

## Access Pharma (ACCP-OTC)

**ACCP: Marketed product coupled with unique drug delivery technologies-  
 Outperform**

<b>Current Recommendation</b>	<b>Outperform</b>
Prior Recommendation	N/A
Date of Last Change	05/17/2010
Current Price (07/26/10)	\$1.85
<b>Six- Month Target Price</b>	<b>\$8.00</b>

### OUTLOOK

Access is a biopharmaceutical company focused on developing a range of pharmaceuticals primarily based upon the company's three key 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 especially impressed with the company's Cobalamin-based oral drug delivery system. 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 six to twelve-month price target is \$8.

### SUMMARY DATA

52-Week High	\$4.70
52-Week Low	\$1.88
One-Year Return (%)	-8.21
Beta	1.30
Average Daily Volume (sh)	31,952

Shares Outstanding (mil)	25.3
Market Capitalization (\$mil)	\$46.8
Short Interest Ratio (days)	0.35
Institutional Ownership (%)	0
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	3
------------	---

Risk Level	Above Avg.,
Type of Stock	N/A
Industry	Med-Drugs
Zacks Rank in Industry	32 of 79

### ZACKS ESTIMATES

#### Revenue

(in millions of \$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2009	0.04 A	0.06 A	0.14 A	0.10 A	0.35 A
2010	0.10 A	0.11 E	0.73 E	1.87 E	2.80 E
2011					17.37 E
2012					63.70 E

#### Earnings per Share

(EPS is operating earnings before non recurring items)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2009	-\$0.24 A	-\$0.24 A	-\$0.37 A	-\$0.17 A	-\$1.02 A
2010	-\$0.13 A	-\$0.11 E	-\$0.11 E	-\$0.10 E	-\$0.44 E
2011					-\$0.04 E
2012					\$0.82 E

Zacks Projected EPS Growth Rate - Next 5 Years %	56
--	----

## WHAT'S NEW

### **Two distribution agreements for MuGard signed**

On July 20, 2010, Access signed an exclusive specialty distribution agreement with **BioScrip** for its lead product, MuGard -- an FDA-approved, oral rinse for the management of oral mucositis.

BioScrip, Inc. is a national provider of specialty pharmacy and home care products and services. BioScrip is a well-established top-tier player in the above area which partners with patients, physicians, hospitals, healthcare payors and pharmaceutical manufacturers to provide clinical management solutions and delivery of cost-effective access to prescription medications.

The agreement will allow Access to use BioScrip's nationwide distribution network. BioScrip's vast clinical, sales and operational specialty pharmacy assets, combined with its deep oncology experience, will greatly help the market penetration of MuGard.

On July 27, 2010, Access signed agreement with e-marketing partner **iMedicor** which commenced the initial phase of a multi-channel marketing program for MuGard through its pharma online marketing portal, ClearLobby, and its direct sales channel, Direct Medical Solutions (DMS). The initial phase of the marketing program includes a targeted MuGard sampling program for to the DMS' physician network.

MuGard is now being introduced to Centers of Excellence, Key Opinion Leaders, cancer research centers and selected physicians in the United States. The initial release of MuGard samples is part of a joint project that includes participation from DMS, a network of direct field representatives with strong relationships to physicians and their practices. The full national launch is expected during the third quarter using iMedicor's highly targeted Physician Communication System (PCS), and iMedicor's strategic partnership with Direct Medical Solutions (DMS) and other strategic partners.

We are very pleased to see the signing of the two distribution agreements which will greatly increase the marketing effectiveness and efficiency of the company. With these two key distribution co-operations in place, we believe Access will begin a very strong launch of MuGard in August. As a result, we expect initial sales ramp will be rapid because of fast and strong market penetration of this new product.

### **MuGard clinical experience presented at MASCC conference**

Access Pharma presented a scientific poster on June 24, 2010 at the Multinational Association of Supportive Care in Cancer (MASCC) Conference in Vancouver, Canada. The poster presentation summarizes MuGard clinical experience from cancer patients globally undergoing radiotherapy and/or chemotherapy. To date, clinical experience shows that MuGard provides significant clinical benefits and is effective in the management of oral mucositis (OM)/stomatitis as well as other conditions of the oral cavity involving erythema.

Key take-aways from the poster include:

- MuGard has been used by over 2000 patients globally. The cancer patients included all tumor types, all different treatment regimens including chemotherapy, radiation therapy and combinations thereof, and the experience includes those that used it in a preventative manner and those that used it only after presenting with OM lesions.
- The European experience is from a "sampling study" – not a formal clinical trial with specific patient entry criteria, such as head and neck cancers, etc. We think the results from the sampling study are important because the data is coming from many different experiences which are closer to reality than the clinical trial data.

- The experience is very positive in our view, especially in the context that there is an urgent need for new regimes for the prevention and treatment of oral mucositis currently. The data shows that documented patients, using prophylactically, had a greater than 40% prevention rate. Those that used it only after presenting with OM experienced greater than 50% reduction in pain and oral discomfort. There was also a reduction in the use of pain meds, which is important from a pharmacoeconomic perspective.
- An evaluation from Access' China partner, RHEI Pharma, showed that patients had lower erythema scores (a precursor inflammatory condition) – including patients with xerostomia, stomatitis and cheilitis. These patients had reduction in pain and oral discomfort consistent with that shown in the European experience.
- The reduction in pain is especially meaningful as MuGard has no pain medicine in it, supporting the thesis that the mechanism/mode of action of providing a protective barrier function is having a positive impact on the underlying condition.
- Clinicians and patients like the “ready-to-use” formulation.
- Treatment was globally well accepted in over 85% of patients and no treatment related adverse events were reported.

However, recent study has shown that competitor **Caphosol** seems to have no influence on the frequency, duration and severity of oral mucositis during (chemo) radiation in head and neck cancer patients. In the study, 59 patients were analyzed, 27 patients in the Caphosol mouth rinse group, 16 standard oral care patients and 16 historical mouth and throat soreness (MTS) control patients. There was no significant difference between the Caphosol mouth rinse and standard oral care group on the development and severity of oral mucositis. A non statistical significant positive trend was found for subjective outcomes on mouth and throat soreness (MTS) for the Caphosol mouth rinse group compared to the historical control group.

### **Commercial launch of MuGard is proceeding well**

Access has been busying with the official launch of MuGard in the US in the past a few months.

In the middle of June 2010, the company initiated its sampling program in the US. This is a broad-scale MuGard Centers-of-Excellence Sampling Program with leading oncology networks in the US.

Sampling efforts for the company include providing large oncology groups with MuGard kits containing six weeks' worth of MuGard therapy for patients undergoing radiation and chemotherapy. Through these oncology groups, Access Pharma initially will provide 500 patients throughout 20 top metropolitan areas full courses of therapy to protect them from oral mucositis. The Company's goal in this initiative, along with building awareness and clinical experience with MuGard, is to provide patients access to an innovative product prior to its commercial launch while oncology teams evaluate MuGard for positioning into their cancer supportive care protocol.

We believe the sampling program is a critical step in successfully launching MuGard in the United States. This program will also allow the company to collect additional data points on the benefits of MuGard.

Reimbursement for MuGard is in process. According to management, official launch of MuGard could take place in August 2010.

### **Agreement signed with a major biotech company to develop oral formulations of leading injectable drug**

On July 15, 2010, Access entered into a pre-licensing feasibility agreement with a leading biotechnology company to develop an oral formulation of its currently-marketed, proprietary injectable drugs.

Access will utilize its proprietary **Cobalamin Oral Drug Delivery Technology** to develop oral formulations of the drug for pre-clinical testing. Although the name and the terms of the agreement 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 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 this deal, 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.

---

## EXECUTIVE SUMMARY

- We maintain our Outperform rating on Access Pharmaceuticals Inc. Our six to twelve-month price target is \$8.
- Access has one product MuGard already approved by US, EU and South Korea health authorities. The company's EU partner **SpePharm Holding, B.V** is already marketing MuGard in some European countries and expansion into other EU countries is under way. Access plans to officially launch MuGard in third quarter of 2010 in the US. Korean partner **JCOM Co., Ltd.** also plans to launch MuGard in Korea soon.
- **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 to late stage of development. ProLindac is in phase II study for relapsed ovarian cancer patients and Access plans to initiate phase 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 oral drug delivery system. 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.
- Current price is under valued 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 primarily based upon the company's **three key drug delivery technologies**: Synthetic Polymer Targeted Drug Delivery System; Cobalamin Mediated Oral Drug Delivery System and Cobalamin Mediated Targeted Drug Delivery System.

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.

**Table 1: Pipeline under development of Access Pharmaceuticals Inc.**

Compound	Originator	Technology	Indication	Clinical Stage
<b>MuGard</b>	Access	Mucoadhesive, liquid	Mucositis	(510k) Marketing clearance received
<b>ProLindac</b>	Access /Univ of London	Synthetic Polymer	Cancer	Phase II
<b>Thiarabine (4-thio Ara-C)</b>	Southern Research Institute	Small molecule	Cancer	Phase I/II
<b>Cobalamin-based Oral Insulin</b>	Access	Cobalamin	Diabetes	Pre-clinical
<b>Other Cobalamin-based Oral Therapeutics</b>	Access	Cobalamin	Various	Pre-clinical
<b>Cobalamin-Targeted Therapeutics</b>	Access	Cobalamin	Anti-tumor	Pre-clinical

Source: Company filing and Zacks Investment Research, Inc.

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 plans to officially launch MuGard in third quarter of this year.

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.

With US launch of MuGard coming soon coupled with international commercialization efforts, we believe the company's top line will be boosted in the coming quarters.

### **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.

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**

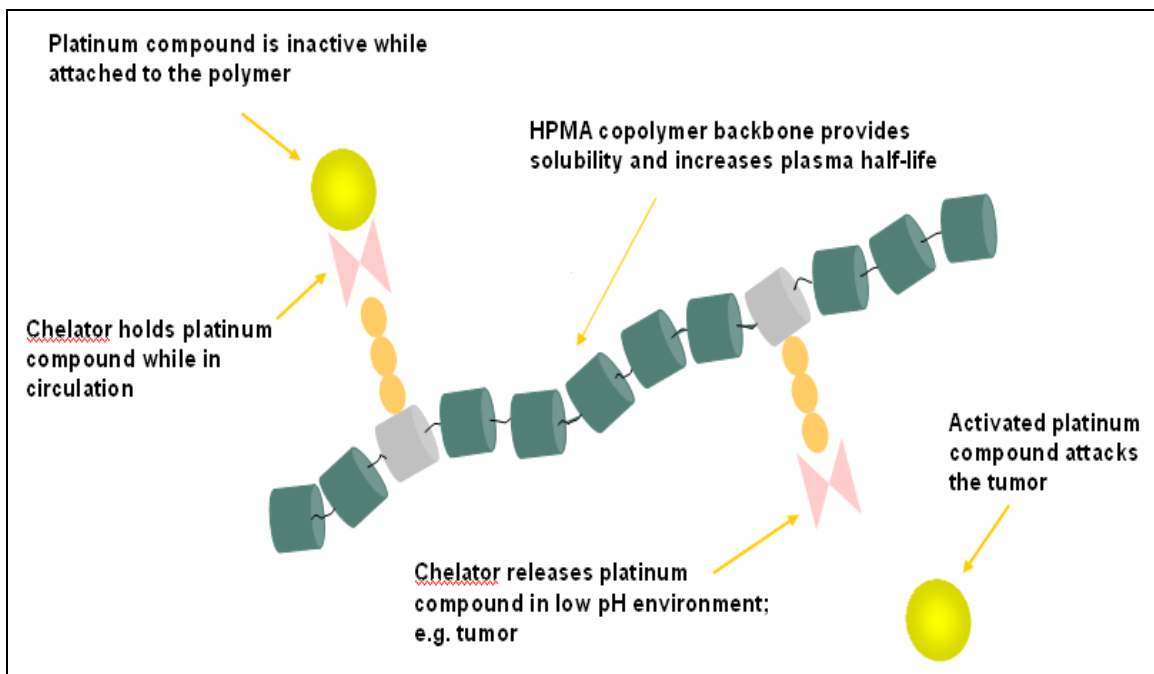
In collaboration with The School of Pharmacy, University of London, Access has developed a **synthetic polymer targeted drug delivery technology**, which utilizes a hydroxypropylmethacrylamide (**HPMA**) polymer as the drug carrier, designed to exploit enhanced permeability and retention effect (EPR), 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.

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.

**Figure 1: Mechanism of Action of ProLindac**



Source: Access Pharmaceuticals Inc.

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 January 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 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 1** 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<sup>2</sup>. Unlike previous observations with gemcitabine and ara-C (where the DLT is myelosuppression, 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 plans to initiate **phase II** clinical trials of Thiarabine in adult AML, ALL and other indications subject to funding or partnering.

### **Cobalamin-based oral insulin targets the diabetes market**

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

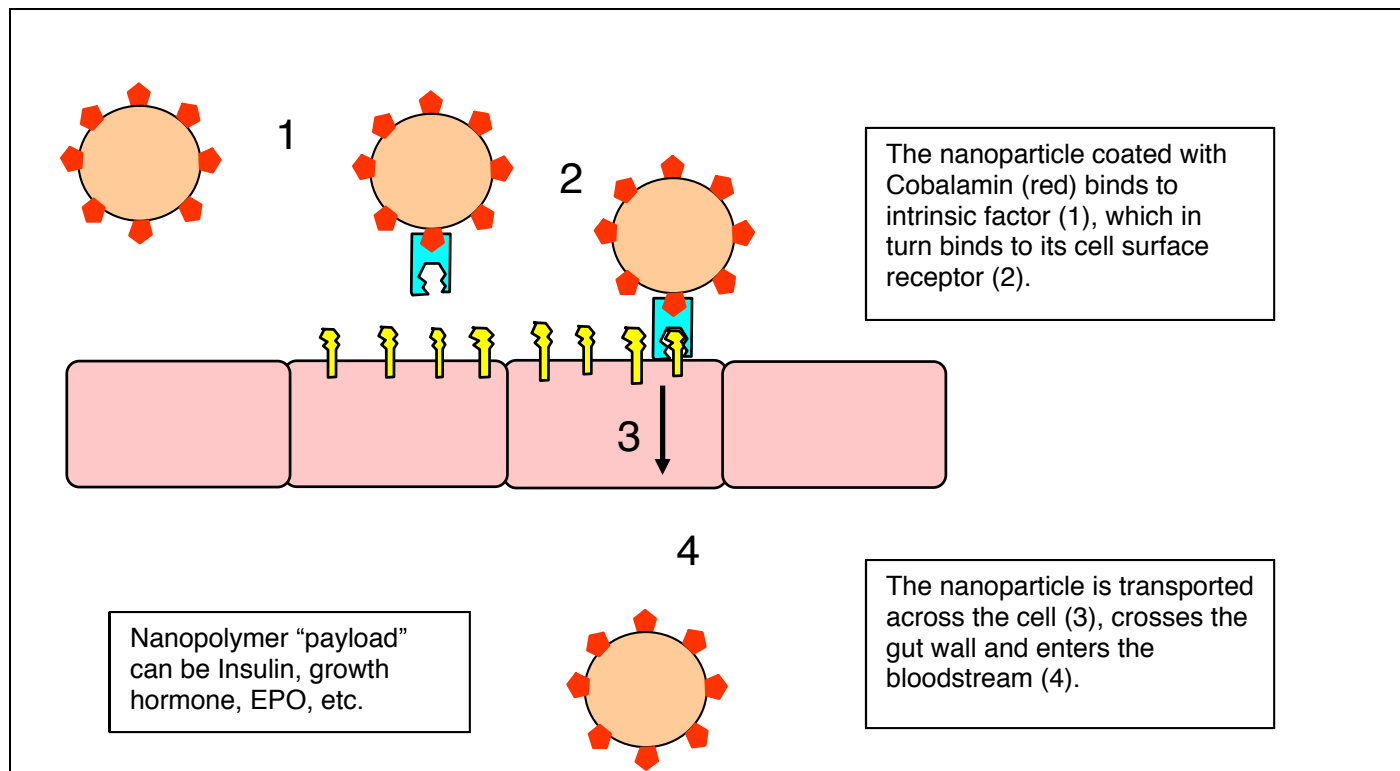
The difficulty in administering proteins orally is their susceptibility to degradation by digestive enzymes, their inability to cross the intestinal wall and their rapid excretion by the body. The field of oral drug

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.

Access' Cobalamin (analogue of VB12) oral drug delivery 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.

**Figure 2: Cobalamin-based drug delivery system**



Sources: Access Pharmaceuticals, Inc.

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** and Cobalamin-based **sRNAi** program. Together, these Cobalamin-based oral drug delivery therapeutics will provide the company great potential to grow.

### **Cobalamin-mediated targeted delivery technology further expands its platform technologies**

While Access' Cobalamin-based oral drug delivery system tries to enhance bioavailability of macromolecules systematically, its Cobalamin-mediated targeted drug delivery system 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** 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.

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.

### ***Experienced management team guarantees the execution of growth strategy***

#### **Jeffrey B. Davis, Chief Executive Officer**

Jeff has been the company's CEO since January 2008. Previously, Jeff was President of SCO Financial Group LLC; Senior Vice President and Chief Financial Officer of a healthcare technology company; Vice President, Corporate Finance, at Deutsche Morgan Grenfell; Senior marketing and product management positions at AT&T Bell Laboratories; Marketing and Product Manager at Philips Medical Systems North America. Mr. Davis obtained his MBA from the Wharton School, University of Pennsylvania; BS Biomedical Engineering, Boston University.

#### **Esteban Cvitkovic, M.D., Vice Chairman, Senior Director, Clinical Oncology R&D**

Dr. Cvitkovic is a board-certified oncologist with more than 30 years experience in oncology therapeutics, including clinical research, clinical pharmacology, design of single-agent and combination regimens, and optimization of clinical efficacy. Dr. Cvitkovic played a fundamental role in the registration strategy and post-registration development of cisplatin and oxaliplatin. Dr. Cvitkovic has held staff and academic appointments at Memorial Sloan Kettering Cancer Center (NY), Columbia Presbyterian (NY), Hospital St. Louis (Paris), Instituto Mario Negri (Milan) and Institut Gustave Roussy (Villejuif).

#### **Frank Jacobucci, Vice President Sales & Marketing**

Mr. Jacobucci has over 20 years experience in sales management, including senior sales executive positions at oncology focused companies including MGI Pharma, Genetics Institute, Wyeth Oncology, Aventis, Precision Therapeutics and CRC Oncology Services.

#### **David P. Nowotnik, Ph.D., Senior Vice President Research and Development**

David has been Sr. VP since 2003. Previously, David was Senior Director, Product Development, at Guilford Pharmaceuticals, Inc.; Group Leader, Bristol-Myers Squibb; Section Leader, Amersham International; Research Chemist, Tate and Lyle and Aspro-Nicholas. Mr. Nowotnik obtained his PhD, Organic Chemistry from University of London.

#### **Stephen B. Thompson, Vice President and CFO**

Stephen has been VP since 2000 and CFO since 1996. Previously, Stephen was Controller and Administration Manager of Access Pharmaceuticals Inc. Before joining Access, Stephen was Controller of Robert E. Woolley, Inc., a hotel real estate company; Controller of OKC Limited Partnership, an oil and gas company. Earlier, Stephen held various accounting and finance positions at Santa Fe International Corporation.

#### **Phillip Wise, Vice President, Business Development and Strategy**

Phillip has been VP Business Development since 2006. Previously, Phillip was VP, Commercial and Business Development and Chief Financial Officer of Enhance Pharmaceuticals; VP, Commercial and Business Development of Ardent Pharmaceuticals; Director of Managed Care Marketing & Director of New Product Planning of GSK. Mr. Wise obtained his MBA from University of Virginia; BS, Industrial and Systems Engineering from Georgia Institute of Technology.

## VALUATION

We maintain our Outperform rating on Access Pharmaceuticals Inc. with a six to twelve-month price target of \$8 per share.

We believe MuGard will strongly boost the company's top line in the coming quarters when the company officially launches MuGard in the third quarter of 2010. MuGard has competitive advantages over its competitors for the management of oral mucositis. World-wide sales could exceed \$300 million in 2015.

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 to late stage of development and both target the multi-billion dollar cancer market.

We see great potential for the company's three key proprietary platform technologies which create multiple product opportunities. We are especially impressed with the company's Cobalamin-based oral delivery system. The oral insulin and oral human growth hormone have already achieved unprecedented oral bioavailability in preclinical studies. The two products boast multi-billion blockbuster potential.

We believe Access is undervalued at current share price compared to its peers. The company will be close to breakeven in 2011 and will be profitable in fiscal 2012 with EPS of \$0.82 per share. From 2012 to 2015, the company will achieve EPS growth of 56% which is amazing. At current price of \$2.45, Access trades at 2.32 x its estimated 2012 EPS of \$0.82 and 0.61 x its estimated 2015 EPS of \$3.12 which are at huge discount compared to its peers in the biotech industry. We believe Access should be trading at the biotech industry mean P/E multiple at about 15 x EPS. Using this P/E multiple and our estimated EPS of \$0.82 in fiscal 2012, discounted at 25% for two years, the fair value should be about \$8 per share.

### Industry Comparables

	P/E (2009)	EPS Gr. 5Yr Est.	P/S (2009)
Access Pharma	N/A	56.2%	7.0x
Biotech Mean	15.8x	12.6%	18.1x
S&P 500	20.6x	7.1%	2.1x
Cell Therapeutics	N/A	N/A	N/A
Celgene, Corp.	32.9x	34%	9.5x
Cyclacel Pharma	N/A	N/A	85.5x
SuperGen	29.8x	N/A	3.8x

## RISKS

*Cash position is our chief concern*

At the end of March 2010, Access had cash and cash equivalents of only \$4.3 million. At the same time, the company had one convertible note outstanding in the principal amount of \$5.5 million which is due September 13, 2011. At March 31, 2010, working capital deficit was \$4.2 million.

Current level of cash may only last for a few quarters. Therefore, the company may need to turn to capital market to seek additional financing. Equity financing may dilute current shareholder base and share price may decline.

### ***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 can not 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	12/09A	Q1	Q2	Q3	Q4	12/10E	12/11E	12/12E	12/13E	12/14E	12/15E
<i>Product Revenue</i>	\$0.00	\$0.00	\$0.00	\$0.50	\$1.50	\$2.00	\$15.00	\$55.00	\$110.00	\$177.50	\$260.00
<i>YOY Growth</i>	-	-	-	-	-	-	650.0%	266.7%	100.0%	61.4%	46.5%
<i>Royalties Revenue</i>	\$0.04	\$0.02	\$0.03	\$0.13	\$0.25	\$0.42	\$1.87	\$7.70	\$18.16	\$25.70	\$35.90
<i>YOY Growth</i>							350.6%	311.8%	135.8%	41.5%	39.7%
<i>License and R&amp;D revenue</i>	\$0.32	\$0.09	\$0.08	\$0.10	\$0.12	\$0.39	\$0.50	\$1.00	\$1.00	\$1.00	\$1.00
<b>Total Revenues</b>	<b>\$0.35</b>	<b>\$0.10</b>	<b>\$0.11</b>	<b>\$0.73</b>	<b>\$1.87</b>	<b>\$2.80</b>	<b>\$17.37</b>	<b>\$63.70</b>	<b>\$129.16</b>	<b>\$204.20</b>	<b>\$296.90</b>
<i>YOY Growth</i>	21.0%	148.8%	66.7%	403.5%	1698.1%	696.0%	519.9%	266.7%	102.8%	58.1%	45.4%
<i>CoGS</i>	\$0.0	\$0.0	\$0.0	\$0.1	\$0.3	\$0.4	\$3.0	\$11.0	\$22.0	\$35.5	\$52.0
<b>Gross Income</b>	<b>0.35</b>	<b>0.10</b>	<b>0.11</b>	<b>0.63</b>	<b>1.57</b>	<b>2.40</b>	<b>14.37</b>	<b>52.70</b>	<b>107.16</b>	<b>168.70</b>	<b>244.90</b>
<i>Gross Margin</i>	100.0%	100.0%	100.0%	86.2%	84.0%	85.7%	82.7%	82.7%	83.0%	82.6%	82.5%
<i>SG&amp;A</i>	\$7.1	\$0.9	\$1.2	\$1.5	\$1.8	\$5.3	\$8.0	\$12.5	\$17.5	\$22.5	\$25.0
<i>% SG&amp;A</i>	2020.5%	880.4%	1142.9%	206.9%	93.6%	190.9%	46.1%	19.6%	13.5%	11.0%	8.4%
<i>R&amp;D</i>	\$2.7	\$0.8	\$1.0	\$1.2	\$1.5	\$4.5	\$6.5	\$9.5	\$15.0	\$25.0	\$35.0
<i>% R&amp;D</i>	754.8%	770.6%	952.4%	165.5%	80.2%	160.1%	37.4%	14.9%	11.6%	12.2%	11.8%
<i>Other</i>	\$0.3	\$0.1	\$0.1	\$0.1	\$0.1	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3	\$0.3
<i>% Other</i>	73.6%	59.8%	62.9%	9.1%	3.5%	9.2%	1.7%	0.5%	0.2%	0.1%	0.1%
<b>Operating Income</b>	<b>(\$9.7)</b>	<b>(\$1.6)</b>	<b>(\$2.2)</b>	<b>(\$2.1)</b>	<b>(\$1.7)</b>	<b>(\$7.7)</b>	<b>(\$0.4)</b>	<b>\$30.4</b>	<b>\$74.4</b>	<b>\$120.9</b>	<b>\$184.6</b>
<i>Operating Margin</i>	-2748.9%	1610.8%	2058.1%	-295.3%	-93.4%	-274.5%	-2.5%	47.7%	57.6%	59.2%	62.2%
<i>Other Net</i>	(\$7.7)	\$2.7	(\$0.1)	(\$0.2)	(\$0.2)	\$2.2	(\$0.8)	(\$1.0)	(\$1.0)	(\$1.0)	(\$1.0)
<b>Pre-Tax Income</b>	<b>(\$17.3)</b>	<b>\$1.1</b>	<b>(\$2.3)</b>	<b>(\$2.3)</b>	<b>(\$1.9)</b>	<b>(\$5.5)</b>	<b>(\$1.2)</b>	<b>\$29.4</b>	<b>\$73.4</b>	<b>\$119.9</b>	<b>\$183.6</b>
<i>Pref. stk Div + oth.</i>	\$1.9	\$0.4	\$0.5	\$0.5	\$0.5	\$1.9	\$2.0	\$2.2	\$2.5	\$3.0	\$3.5
<i>Taxes + Other</i>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.7	\$3.7	\$12.0	\$27.5
<i>Tax Rate</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.5%	5.0%	10.0%	15.0%
<b>Reported Net Income</b>	<b>(\$19.2)</b>	<b>\$0.6</b>	<b>(\$2.8)</b>	<b>(\$2.8)</b>	<b>(\$2.4)</b>	<b>(\$7.4)</b>	<b>(\$1.2)</b>	<b>\$28.7</b>	<b>\$69.7</b>	<b>\$107.9</b>	<b>\$156.1</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	143.1%	54.8%	44.6%
<i>Net Margin</i>	-5461.9%	634.3%	2672.4%	-387.0%	-130.0%	-264.0%	-6.8%	45.0%	54.0%	52.8%	52.6%
<i>Shares Out</i>	11.8	17.8	25.3	25.4	25.5	23.5	28.5	35.0	40.0	45.0	50.0
<b>Reported EPS</b>	<b>(\$1.63)</b>	<b>\$0.04</b>	<b>(\$0.11)</b>	<b>(\$0.11)</b>	<b>(\$0.10)</b>	<b>(\$0.31)</b>	<b>(\$0.04)</b>	<b>\$0.82</b>	<b>\$1.74</b>	<b>\$2.40</b>	<b>\$3.12</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	112.7%	37.6%	30.2%
<i>One time charge</i>	\$7.15	(\$2.88)	\$0.00	\$0.00	\$0.00	(\$2.88)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
<b>Non GAAP Net Income</b>	<b>(\$12.1)</b>	<b>(\$2.2)</b>	<b>(\$2.8)</b>	<b>(\$2.8)</b>	<b>(\$2.4)</b>	<b>(\$10.3)</b>	<b>(\$1.2)</b>	<b>\$28.7</b>	<b>\$69.7</b>	<b>\$107.9</b>	<b>\$156.1</b>
<b>Non GAAP EPS</b>	<b>(\$1.02)</b>	<b>(\$0.13)</b>	<b>(\$0.11)</b>	<b>(\$0.11)</b>	<b>(\$0.10)</b>	<b>(\$0.44)</b>	<b>(\$0.04)</b>	<b>\$0.82</b>	<b>\$1.74</b>	<b>\$2.40</b>	<b>\$3.12</b>

Source: Company filings and Zacks Investment Research Inc. estimates

## HISTORICAL ZACKS RECOMMENDATIONS



## DISCLOSURES

The analysts contributing to this report do not hold any shares of ACCP. Zacks EPS and revenue forecasts are not consensus forecasts. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts' personal views as to the subject securities and issuers. Zacks certifies that no part of the analysts' compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report. Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed herein are subject to change. This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time. Zacks uses the following rating system for the securities it covers. **Outperform**- Zacks expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. **Neutral**- Zacks expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. **Underperform**- Zacks expects the company will under perform the broader U.S. Equity market over the next one to two quarters. The current distribution of Zacks Ratings is as follows on the 1010 companies covered: Outperform- 13.6%, Neutral- 80.4%, Underperform – 5.4%. Data is as of midnight on the business day immediately prior to this publication.