# Elle Investments Research Report: OMER

Company: Omeros Corporation
Symbol: **OMER**
Analysis Date: 7/5/19
Analysis Price: $14.69
Price Target (PT): $31.30/share (without Omidria), $39.10/share (with Omidria)
Upside: **113%-166%**
Dividend: NA
Recommendation: **Strong Buy**

## OMER: 1-Year Chart


Source: Seeking Alpha

**INVESTMENT THESIS:**

OMER has one of the most promising candidates in all of biotech in narsoplimab, currently in three phase 3 trials targeting three indications with a high unmet need. The commercial success of ALXN's Soliris, which had $3.6B in global sales in 2018, validates the opportunity for narsoplimab given that they target indications of similar patient sizes. Liquidity may become an issue after October 1, 2020, when pass-through status for Omidria is set to expire. Until then, however, we feel confident that Omidria will continue to bring in $100M+/yr in sales, which will fund the development of narsoplimab and the expected launch (pending approval) in 2020.

**LIQUIDITY POSITION:** Fair

As of 1Q19 (ended March 31), OMER had $47M of cash and equivalents and is finalizing a $50M line of credit, which would bring their total liquidity to $97M. They have $151M of long-term debt, and $0M of current debt. With the quarterly cash burn running at $13M, should their line of credit agreement go through, the available liquidity should be ample to reach commercialization of narsoplimab, which we expect to occur at some point during 2020 (pending FDA approval).

At that point, the question will be how fast sales of this candidate ramp up in the event that Omidria loses pass-through status, which expires October 1, 2020. Should this occur, cataract surgery centers would no longer be reimbursed by Medicare for the high price of Omidria and they would switch to a cheaper option. Sales would then dwindle from the current level of $100M+/yr to under $5M/quarter (as happened during 1H18 before pass-through status was re-instated in October).

While the risk of dilution is low right now, we see the chances of further cash raises in 1-2 years' time as 50/50.

**COMMERCIAL PROSPECTS:** Excellent

**Omidria (ketorolac and phenylephrine)**
*Value: $0M (without permanent reimbursement status), $474M (with permanent reimbursement status)*

Omidria is a phenylephrine and ketorolac intraocular solution that is used to prevent miosis (pupil constriction) and for the reduction of postoperative pain stemming from cataract surgery. It was approved in the US in June 2014 and launched in April 2015. It was approved in the EU in August 2015 but was not launched (and only on a limited basis) until August 2018. As of 1Q19, management has not commented further on their EU commercialization plan, saying only that the focus continues to be expanded usage of Omidria in the US.

Omidria currently receives a special pass-through status that allows ambulatory surgical centers ("ASCS") to bill Medicare separately for it. When a drug loses its pass-through status, the price usually is lowered substantially, as ASCSs instead only receive a pre-determined "bundle" payment for whatever procedure they are performing. In order to maximize profit, the surgical centers look to substitute in cheaper alternatives to be utilized during the procedure. This is what happened when Omidria temporarily lost its pass-through status at the end of 2017, when it saw Omidria's sales plunge to under $5M/quarter. Pass-through status was reinstated on October 1, 2018, and annual sales are now back up to a run-rate of $100M+.

Generally, these pass-through payments are authorized for a limited amount of time (2-3 years), so at this point, it's unclear if OMER will be able to obtain permanent reimbursement status for Omidria past October 1, 2020. Management is focused on obtaining this permanent reimbursement, but there are no updates to report as of 1Q19.

**Narsoplimab (OMS721)**
*Value: $1.9B*

Lead candidate narsoplimab, formerly OMS721, is also in phase 2 testing for lupus nephritis and other renal diseases, but our valuation consists of just the indications for which phase 3 testing has commenced: HSCT-TMA, IgAN, and aHUS. Impressively, narsoplimab has managed to garner a bevy of special designations across three therapeutic areas:

HSCT-TMA: Orphan Drug (US/EU), Breakthrough Therapy (US)
IgAN: Orphan Drug (US/EU), Breakthrough Therapy (US)
aHUS: Orphan Drug (US), Fast Track (US)

Validating narsoplimab's potential for commercial success is Alexion Pharmaceuticals' (ALXN) blockbuster drug Soliris (eculizumab), which had global sales of $3.6B in 2018, and the expected success of its less frequent dosing formulation of Soliris, called Ultomiris. Soliris is currently approved for patients with aHUS (which overlaps with OMER's area of investigation), along with PNH, gMG in adult patients who are AchR antibody positive, and NMOSD in adult patients who are AQP4 antibody positive.

Through the end of 2017, only 43 gMG patients were on Soliris in the US, meaning that the overwhelming majority of Soliris' 2016 US net sales of $1.1B came from the PNH and aHUS indications (Soliris was not approved for NMOSD until June 2019, and so this indication has not yet contributed materially to net sales). ALXN investor relations said that they do not break out the sales split between PNH and aHUS, but it's likely that the majority of sales came from PNH patients given the significantly larger patient pool.

What we simply want to convey is that the patient pools for PNH and HSCT-TMA are similar (with HSCT-TMA even being a bit larger). While we do not think that OMER will price narsoplimab close to Soliris' annual price tag of $500K+, at a price of $250K/yr and 25% market share, OMER can realize commercial success given the lack of proven treatment options for HSCT-TMA and IgAN (the aHUS patient pool is very small and does not contribute materially to our valuation).

**Remaining pipeline candidates and indications**
*Value: none assigned*

## CONCLUSION:

We think that OMER's narsoplimab is one of the most promising candidates in all of biotech. The commercial opportunity has been validated by the success of ALXN's Soliris, and given the similar patient pools for the indications targeted by these two drugs, we think that bodes well for narsoplimab's prospects. The main risk here is the balance sheet, as it's unclear at this time whether Omidria will continue to generate $100M+/yr in sales past October 1, 2020. Should Omidria not be granted permanent reimbursement status, sales would decline significantly, and OMER would likely need to raise money to support the commercialization of narsoplimab and further pipeline development. But we think this is an acceptable risk. We rate OMER a Strong Buy.

## GLOSSARY:

AchR: antiacetylcholine receptor
aHUS: atypical hemolytic uremic syndrome
ASCS: ambulatory surgical centers

AQP4: antiaquaporin-4
gMG: generalized myasthenia gravis
IgAN: immunoglobulin A nephropathy
HSCT-TMA: hematopoietic stem cell transplant-associated thrombotic microangiopathy
NMOSD: neuromyelitis optica spectrum disorder
PNH: paroxysmal nocturnal hemoglobinuria

*Note: Additional commentary from Elle Investments can be found at http://elle-investments.com. We welcome your feedback. Additionally, we are thinking of launching a subscription service that would offer early access to our research, along with some other features that investors might find useful (i.e. general portfolio management strategies, live blog updates highlighting our reaction to breaking news, etc.). If you would be interested in subscribing to such a service, please let us know.*

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