Zacks Small-Cap Research

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Access Pharma (ACCP-OTC)

ACCP: Sales momentum continues for MuGard in 2Q12--Outperform

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	02/23/2012
Current Price (08/28/12)	$0.60
12-month Target Price	**$1.50**

OUTLOOK

Access reported meaningful sales number for **MuGard** in 4Q11 for the first time since the launch of the product in August 2010. Sales continued to grow by 7.5% quarter over quarter in 2Q12.

Although a US partnership for MuGard may not be sealed soon, based on information we have gathered so far, organic growth of MuGard sales will continue current momentum throughout the year of 2012.

We maintain an Outperform rating on ACCP shares.

SUMMARY DATA

52-Week High	**$2.10**
52-Week Low	**$0.34**
One-Year Return (%)	**-69.35**
Beta	**1.08**
Average Daily Volume (sh)	**28,253**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$15**
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)
2011	0.15 A	0.15 A	1.04 A	0.51 A	1.85 A
2012	1.86 A	0.69 A	0.91 E	1.27 E	4.73 E
2013					8.50 E
2014					17.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.14 A	-$0.16 A	-$0.13 A	-$0.05 A	-$0.47 A
2012	-$0.11 A	-$0.09 A	-$0.08 E	-$0.08 E	-$0.34 E
2013					-$0.05 E
2014					$0.08 E

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

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WHAT'S NEW

Sales Momentum Continues for MuGard in 2Q12

ACCP reported financial results on August 13, 2012 for the second quarter ending June 30, 2012

Sales of MuGard in the United States totaled $615,000 for the second quarter of 2012 as compared with $42,000 for the same period of 2011, an increase of $573,000. On a quarterly basis, sales of MuGard in 2Q12 increased 7.5% compared to $572,000 in 1Q2012.

Licensing revenue for the second quarter of 2012 was $60,000 as compared to $87,000 for the same period of 2011, a decrease of $27,000.

Royalty revenue for MuGard in Europe was $15,000 for second quarter of 2012 as compared to $21,000 for the same period of 2011, a decrease of $6,000.

Total research and development spending for the second quarter of 2012 was $654,000, as compared to $903,000 for the same period of 2011, a decrease of $249,000. The decrease in expenses was primarily due to decreased clinical development with trials for ProLindac, MuGard and Thiarabine, decreased stock compensation expense, and decreased external lab costs.

Total selling, general and administrative expenses were $1,406,000 for the second quarter of 2012, an increase of $2,000 compared to the same period in 2011 of $1,404,000.

Total operating expenses for the second quarter of 2012 year were $2,142,000 as compared to total operating expenses of $2,403,000 for the same period of 2011, a decrease of $261,000 for the reasons listed above.

Net loss allocable to common stockholders for the second quarter of 2012 was $11,039,000, or a $0.46 basic and diluted loss per common share, compared with a net loss of $1,706,000, or a $0.09 basic and diluted loss per common share, for the same period in 2011, an increased loss of $9,333,000.

On an adjusted basis, net loss was $2.1 million or $0.09 per share for 2Q12 compared to net loss of $3.0 million or $0.16 per share for 2Q11.

Positive MuGard Phase IV Data Reported

On June 28, 2012, Dr. Ron Allison of Carolina Radiation Medicine presented interim results from the Company's ongoing MuGard post marketing clinical trial (**Phase IV**) in oral mucositis at the Multinational Association of Supportive Care in Cancer (MASCC) Conference in New York City.

The trial design and populations:

As a reminder, Access initiated the Phase IV clinical trial of MuGard in 2010 with first sites opened and subjects enrolled in the first quarter of 2011. Head and neck cancer patients whose treatment plan calls for receiving up to a maximum cumulative radiation dose of 72 Gray (Gy) are randomized into the MuGard arm or a control rinse (sham) arm.

Data are collected and reported for two populations: the efficacy analysis population **(EFF)** are patients that stayed on study treatment throughout chemoradiation treatment (approximately seven weeks), and the full analysis set **(FAS)** are all subjects enrolled and randomized and have at least 1 post-radiotherapy assessment. Data presented was from the first 70 of a planned 120 patients. The patient populations in

each arm were well balanced as to age, gender, ethnicity, and mean Karnofsky score (a measure of functional impairment of patients).

In addition to the primary study endpoints which assess MuGard's efficacy, the protocol provides for the collection of a range of other endpoints including quality of life and pharmacoeconomic outcomes.

Key findings from the MASCC presentation

The presentation summarized data from 70 cancer patients undergoing mouth and throat soreness.

- ***Pain***: Patients taking MuGard throughout their treatment regimen had a statistically significant reduction in pain. The pain endpoint is a measure of reduction in mouth and throat soreness (MTS) over the course of cancer therapy as measured with the oral mucositis daily questionnaire (OMDQ), a validated mucositis assessment tool. MuGard patients in the EFF population experienced a statistically significant reduction in MTS pain relative to the control rinse (p=0.041). MuGard patients in the FAS population showed a strong trend in pain reduction relative to the control rinse (p=0.110).

- ***Delay to Onset***: This endpoint is the delay in onset of oral mucositis as measured in cumulative dose of radiation (measured in grays). MuGard patients in the EFF and FAS populations both experienced a statistically significant delay to onset of oral mucositis (p=0.020 and p=0.007, respectively). The ability to extend the onset of oral mucositis out in time during treatment is important clinically and from a quality-of-life (QOL) perspective.

- ***Time to First Occurrence***: This endpoint is a measurement, in days, to the time of first occurrence of oral mucositis. MuGard patients in the EFF and FAS populations both experienced a statistically significant delay in time to first occurrence (p=0.022 and p=0.009, respectively). This statistically significant delay in first occurrence of OM occurred in both the EFF and FAS populations, which is both clinically important and beneficial from a QOL perspective.

- ***Maintenance of Weight***: The study also measured changes in patient weight, in kilograms, at various periods during the study. MuGard patients in the EFF population experienced a statistically significant reduction in weight loss (p=0.036) between their start and completion of radiation treatment. Mean weight loss was 9.1 kg (~20.0 lbs) and 5.2 kg (~11.4lbs) for the control and the MuGard arms, respectively. A reduction in weight loss suggests that patients on MuGard were able to keep themselves better nourished during chemoradiation, which presumably enables them to better tolerate this rather challenging treatment regimen.

Our Takeaways from the Phase IV Trial of MuGard

This is a rigorous trial design for a medical device, which is unprecedented and sets a high bar for competing products in the market in our view.

The rigorously designed trial is a prospective, randomized, multi-center, double-blind, placebo-controlled study to evaluate the efficacy of MuGard in controlling symptoms caused by oral mucositis in subjects receiving chemoradiation therapy for the treatment of cancers of the head and neck. The protocol, whose primary contributor was Stephen T. Sonis, DMD, DMSc, a thought leader in oral mucositis, is designed to evaluate MuGard with a rigor that is typically associated with drugs or biological.

This trial design is the first to be used to evaluate a device for an oral mucositis indication and distinguishes Access and MuGard from competing companies and products.

The MuGard data are ground breaking and unique from at least two perspectives. First, this is the first product that has ever shown a statistically significant positive clinical benefit in managing the pain symptoms and delaying the onset of oral mucositis in the very difficult to treat head and neck cancer

population. Second, the rigorous design of the MuGard trial is the first of its kind in a medical device treatment option for oral mucositis, setting a new standard in this area. The clinical and quality-of-life benefits shown in this data echoes what we hear in the marketplace and that is evidenced in the increasing commercial adoption of MuGard.

Update on MuGard Commercial Activities

ACCP recently updated investors on a couple of fronts the Company is working at.

On the side of MuGard commercial activities, the Company is continuing to push for adoption of this product in the oncology supportive care community. Over one year of sampling program and focused marketing efforts are paying off. Currently, over 50 contract sales reps are promoting MuGard. Management indicated that MuGard could break even in 4Q12. With the sales uptake accelerates, we think this is achievable if not at 4Q12 it may be achieved in 1H13.

According to management, MuGard is becoming a brand in the cancer supportive care community. Its efficacy and safety are being recognized by many physicians and nurses in the oncology supportive care area. Although it's hard to judge MuGard market share, however, MuGard is gaining market share from Caphosol and Gelclair, because they don't sample due to a higher cost of goods sold.

Access is approaching approximately 1000 doctors who have written scripts. The initial targets are the roughly 2500 radiation oncologists and rough 10000 medical and hematological oncologists. After these two big groups, Access plans target dental oncologists, dentists (who often see patients with mucositis), oncology nurses and nurse practitioners (who can write scripts in many states). The agreement with Premier Health Alliance should greatly facilitate adoption by hospitals. Premier is the largest group purchasing organization for hospitals in the US with 2500 hospital members (approximately 600 provide oncology services) and another 80000 other healthcare facilities.

Access has been working on the reimbursement for MuGard since its launch in August 2010 and has made terrific progress so far. Many third party payers have coverage for MuGard and the number continues to grow. Reimbursement rate has increased to over 60% in 1Q12 from about 50% in 4Q11 and single digits in 1Q11. The Company plans to submit reimbursement documents to Medicare for endorsement of MuGard in 2H12, and expect the approval in 2013. Positive data from the ongoing Phase IV trial of MuGard and continued sales uptake will be the two pieces of important evidence for Medicare endorsement. The Company already reported positive interim data from the Phase IV study at the MASCC (Multi-National Association of Supportive Care in Cancer) Congress in New York City this June 28-30.

At the front of US partnership talks, management indicated that there are still talks going on, but management did not give any specifics with regard to when a deal could be sealed. Our understanding is that this may be an ongoing process, but there is no guarantee that a deal could be closed any time soon. Management will focus on organic growth of MuGard at the same time, which we think makes sense since the Company has put great resources in sampling and marketing over the one and half years and has seen meaningful sales growth in the past three quarters.

Our overall impression is that the Company is moving forward with a focus on organic growth of MuGard sales and is making great progress in MuGard commercialization. We have begun to see the results which have been evidenced by the sales growth in the last three quarters.

What's next for MuGard?

In the EU: the Company has terminated the EU partnership agreement with SpePharm by mutual agreement. Per terms of the agreement, MuGard will continue to be commercially available for up to six months in Europe through SpePharm. ACCP is actively seeking a new European commercial partner for MuGard.

We view the termination with SpePharm as positive. MuGard has been launched in Germany, Italy, the UK, Greece and the Nordic countries by SpePharm. However, sales have been non-material. ACCP has been receiving royalties less than $100,000 a year. The Company believes, given its success in the US, that the lack of success from SpePharm is attributed to lack of focus and prioritization of MuGard in the SpePharm portfolio, rather than a MuGard issue.

With the removal of SpePharm, Access now has two different ways to move forward.

- One option is to find a new EU partner,
- Find a global partner including the EU rights to MuGard.

A stronger partner could mean increased sales of MuGard and increased royalty revenue for ACCP. A new partnership may also provide a fresh upfront for the Company.

In the US: ACCP is continuing the training of third-party MuGard representatives on the product, on the oral mucositis condition and on its sales strategy. MuGard prescriptions are growing quarter by quarter and the Company has placed emphasis on its sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake.

ACCP is working closely with specialty pharmacies and pharmacy benefit managers (PBMs) to make MuGard accessible to cancer patients who need supportive care. As a result of this effort by the Company, on April 4, 2012, Memorial Sloan-Kettering Cancer Center (MSKCC) has added MuGard to its cancer supportive care pharmacy formulary. Patients undergoing cancer treatment will now have direct access to MuGard from the first day of cancer treatment to manage oral mucositis. This is an important milestone for MuGard and the Company as MSKCC is a world-renowned cancer institution, which treats numerous cancer patients each year.

Management is focused on organic growth of MuGard in the US, which is the worst case scenario without a partner for MuGard in the US. MuGard sales started to be meaningful in 4Q11 with quarterly sales of $0.41 million. In 1Q12, MuGard sales were $0.57 million, a 40% increase quarter over quarter. In 2Q12, MuGard sales increased to $$0.62 million. Our estimate of MuGard sales for 2012 is $3.2 million, which is achievable in our view. ACCP will be profitable in 2014 with EPS of $0.08 on total revenue of $17.5 million without a US partner for MuGard.

In China: ACCP's partner Rhei Pharmaceuticals HK Ltd. received regulatory and marketing approval for MuGard from the State Food and Drug Administration to treat oral mucositis in cancer patient in March 2012.

Access met with its China partner in NY in late April, and they promised to have a marketing plan in 4 to 6 weeks. Access has been working with them to finalize the first manufacturing run – meaning they have been going back and forth on packaging, labeling, pricing, etc. Access is going to be doing the manufacturing for its China partner, for at least the first couple of years. Management indicated that its China partner is going to start marketing MuGard in the last half of this year. ACCP should book some manufacturing and royalty revenue from MuGard sales in China in 2H2012.

For the reasons mentioned above, we think sales could accelerate from 2012 onwards. We will closely watch MuGard sales ramp in the coming quarters and update investors in this regard.

VALUATION AND RECOMMENDATION

We maintain our Outperform rating on Access Pharma, and reiterate our 12-month price target of $1.50 per share based on recent developments.

MuGard sales finally broke out in 4Q11 though it came a little later than we have expected. Sales continued to grow significantly in 1Q12 and 2Q12. Based on all the information we have gathered, we believe MuGard will strongly boost the Company's top line in the coming quarters.

Some investors have been expecting a strong US partner for MuGard in past few months, but disappointed that it did not materialize. Our position is that even without a marketing partner, ACCP can still achieve significant MuGard sales increase from 2012 onwards due to over one year committed efforts in marketing and sales.

MuGard has competitive advantages over its competitors for the management of oral mucositis. Our confidence in MuGard 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 has been 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 CAGR of 107% from 2012 to 2015 according to our long term model.

We believe Access is undervalued at current share price. The Company will be profitable in fiscal 2014 with EPS of $0.08 per share. From 2012 to 2015, top line will grow at a CAGR of 107%. At current price of $0.60, Access trades at 7.3 x our estimated 2014 EPS of $0.08 and 3.2 x our estimated 2015 EPS of $0.19 which is at deep discount compared to its peers. We believe Access should be trading at a P/E multiple of 20x, which translate into per share price of $1.50 based on our estimated EPS of $0.19 in fiscal 2015, discounted at 30% for three years.

Our valuation exclude any value from the Company's other programs. In addition to MuGard, the company's pipeline also includes **ProLindac** and **Thiarabine,** both are in middle stage of development and both target the large cancer market.

But keep in mind that ACCP need further financing if a partnership deal cannot be closed soon.

As of June 30, 2012, Access had cash and cash equivalents of $0.6 million, and net cash burn rate for the six months ended June 30, 2012, was approximately $263,000 per month. Current cash can only last into third quarter. The Company may need to tap the capital market very soon. However, if ACCP can find a new EU partner, the upfront payment may ease the need for immediate financing.

PROJECTED INCOME STATEMENT

$ in million except per share data	12/10A	Q1	Q2	Q3	Q4	12/11A	Q1A	Q2A	Q3E	Q4E	12/12E	12/13E	12/14E	12/15E
Product Revenue	$0.00	$0.01	$0.04	$0.08	$0.41	$0.55	$0.57	$0.62	$0.85	$1.20	$3.24	$7.50	$15.00	$28.50
YOY Growth	-	-	-	-	-	-	*39.5%*	*1330.2%*	*936.6%*	*192.7%*	*490.7%*	*131.7%*	*100.0%*	*90.0%*
Royalties Revenue	$0.08	$0.02	$0.02	$0.02	$0.03	$0.09	$0.02	$0.02	$0.04	$0.05	$0.13	$0.50	$1.50	$2.00
YOY Growth						*17.1%*					*41.6%*	*296.8%*	*200.0%*	*33.3%*
License and R&D revenue	$0.41	$0.12	$0.09	$0.94	$0.07	$1.21	$1.26	$0.06	$0.02	$0.02	$1.36	$0.50	$1.00	$1.00
Total Revenues	**$0.48**	**$0.15**	**$0.15**	**$1.04**	**$0.51**	**$1.85**	**$1.86**	**$0.69**	**$0.91**	**$1.27**	**$4.73**	**$8.50**	**$17.50**	**$31.50**
YOY Growth	*35.8%*	*47.1%*	*43.8%*	*719.7%*	*251.4%*	*286.6%*	*1136.7%*	*357.0%*	*-12.6%*	*151.0%*	*155.7%*	*79.9%*	*105.9%*	*80.0%*
CoGS	$0.0	$0.1	$0.0	$0.5	$0.6	$1.2	$0.5	$0.1	$0.4	$0.5	$0.6	$1.5	$3.0	$5.7
Gross Income	**0.48**	**0.06**	**0.11**	**0.59**	**-0.13**	**0.63**	**1.32**	**0.63**	**0.51**	**0.74**	**3.20**	**7.00**	**14.50**	**25.80**
Product Gross Margin	*100.0%*	*38.7%*	*75.5%*	*56.4%*	*-25.1%*	*34.2%*	*6.1%*	*89.8%*	*52.9%*	*55.8%*	*80.0%*	*80.0%*	*80.0%*	*80.0%*
SG&A	$4.5	$1.0	$1.4	$1.1	$0.6	$4.1	$1.0	$1.4	$1.5	$1.6	$5.5	$6.5	$8.5	$12.5
% SG&A	*943.7%*	*684.0%*	*929.8%*	*102.1%*	*115.0%*	*220.5%*	*52.8%*	*203.8%*	*164.8%*	*126.0%*	*116.1%*	*76.5%*	*48.6%*	*39.7%*
R&D	$3.3	$1.1	$0.9	$1.3	$0.9	$4.2	$1.0	$0.7	$0.6	$0.5	$2.7	$2.0	$2.0	$3.5
% R&D	*700.6%*	*746.7%*	*598.0%*	*120.3%*	*182.8%*	*227.3%*	*52.5%*	*94.8%*	*65.9%*	*39.4%*	*57.7%*	*23.5%*	*11.4%*	*11.1%*
Other	$0.4	$0.1	$0.1	$0.1	$0.1	$0.2	$0.1	$0.0	$0.1	$0.1	$0.3	$0.3	$0.3	$0.3
% Other	*79.1%*	*40.7%*	*39.1%*	*5.4%*	*11.3%*	*12.6%*	*2.9%*	*2.8%*	*11.0%*	*7.9%*	*5.8%*	*3.5%*	*1.7%*	*1.0%*
Operating Income	**($7.8)**	**($2.1)**	**($2.3)**	**($1.8)**	**($1.7)**	**($7.9)**	**($0.7)**	**($1.5)**	**($1.7)**	**($1.5)**	**($5.3)**	**($1.8)**	**$3.7**	**$9.5**
Operating Margin	- *1623.4%*	- *1432.7%*	- *1491.4%*	*-171.4%*	*-334.2%*	*-426.2%*	*-37.1%*	*-210.4%*	*-185.7%*	*-115.0%*	*-112.0%*	*-21.2%*	*21.1%*	*30.2%*
Other Net	$0.2	$0.3	$1.0	$2.1	$2.0	$5.4	($4.2)	($9.1)	$0.0	$0.0	($13.4)	$0.0	$0.0	$0.0
Pre-Tax Income	**($7.5)**	**($1.9)**	**($1.3)**	**$0.4**	**$0.3**	**($2.5)**	**($4.9)**	**($10.6)**	**($1.7)**	**($1.5)**	**($18.6)**	**($1.8)**	**$3.7**	**$9.5**
Pref. stk Div + oth.	$1.8	$0.4	$0.4	$0.4	$0.4	$1.8	$0.4	$0.4	$0.6	$0.8	$2.3	$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	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-1.0%*	*-0.7%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($9.3)**	**($2.3)**	**($1.7)**	**($0.1)**	**($0.2)**	**($4.3)**	**($5.3)**	**($11.0)**	**($2.3)**	**($2.3)**	**($20.9)**	**($1.8)**	**$3.7**	**$9.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*156.8%*
Net Margin	- *1952.1%*	*108.7%*	*75.7%*	*5.4%*	*9.9%*	*-233.0%*	*773.9%*	*760.3%*	*135.5%*	*154.8%*	*-442.8%*	*-21.2%*	*21.1%*	*30.2%*
Shares Out	*15.7*	*19.2*	*19.4*	*19.5*	*21.8*	*20.0*	*24.1*	*24.2*	*29.0*	*30.0*	*26.8*	*35.0*	*45.0*	*50.0*
Reported EPS	**($0.60)**	**($0.12)**	**($0.09)**	**($0.00)**	**($0.01)**	**($0.22)**	**($0.22)**	**($0.46)**	**($0.08)**	**($0.08)**	**($0.78)**	**($0.05)**	**$0.08**	**$0.19**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	*131.1%*
One time charge	($0.13)	($0.41)	($1.34)	($2.42)	($0.82)	*($4.99)*	*$2.77*	*$8.98*	*$0.00*	*$0.00*	*$11.75*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($9.5)**	**($2.7)**	**($3.0)**	**($2.5)**	**($1.0)**	**($9.3)**	**($2.6)**	**($2.1)**	**($2.3)**	**($2.3)**	**($9.2)**	**($1.8)**	**$3.7**	**$9.5**
Non GAAP EPS	**($0.60)**	**($0.14)**	**($0.16)**	**($0.13)**	**($0.05)**	**($0.47)**	**($0.11)**	**($0.09)**	**($0.08)**	**($0.08)**	**($0.34)**	**($0.05)**	**$0.08**	**$0.19**

Source: Company filings and Zacks Investment Research Inc. estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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