

# at a glance™



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**Recent Events: US launch of MuGard™ into \$1.5 billion oral mucositis market set for first quarter of 2010; pivotal trials scheduled to start mid-2010 for platinum drug candidate aimed at sanofi-aventis' \$2.5 billion Eloxatin® franchise; novel nucleoside analogue ready for Phase II trial at M.D. Anderson; Company completed \$6.3 million equity financing.**

## KEY CONSIDERATIONS

- Access Pharmaceuticals' proprietary technology platforms are generating new chemical entities that target several large oncology markets. The Company has several oncology candidates in late-stage development.
- MuGard™, the Company's lead product, has been approved by the FDA for the management of oral mucositis, a common side effect of radiation and chemotherapy. The product was introduced under license in Europe in 2009, with US launch anticipated for 1H 2010.
- ProLindac™, a next-generation DACH platinum for treating solid tumors, is set to enter pivotal clinical trials which are being funded by Access Pharma's marketing partners. Early studies indicate that ProLindac significantly improves on the efficacy and safety profile of Eloxatin®, a \$2.5 billion market leader from sanofi-aventis.
- Access Pharma is developing thiarabine, a successor nucleoside analogue that holds potential in treating blood tumors, in partnership with M. D. Anderson.
- In addition, Access Pharma's novel Cobalamin™ VB-12 oral delivery vehicle may provide multiple significant drug delivery opportunities, including insulin, human growth hormone, EPO, and others.
- Access Pharma's model of forging strategic partnerships to offset clinical development costs while retaining approval of trial protocols provides for a controlled cash burn. The Company has completed six partnerships in the past 18 months, with additional talks ongoing.

## COMPANY OVERVIEW

Over the past four years Access Pharmaceuticals has channeled its efforts

### Access Pharmaceuticals, Inc. (OTCBB: ACCP)

Recent Price:	\$3.00
Common Shares:	23 million
Approx. MktCap:	\$69 million
Avg. Daily Volume:	50,800
Fiscal Year Ends:	Dec. 31

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into developing next-generation oncology products based on several proprietary technology platforms. The Company now has two drug candidates in late-stage development and is planning to launch its lead therapy, US FDA-approved MuGard™ for oral mucositis, in January 2010. This is a \$1.5 billion market opportunity for managing oral mucositis, or OM, a debilitating condition that causes painful mouth and throat lesions in roughly 80 percent of cancer patients who undergo radiation treatment and in 40 percent of those who undergo chemotherapy.

The Company's risk-mitigated portfolio includes two promising cancer treatments - one moving into pivotal trials - and a novel delivery platform that uses the body's own Vitamin B-12 absorption system to enable drug delivery through the gut wall. The pivotal trial-ready cancer therapy candidate ProLindac™ is aimed squarely at sanofi-aventis' \$2.5-billion Eloxatin® franchise by offering a superior profile - it delivers far more cancer-killing platinum to the tumor, with significantly milder side effects.

### MUGARD FOR ORAL MUCOSITIS

MuGard is a tasteless viscous mouth rinse for treating and preventing oral mucositis. Oral mucositis, or OM, is the inflammation and ulceration of the oral mucosa of the mouth that can extend to the esophagus. The condition is common in patients receiving radiotherapy and/or chemotherapy, and in its mildest form may cause redness and tenderness in the mouth. Severe cases can be extremely debilitating, involving ulcerations of the

mouth, gums and throat tissue that may prohibit swallowing of food or fluids. These ulcerations are also prone to infection and may be exacerbated by the vomiting that frequently accompanies chemotherapy treatment; ultimately, the condition may lead to gum deterioration and loss of teeth.

MuGard is designed to be swallowed, making it especially effective in treating esophageal lesions caused by OM which are often the most painful. A proprietary polymer blend, MuGard also holds potential as a drug delivery vehicle - of anti-inflammatory drugs or antibiotics, for example, to prevent inflammation and infection of active mouth and throat lesions - and the Company's patent provides for this application as well.

***"MuGard...is a \$1.5 billion market opportunity for managing oral mucositis, or OM..."***

There is a high incidence of OM in patients undergoing radiotherapy - 80 percent of those undergoing radiation develop some grade of OM, with 100 percent occurrence rate in patients who undergo head and neck radiation. In addition, 40 percent of chemotherapy patients develop OM. In fact, oral mucositis is listed as a known side effect of several widely prescribed chemotherapy agents.

Preliminary results of European partner SpePharm's post-approval study of MuGard in 280 OM patients in the UK this past summer showed an unprecedented 100 percent efficacy in preventing the onset of OM in the first 140 patients enrolled. SpePharm's seeding study has been expanded to include more than 1200 patients in the UK, Germany and Italy.

### TREATMENT AND PREVENTION OF OM

Currently marketed products for treating OM include Gelclair®, a topical analgesic gel for managing pain caused by mouth sores, and Caphosol®, a mouth rinse for mineralization and lubrication of the oral mucosa. Unfortunately for OM sufferers, neither therapy has proven to be particularly effective in providing pain

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relief or healing mouth lesions. As a result, clinicians often resort to administering an unstandardized "magic mouthwash," a home brew mixture of lidocaine, saline, and Maalox®, in an attempt to provide some symptom relief to OM sufferers.

In addition, none of these treatments is ingestible and as such is not effective in treating the esophageal lesions that very often occur in OM patients. These debilitating throat ulcers often become so painful that they make swallowing of liquid or food impossible. As such, they may lead to patient hospitalization for intravenous feeding/hydration, a proposition that is both uncomfortable and costly. Severe OM may also necessitate interruption in the cancer treatment course, which has obvious consequences. MuGard is flavorless and safe to swallow, allowing the therapeutic agent to prevent or treat painful throat lesions.

In view of its preventative properties, MuGard can be prescribed prior to and following radiation and chemo courses along with anti-emetics and other preventive measures often initiated prior to treatment in order to guard against common and uncomfortable side effects. By addressing the unmet medical need of the large patient population of OM sufferers, and as a preventative program for avoiding an unpleasant and painful common side effect of cancer therapies, the market opportunity for MuGard is believed to be larger than for any other OM-approved product.

Access Pharma has hired a US contract manufacturer to produce launch quantities of MuGard. A dedicated internal team, together with a small contract sales force, will focus marketing efforts on high-prescribing opinion leaders, cancer centers and oncology networks.

#### PLATINUM CANCER THERAPEUTIC

ProLindac, Access Pharma's novel DACH platinum chemotherapeutic agent, addresses a \$3 billion+ market opportunity. This water-soluble compound contains the same active agent – DACH platinum – as sanofi-aventis' blockbuster Eloxatin for treatment of colorectal cancer. However, Access Pharma's unique design allows the active platinum compound to remain inactive while attached to its proprietary nano-polymer background, avoiding the adverse systemic reactions that commonly occur during injection with Eloxatin. Once ProLindac comes in contact with a low pH environment in the body, like a tumor site, its chelator releases the platinum in a very localized and targeted manner. Studies show it remains in the body for up to four days, allowing for a sustained, targeted release.

Results from ProLindac's initial European Phase I/II trial in late-stage solid tumors showed significant drug activity in 45 percent of the evaluable patients, with no

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unanticipated adverse events occurring and no acute neurotoxicity evident – a key differentiator to Eloxatin's safety profile. In a European Phase II trial with ProLindac in relapsed ovarian cancer patients, the platinum compound once again exhibited strong tumor activity along with tolerability of significantly higher doses of platinum than that of Eloxatin – all without causing neurotoxicity, nephrotoxicity or increased emesis.

Access Pharma has signed partnerships for developing ProLindac with Aosaikang Medicinal Group (ASK) in China and with JCOM in Korea, both of which entail upfront payments that are serving to offset development costs. The Company believes ProLindac may also show great activity as a combination cancer therapy, and it anticipates that the pivotal studies of ProLindac in combination with taxol (for ovarian cancer) and with gemcitabine (for liver/pancreatic cancer) could start as soon as 1H-10, pending final regulatory approval.

In addition, sanofi-aventis will lose patent protection for oxalipatin in the US within the next year.

#### NEW NUCLEOSIDE ANALOGUE

Thiarabine is a "new and improved" version of the widely used nucleoside analogue cytarabine (commonly known as Ara-C), an existing, approved cytotoxic chemotherapy. Its mechanism of action involves suppression of white blood cells which are overexpressed in blood cell cancers like leukemia.

Access Pharma is working with Hagop Kantarjian, MD, Chairman of the Leukemia Department at the University of Texas

M.D. Anderson Cancer Center, to finalize Phase II trial designs and protocols in leukemia, B-cell lymphoma and other indications. Dr. Kantarjian has significant expertise in the field of leukemia. He served as a key investigator in clinical trials that led to the approval of Gleevec® for chronic myeloid leukemia.

The Company plans to initiate two single-site, open-label Phase II trials with thiarabine to assess dosing and to identify the most appropriate patient population for a multi-site Phase II trial.

#### NOVEL DRUG DELIVERY PLATFORM

The Company is in the early stages of developing its Cobalamin™-coated nano-polymer platform as an oral delivery system for large molecule therapies like insulin, human growth hormone, EPO, and interferon that currently are delivered by injection. The novel delivery platform uses a Vitamin B-12 analogue as a coating to take advantage of the body's natural receptor-based transport system. Preliminary studies of oral insulin delivery with Cobalamin in animal models showed that glucose was lowered to clinically relevant levels. In fact, Access has achieved very high bioavailability of insulin in animal models. Next development steps include additional animal studies and proof-of-concept in humans.

The Cobalamin platform also holds potential for use in delivering therapies in a wide variety of disease states where vitamin intake is up-regulated. Access Pharma has already signed two collaborative agreements for Cobalamin, and plans to pursue additional trial programs and global partners for the platform going forward.

#### SUMMARY POINTS

- **MuGard is the only therapy shown to prevent the onset of oral mucositis. All other products -- Gelclair, Caphosol, and "magic mouth-wash" (every hospital's home brew) -- are designed mainly for palliative care. The US launch is set for the first quarter of 2010.**
- **Eighty percent of patients undergoing radiation, and 40 percent on chemotherapy, experience OM. All told, more than 500,000 US cancer patients are afflicted with oral mucositis at any given time. The potential market for MuGard is estimated at \$1.5 billion.**
- **Two cancer treatments, one moving into pivotal trials, round out Access' oncology portfolio. The pivotal trial-ready candidate, called ProLindac, is aimed squarely at sanofi-aventis' \$2.5 billion Eloxatin franchise by offering a superior profile – more platinum punch to the tumor with significantly milder side effects. Impressive data now issuing.**
- **With critical scientific achievements behind it, Access Pharma is entering an investor-favored phase during which the expected revenue growth from a marketed product will underpin near-term valuation, while additional candidates will advance through the clinic with funding mainly from non-dilutive sources.**