peers, and the company has signed two key distribution agreements, a slow initial sales ramp after its official launch cannot be ruled out completely. If the sales of MuGard fails match the estimates by the Street, the share price may suffer.

Regulatory and Clinical Hurdles are High

Access is operating within the biotech industry which is a very special industry. The Company must successfully navigate both clinical and regulatory process in order to bring a product into the market. The hurdles are high as we have seen in the past. Our financial model suggests the successful approval of the Company's candidates by appropriate health authorities in the world. If that's not the case, then the Company's share price may drop sharply.

PROJECTED INCOME STATEMENT

$ in million except per share data	Q1	Q2	Q3	Q4	12/10A	Q1	Q2	Q3	Q4E	12/11E	12/12E	12/13E	12/14E	12/15E
Product Revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.01	$0.04	$0.08	$0.50	$0.64	$15.00	$35.00	$87.50	$165.00
YOY Growth	-	-	-	-	-	-	-	-	-	-	*2251.1%*	*133.3%*	*150.0%*	*88.6%*
Royalties Revenue	$0.02	$0.02	$0.02	$0.02	$0.08	$0.02	$0.02	$0.02	$0.02	$0.08	$1.65	$2.75	$6.70	$16.90
YOY Growth										*10.5%*	*1864.3%*	*66.7%*	*143.6%*	*152.2%*
License and R&D revenue	$0.09	$0.09	$0.11	$0.12	$0.41	$0.12	$0.09	$0.94	$0.12	$1.26	$1.00	$1.00	$1.00	$1.00
Total Revenues	**$0.10**	**$0.11**	**$0.13**	**$0.14**	**$0.48**	**$0.15**	**$0.15**	**$1.04**	**$0.64**	**$1.98**	**$17.65**	**$38.75**	**$95.20**	**$182.90**
YOY Growth	*148.8%*	*66.7%*	*-11.8%*	*38.5%*	*35.8%*	*47.1%*	*43.8%*	*719.7%*	*344.4%*	*314.6%*	*790.5%*	*119.5%*	*145.7%*	*92.1%*
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.3	$0.5	$0.1	$0.9	$3.0	$7.0	$17.5	$33.0
Gross Income	**0.10**	**0.11**	**0.13**	**0.14**	**0.48**	**0.06**	**(0.12)**	**0.59**	**0.54**	**1.07**	**14.65**	**31.75**	**77.70**	**149.90**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*38.7%*	*-76.2%*	*56.4%*	*84.4%*	*54.0%*	*83.0%*	*81.9%*	*81.6%*	*82.0%*
SG&A	$0.9	$1.3	$1.2	$1.2	$4.5	$1.0	$1.0	$1.1	$1.1	$4.2	$10.0	$15.0	$35.0	$55.0
% SG&A	*880.4%*	*1193.3%*	*917.3%*	*829.9%*	*943.7%*	*684.0%*	*674.8%*	*102.1%*	*178.1%*	*214.3%*	*56.7%*	*38.7%*	*36.8%*	*30.1%*
R&D	$0.8	$0.7	$1.2	$0.6	$3.3	$1.1	$1.1	$1.3	$1.4	$4.8	$9.5	$15.0	$25.0	$35.0
% R&D	*770.6%*	*698.1%*	*944.1%*	*438.2%*	*700.6%*	*746.7%*	*702.0%*	*120.3%*	*218.8%*	*243.8%*	*53.8%*	*38.7%*	*26.3%*	*19.1%*
Other	$0.1	$0.1	$0.1	$0.2	$0.4	$0.1	$0.1	$0.1	$0.1	$0.3	$0.3	$0.3	$0.3	$0.3
% Other	*59.8%*	*56.2%*	*46.5%*	*138.2%*	*79.1%*	*40.7%*	*39.1%*	*5.4%*	*15.6%*	*13.9%*	*1.7%*	*0.8%*	*0.3%*	*0.2%*
Operating Income	**($1.6)**	**($1.9)**	**($2.3)**	**($1.9)**	**($7.8)**	**($2.1)**	**($2.3)**	**($1.8)**	**($2.1)**	**($8.3)**	**($5.2)**	**$1.5**	**$17.4**	**$59.6**
Operating Margin	*-1610.8%*	*-1847.6%*	*-1807.9%*	*-1306.3%*	*-1623.4%*	*-1432.7%*	*-1492.1%*	*-171.4%*	*-328.1%*	*-418.1%*	*-29.2%*	*3.7%*	*18.3%*	*32.6%*
Other Net	$2.7	$3.7	($10.4)	$4.2	$0.2	$0.3	$1.0	$2.1	($0.2)	$3.2	($1.0)	($1.0)	($1.0)	($1.0)
Pre-Tax Income	**$1.1**	**$1.8**	**($12.7)**	**$2.3**	**($7.5)**	**($1.9)**	**($1.3)**	**$0.4**	**($2.3)**	**($5.1)**	**($6.2)**	**$0.5**	**$16.4**	**$58.6**
Pref. stk Div + oth.	$0.4	$0.4	$0.5	$0.5	$1.8	$0.4	$0.4	$0.4	$0.5	$1.8	$2.2	$2.5	$3.0	$3.5
Taxes + Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($0.2)	$0.0	$1.6	$8.8
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*2.5%*	*5.0%*	*10.0%*	*15.0%*
Reported Net Income	**$0.6**	**$1.3**	**($13.2)**	**$1.8**	**($9.3)**	**($2.3)**	**($1.7)**	**($0.1)**	**($2.8)**	**($6.9)**	**($6.0)**	**$0.4**	**$14.8**	**$49.8**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*-107.1%*	*3352.6%*	*237.5%*
Net Margin	*634.3%*	*1280.0%*	*-10370.9%*	*1284.0%*	*-1952.1%*	*108.7%*	*75.7%*	*5.4%*	*133.3%*	*-350.2%*	*-34.0%*	*1.1%*	*15.5%*	*27.2%*
Shares Out	*17.8*	*27.9*	*15.8*	*15.7*	*15.7*	*19.2*	*19.4*	*19.5*	*21.9*	*20.0*	*25.0*	*35.0*	*45.0*	*50.0*
Reported EPS	**$0.04**	**$0.05**	**($0.83)**	**$0.12**	**($0.60)**	**($0.12)**	**($0.09)**	**($0.00)**	**($0.13)**	**($0.35)**	**($0.24)**	**$0.01**	**$0.33**	**$1.00**
YOY Growth	-	-	-	-	-					-	-	*-105.1%*	*2585.4%*	*203.7%*
One time charge	($2.88)	($3.36)	*$10.31*	($4.20)	($0.13)	($0.41)	($1.34)	($2.42)	$0.00	*($4.17)*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($2.2)**	**($2.0)**	**($2.9)**	**($2.4)**	**($9.5)**	**($2.7)**	**($3.0)**	**($2.5)**	**($2.8)**	**($11.1)**	**($6.0)**	**$0.4**	**$14.8**	**$49.8**
Non GAAP EPS	**($0.13)**	**($0.07)**	**($0.18)**	**($0.15)**	**($0.60)**	**($0.14)**	**($0.16)**	**($0.13)**	**($0.13)**	**($0.56)**	**($0.24)**	**$0.01**	**$0.33**	**$1.00**

Source: Company filings and Zacks Investment Research Inc. estimates

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