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Omeros Corporation

Equity Research

June 2, 2017

Price: \$15.37 (06/1/2017) **Price Target: NA**

OUTPERFORM (1)

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Key Data

Symbol NASDAQ: OMER

Market Cap (MM) \$675.4

Quick Take: Innovations

Investors Should Be Paying More Attention To 721's Potential In Renal Diseases

The Cowen Insight

In advance of the ERA-EDTA presentation this weekend, we conducted physician consulting calls and the primary takeaway is that OMS721's treatment effect in renal disease appears to be real and dramatic. While much of the focus has been on the aHUS program that is further along, we believe investors should seriously contemplate the significant opportunity for OMS721 in renal diseases.

Responses Of This Magnitude Have Never Been Observed Before

Omeros' lead pipeline candidate is OMS721, which is an antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the lectin pathway of the complement system. OMS721 is in Phase II/III development for complement-mediated diseases such at aHUS, renal diseases, and HSCT-associated thrombotic microangiopathies (TMAs). Improvements in important TMA markers have been observed to date in the lead aHUS indication, which understandably has captured most of investors' focus given that it is further along in development and entering a Phase III clinical trial. Additionally, the aHUS market opportunity has been well established by Alexion's Soliris. However, we also acknowledge that some investors have also been reluctant to ascribe significant value to this program given the high hurdle set by standard of care Soliris.

All the while, Omeros continues to rapidly move OMS721 forward in clinical development for renal diseases with fairly low visibility. Given the recent updated data in renal diseases and the expected presentation this Sunday at the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) Congress in Madrid, Spain, we recently conducted calls with thought-leading renal consultants. And despite the small number of patients treated to date, our consultants were unanimously positive as the observed treatment responses have been "tremendous," "spectacular," and based on the initial data, OMS721 appears to be the "most efficacious treatment ever tested in IgA nephropathy." Additionally, these complementassociated renal indications (IgA nephropathy, membranous nephropathy, lupus nephritis, and complement component 3 (C3) glomerulopathy) are severe like aHUS, but Soliris is not indicated for these diseases and patients lack viable treatment options, so there is a low barrier to entry. Specifically for IgA nephropathy, for which we have the most data and is the focus of our note, no treatments are currently approved. The bottom line is that OMS721 appears to be a very promising treatment for IgA nephropathy and we believe that investors need to begin to contemplate the potential sizable opportunity in renal diseases.

In mid-May, Omeros provided an update on the completion of the IgA nephropathy cohort in the renal disease program. All of these patients had pre-existing renal impairment and must have had high levels of proteinuria despite well-controlled blood pressure, stable dosing with ACE inhibitors, and ongoing treatment with steroids. Essentially the patients were all on standard of care treatment as they entered the

trial. All four patients were very severe as they had Stage 3B chronic kidney disease and three of the four had nephrotic-range proteinuria. Not only were these patients not responding to treatment, they had failed as the so-called standard of care doesn't really work for these patients. This is best evidenced by the STOP trial that showed no benefit to renal outcomes three years later following immunosuppressive therapy. These patients are progressing rapidly to dialysis and ultimately renal failure. The standard of care is very poor, the unmet need is very significant, and these patients desperately need new and effective options.

The endpoints of urine albumine-to-creatinine ratio (uACR) and total 24-hour urine protein excretion were measured throughout the 12 weeks of treatment and patients were followed post-treatment for an additional 6 weeks. Our consultants state that these measures are predictive of kidney failure and reductions in proteinuria are associated with slowing the progression of kidney function loss and better clinical outcomes. Taken one step further, the percent reduction in proteinuria roughly translates directly to the percent reduction in the risk of renal failure.

The Observed Reductions In Proteinuria With OMS721 Are Rapid And Magnitudes Better Than What Has Ever Been Observed

All patients demonstrated marked mean reductions in uACRs and 24-hour protein excretion measures of 77% (from 1,457 to 332 mg/g) and 73% (from 3,935 to 1,067 mg/day) at the end of the follow-up period. Based on prior data releases, these reduction appear to be getting more significant over time and throughout the followup period. We understand that some investors may be skeptical given that it is only four patients, but our consultants noted that these responses were consistent in all four patients, across both clinical endpoints for proteinuria, which should be highly correlated. Further, per our consultants, these magnitudes of proteinuria reductions have never been observed spontaneously or with existing treatments and the chance of these being due to chance alone is virtually zero. For additional perspective, the target proteinuria reductions of other programs in clinical development is in the 20-30% range after 9-12 months of treatment; almost 3-4x lower than what has been observed in the OMS721 clinical trials and over a 2-3x longer time period. Per our consultants, if the reductions observed to date with OMS721 in IgA nephropathy are replicated in a larger study, it would almost certainly have the potential to stop the risk of end-stage renal disease (ESRD) and ultimate kidney failure. Our consultants are observing clinical responses that they have never seen before.

No Patients Have Relapsed To Date And The Effect Appears Durable

Additionally, all patients achieved partial remissions based on proteinuria, the one patient with nephrotic-range proteinuria achieved a 95% reduction reaching normal urine protein levels, and another patient's uACR measure normalized by the end of the study. Renal function in these patients continued to improve throughout the study and to-date, no patients have relapsed despite that fact that some patients are now several months out from treatment ending. A legacy effect of continued improvement has been observed in each of the four patients following treatment. Moreover, patients also either eliminated or greatly reduced their steroid dosing, which is clinically meaningful per our consultants. No significant safety concerns have been observed and the most commonly reported adverse events were fatigue and anemia. OMS721 appears to be very well tolerated. Interestingly, similar effects have been observed in lupus nephritis too, which has historically been a tough indication to develop drugs in.

The company has requested Fast Track designation for IgA nephropathy and at the suggestion of the FDA, plans to pursue breakthrough therapy designation and

accelerated approval based on a proteinuria endpoint. Omeros recently met with the Agency, is advancing this program as quickly as possible, and plans to initiate a Phase III trial later this year. While preparing for the Phase III trial, the company continues to conduct a second stage of the Phase II trial evaluating steroid-naive patients with IgA nephropathy.

The Potential Market Opportunity In IgA Nephropathy Alone Is Very Significant

In terms of the market opportunity, consultants estimate that there are almost 200K patients in the US that have IgA nephropathy and as many as 40% of them or roughly 80K will develop end-stage renal disease eventually requiring dialysis or kidney transplant. And even roughly 50% of patients who receive a transplant will develop the disease again. Therefore, assuming a ~\$70K cost of treatment similar to chronic branded MS therapies, which have roughly the same number of patients, this could result in ~\$700MM in peak revenues if only a fraction of (10-15%) or 10K IgA ESRD patients are treated. Our consultants believe that all ~80K of IgA ESRD patients should be treated, which could theoretically result in a multi-billion market opportunity for a novel and effective product. This is in the US alone, while Europe has a similar number of patients. Either way, the market opportunity for OMS721 appears very substantial in this patient population alone.

Below, we provide an overview of additional historical data from the OMS721 clinical program in other indications as well recent program updates from the Q1 earnings call.

Additional Background: Significant Clinical Progress Continues To Be Made For OMS721

As for OMS721, recall that in August 2015 Omeros previously announced positive data from the mid and high-dose cohorts in the Phase II clinical trial of OMS721 for the treatment of TMAs where consistent and robust improvements in efficacy measures was observed. Importantly, OMS721 has been well tolerated by all patients in all dosing cohorts and to date, the company has dosed more than 80 patients with OMS721 and has seen clinically meaningful improvements in aHUS and other TMAs with no concerning safety signals. Recent data presented at the World Congress in Mexico City in late April were similarly positive.

Most importantly, the OMS721 **aHUS program continues to advance into Phase III** as Omeros recently announced that a clinical trial will begin enrolling patients following recent successful meetings with the FDA and the EMA. Taking into account the regulatory feedback from both agencies, Omeros expects to enroll 40 patients and the Phase III program will consist of a single open-label clinical trial enrolling newly diagnosed or ongoing aHUS patients with the plan of producing an overall package similar to Alexion's Soliris. Patients in both the U.S. and ex-U.S. will be enrolled and the same Phase III clinical trial should support the submission package for marketing approvals in both the E.U. and U.S.

We believe that the initiation of Phase III patient enrollment being allowed by the EMA and FDA is a significant disclosure as we doubt the regulatory authorities would allow Omeros to move forward with this program if they weren't observing the requisite safety and efficacy in what is a very severe patient population. Therefore, we believe

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the allowance to begin dosing patients in Phase III should not be overlooked and is a positive confirmation of the efficacy and safety of OMS721. This gives us additional confidence in all OMS721 programs moving forward.

Additionally, based on regulatory feedback, the company plans to pursue accelerated approval to allow marketing of the product while confirmatory clinical data is obtained.

For the HSCT-TMA Phase II program, clinically meaningful improvements in measures of red blood cell destruction, platelet counts, lactate dehydrogenase (LDH), and haptoglobin levels have been observed. Nine patients have been treated to date with life-threatening post-transplant TMAs and seven improved. The two patients who did not stopped the study for reasons unrelated to study drug and unfortunately later passed. Recently in March, Omeros reported additional data from the Phase II trial that was consistent with these prior results and showed statistically significant and clinically meaningful improvements in TMA disease activity over the course of treatment. Similar to IgA nephropathy, Omeros will also pursue breakthough for the HSCT-TMA indication as well as accelerated approval. The company is advancing this program as quickly as possible and plans to initiate a Phase III trial in HSCT-associated TMAs later this year.

Of note, the compassionate use program for OMS712 in these various indications continues to remain active.

Valuation Methodology And Risks

Valuation Methodology

Pharmaceuticals/Specialty

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach and additional assumed business development to derive our 12-month price target.

Investment Risks

Pharmaceuticals/Specialty

Risks include: (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

Risks To The Price Target

Risks to our Outperform rating on OMER shares include: (1) failure to successfully commercialize Omidria; (2) clinical setback in pipeline programs; and (3) the potential for additional capital raises to finance further development and commercialization.

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| Ticker | Company Name |
|--------|--------------------|
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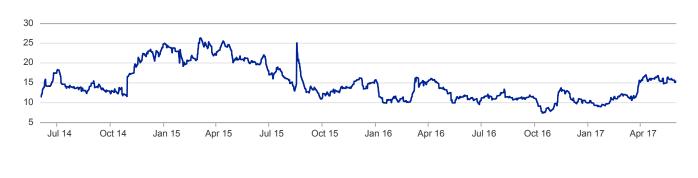
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| Buy (a) | 441 | 58.57% | 86 | 19.50% |
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Initiated Coverage - 8/13/2012 - Rating Outperform

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

Closing Price

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Target Price

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