FourWorld
CAPITAL MANAGEMENT

Omeros Corporation: Far Less than Meets the Eye

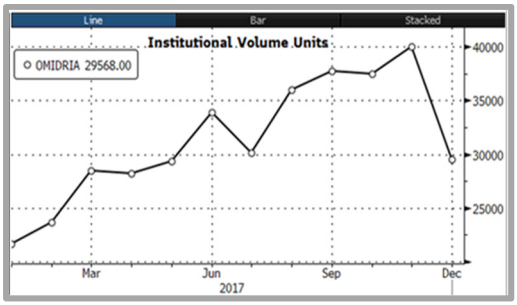
February 14, 2018 | **NYSE: OMER** | **Mkt Cap*: $665M** | **Price*: $13.86** | **Price Target: $4.00**

Omeros Corporation ("OMER") is a biopharmaceutical company with a single approved drug ("OMDIRIA") representing its sole source of revenue. On January 1, 2018, OMIDRIA's time under a Medicare reimbursement program expired and hopes for a legislative solution are now effectively gone. We estimate an 80% decline in Company revenue, unsustainable levels of cash burn, and vanishing liquidity options under its term loan that leaves a $400 million funding gap over the next four years.

OMIDRIA legislative hopes come up empty. Despite continuous "optimistic" rhetoric from management for a successful legislative solution to pass-through expiration, all realistic hopes finally withered with the passing of the Bipartisan Budget Act of 2018 on February 9th.

- Despite numerous public rejections over the past few years by CMS (Medicare) of Omeros' administrative efforts to extend reimbursement, we believe management comments continued to create confusion and hope for investors.
- In our view, the final dagger was the signing of the Bipartisan Budget Act of 2018, whereby Congress dealt with healthcare spending and did not include the legislative actions being pushed by Omeros to extend OMIDRIA reimbursement.

On February 9, 2018, President Trump signed the Bipartisan Budget Act of 2018 (H.R. 1892). In it, Congress dealt with healthcare spending and did not include the legislative actions being pushed by Omeros to extend OMIDRIA reimbursement.



Source: Bloomberg

Cracks from Medicare loss showing. Financial deterioration imminent? Inventory buybacks, free samples and dismal December sales data point to a pending revenue collapse.

- Omeros sent a letter to customers in December offering to buy back inventory purchased prior to year-end. Channel checks with pharma reps and ASC surgeons indicate buyback utilization will be high.
- December data from Symphony Health shows a 26% drop in institutional sales volume.

Liquidity catch-22 could precipitate large dilution events. Omeros will need the additional $45 million available under its term loan with CRG, Omeros' primary lender. However, drawing to the full $125 million limit will increase the probability of a covenant breach. Furthermore, loan provisions provide CRG avenues to deny this capital and protect the lender from Omeros' financial deterioration.

- MAC provisions (and Inspection Rights to closely monitor the financial performance of Omeros) make it difficult to tap this liquidity if revenues have fallen precipitously.
- Covenants requiring minimum revenue or market cap and continuous minimum liquidity make a future default highly likely, in our view. We note that the entire pipeline is pledged as collateral for the loan.
- An Event of Default, by MAC or covenant, gives CRG the right to accelerate the loan.
- In our view, this will be addressed with a large equity raise to repay the loan. Additional equity raises would be needed to fund the business and clinical programs.

Omeros pipeline is highly speculative and commercialization potential is years away, if ever. OMS721 is the drug of promise for Omeros, but questionable clinical trial designs, scant patient sample sizes continuous patient enrollment delays and future funding concerns call into serious question the probability of success of any OMS721 indication.

- Omeros appears to have financially abandoned all clinical programs outside of OMS721 and OMIDRIA, having spent just $22k in total on them in Q3 2017.
- Despite a myriad of headwinds, our research suggests that at best OMS721 will produce meaningful phase 3 trial data in 2020, putting commercialization prospects into 2021 or later, if ever.

Our discounted cash flow based price target for Omeros common stock is $4.00 per share.

See the full report available for download at www.fourworldcapital.com

** Closing price on February 12, 2018*

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FourWorld Capital Management LLC ("FourWorld") is an SEC registered investment advisor based in New York, New York. The views expressed in this research paper represent the opinions of FourWorld. As of the publication date of this presentation, FourWorld, and FourWorld managed accounts, have a direct or indirect short position in Omeros Corporation. ("Omeros") stock, and therefore stand to realize significant gains in the event that the price of Omeros stock declines. Following publication of this presentation, we intend to continue transacting in the securities covered herein, and we may be long, short, or neutral at any time hereafter regardless of our initial recommendation.

FourWorld's Key Takeaways

1. We forecast an 80% YOY revenue decline and a 90% price decline for OMIDRIA as Omeros has exhausted all viable regulatory and legislative options to extend reimbursement status.
2. Omeros has offered to repurchase unopened inventory from customers purchased before December 31, 2017. Cracks in OMIDRIA revenues are now visible; data from Symphony Health shows a 26% decline in December 2017 sales volume for OMIDRIA. Channel checks with several surgeons representing major ASC's in six states indicated none of them were purchasing OMIDRIA after January 1, 2018 and all planned to discontinue use of the drug in their normal practice given the loss of Medicare support.
3. OMER's term loan contains provisions that leave Omeros in a catch 22 – it needs to draw the additional liquidity in the face of collapsing revenues, but doing so will very likely cause a default on the loan or necessitate a series of large equity dilution events.
4. We believe legislative options to extend OMIDRIA reimbursement status are now effectively dead, as Congress dealt with healthcare spending in the Bipartisan Budget Act of 2018 that was signed into law on February 9, 2018.
5. We believe OMER management squandered an opportunity to secure a pricing model independent of the 'transitional' Medicare program and continued promoting legislative and regulatory solutions for reimbursement even though there appeared to be a very low chance of success, given CMS explicitly denied the Company's requests to extend the pass-through period for OMIDRIA on multiple occasions.
6. Without OMIDRIA, we forecast a funding shortfall of $400 million over the next four years. We believe Omeros must raise this capital to realize any commercial value from its speculative pipeline.
7. We believe OMS721 represents the only drug of any value in the Omeros drug pipeline, and estimate that OMS721 will not produce any clinical trial data until 2020 due to complications with enrollment for Phase 3 trials in aHUS and IgA Nephropathy.

Introduction

Omeros Corporation ("OMER" or the "Company") is a Seattle-based biopharmaceutical company that is solely revenue-dependent on OMIDRIA: in our view, a hyper-overpriced FDA approved drug that has lost its Medicare pricing safety net – the only insulation from cheap alternatives available at one-tenth the price. Without this revenue lifeblood, we believe the Company will struggle to bridge the multi-year gap to its highly speculative pipeline of new drugs currently in various stages of development. Throughout

2017, Omeros promoted three potential avenues to sustain OMIDRIA revenues that we now know are effectively dead: (1) the explicit designation for OMIDRIA to be fully reimbursed by Medicare at 106% of cost; (2) a billing code specifically designated for surgeries where OMIDRIA is used, providing additional reimbursement for the increase in surgical expenses associated with OMIDRIA; and (3) an extension of the Medicare pass-through transitional period via legislative action tied to "must-pass" legislation.[1]

The Centers for Medicare and Medicaid Services ("CMS") published the Calendar Year 2018 ASC Payment Update on November 1, 2017,[2] which did not increase the cataract surgery facility fee to package OMIDRIA. Medicare extenders were dealt with in the Bipartisan Budget Act signed into law on February 9, 2018, and did not include either of the two bills[3] introduced that could have extended the reimbursement period to five years from the current maximum of three.[4] According to our government experts in Washington, D.C., the chances any new Medicare spending legislation will be introduced are effectively nil for the foreseeable future. We believe Omeros now faces a pending liquidity crisis likely to trigger a covenant breach or an Event of Default under the Company's Term Loan Agreement (TLA) as OMIDRIA demand, pricing and revenues crater. This will leave few options – all likely devastating to current shareholders – to fund the growing R&D spend required to pursue its pipeline of speculative new drugs.

As we understand, OMIDRIA costs approximately $2.50 per vial to manufacture but has an Average Wholesale Price (AWP)[5] of $465. In our view, this drug has maintained its post-rebate $350 average sale price (ASP) and 99% gross profit margins by taking advantage of a US Medicare program designed to provide Medicare patients with access to innovative new drugs and therapies. For the last three years, CMS covered the $350 ASP for OMIDRIA and paid an additional 6% on top to the surgery providers. As long as Medicare was willing to cover the cost and pay a 6% premium, ASCs and Hospital Outpatient Departments ("HOPD") were incentivized to use $350 per dose OMIDRIA instead of paying $30 per dose for alternatives out of pocket. Taking this Medicare shield away exposes the bottom lines of these surgical facilities, who will be hard-pressed to pay a large portion of their overall surgery fee to cover the cost of this drug. Please see Appendix D for additional detail on OMIDRIA composition, administration, and alternatives.

[1] Greg Demopulos on the Q3 2017 earnings call. November 9, 2017. Transcript from Bloomberg.
[2] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-01.html
[3] These bills were designed to extend the pass-through transitional window from three years to five years
[4] https://www.appropriations.senate.gov/imo/media/doc/Bipartisan%20Budget%20Act%20of%202018.pdf
[5] 1833. [42 U.S.C. 1395] (G) —The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

Figure 1: Cost of OMIDRIA Alternatives

Cost of OMIDRIA Alternatives			
Drug	Purpose	Price	Delivery*
OMIDRIA	Pupil dilation and postoperative pain	$350	IC
OMIDRIA Components			
Phenylephrine	Pupil dilation	$17	IC/T
Ketorolac	Postoperative pain & pupil dilation	$15	T
OMIDRIA Alternatives			
Shugarcaine	Pupil dilation & anasthetic	$28	IC
Behndig's Solution	Pupil dilation & anasthetic	$26	IC
Epinephrine	Pupil dilation	<$10	IC
Lidocaine	Pupil dilation & anasthetic	<$10	IC/T
Tropicamide	Pupil dilation	<$10	IC/T
Cyclopentolate	Pupil dilation	<$10	IC/T
Capsular Ring	Mechanical pupil dilation	$120	n/a
Iris Hooks	Mechanical pupil dilation	$100	n/a

*IC=intracameral delivery (intraoperative); T=topical, generally applied before surgery, after, or both

In rare cases where patients are unable to maintain adequate dilation, physicians use capsular rings or iris hooks to mechanically dilate the iris.

OMIDRIA is a patented combination of legacy generic pupil dilation and pain relief drugs for use in cataract surgeries. Cataract surgery is among the most common and successful surgical procedures performed today – an estimated four million procedures were performed in the US in 2017 with a success rate of 99%. Omeros claims to have spent $350 million over a 10-year development process that culminated in FDA approval for OMIDRIA.[6] The problem Omeros has it that it spent all of that money to show that adding $2 of ketorolac provides, we have learned, a very mild clinical benefit to an already 99% successful procedure that uses drugs costing less than $30. Ophthalmologists we consulted asserted that at best OMIDRIA provides a very mild clinical benefit, but did not justify much, if any, pricing premium over generic alternatives that have been used with great success for decades. Simply put, many surgeons used the drug in qualifying Medicare patients largely because it was free to patients and added revenues for ambulatory surgical centers, but intend to drastically reduce, or discontinue altogether, the use of OMIDRIA given the loss of reimbursement status.

Based on our research, we believe this shift of costs has already caused a massive exodus away from OMIDRIA.[7] Furthermore, per the CEO's own comments, the Company relies heavily on OMIDRIA sales to fund the R&D for its pipeline. We believe Omeros will have no place to turn to address its capital needs outside of the equity markets. In our opinion, the TLA's covenants and MAC clause make an equity offering to both repay the loan and fund cash burn highly likely. We estimate this will result in an immediate $100-150 million dilution for shareholders and total dilution over the next four years of $400 million.

[6] Medical Affairs, Omeros Corporation. "Letter re: Statements about Omidria." Ocular Surgery News U.S. Edition, March 10, 2016.

[7] Symphony December 2017 script data showed a 26% drop in Omidria as compared to the previous month. Symphony is a leading provider of US prescription data and is widely followed on Bloomberg. See Figure 4.

Lost Pass-Through Status and Deep Price Cut for OMIDRIA

Key Takeaway: We forecast an 80% YOY revenue decline and a 90% price decline for OMIDRIA as Omeros has exhausted all viable regulatory and legislative options to extend reimbursement status.

Following the loss of OMIDRIA pass-through status on January 1, 2018 and elimination of any viable legislative options to extend it in the near future, we believe no ASC or Hospital customer should be willing to pay anywhere near the current ASP for OMIDRIA. Simply put, we estimate a 20%, 30% or even 50% price cut will not maintain the drug's current market share as some analysts have suggested, let alone capture the additional market share necessary to make up for the price cut. **Based on our conversations with cataract surgeons at several ASCs located across the country, we believe OMER will have to cut the price of OMIDRIA to no more than a 10% premium to generic alternatives priced at $30, implying a 90% reduction from current prices, in order to maintain market share.**

In our view, OMIDRIA revenues have relied almost entirely upon its Medicare pass-through reimbursement status, as this program transformed a high-cost line item to a revenue item for its ASC and Hospital customers. In 2014, it was estimated that 73% of cataract surgeries were performed in ASCs (as opposed to hospitals), up from 44% in 2001 and continue to trend higher today.[8] Industry experts we have spoken with confirm this trend and state that over 80% of cataract procedures take place in ASCs today. When a cataract surgery is performed at an ASC; the ASC is paid a facility fee from Medicare of approximately $991.95 (for illustrative purposes, we round this payment to $1,000 hereafter).[9] In other words, every time a cataract procedure is performed, an ASC receives a $1,000 facility fee from CMS. The facility fee represents the gross revenue for the procedure from which certain costs, including drugs used in the procedure, are deducted to find the net profit to the ASC/HOPD. Absent Medicare pass-through status, OMIDRIA's $350 ASP per dose would reduce the $1,000 facility fee dollar-for-dollar to $650, an unfathomable cost when alternative drugs that have been around for decades and cost less than $30 per dose can be used instead (and, in fact, were used in ~95% of cataract surgeries in 2017). However, when a drug has pass-through status, a full 106% of the ASP is reimbursed separately from the facility fee by CMS to the ASC/HOPD. In effect, a $350 cost is transformed into a $21 revenue item.

According to the several cataract surgeons we spoke to, because the cost risk to ASCs/HOPDs associated with non-reimbursement for OMIDRIA is so high and costs borne by the patient may be higher, only Medicare patients with supplemental insurance (known as "Med Supp" or "Medigap" insurance plans) would generally be administered OMIDRIA while the drug had pass-through status; Original Medicare and Medicare Advantage would not always result in full reimbursement to the patient, who would be responsible for a 20% copay for OMIDRIA. Consequently, when a patient with Medigap insurance required cataract surgery, ASCs were incentivized to avoid the ~$30 cost of alternatives and secure the $21 pass-through sweetener, pocketing the $51 difference and leaving the federal government (and US taxpayer) to pick up the $371 tab.

[8] https://www.healio.com/ophthalmology/cataract-surgery/news/online/%7B4cf392e1-b1e4-466e-98a0-a5f4b5351d01%7D/cataract-surgery-shifting-to-ascs

[9] Hospitals are also paid a facility fee, which is higher than that paid to ASCs (2018 reimbursement is $1,921. We focus on ASCs as we believe 80% or more of cataract surgeries are performed at ASCs and expect that percentage to increase over time.

Figure 2: OMIDRIA Single Case Profitability Analysis

OMIDRIA - Single Case Profitability Analysis*			
	Omidria Reimbursement		
Revenue Items	Cost plus 6% (Pre Jan. 1, 2018)	Bundled Payment (Post Jan. 1, 2018)	Generic Alternative Drug Used
Facility Fee	$1,000	$1,000	$1,000
OMIDRIA	($350)	($350)	n/a
Reimbursement	$350	n/a	n/a
6% Payment	$21	n/a	n/a
Supplies:			
Facility Staffing*	($48)	($48)	($48)
Balanced Salt Solution	($8)	($8)	($8)
Phaco Tubing	($20)	($20)	($20)
Cataract Lens Implant	($75)	($75)	($75)
Cataract Pack	($30)	($30)	($30)
Vicoelastic	($33)	($33)	($33)
Disposable Surgical Equipment	($30)	($30)	($30)
Generic Drugs	n/a	n/a	($30)
Finance Premium on Capital Equipment	($25)	($25)	($25)
Profit per Procedure	**$753**	**$382**	**$702**

*No overhead expenses for rent, malpractice insurance etc. are included in these figures

*Facility staffing is calculated using the assumption that each ASC utilizes two scrubtechs (two active OR's per surgeon), one nurse and a receptionist at a cost of $40/hour

ASCs often perform several thousand cataract procedures per year. The financial impact of continued OMIDRIA use after the pass-through expiration would be devastating to an ASC.

We believe Omeros discerned that while the components of OMIDRIA had been previously approved by the FDA for topical ocular use, neither drug had been approved for intracameral applications (uses inside of the anterior eye cavity), even though surgeons already commonly used phenylephrine in that capacity. In short, OMIDRIA approval for intracameral use gives surgeons the ability to circulate a constant concentration of phenylephrine and ketorolac inside the eye during surgery, maintaining a consistently dilated iris throughout the procedure. The surgeons we consulted characterized the clinical benefits of OMIDRIA as mild at best, but not worth much, if any, additional cost over available alternatives.

ASCs are often surgeon owned with a sophisticated facility staff very focused on expenses. Pharmaceutical sales reps **we have spoken with discussed illustrative situations where ASCs dropped a product due to an incremental cost of just $5 per procedure**. Thus, we believe the sophisticated, profit-focused ASCs were the primary drivers of OMIDRIA growth when reimbursement was set at 106% of cost and will be the primary drivers of the collapse, as the lost pass-through increases the drug's cost to 35% of ASCs gross revenues (per case) beginning January 1, 2018. As surgeons do not own a stake in hospital outpatient centers and generally receive a flat fee for each procedure in that setting, the incentives of doctors and hospital outpatient surgical centers are not as aligned as they are in ASCs. Additionally, as we noted previously, hospitals are often non-profits, and reimbursement rates for hospital outpatient sites under Medicare are much higher than those for ASCs. For those reasons, a drop-off in OMIDRIA sales may occur more slowly in hospitals. We note that ASCs continue to perform a greater share of outpatient procedures each year, further mitigating any potential for hospitals to support OMIDRIA sales in the future.[10]

[10] Industry experts we have spoken estimate that the number of cataract procedures performed in ASCs today is 80% and growing.

OMIDRIA Buy Backs and Free Samples Likely to Cause Revenue Misses in Q4 2017 & Q1 2018

Key Takeaway: Omeros has offered to repurchase unopened inventory from customers purchased before December 31, 2017. Cracks in OMIDRIA revenues are now visible; data from Symphony Health shows a 26% decline in December 2017 sales volume for OMIDRIA. Channel checks with several surgeons representing major ASC's in six states indicated none of them were purchasing OMIDRIA after January 1, 2018 and all planned to discontinue use of the drug in their normal practice given the loss of Medicare support.

In what we view as a desperate attempt to prevent a mass exodus of current customers following the loss of "pass-through" reimbursement status, OMER sent a letter to current OMIDRIA customers pledging to repurchase any unused inventory purchased prior to December 31, 2017. We also understand Omeros was handing out a significant quantity of free samples of OMIDRIA while the Company pursued the legislative actions that are now effectively dead. Based on our many conversations with surgeons, we expect bottom-line savvy ASCs to take advantage of this buyback offer and seek a refund for their entire unused inventory from the Company. As the company usually books revenue when products are shipped to wholesalers, we expect repurchases to create a meaningful decrease in Q4 2017 revenues.

Figure 3: Excerpt from Omeros Letter to OMIDRIA Customers

In the event that pass-through for OMIDRIA is not extended beyond January 1, Omeros will also implement a special returned goods policy for OMIDRIA, which will be effective January 1 through January 26, 2018. Throughout the policy's duration, Omeros will allow its customers to return directly to an Omeros-designated agent any unopened vials of OMIDRIA that they purchased on or before December 31, 2017. Omeros will then refund the customer's original purchase price less any discounts or credits received on these unused OMIDRIA vials. Returned vials will not be included in qualifying totals under any OMIDRIA Discount Pricing Agreement.

Should you or your colleagues have any questions regarding returns, our service programs or any other OMIDRIA matter, your OMIDRIA sales representative together with Omeros' corporate team remain readily available to assist.

I appreciate your patience and support as we work through the potential solutions to secure permanent separate reimbursement for OMIDRIA. Ophthalmic surgeons are increasingly recognizing that OMIDRIA improves surgical outcomes, and all of us at Omeros are dedicated to continuing to help ensure the best care for your patients.

Sincerely,

Gregory A. Demopulos, M.D.
Chairman and CEO
Omeros Corporation

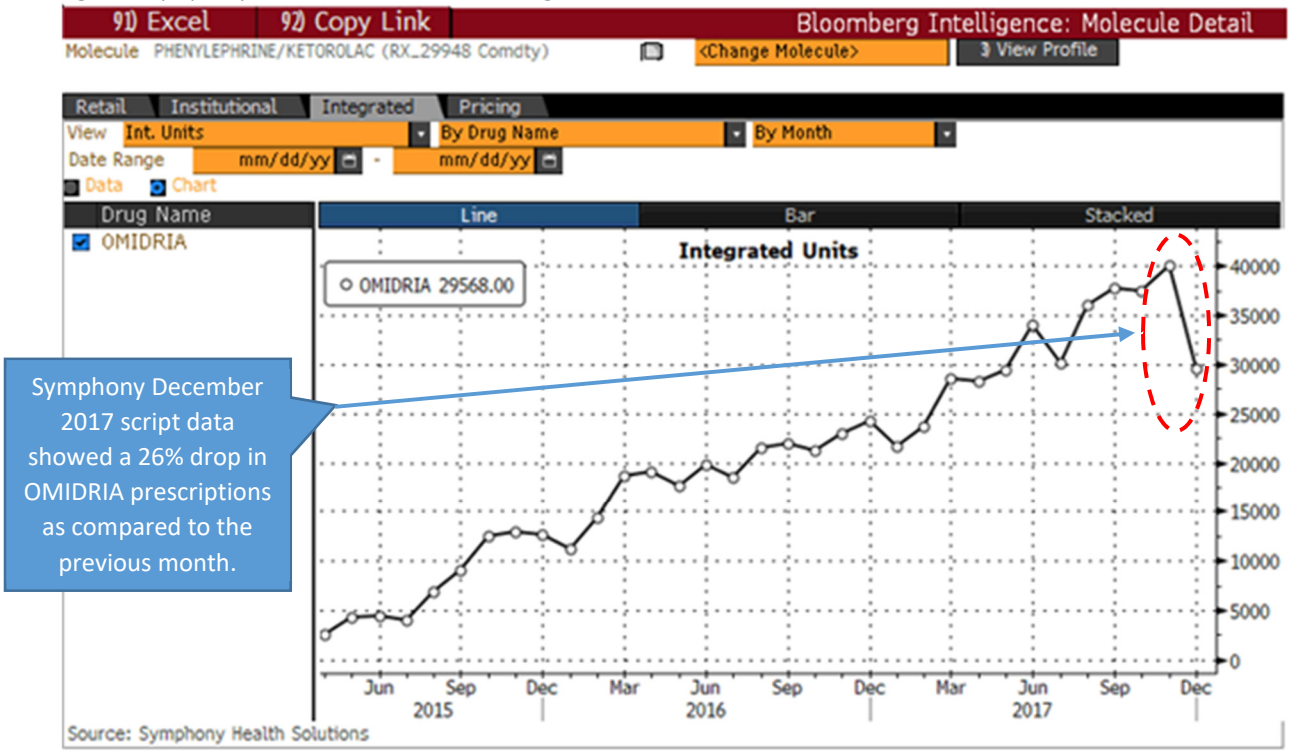
See Appendix A for a complete copy of the Omeros letter to customers

We believe a material revenue miss versus estimates in the fourth quarter 2017 and the first quarter of 2018 is likely for the following reasons:

1. We have concluded that ASCs and wholesalers were aware of the reimbursement issue and reduced purchases in the 4th quarter (see Symphony prescription data).
2. For certain customers (at least), **Omeros has been repurchasing inventory acquired before December 31st at full cost.**
3. According to industry contacts, Omeros sales representatives have been giving out large quantities of free samples of OMIDRIA since January 1, 2018.

4. **Channel checks with several surgeons representing major ASC's in six states indicated all of them were no longer purchasing OMIDRIA after January 1, 2018 and planned to discontinue use of the drug in their normal practice given the loss of Medicare support.**

Figure 4: Symphony Data on OMIDRIA Sales through December 2017[11]



<u>The Term Loan Agreement Catch 22: Liquidity versus Potential Default Risk</u>

Key Takeaway: OMER's term loan contains provisions that leaves Omeros in a catch 22 – it needs to draw the additional liquidity in the face of collapsing revenues, but doing so will very likely cause a default on the loan or necessitate a series of large equity dilution events.

Omeros signed a $125 million term loan agreement with CRG Financial on October 26, 2016 that matures on October 31, 2022 and is collateralized by substantially all of its assets, including its drug pipeline. In our view, the loan contains covenants that leave Omeros in a serious dilemma – it will need the additional liquidity available (only available until March 21, 2018) under the term loan to fund its operations, but doing so makes the probability much higher that the Company will fail the covenant tests based on its 2018 financials. Breaching a covenant is an event of default. In addition to covenant tests, the Material Adverse Change (MAC) provisions (and Inspection Rights to monitor the financial performance of Omeros) under the term loan provide an aggressive lender like CRG an avenue to claim a MAC has occurred (should revenues plummet) and thereby 1) assert an event of default and/or 2) deny Omeros the ability to draw

[11] Symphony Health Solutions Company ("Symphony") is the provider of U.S. prescription audit data to Bloomberg. Symphony is an industry leader and one of the most widely followed sources for prescription data.

the remaining $45 million in available debt capacity. Denying access to the remaining $45 million tranche of capital will leave Omeros with few places to turn for capital other than the equity markets, whereas asserting an event of default would permit CRG to demand immediate repayment of the debt and increase the interest rate by an additional 4%. Either option would leave Omeros with few places to turn for capital other than the equity markets. In our opinion, this dilemma, the threat of default and the possibility of debt acceleration will at best be a lasting overhang on the OMER stock price, and at worst cause a very large dilution event at any time, which could catch OMER shareholders by surprise.

Readers should consider the likelihood of completing one or more equity offerings at, or near, the current share price as we believe it is the Company's only practical option to avoid default under the loan agreement.

The "Conditions to Borrowing" Provide CRG Avenues to Deny Access to Additional Liquidity

In order to access the remaining $45 million under the term loan, the Conditions to Each Borrowing (Section 6.05) requires Omeros to certify that "no Material Adverse Effect has occurred or is reasonably likely to occur after giving effect to such proposed Borrowing."[12] We have not spoken with CRG and do not know what action it would take in this circumstance in order to assess the financial condition of the Company. We believe however that this circumstance provides an opportunity under the term loan for CRG to request information into the Company's financial condition, including OMIDRIA sales figures, the amount of product buybacks and sales forecasts.[13] Moreover, our understanding is CRG's business model is to provide loans against cash flows for FDA approved drugs with reimbursement or drugs with distinct pricing advantages. In our view, should CRG remain unconvinced that a Material Adverse Change has not occurred, it will deny access to the $45 million under the term loan and try to prevent the Company from burning through its remaining cash.

Readers should consider whether a disciplined lender would loan another $45 million in capital to a Company with such significant revenue headwinds and high levels of cash burn.

Financial Covenant Tests Leave a Large Overhang for OMER Shares

Section 10 of the Term Loan Agreement contains three financial covenants – a "Minimum Liquidity" test, "Minimum Revenue" test and "Minimum Market Capitalization" test. To remain in compliance, Omeros must meet the Minimum Liquidity test at all times and must meet either the Minimum Revenue test (determined as of December 31 of the calendar year) or the Minimum Market Cap test (determined as of the fifth day following the announcement of earnings results for such calendar year) annually.

The Minimum Liquidity covenant requires the Company to maintain at least $5 million in "Liquidity" at all times. Liquidity is defined as unencumbered cash or cash equivalents (which does not include undrawn credit lines) held in an account over which CRG has a perfected security interest.[14] We question whether the Company will be able to meet this requirement at all times in 2018 given its aggressive outlook for cost-intensive clinical trials and our expectation of an 80 percent decrease in Company revenues. **The**

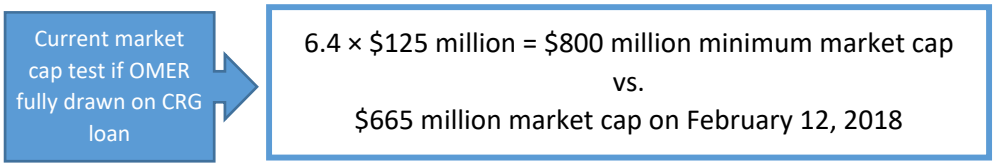
[12] Company Term Loan Agreement, p. 41
[13] Section 6.05 invokes Sections 7 & 8, which call for the delivery of financials and financial forecasts.
[14] Company Term Loan Agreement, p. 12

Company itself stated in its latest 10Q that even with the additional $45 million of liquidity under the term loan, it is only able to meet its future financial obligations through November 9, 2018.[15] We forecast it will fall below this threshold in Q2 2018, as we believe the additional capacity under the term loan will not be available.

> *We believe that our assets, together with these incremental sources of funds, are adequate to fund our future financial obligations as they become due through November 9, 2018 regardless of the outcome of the separate-payment status for Medicare patients treated with our commercial product, OMIDRIA.*

The Minimum Revenue test requires Omeros to achieve revenues of $55 million for 2017 and $65 million for calendar year 2018 (and higher amounts for each subsequent year thereafter). With a reported $51.2 million of OMIDRIA sales in the nine months ending September 30, 2017, it seems likely that Omeros can survive the $55 million threshold for 2017 despite headwinds related to the loss of reimbursement status. We believe it is a virtual certainty that Omeros will not achieve the $65 million minimum threshold required for calendar year 2018. This eventuality should be apparent to investors and analysts as soon as the Company provides its Q4 financials and forward revenue guidance. In our view, this looming covenant breach should cause a large overhang on the stock.

The Minimum Market Capitalization tests require Omeros to maintain a market cap of at least 6.4 times the term loan amount outstanding. Assuming $80 million of debt outstanding as of September 30, 2017, this equates to $512 million. Using the closing price of OMER on Monday, February 12, 2018 of $13.86, the market capitalization of Omeros was $665 million, which meets the test requirement for calendar year 2017. However, this test will be conducted five business days after the release of annual financials (forecasted by Bloomberg to occur on March 15, 2018), which means a deterioration in OMER to below $10.67 per share would cause it to fail to satisfy this alternative test as well as the covenant, unless Omeros satisfies the Minimum Revenue prong for calendar year 2017.



In our view, the expiration date of OMIDRIA's reimbursement status proved fortuitous for Omeros, as it allows the Company to rely on revenues generated in 2017 – while the drug had Medicare support – in order to meet a covenant to draw additional operating capital in 2018 when OMIDRIA revenues have lost Medicare support. Since the Company must meet either the Minimum Revenue or the Minimum Market Cap test only once each year, Omeros is likely to try to draw the additional $45 million in debt capacity by March 21, 2018 knowing it will pass the $55 million revenue test this year. However, in our opinion, if the Company is successful in its attempt, doing so will very likely cause it to fail both alternative tests in 2018, putting creditors and shareholders on notice that the Company is highly likely to default five days after the release of the 2018 annual financials (March 2019). We believe the market will realize this almost immediately and will punish the stock for such a critical overhang.

[15] Company Q3 2017 10Q, p. 21

Should the Company fail to meet either of these tests, it can satisfy its requirement by issuing equity or subordinated debt in an amount equal to the shortfall between the applicable year's Minimum Revenue threshold amount and actual revenue that year, with the proceeds used to pay down the loan amount. We forecast a shortfall of $53 million for 2018, $67 million for 2019, $80 million for 2020 and $88 million for 2021.

Readers should consider what financing or strategic options would be available to a company in the circumstances described herein.

Additional Term Loan Provisions Leave the Door Open for an Immediate Event of Default

The Material Adverse Change definition provides that the deterioration of the Company's overall financial condition could give rise to a MAC, which pursuant to Section 11(n), would be an immediate Event of Default. In our view, CRG Financial was keenly aware of and specifically concerned about the loss of reimbursement status. The Term Loan definition of a MAC includes:

> *…that a Material Adverse Change or Material Adverse Effect shall not be deemed to occur solely because of the expiration of the pass-through reimbursement status for the Product on December 31, 2017;* ***provided that the deterioration of Borrower's overall financial condition (whether or not as consequence of such expiration), taken as a whole, could give rise to a Material Adverse Change or Material Adverse Effect.*** [emphasis added]

The definition states that the loss of reimbursement status itself is not a MAC; **however, the deterioration of the overall financial condition stemming from such an event -- whether alone or in combination with other circumstances -- could give rise to a MAC.** As discussed throughout this paper, we believe the loss of reimbursement status will be devastating to Omeros' financial condition. Thus, we believe an aggressive lender could use this provision to assert an event of default and demand full payment of all principal and interest immediately.

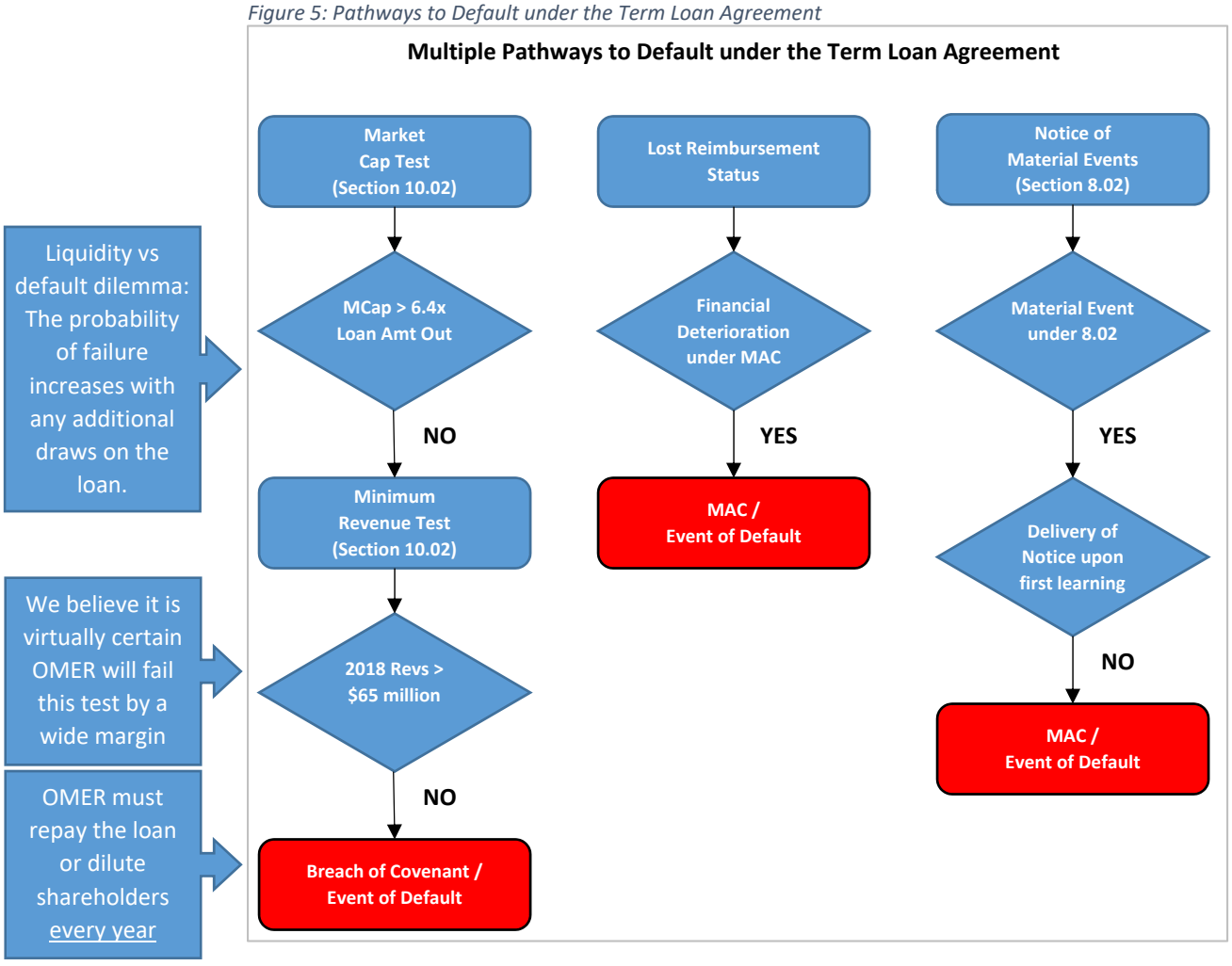
Another such provision in the term loan is the "Notices of Material Events" under Section 8.02, which requires Omeros to provide written notice to the Lender "promptly after a Responsible Officer first learns of the existence of" a number of events. In particular, 8.02(l) and (m) state:

> *(l) any other development that results in, or could reasonably be expected to result in, a Material Adverse Effect;*
>
> *(m) promptly after receipt thereof, notices on any developments on the pass-through reimbursement status (or any successor payment methodology thereto) on Product;*

We believe the deterioration in OMIDRIA sales constitutes a development that could reasonably be expected to result in a MAC. Furthermore, we believe multiple notices were provided to Omeros (e.g. the CMS preliminary and final rulings) that constitute a development on the pass-through reimbursement status. While we are unsure whether Omeros has provided any such notices to CRG, we note that **a failure to deliver a Notice of Material Event would constitute an event of default.**

Readers should consider the implications of choosing to deliver a Notice of Material Event or not, and then decide if either declaring a possible MAC or leaving a possible pathway to an event of default can have a favorable outcome for the Company.

Figure 5: Pathways to Default under the Term Loan Agreement



Given the numerous conditions described above, we believe the lenders will assert a MAC very soon in order to prevent the Company from burning through its remaining cash. Moreover, we expect CRG to aggressively pursue the repayment of its loan. To address this issue, we believe the Company will have few places to turn other than equity markets to raise the funds required to repay the loan.

Readers should consider the likelihood a company with material financial deterioration will be able to secure alternative financing on favorable terms.

Pass-Through Extension Legislation Is Effectively Dead

> **Key Takeaway:** We believe legislative options to extend OMIDRIA reimbursement status are now effectively dead, as Congress dealt with healthcare spending in the Bipartisan Budget Act of 2018 that was signed into law on February 9, 2018.

The Bipartisan Budget Act of 2018 was signed into law on February 9, 2018. Over half of the 652 page bill is dedicated to healthcare, including Medicare extenders. After extensive due diligence working closely with major law firms and government affairs consultants with extensive experience with Medicare/CMS, we believe OMER's only real chance at extending reimbursement status for OMIDRIA was for a pass-through extension to be included in the Bipartisan Budget Act's Medicare extenders package.[16] Note that the Bipartisan Budget Act of 2018 was passed on February 9, 2018, and did not include any provision for extending the pass-through period as relevant to OMIDRIA. The Company's legislative path to continued reimbursement was dependent upon two bills, HR 4679 and HR 4683, designed to extend the pass-through transitional window from three years to five years.[17] H.R. 4679 and H.R. 4683 were introduced in the House on December 18, 2017 and December 19, 2017, respectively. Both bills were referred to the Ways and Means Committee (which has jurisdiction over Medicare issues) and the Energy and Commerce Committee (which has jurisdiction over drug and FDA issues). We have concluded that neither bill has received serious consideration for inclusion in any must-pass legislation that might be considered this year; in fact, **neither bill has been scored by the Congressional Budget Office ("CBO"), an initial step essential for any bill to be legislatively considered by the House.**

H.R. 4679 was introduced by Rep. Tom Reed (R-NY-23) and cosponsored by Rep. David G. Reichert (R-WA-8). The bill makes changes to various adjustments to both Inpatient prospective treatment reimbursements and outpatient procedures and treatments. One of the 7 changes the bill proposes is to extend the current "pass-through" period from "at least 2 years, but not more than 3 years" to "5 years".

H.R. 4683 was introduced by Rep David G. Reichert (R-WA-8) and cosponsored by Rep Suzan K. DelBene (D-WA-1), Rep Cathy McMorris Rodgers (R-WA-5), Rep. Terri A. Sewell (D-AL-7), Rep. Bonnie Watson Coleman (D-NJ-12) and Rep. Leonard Lance (R-NJ-7). This bill's only amendment is to the "pass-through period" for both inpatient and outpatient new drugs and devices. The language in this bill referring to outpatient reimbursement is identical to H.R. 4679. Given the limited scope of H.R. 4683, it would have been a much easier bill to include with the Medicare Extender package, as the cost of the adjustment would be less than the larger extender (4679). Also note that three of the bill's cosponsors are from Washington State, home of Omeros. Again, neither 4679 nor 4683 were included as a part of the Medicare extenders package passed as a part of the Bipartisan Budget Act of 2018, we view both bills as effectively dead.

Medicare Transitional Pass-Through Provision's Purpose and Why OMIDRIA's Time is Up

In order to support innovation of and access by Medicare patients to novel therapies, Congress set up a special provision in the law—Social Security Act §1833(t)(6)—to encourage the use of innovative products

[16] We also believed Omidria's reimbursement status had a chance of piggybacking on CHIP (Children's Health Insurance Program) funding, which was dealt with in the continuing resolution signed into law on January 22, 2018.

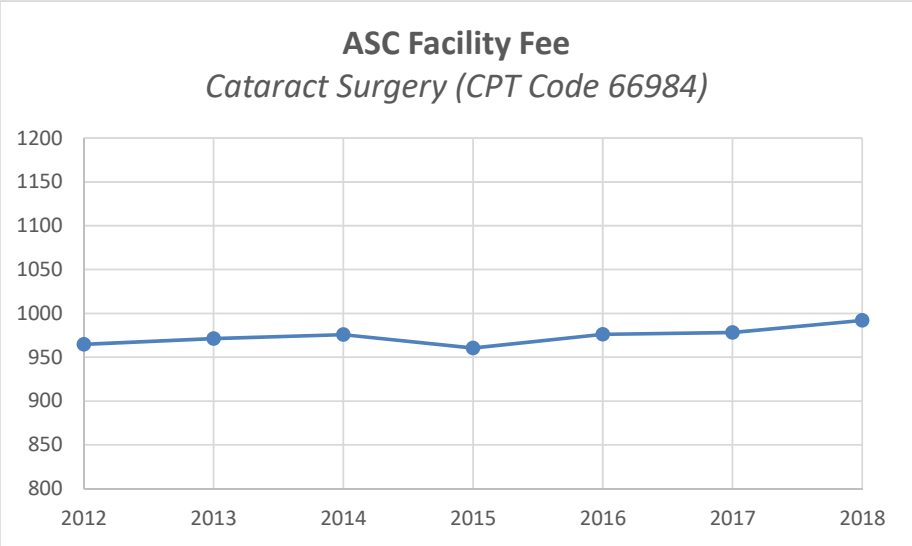
[17] See Appendix C for copies of HR 4679 and HR 4683.

without raising the costs to ASCs as well as outpatient hospital centers. This is done by the Centers for Medicare and Medicaid Services ("CMS") by making extra payments to ASCs on top of the packaged procedural payment for Medicare patients undergoing certain procedures. This special provision is "transitional" because it is meant to provide a temporary window of no more than three years during which market adoption can be measured by CMS without consideration for the cost.[18] This data is used to determine whether the medical product will be included in the packaged procedural payment (aka "facility fee"), with that facility fee being adjusted upwards to reflect utilization of the product while it was in pass-through status. In simple terms, a new drug has up to three years to prove it is worthy of being permanently priced into the CMS payment rate of the procedure. If it does, the gross fee paid to a surgical provider will be adjusted upward by an amount that reflects how much the drug was utilized during the transitional period.

OMIDRIA was granted pass-through status effective January 1, 2015 and was provided the maximum permitted transitional period of three years. During that time, any cataract surgery performed on a patient with proper Medicare coverage would permit the ASC to be reimbursed for 106% of the cost of OMIDRIA. During the transitional period, OMER claimed a peak market share for OMIDRIA of approximately 8% of cataract surgeries,[19] suggesting that more than nine out of ten cataract surgeries used an OMIDIRA alternative. Following the expiration of the transitional period on January 1, 2018, the ASC facility fee for 2018 was set at $991.95, an increase of 1.4% over 2017.[20] The 1.4% increase is attributable to the annual adjustment by CMS for inflation. By denying any extension of pass-through status through an amendment to Social Security Act §1833(t)(6) and by increasing the ASC facility fee for cataract surgeries by just 1.4% to adjust for inflation, it is clear that CMS believes OMIDRIA failed to justify its cost and worthiness to package into the cataract surgery facility fee during its grace period. At an ASC facility fee of $991.95 for 2018, it seems no reasonable ASC could justify paying more than a third of its facility fee to use OMIDRIA when alternatives used in 95% of cataract surgeries are available at one-tenth the price. Furthermore, a cut of 20, 30 or 50% to OMIDRIA's ASP of $350 will do little to change this dynamic. Based on our conversations with ASC cataract surgeons, OMIDRIA would need to reprice at a 90% discount to start being of interest. We believe these cost cuts represent the bare minimum cut to OMIDRIA's price for OMER to have any chance of defending its current market share.

[18] Gustafson, T. Transitional Pass-Through Payments. ASC Focus (Sept) 2015.
[19] Note we estimate OMIDRIA market share of 5% for 2017.
[20] ASC Payment Rate data from www.CMS.gov

Figure 6: ASC Facility Fee – Cataract Surgery



To illustrate the sensitivity to drug prices in these surgeries, take the generic ingredient in OMIDRIA, phenylephrine. In 2013, Paragon Biotek won formal FDA-approval as a "new drug" for its ophthalmic phenylephrine hydrochloride product, a topical eye-drop that ophthalmologists have used in generic form for decades. Within four months of the FDA's decision, all three makers of generic phenylephrine eye drops withdrew from the market and Paragon Biotek increased the price from under $10 per bottle to between $30 and $100 per bottle as supply dried up. In response, many ophthalmologists turned to less effective alternatives or only used the product in more difficult cases.[21] The subsequent entrance of additional FDA-approved competitors to Paragon Biotek in 2015 has brought the cost of phenylephrine eye drops to under $20 per bottle today. In short, an increase of $20 to $90 in the price of a drug that could be spread over numerous surgeries was enough to cause a major shift in usage by ophthalmologists. Anecdotally, we believe this case represents a good proxy for projecting OMIDRIA demand following the expiration of the pass-through.

Credibility Issues: CMS Explicitly Denied Pass-Through Extension Multiple Times

Key Takeaway: We believe OMER management squandered an opportunity to secure a pricing model independent of the 'transitional' Medicare program and continued promoting legislative and regulatory solutions for reimbursement even though there appeared to be a very low chance of success, given CMS explicitly denied the Company's requests to extend the pass-through period for OMIDRIA on multiple occasions.

In our view, the Company failed to execute in multiple respects during the three year reimbursement period it was provided by Medicare. Not only did Omeros fail in its mission to secure an extension of reimbursement, it failed what should have been its broader mission - to secure a viable pricing model for OMIDRIA that was independent of the, by design, 'transitional' Medicare program. In doing so, it

[21] Roach, L. The State of Generic Drugs. EyeNet (January) 2015. p 46.

squandered a multi-year opportunity to market test its new drug, determine the proper business plan for OMIDRIA post Medicare expiration, and develop proper contingency plans. Instead, as discussed below, it appears the Company focused on the smaller picture of trying to extend the reimbursement program that supported an unsustainable pricing model.

Omeros has not hidden the fact that losing Medicare pass-through reimbursement status could lead to pricing reductions for OMIDRIA. However, we ask investors to compare the following excerpts from CMS documents to statements from management and assess for themselves the credibility of management's communications to investors regarding their professed expectations of securing any regulatory or legislative remedy. The annual CMS OPPS/ASC final rules for CY 2014 through CY 2018 noted below set payment rates for hospital outpatient facilities and ambulatory surgical centers and provide responses to specific requests from outside commenters.

Figure 7: Comparison of CMS Rulings and OMER Management Statements

CMS Formal Rulings	OMER Management Statements
December 10, 2013 CMS CY 2014 OPPS/ASC Final Rule: "As stated...throughout the proposed rule, we believe packaging is appropriate for items and services that are integral or ancillary or supportive or dependent or adjunctive to the primary procedure. Therefore, items and services that fall within any of these categories may be properly packaged in the OPPS."	March 16, 2015 Q4 2014 Earnings Call: "The question is what really could be done with OMIDRIA after expiration of pass through. One is obviously CMS can look at the utilization, look at the value proposition and decide to do something with OMIDRIA outside the bundle. CMS has the potential to bundle OMIDRIA within the Cataract procedure or the ambulatory payment classification. If that is done then one would expect that the APC would increase to accommodate and to reflect the utilization of OMIDRIA within cataract surgery."
November 13, 2015 CMS CY 2016 OPPS/ASC Final Rule: "**We are finalizing our proposal to package the drug described by HCPCS code C9447 [HCPCS code C9447 specifically refers to Omidria]...beginning in CY 2018 and subsequent years.** We are not creating a separate APC with a higher payment for cataract surgery that uses the drug described by HCPCS code C9447, as the commenter requested. We believe that doing so would be inconsistent with the packaging policy. The payment for cataract surgery is a total payment that includes all necessary equipment and supplies, including drugs and biologicals that are employed before, during, and after a surgery." [emphasis added]	March 8, 2016 Q4 2015 Earnings Call: No mention of negative CY 2016 CMS ruling or pathway to continued reimbursement after January 1, 2018. May 5, 2016 Q1 2016 Earnings Call: No mention of negative CY 2016 CMS ruling or pathway to continued reimbursement after January 1, 2018. August 10, 2016 Q2 2016 Earnings Call: No mention of negative CY 2016 CMS ruling or pathway to continued reimbursement after January 1, 2018. November 11, 2016 Q3 2016 Earnings Call: No mention of CMS ruling or pathway to continued reimbursement after January 1, 2018; during Q3 2016, OMER entered the TLA with CRG, which contains hurdles referring to OMIDRIA sales.
November 14, 2016 CMS CY 2017 OPPS/ASC Final Rule: "In the CY 2014 OPPS/ASC final rule with comment period, in discussing the surgical supplies packaging policy as it applies to another drug used in an eye surgery, we stated that "**we believe packaging is appropriate for items and services that are integral or ancillary or supportive or dependent or adjunctive to the primary procedure.** Therefore, items and services that fall within any of these categories may be properly packaged in the OPPS" (78 FR 74938). **Any and all of these descriptive terms apply to Omidria, which is integral and ancillary and supportive and dependent and adjunctive to cataract surgery.**"	March 17, 2017 CEO Greg Demopolus on Q4 2016 earnings call: "We also are working hard to secure a separate payment for OMIDRIA following expiration of pass-through on January 1, 2018. **Our efforts on this front are focused on both legislative and administrative solutions, and, while we alone do not control the outcome, we expect that we will be successful...**" [emphasis added] "We are pursuing a dual-pronged approach, one is legislatively and the second is administratively. So we're obviously working through congressional avenues, the second working with CMS directly. **I think that there is a good amount of support for the concept that drugs used during surgical procedures should not be packaged**...And we expect again that we will be successful in this effort."
November 1, 2017 CMS CY 2018 OPPS/ASC Final Rule: "We have addressed many of these comments in prior rulemaking. **We refer readers to the CY 2017 OPPS/ASC final rule with comment period for a detailed discussion on why we believe OMIDRIA is a drug that functions as a surgical supply (81 FR 70668).** We did not propose any policy changes to the criteria applied to a drug that functions as a surgical supply when used in a surgical procedure in the CY 2018 OPPS/ASC proposed rule, nor did we believe the commenters provided any new information that would cause us to change our position that Omidria is a drug that functions as a surgical supply. Therefore, we are not addressing these comments in this final rule with comment period." [emphasis added]	November 9, 2017 CEO Greg Demopolus on Q3 2017 earnings call: "Pass-through extension is good policy, enabling physicians and patients to access outcome-improving drugs that otherwise would not be accessible. And there is strong bipartisan and bicameral support. Funds already exist within the pass-through program to pay for such an extension. **While there are no guarantees, we remain optimistic that pass-through extension or some other means of securing continued separate payment will occur this year.**" [emphasis added]
February 9, 2018 Bipartisan Budget Act of 2018 signed into law with no provisions included to extend the pass-through period as relevant to OMIDRIA.	February 14, 2018 OMER management yet to make any statements regarding the Bipartisan Budget Act's effect on reimbursement for OMIDRIA.

CMS states its position that OMIDRIA should be bundled ("packaged") with facility fees for cataract procedures.

CMS reiterates its position that OMIDRIA should be bundled ("packaged") with facility fees for cataract procedures.

CMS references previous responses to rebut all arguments presented in support of administrative remedies for OMIDRIA reimbursement in CY2018. Investors should consider whether any administrative solutions were available at this point.

Beginning in Q4 2016, as the looming pass-through expiration began to resurface with investors, Omeros management pinned investor's hopes to regulatory and legislative actions that would either: (1) extend the pass-through window beyond January 1, 2018 for OMIDRIA; or, (2) reclassify OMIDRIA from a supply item during surgery to a non-surgical drug eligible for reimbursement under Medicare Part B. As demonstrated above, Omeros CEO Greg Demopulos made multiple statements to investors that he remained "optimistic" about the success of these legislative actions and that Omeros had made "good progress" toward securing a Medicare reimbursement extension by year end.[22,23] We note that at this point in time, CMS had explicitly denied Omeros' requests in two successive rulings, responding each year with nearly identical arguments, and was in the process of communicating a third denial for CY 2018. Not only did the pass-through status fail to get an extension by the end of 2017, the proposed bills put forth to extend Medicare pass-through were not included in the Medicare Extender package encompassed in the Bipartisan Budget Act of 2018, all but sealing the fate for this legislation to ever pass according to our government affairs experts.

Readers should consider whether management adequately and effectively communicated important developments to investors, analysts and capital markets participants or should have had contingency plans in place for the foreseeable circumstances it finds itself.

Omeros Financial Picture Post OMIDRIA Collapse

Key Takeaway: Without OMIDRIA, we forecast a funding shortfall of $400 million over the next four years. We believe Omeros must raise this capital to realize any commercial value from its speculative pipeline.

OMIDRIA is the sole revenue generator for Omeros and the primary financial support for the development of the Company's pipeline. Another source of liquidity touted by the Company includes the ability to draw an additional $45 million in debt under its Term Loan Agreement with CRG. As noted previously, we believe this debt capacity is likely unavailable due to the Company's financial deterioration.

In this section, we focus on the next four years, as we believe the pipeline will not produce any material revenues until at least 2022. Unless Omeros addresses the imminent funding concerns, we believe it will be unable to bridge the gap to their speculative pipeline. We estimate Omeros is facing an annual cash deficit of approximately $100 million. Please see Appendix B for our full DCF model that includes estimated cash flows through 2035 for OMIDRIA and the OMS721 pipeline drugs.

[22] "Pass-through reimbursement for OMIDRIA is currently scheduled to end as 2018 begins. While there can be no guarantees, we have made good progress and remain optimistic that before year-end our administrative and legislative efforts will successfully secure ongoing Medicare reimbursement for OMIDRIA." CEO Greg Demopolus on the Q2 2017 earnings call. August 8, 2017. Transcript from Bloomberg.

[23] "While there are no guarantees, we remain optimistic that pass-through extension or some other means of securing continued separate payment will occur this year." CEO Greg Demopolus on the Q3 2017 earnings call. November 9, 2017. Transcript from Bloomberg.

Omeros is currently running two Phase 3 trials for OMS721 and expects to start a third in 2018. As noted previously, the clinical trial design required by the FDA for the OMS721 IgA Nephropathy indication requires enrollment of seven times the number of patients (280) than the aHUS indication (40). Running clinical trials is expensive, so the R&D requirements to support the pipeline will be extensive. The R&D expense for the latest reported quarter was $14.8 million, or a run rate of approximately $60 million. We have assumed R&D increases by $5 million per year until 2021 to support the OMS721 clinical trials and then decreasing thereafter.

Omeros has over 150 employees with a sales force of over 40 people to market and sell OMIDRIA. The trailing twelve-month SG&A spend for Omeros was $52 million and analyst estimates for CY 2017 are $50 to $60 million. We believe a prudent response to the collapse of OMIDRIA pricing would be a reduction in SG&A in order to reduce some of the cash burn. We assume the mid-point at $55 million and then haircut it to $40 million per annum from 2018 to 2021, after which it increases in order to support the rollout of the pipeline drugs.

For the reasons set forth below, we believe the pipeline of new drugs will not result in any material revenues prior to YE 2021 (if ever). The table below illustrates the quantum of cash deficit the Company faces, which will need to be addressed by most likely tapping the capital markets, in our view.

Figure 8: OMER Pro Forma Financials

Omeros Proforma Income Statement

	2017E	2018E	2019E	2020E	2021E
Total Omidria sales	**$70.0**	**$12.4**	**$7.7**	**$9.5**	**$11.8**
Growth - YoY%		*(82%)*	*(38%)*	*23%*	*24%*
Cost of goods sold	$0.7	$0.1	$0.1	$0.1	$0.1
Research & Development	$55.0	$60.0	$65.0	$70.0	$75.0
SG&A	$55.0	$40.0	$40.0	$40.0	$40.0
Operating expenses	$110.7	$100.1	$105.1	$110.1	$115.1
EBIT	**($40.7)**	**($87.8)**	**($97.4)**	**($100.6)**	**($103.3)**
Interest expense	$11.0	$11.0	$11.0	$11.0	$11.0
Pre-Tax Income	**($51.7)**	**($98.7)**	**($108.3)**	**($111.6)**	**($114.3)**
Income Tax Expense	–	–	–	–	–
Net Income	**($51.7)**	**($98.7)**	**($108.3)**	**($111.6)**	**($114.3)**

OMIDRIA revenues collapse post loss of reimbursement status

Cash Deficit Forecast - Debt Repayment assumed in 2018

	2018E	2019E	2020E	2021E
EBIT	**($87.8)**	**($97.4)**	**($100.6)**	**($103.3)**
Beginning Cash Balance	$71.7	–	–	–
Repayment of Debt (in Default)				
Principal	($80.0)			
PIK Principal	($3.0)			
Prepayment Penalty (6%)	($4.8)			
Interest expense	($3.0)	–	–	–
Ending Cash Balance	**($106.8)**	**($97.4)**	**($100.6)**	**($103.3)**
Cumulative Cash Balance (Deficit)	**($106.8)**	**($204.2)**	**($304.8)**	**($408.2)**

We believe the CRG loan will be repaid in 2018 when the financial deterioration of OMIDRIA materializes

Without OMIDRIA, OMER will need to raise hundreds of millions in order to address its operating expenses & loan repayment

Estimated Cash Positon by Month - Q3 2017 to Q1 2018

	Q3 2017	Q4 2017	1/31/2018	2/28/2018	Q1 2018
Beginning Cash & Equiv	$29.7	$85.7	$71.7	$60.4	$51.4
OMIDRIA Revenues (net)	$21.7	$18.8	$2.5	$2.0	$2.0
OMIDRIA Buybacks	–	–	($2.8)	–	–
R&D	($14.8)	($15.0)	($5.0)	($5.0)	($5.0)
SG&A	($11.7)	($15.0)	($5.0)	($5.0)	($5.0)
Interest Expense	($2.8)	($2.8)	($1.0)	($1.0)	($1.0)
Equity / Debt Issuance Proceeds (net)	$63.6	–	–	–	–
Ending Cash Balance	**$85.7**	**$71.7**	**$60.4**	**$51.4**	**$42.4**

Without OMIDRIA revenues, the cash burn becomes an increasing burden to OMER's financials

The Company reported $85.8 million of cash as of September 30, 2017. On the Q3 earnings call, Management stated, "Our fourth quarter revenues will in part depend on the status of CMS reimbursement for OMIDRIA before January 1, 2018. Should separate payment not be obtained, wholesaler purchases would likely decrease as we approach year-end." Separate payment was not obtained. Furthermore, as noted previously, the Company sent a letter dated December 20, 2017 to OMIDRIA customers instituting a buyback program should reimbursement status not be extended. Given the above, we estimate Q4 revenues at $18.8 million. As a result of slowing Q4 revenues, we estimate that Omeros will enter 2018 with approximately $72 million in cash.

Omeros has told investors that the Company has "incremental sources of funds" to fund the business only until November 9, 2018 "regardless of the outcome of the separate-payment status for Medicare patients treated with our commercial product, OMIDRIA."[24] As we described above, given the covenants in the Term Loan, we believe there are few incremental funds at its disposal, and the Company will be facing a budget crisis in the face of collapsing OMIDRIA revenues and rising operating expenses. With the debt markets likely closed to Omeros following the loss of reimbursement status for its only revenue producing drug and a pipeline unlikely to provide enough collateral value to justify a significant loan size, we believe Omeros will have to do a series of large equity offerings to fund its operating expenses. Other, less likely in our view, options would be to explore strategic alternatives, such as a sale of OMIDRIA or the OMS721 pipeline.

The most immediate source of equity capital could be to sell common stock under the At-Market Issuance Sales Agreement ("ATM Agreement") with JonesTrading Institutional Services LLC ("JonesTrading"). Per the latest 10Q, Omeros is "currently permitted to sell shares of our common stock having an aggregate offering amount of up to $50.0 million under the ATM Agreement."[25] To utilize this facility, as it has done in the past, Omeros will need to put out a prospectus and provide a rep to JonesTrading that there has not "been a Material Adverse Event and any development that is reasonably expected to have a Material Adverse Event", or JonesTrading can terminate the ATM Agreement. We believe that the financial deterioration stemming from the loss of reimbursement status for OMIDRIA will be reasonably expected to have a Material Adverse Event on Omeros, which could eliminate this access to capital.

To address the near-term liquidity needs we forecast above, we estimate that Omeros will need to do a $150 million equity offering in the very near future, with at least $90 million used to repay the CRG Loan

[24] Company Q3 2017 10Q, p 6.
[25] Company Q3 2017 10Q

and the remaining $60 million, together with the remaining cash on hand, to fund its operations for 2018. In subsequent years, we believe Omeros will need to raise an additional $100 million per year to fund its operations until drugs in its pipeline either produce material revenues or reach milestones that have significant collateral value to justify a debt offering (e.g. full FDA approval), which we estimate will not happen until 2022, if at all. In total, we estimate that current investors could be looking at approximately $400 million in capital raising requirements over the next four years.

Readers should consider the likelihood a company with a deteriorating financial condition could execute large equity issuances at prices near their current trading levels.

Pipeline of New Drugs Is Speculative and Further Away Than Investors May Think

Key Takeaway: We believe OMS721 represents the only drug of any value in the Omeros drug pipeline, and estimate that OMS721 will not produce any clinical trial data until 2020 due to complications with enrollment for Phase 3 trials in aHUS and IgA Nephropathy.

The Company's pipeline, which, as discussed above, is pledged entirely to creditors under the term loan, consists of four clinical programs (OMS721, OMS824, OMS405 and OMS201) in various phases of the FDA approval process and a number of preclinical programs. In reality, the OMS721 program is the drug the Company, and most investors, are pinning their hopes to.

We believe the value of OMER's pipeline has been vastly overstated based on the following:

- In their 3Q 2017 financials, Omeros reported total direct external expenses related to Clinical research and development of $6.9 million. Of this amount, **just $0.02 million (or 0.3%) was spent on the ENTIRE pipeline outside of OMS721 (93.4%) and OMIDRIA (6.3%).** This level of spending indicates that OMER has concluded none of these drugs are marketable or capable of gaining approval. It would appear that Management has no faith in any pipeline drugs outside of OMS721.
- For its "crown jewel" OMS721, OMER has not produced any statistically significant scientific data indicating favorable results in testing across any of the three indications it is pursuing.
    - The initial OMS721 hype in August 2015 centered on evidence in the aHUS indication from a Phase 2 clinical trial of <u>just three patients</u> to treat atypical hemolytic uremic syndrome ("aHUS"), an extremely rare, life-threatening progressive renal disease.[26] The released results showed unscientific data and anecdotal results and no placebo baseline for comparison was used. It was lauded by the Company as the first potential competitor to the wildly successful drug Soliris from Alexion – the most expensive drug in the US at $500,000 per patient per year.
    - OMER announced the conclusion of talks with FDA on the Phase 3 trial design for aHUS in March 2016. It took over a year to begin recruitment. It is our understanding that recruitment has not been going well and the Company has effectively back-burnered the aHUS trial entirely in order to focus on a Phase 3 trial for an indication in IgA Nephropathy.
    - The IgA indication had, like aHUS, a wholly unscientific Phase 2 trial in 2016 with <u>just four patients</u> that produced no structured data, no placebo baseline and largely anecdotal

[26] Press Release, August 18, 2015, "Omeros Announces Additional Positive Data in OMS721 Phase 2 Clinical Trial"

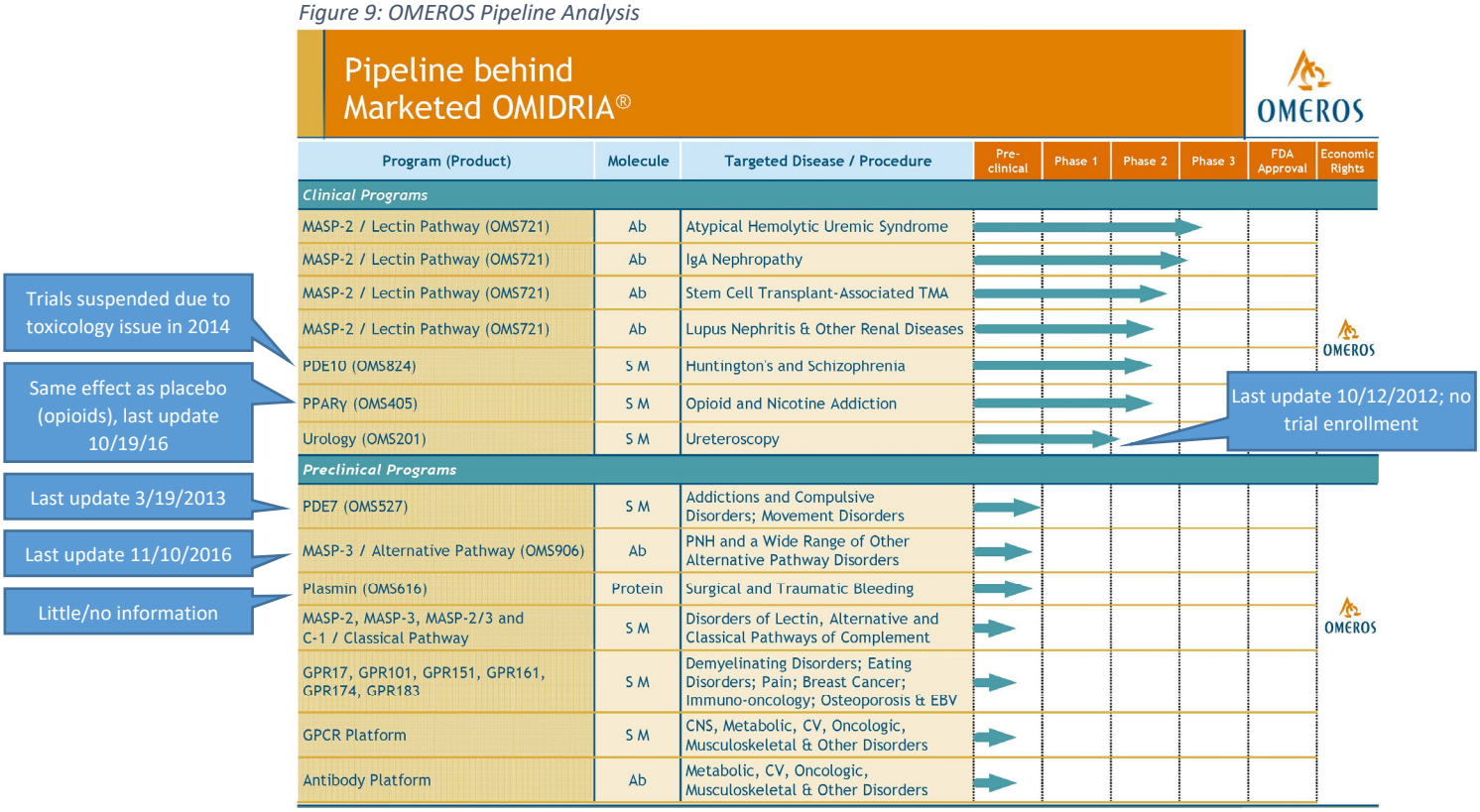
results. For comparison, two competitors, RIGL and ANTH, each ran double-blind Phase 2 trials of 24 weeks and 168 weeks, respectively, with over 30 patients and published structured, scientific data to back up their conclusions.

- The FDA granted a Phase 3 trial for OMS721 IgA indication but was not willing to let OMER get away with a low sample, non-blind trial this time. Instead of a 40 patient, no placebo clinical trial as OMER initially indicated, the FDA has mandated a 140 patient per side, double-blind study. We believe this will add 1 to 2 years to the timeline just to recruit the necessary patients and millions more in R&D expenses.

Pursuing approval across all three indications simultaneously will result in large operating expenses that the Company may not be able to bear following a decline in OMIDRIA sales.

- OMER spent $6.5 million in direct external clinical R&D expenses on OMS721 alone in Q3 2017 for a patient size that was likely under ten people. Facing a 280 patient Phase 3 trial size, this expense could grow to $40-60 million per annum alone (the TTM R&D expenses for the entire Company is $53 million).

Figure 9: OMEROS Pipeline Analysis



At best, we estimate that OMS721 will not produce any clinical trial data until 2020, and, even if it shows dramatic results, will not receive FDA-approval for sales until 2021. In order to bridge that gap, OMER will need considerably more cash than it currently has and more than OMIDRIA is likely to provide.

OMS721: IgA Nephropathy

We note that significant competition exists among drug companies within this indication. As outlined in Figure 7, the market for drugs addressing indications in IgA nephropathy is crowded, with several drugs from various manufacturers in Phase 2/3. While OMS721 is the only one of these drugs currently in Phase 3, we note that the Company's Phase 2 study was only conducted across a sample of four patients treated

for 12 weeks. Phase 2 trials are primarily intended to assess the efficacy and side effects of new drugs; as such, we question whether a four patient test group over just 12 weeks of treatment represents a large enough sample size for anyone to have a true understanding of the drug's efficacy or safety. Of the four patients in the Phase 2 trial, three showed improvement. We ask investors to consider whether it's reasonable to place significant value on such a small data sample. Further, we wonder how many of the four Phase 2 participants were prescribed steroids during or prior to the study, as such a variable could add additional noise to an already limited data set. Consequently, the FDA has requested the Phase 3 study to consist of a double-blind trial with 140 patients per side in order to ensure the drug's safety and efficacy are fully understood before any approval decision is made. We believe enrollment for a study of this size is likely to take an additional two to three years to complete, and emphasize the Company's past issues with enrollment in much smaller studies.

While OMS721, to be administered via IV on a weekly basis in its Phase 3 trial, does have potential, we emphasize that several manufacturers are pursuing approval for drugs administered via subcutaneous injection, which represents a massive selling point for the drug if approved. Omeros initially intended to pursue subcutaneous delivery in the Phase 3 trial and communicated the same to investors. However, after a long series of negotiations with the FDA over the Phase 3 protocol, the Company announced it would be administering the drug intravenously per the Agency's request. While intravenous administration may seem like a minor setback for what could potentially be the first drug approved to treat IgA nephropathy, we highlight that the delivery method of every competing drug comes in oral or subcutaneous form. Patients prescribed a weekly IV infusion of OMS721 will be significantly worse off than patients who are administered oral or subcutaneous dosing, and sales of the drug will be significantly affected in the event any other IgA drug is approved. We also note that the strongest competitor to date, Rigel's Tavalisse, is supported by a much more robust Phase 2 trial that included 38 participants (12 placebo and 26 Tavalisse) and produced statistically significant data, and will likely enter its Phase 3 trial in pill form, the most preferred method of delivery.

Figure 10: Selected Products in Development for IgA Nephropathy

Selected Products in Development for IgA Nephropathy (IgAN)

Company	Omeros	Rigel	Novartis	Anthera	Merck	Alexion
Market Cap	$665 million	$540 million	$200 billion	$22 million	$150 billion	$25 billion
Drug Name	OMS721	Tavalisse	LNP023	Blisibimod	Atacicept	ALXN1210
Current Phase	Phase 3	Phase 2	Phase 2	Phase 2	Phase 2	Preclinical
Mechanism	MASP-2 inhibitor	SYK inhibitor	Complement Factor B inhibitor	BAFF inhibitor	BAFF inhibitor	Complement C5 Inhibitor
Designation	Orphan (U.S., EU) Breakthrough (FDA)	N/A	N/A	Orphan (U.S.)	N/A	N/A
Administration	IV	Oral	-	Subcutaneous	Subcutaneous	Subcutaneous
Ph2 Patient Sample Size	n=4	n=38	n=~60	n=58	n=100	N/A

IgAN=IgA Nephropathy; uACR = urine albumin-to-creatinine ratio; BAFF = B-cell activating factor; SYK = spleen tyrosine kinase

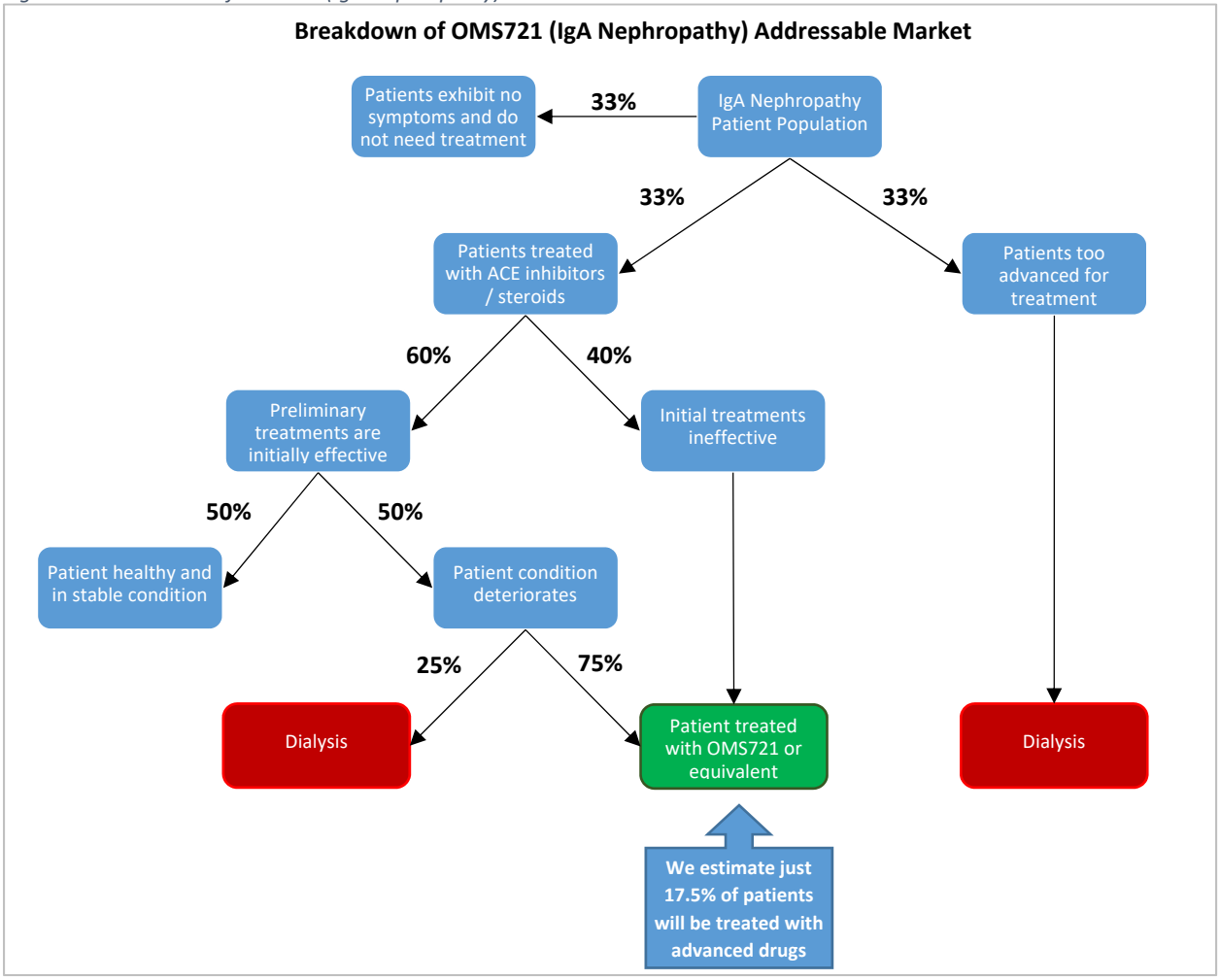
Source: Jefferies RIGL report dated 1/31/2018

We wonder why OMER's Phase 2 study included a sample size of just 4 patients, a tiny fraction of the groups used by other companies pursuing an indication for IgA Nephropathy

We also believe OMS721 will suffer as a result of a patient population that is much smaller than first glance would indicate. According to experts, we believe that of the patients with IgA nephropathy in the United States (~120,000), only ~17.5% (or ~21,000) are likely to receive advanced forms of treatment like OMS721. Because IgA Nephropathy eventually causes irreparable damage to the kidneys, roughly one-third of all patients with the disease are not candidates for these sorts of therapies at all; once the kidneys cease to function, dialysis is the patient's only choice going forward. Conversely, one-third of patients have no symptoms associated with the disease outside of blood in their urine and are able to live without

damage to their kidneys for many years, requiring no treatment at all. This leaves just one-third of the total IgA Nephropathy patient population open to treatment with drugs. Because the disease generally develops slowly, early cases are typically treated with ACE inhibitors and steroids if the initial treatments are not effective. Only once these alternatives are expended would physicians turn to more aggressive, expensive treatments like OMS721. For additional detail, the figure below illustrates our methodology for calculating the total addressable market for OMS721 in IgA Nephropathy.

Figure 11: Breakdown of OMS721 (IgA Nephropathy) Addressable Market



We have spoken with nephrologists to understand the potential results of an FDA approval for OMS721 and note that physicians may find it very difficult to prescribe OMS721 if the drug's cost is as high as current projections. While Alexion might be able to charge $500k/year for treatment of aHUS patients with Soliris, we note that the prevalence of IgA Nephropathy is 3-5x higher than that of aHUS. Insurance companies will likely be unwilling to pay $75,000 to 100,000 per year as currently projected by the analyst community, especially as it will be difficult for doctors to ensure the drug is only given to higher risk patients in need of treatment beyond ACE inhibitors and steroids.

OMS721: aHUS

In order to properly handicap the effect of a successful Phase 3 trial for OMS721 in the aHUS indication, we believe investors should examine the massive success of Alexion's preexisting drug, Soliris, for the same indication. While OMS721, administered via daily subcutaneous injections (Soliris is given in the form of bi-weekly IV treatment), does have the potential to compete for market share with Soliris if approved, we emphasize that Alexion is pursuing approval for another aHUS drug administered via IV once every eight weeks. IV administration represents a massive selling point for the drug if approved. Alexion is pursuing an indication for subcutaneous injection in Soliris as well. Even if OMS721 produced Phase 3 results similar to Soliris, capturing market share from Alexion is likely to be difficult, as patients and physicians will be reluctant to switch away from a drug that has been so successful to date.

Although management continues to promote the aHUS indication for OMS721, their actions indicate their faith in the project's success may have waned. We note that although the Company concluded Phase 3 trial talks with the FDA in March of 2016, enrollment for the study did not begin until mid-2017, and we believe trials are still yet to begin due to a lack of patients. While the rarity of the aHUS condition certainly is a factor in OMER's struggle to find participants, we strongly believe that the success of Soliris has significantly decreased the pool of candidates. In addition to absorbing patients previously diagnosed with the condition, we believe the proven efficacy of Soliris presents a far better option for patients than participation in the OMS721 trial, and struggle to see why any physician would recommend the patient forgo an FDA approved treatment with a formidable track record of success for OMER's still unproven drug.

OMS721: Everything Else

OMER claims to be pursuing approvals for OMS721 to treat stem cell transplant-associated TMA and Lupus Nephritis on top of indications for aHUS and IgA Nephropathy. We believe that the Company is no longer petitioning the FDA for a Phase 3 trial for Lupus, as the drug did not overwhelm in Phase 2 studies.[27] We also note that while the TMA application is designated for a Phase 3 trial according to the Company, the total number of patients with this condition is less than 4,000 per year in the United States, representing a very small target market even if the Company were able to charge an exorbitant amount for each treatment.

See the enclosed appendices for additional detail, modeling assumptions and support for the conclusions presented in this paper. These materials are also available at the FourWorld website.

Disclosure: FourWorld reached out to Omeros, but communications were not returned.

[27] Discussion with expert, February 5, 2018.

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Appendix

Appendix A: Letter to OMIDRIA Customers

December 20, 2017

To Current Customers of OMIDRIA®:

As you might know, the pass-through status for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is slated to end on January 1, 2018. Reimbursement under pass-through status applies only to patients covered by Medicare Part B. For these patients undergoing cataract surgery during the pass-through period, Medicare reimburses facilities for use of OMIDRIA separately from and in addition to the facility fee. Currently, legislative and administrative (i.e., CMS) efforts are progressing to secure permanent separate Medicare payment for use of OMIDRIA that will continue beyond January 1.

On December 18, members of the House Ways and Means Committee introduced in Congress the bill H.R. 4679, which provides for permanent separate payment for innovative drugs, like OMIDRIA, that have been granted pass-through status. This comprehensive legislation also calls for Medicare's pass-through duration to be extended from its current three years to five years. The bill could permanently secure Medicare reimbursement for OMIDRIA. Yesterday, a second bill – H.R. 4683 – was introduced that focuses narrowly on the three-to-five-year pass-through extension. Each of these bills could be passed this year or early in 2018. With the passage of one or both of the bills, separate payment for OMIDRIA would continue until January 1, 2020 and, potentially, permanent separate reimbursement would be established.

Even if Medicare's reimbursement for OMIDRIA lapses, you and your facility will still be able to access the product through your usual wholesaler, and other insurance carriers may continue to reimburse your facility when OMIDRIA is used for their respective beneficiaries. Omeros remains committed to supporting OMIDRIA customers, and you will be able to access all of our services to which you have become accustomed and consistent with their current terms, including inventory consignment that enables you to hold product at your facility without cost until it is used. The OMIDRIAssure® program will similarly remain fully accessible, including the We Pay the Difference co-payment assistance program under which Omeros reimburses, on behalf of your commercially insured patient, the difference between your facility's acquisition cost for OMIDRIA and the amount covered by the patient's insurance. Also, ASCs that currently are enrolled in the OMIDRIA Discount Purchase Program will see their existing contract terms extended with the same purchase-tier targets and rebate amounts.

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Omeros offered to repurchase unopened inventory. We believe this will pressure Q4 2017 revenues and cash during a sensitive period

In the event that pass-through for OMIDRIA is not extended beyond January 1, Omeros will also implement a special returned goods policy for OMIDRIA, which will be effective January 1 through January 26, 2018. Throughout the policy's duration, Omeros will allow its customers to return directly to an Omeros-designated agent any unopened vials of OMIDRIA that they purchased on or before December 31, 2017. Omeros will then refund the customer's original purchase price less any discounts or credits received on these unused OMIDRIA vials. Returned vials will not be included in qualifying totals under any OMIDRIA Discount Pricing Agreement.

Should you or your colleagues have any questions regarding returns, our service programs or any other OMIDRIA matter, your OMIDRIA sales representative together with Omeros' corporate team remain readily available to assist.

I appreciate your patience and support as we work through the potential solutions to secure permanent separate reimbursement for OMIDRIA. Ophthalmic surgeons are increasingly recognizing that OMIDRIA improves surgical outcomes, and all of us at Omeros are dedicated to continuing to help ensure the best care for your patients.

Sincerely,

Gregory A. Demopulos, M.D.
Chairman and CEO
Omeros Corporation

Appendix B: Financial Model & Discussion of Key Assumptions

Valuation Method and Price Target

Our $4.00 price target is based on our estimate of the sum of risk-adjusted NPV of future cash flows associated with FDA-approved OMIDRIA and the three clinical-stage programs for OMS721. We use a discount rate of 15% and a terminal growth rate of 2.0% on the 2035E free cash flow in our DCF model. We arrive at probability adjusted, fully-taxed NPV of $202 million for these cash flows, which adjusted for projected net debt of $13.1 million as of December 31, 2017, equates to an equity value of $191 million, or $4 per share.

Discussion of Key Modeling Assumptions

OMIDRIA

- While we firmly believe the average price ophthalmologists would pay for OMIDRIA is $30 per vial based on the plethora of proven generic alternatives, we have conservatively modeled the average selling price of OMIDRIA at $100 per vial in 2018 and $50 per vial thereafter.
- We estimate that OMIDRIA's market share will fall from approximately 5% in 2017 to 3% in 2018 as customers balk at the cost without Medicare reimbursement.
- Once the price falls to $50 per vial, we assume market share grows at 20% per annum until it reaches a peak market penetration of 10%. It is worth noting that even when customers were being paid to use OMIDRIA, the highest market share run rate was just 6.2% (using Q3 2017 revenues of $21.7 million with an average selling price of $350 per vial and four million cataract surgeries per annum in the US).
- We assume that OMIDRIA will not launch in Europe as Omeros has been unable to secure a single distributor in any European country despite having approval to do so for the last two years. Our understanding is this approval expires in mid-2018.

OMS721

- For each of the three clinical-stage programs for OMS721, we assign the following probability of successful FDA approval, year of initial commercial launch and treatment cost per annum:
  - aHUS – **40%, 2023, $300k**
  - IgA Nephropathy – **50%, 2022, $75k**
  - HSCT-TMA – **50%, 2022, $100k**

  A widely cited study shows the probability of success for a Phase 3 drug trial is 58%.[28] For the reasons discussed in detail in the "Pipeline of New Drugs" section, we have applied haircuts to each indication to account for factors such as poor Phase 2 trial structure, low patient sample sizes (e.g. IgAN had a Phase 2 trial with just four patients), lack of published data, consistently missed timing milestones, low enrollment rates and inexperience conducting rare disease clinical trials. We believe the severity of these factors warrants a haircut much larger than represented above; however, we have modeled cash flows based on the above percentages to be conservative.

[28] Thomas, D. Burns, J, et. al. *Clinical Development Success Rates 2006-2015* – BIO Industry Analysis 2016, p. 11.

We estimate the first year any OMS721 drug could be commercially ready is 2022 based on a history of clinical trial delays, slow enrollment progress, and FDA mandated large trial sizes (e.g. IgAN requires 280 patients for Phase 3 trial). Despite aHUS being the first indication to reach Phase 3 trials in early 2016, the 15-month delay to even begin enrollment, combined with Omeros' refocus on IgAN and HSCT-TMA, cause us to believe aHUS has been put on the back burner, increasing the chances of failure and delays.

- *IgAN*
  - Annual incidence rate: **30 cases per 100,000 persons (0.03%)**
    The New England Journal of Medicine states the incidence rate of biopsy-proven nephropathy is just 1 case per 100,000 persons in the United States.[29] This is likely low given the rate of biopsy testing in the general population. A study in Finland showed an annual occurrence rate of 94 cases per 100,000 in young males tested upon induction into the military.[30] This rate is likely too high for a general incidence rate given IgA nephropathy affects males two to three times more often than females and IgA most often occurs in young adults between the ages of fifteen and thirty-five. Taking these factors into account, we have assumed a general incidence rate of 30 cases per 100,000.
  - Total addressable market for OMS721: **17.25% of the total cases of IgAN**
    As discussed in the "Pipeline of New Drugs" section, only a small subsection of patients diagnosed with IgAN would be likely candidates for a strong drug therapy like OMS721.
  - Treatment cost per annum per patient: **$75,000**
    Based on analysts we have spoken to, the estimated price for a highly effective treatment for IgAN could be $100,000 or more per annum. According to nephrologists we have consulted, this price would not be supported by insurance providers and would need to be $10,000 or less. We believe we have been conservative in assuming a price of $75,000.

- *aHUS*
  - Annual incidence rate: **2 cases per 1,000,000 persons (0.0002%)** based on rate published in the Orphanet Journal of Rare Diseases.[31]
  - Total addressable market for OMS721: **75% of the total cases of aHUS**
    Based on conversations with experts, potent drug therapies (such as Soliris) are not the standard of care for aHUS patients, as fifty percent or more using treatments such as plasmatherapy or dialysis. To be conservative, we have assumed 75% consider a drug therapy like Soliris or OMS721.
  - Treatment cost per annum per patient: **$300,000**
    Alexion has a widely used drug, Soliris, for this very rare disease that costs as much as $500,000 per annum in the United States. Without a noted advantage (i.e. sub-cutaneous versus intravenous) over this established drug and with increased focus by governments and regulatory authorities on drugs with extremely high prices, we have assumed OMS721 for aHUS would need to price at $300,000 or lower.
- *HSCT-TMA*
  - Assumed annual incidence rate: **11 cases per 1,000,000 persons (0.0011%)**

[29] https://blogs.nejm.org/now/index.php/iga-nephropathy/2013/06/21/
[30] https://rarediseases.org/rare-diseases/iga-nephropathy/#affected-populations
[31] Loirat, C. and Frémeaux-Bacchi, V. Orphanet Journal of Rare Diseases. 2011 (6:60). https://doi.org/10.1186/1750-1172-6-60

Calculated based on approximately 20,000 HSCT procedures per annum in the US, according to Omeros,[32] with a 17.5% prevalence of transplant-associated TMA for these procedures based on the midpoint of a study published in Blood Journal stating, "Most large, retrospective studies report a TA-TMA prevalence of 10%-25%, probably reflecting the true burden of disease."[33]

- Treatment cost per annum per patient: **$100,000**
  Based on analysts we have spoken to, the estimated price for a highly effective treatment for HSCT-TMA could be $100,000 per annum. Given the rarity of the disease relative to IgAN, we have assumed a higher relative price of $100,000.

Research & Development Expenses

- We have assumed a 2018 R&D expense of $60 million based upon the Q3 2017 R&D expense ($14.8 million) run rate. The largest component of the Q3 2017 R&D expense was the direct costs of the OMS721 clinical trials ($6.5 million). In addition to the aHUS Phase 3 trial in 2017, Omeros intends to launch and begin enrolling patients in two additional Phase 3 trials for IgAN and HSCT-TMA. As noted elsewhere in the paper, the IgAN trial will be several times larger than the aHUS trial. HSCT-TMA Phase 3 trial requirements have not been disclosed yet, but we assume they will need to be substantial as well to meet FDA guidelines. Relative to the number of patients in Phase 2 or Phase 3 clinical trials in 2017, the number of patients required for the clinical trials in 2018 and beyond will be considerably higher. To run all three Phase 3 trials, in addition to the existing preclinical R&D programs, we estimate R&D expenses will continue to grow over the coming years until these trials conclude. We have modeled an annual increase in R&D expense of $5 million for years 2019 to 2021, and then a subsequent decline once the trials conclude. We believe an annual increase of 7 to 8% in R&D expense for these years is reasonable and likely conservative. It is worth noting that the average orphan drug Phase 3 trial costs an estimated $103 million and includes 761 patients, according to the EvaluatePharma Orphan Drug Report (see table below).[34]

Figure 12: Average Phase 3 Trial Sizes

Average Phase III Trials Sizes (All New Drug Products Entering Phase III from 1 JAN 2000)

Source: EvaluatePharma® 30 September 2015

Product Type	Phase III Trial Size					Phase III Cost ($m) Estimated*			Potential 50% US Tax Credit	
	Median	Average	No. of Products (n=)	Total Patients	% of	Median	Average	Total	Median	Average
Orphan	538	761	466	354,705	10%	99	103	47,929	49	51
Non-Orphan	1,558	3,549	952	3,378,809	90%	150	193	183,543	150	193
All	921	2,633	1,418	3,733,514	100%	127	163	231,472		
Orphan / Non-Orphan =	34.5%	21.4%	48.9%			65.7%	53.3%	26.1%	32.9%	26.7%

[32] Omeros Press Release on March 28, 2017, "Omeros Announces OMS721 Presentation at Annual Meeting of the European Society for Blood and Marrow Transplantation"
[33] Laskin, B., Goebel, J. et al. Blood 2011 118:1452-1462. http://www.bloodjournal.org/content/118/6/1452?sso-checked=true
[34] http://info.evaluategroup.com/rs/607-YGS-364/images/EPOD15.pdf

Selling, General & Administrative

- We have assumed an annual SG&A expense of $40 million for each year from 2018 to 2021. This is a 27% decrease from estimated 2017 SG&A expense of $55 million. The decrease is based upon an expectation of cost-cutting measures by the Company in the face of collapsing OMIDRIA prices and revenues. After 2021, we model a ramp up in SG&A expenses to support the rollout of the OMS721 commercial programs in the US and Europe. After reaching market saturation, we model a corresponding decline in SG&A expenses.

Omeros Corp.
Market Build & DCF Valuation

US Population (mm)		325.44	327.72	330.01	332.32	334.65	336.99	339.35	341.73	344.12	346.53	348.95	351.39	353.85	356.33	358.83	361.34	363.87	366.41	368.98
EU (G6) Population (mm)		348.00	350.44	352.89	355.36	357.85	360.35	362.87	365.41	367.97	370.55	373.14	375.75	378.38	381.03	383.70	386.39	389.09	391.81	394.56
Population 65 & Over - US		51.00	52.50	54.50	56.00	58.00	59.00	61.50	62.50	63.50	65.00	66.50	68.00	70.00	71.50	72.00	73.00	73.50	74.25	75.00
Cataract Surgeries per annum - US	7.8%	4.00	4.12	4.27	4.39	4.55	4.63	4.82	4.90	4.98	5.10	5.22	5.33	5.49	5.61	5.65	5.73	5.76	5.82	5.88

OMIDRIA - U.S. Market		**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**	**2033E**	**2034E**	**2035E**
Number of Lens Replacement Surgeries (mm)		4.00	4.12	4.27	4.39	4.55	4.63	4.82	4.90	4.98	5.10	5.22	5.33	5.49	5.61	5.65	5.73	5.76	5.82	5.88
Market Share		5.0%	3.0%	3.6%	4.3%	5.2%	6.2%	7.5%	9.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%
Patients treated		0.20	0.12	0.15	0.19	0.24	0.29	0.36	0.44	0.50	0.51	0.52	0.53	0.55	0.56	0.56	0.57	0.58	0.58	0.59
Omidria net cost per vial		350	100	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50
Change YoY%			*(71.4%)*	*(50.0%)*	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Total Omidria sales - US		**$70.0**	**$12.4**	**$7.7**	**$9.5**	**$11.8**	**$14.4**	**$18.0**	**$22.0**	**$24.9**	**$25.5**	**$26.1**	**$26.7**	**$27.5**	**$28.0**	**$28.2**	**$28.6**	**$28.8**	**$29.1**	**$29.4**
Cost of goods sold	1.0%	$0.7	$0.1	$0.1	$0.1	$0.1	$0.1	$0.2	$0.2	$0.2	$0.3	$0.3	$0.3	$0.3	$0.3	$0.3	$0.3	$0.3	$0.3	$0.3

OMS721 - US & EU Market		**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**	**2033E**	**2034E**	**2035E**
aHUS																				
Total cases - US & EU	0.0002%	1,347	1,356	1,366	1,375	1,385	1,395	1,404	1,414	1,424	1,434	1,444	1,454	1,464	1,475	1,485	1,495	1,506	1,516	1,527
Treatment Share	75.0%	1,010	1,017	1,025	1,031	1,039	1,046	1,053	1,061	1,068	1,076	1,083	1,091	1,098	1,106	1,114	1,121	1,130	1,137	1,145
Market share		–	–	–	–	–	–	5.0%	6.0%	7.2%	8.6%	10.4%	12.4%	14.9%	17.9%	20.0%	20.0%	20.0%	20.0%	20.0%
Patients treated		–	–	–	–	–	–	53	64	77	93	112	136	164	198	223	224	226	227	229
Treatment cost per annum		–	–	–	–	–	–	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000
Total sales - US & EU		**–**	**–**	**–**	**–**	**–**	**–**	**$15.9**	**$19.2**	**$23.1**	**$27.9**	**$33.6**	**$40.8**	**$49.2**	**$59.4**	**$66.9**	**$67.2**	**$67.8**	**$68.1**	**$68.7**
Probability-adjusted total sales	40.0%	**–**	**–**	**–**	**–**	**–**	**–**	**$6.4**	**$7.7**	**$9.2**	**$11.2**	**$13.4**	**$16.3**	**$19.7**	**$23.8**	**$26.8**	**$26.9**	**$27.1**	**$27.2**	**$27.5**
IgAN																				
Total cases - US & EU	0.0300%	97,632	203,446	204,870	206,304	207,749	209,203	210,667	212,142	213,627	215,122	216,628	218,145	219,672	221,209	222,758	224,317	225,887	227,468	229,061
Treatment Share	17.3%	16,842	35,094	35,340	35,587	35,837	36,088	36,340	36,594	36,851	37,109	37,368	37,630	37,893	38,159	38,426	38,695	38,966	39,238	39,513
Market share		–	–	–	–	–	5.0%	6.0%	7.2%	8.6%	10.4%	12.4%	14.9%	17.9%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%
Patients treated		–	–	–	–	–	1,804	2,180	2,635	3,184	3,847	4,649	5,618	6,789	7,632	7,685	7,739	7,793	7,848	7,903
Treatment cost per annum		–	–	–	–	–	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000
Total sales - US & EU		**–**	**–**	**–**	**–**	**–**	**$135.3**	**$163.5**	**$197.6**	**$238.8**	**$288.5**	**$348.7**	**$421.4**	**$509.2**	**$572.4**	**$576.4**	**$580.4**	**$584.5**	**$588.6**	**$592.7**
Probability-adjusted total sales	50.0%	**–**	**–**	**–**	**–**	**–**	**$67.7**	**$81.8**	**$98.8**	**$119.4**	**$144.3**	**$174.3**	**$210.7**	**$254.6**	**$286.2**	**$288.2**	**$290.2**	**$292.2**	**$294.3**	**$296.4**
HSCT-TMA																				
Total cases - US & EU	0.0011%	7,243	7,293	7,344	7,396	7,448	7,500	7,552	7,605	7,658	7,712	7,766	7,820	7,875	7,930	7,986	8,042	8,098	8,154	8,212
Treatment Share	100.0%	7,243	7,293	7,344	7,396	7,448	7,500	7,552	7,605	7,658	7,712	7,766	7,820	7,875	7,930	7,986	8,042	8,098	8,154	8,212
Market share		–	–	–	–	–	10.0%	12.0%	14.4%	17.3%	20.7%	24.9%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Patients treated		–	–	–	–	–	750	906	1,095	1,323	1,599	1,932	1,955	1,969	1,983	1,997	2,011	2,025	2,039	2,053
Treatment cost per annum		–	–	–	–	–	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000
Total sales - US & EU		**–**	**–**	**–**	**–**	**–**	**$75.0**	**$90.6**	**$109.5**	**$132.3**	**$159.9**	**$193.2**	**$195.5**	**$196.9**	**$198.3**	**$199.7**	**$201.1**	**$202.5**	**$203.9**	**$205.3**
Probability-adjusted total sales	50.0%	**–**	**–**	**–**	**–**	**–**	**$37.5**	**$45.3**	**$54.8**	**$66.2**	**$80.0**	**$96.6**	**$97.8**	**$98.5**	**$99.2**	**$99.9**	**$100.6**	**$101.3**	**$102.0**	**$102.7**
Total OMS721 Probability-adjusted Sales		**–**	**–**	**–**	**–**	**–**	**$105.2**	**$133.4**	**$161.2**	**$194.8**	**$235.4**	**$284.4**	**$324.7**	**$372.7**	**$409.1**	**$414.8**	**$417.6**	**$420.6**	**$423.5**	**$426.5**
Cost of goods sold	10.0%	–	–	–	–	–	$10.5	$13.3	$16.1	$19.5	$23.5	$28.4	$32.5	$37.3	$40.9	$41.5	$41.8	$42.1	$42.3	$42.6

Total Product Sales		**$70.0**	**$12.4**	**$7.7**	**$9.5**	**$11.8**	**$119.5**	**$151.4**	**$183.2**	**$219.7**	**$260.9**	**$310.5**	**$351.4**	**$400.2**	**$437.1**	**$443.0**	**$446.3**	**$449.4**	**$452.6**	**$455.9**
Growth - % YoY			*(82.4%)*	*(37.7%)*	*23.3%*	*24.3%*	*913.8%*	*26.7%*	*21.0%*	*19.9%*	*18.7%*	*19.0%*	*13.2%*	*13.9%*	*9.2%*	*1.3%*	*0.7%*	*0.7%*	*0.7%*	*0.7%*
Cost of goods sold		$0.7	$0.1	$0.1	$0.1	$0.1	$10.7	$13.5	$16.3	$19.7	$23.8	$28.7	$32.7	$37.5	$41.2	$41.8	$42.1	$42.3	$42.6	$42.9
Operating expenses																				
Research & Development		$55.0	$60.0	$65.0	$70.0	$75.0	$70.0	$50.0	$30.0	$25.0	$20.0	$20.0	$15.0	$15.0	$15.0	$10.0	$10.0	$10.0	$10.0	$10.0
SG&A		$55.0	$40.0	$40.0	$40.0	$40.0	$60.0	$80.0	$100.0	$100.0	$100.0	$100.0	$100.0	$90.0	$80.0	$70.0	$60.0	$60.0	$60.0	$60.0
Operating expenses		$110.7	$100.1	$105.1	$110.1	$115.1	$140.7	$143.5	$146.3	$144.7	$143.8	$148.7	$147.7	$142.5	$136.2	$121.8	$112.1	$112.3	$112.6	$112.9
EBIT		**($40.7)**	**($87.8)**	**($97.4)**	**($100.6)**	**($103.3)**	**($21.1)**	**$7.9**	**$36.9**	**$75.0**	**$117.1**	**$161.8**	**$203.7**	**$257.6**	**$301.0**	**$321.3**	**$334.2**	**$337.1**	**$340.0**	**$343.0**
Interest expense		$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0	$11.0
Pre-Tax Income		**($51.7)**	**($98.7)**	**($108.3)**	**($111.6)**	**($114.3)**	**($32.1)**	**($3.1)**	**$25.9**	**$64.0**	**$106.1**	**$150.8**	**$192.7**	**$246.7**	**$290.0**	**$310.3**	**$323.3**	**$326.1**	**$329.0**	**$332.0**
Income Tax Expense	21.0%	–	–	–	–	–	–	–	$5.4	$13.4	$22.3	$31.7	$40.5	$51.8	$60.9	$65.2	$67.9	$68.5	$69.1	$69.7
Net Income		**($51.7)**	**($98.7)**	**($108.3)**	**($111.6)**	**($114.3)**	**($32.1)**	**($3.1)**	**$20.5**	**$50.6**	**$83.8**	**$119.1**	**$152.2**	**$194.9**	**$229.1**	**$245.1**	**$255.4**	**$257.6**	**$259.9**	**$262.3**
NOPAT		($40.7)	($87.8)	($97.4)	($100.6)	($103.3)	($21.1)	$7.9	$31.4	$61.5	$94.8	$130.1	$163.2	$205.8	$240.1	$256.1	$266.3	$268.6	$270.9	$273.2
Adjustments																				
Capex		($1.0)	($2.0)	($3.0)	($4.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)	($5.0)
D&A		$0.5	$1.0	$2.0	$3.0	$4.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0	$5.0
Change in WC	5.0%	$10.0	$5.0	–	($1.0)	($1.1)	($1.1)	($1.2)	($1.2)	($1.3)	($1.3)	($1.4)	($1.5)	($1.6)	($1.6)	($1.7)	($1.8)	($1.9)	($2.0)	($2.1)
Free Cash Flow		**($31.2)**	**($83.8)**	**($98.4)**	**($102.6)**	**($105.4)**	**($22.2)**	**$6.7**	**$30.2**	**$60.2**	**$93.4**	**$128.7**	**$161.7**	**$204.3**	**$238.4**	**$254.4**	**$264.5**	**$266.7**	**$268.9**	**$271.2**

DCF Valuation - perpetuity growth method	
Assumptions:	
Discount Rate	15.0%
Terminal Growth Rate	2.0%
Shares Outstanding	48.0
Vested Stock Options	9.5
Weighted Avg Exercise Price per Share	$10.1
Additonal shares out (Treasury Stock Method)	–
Warrants	0.1
Weighted Avg Exercise Price per Share	$9.9
Additonal shares out (Treasury Stock Method)	–
Fully Diluted Shares Outstanding	48.0
Output:	
Terminal Value	$2,127.6
Total Cash Flow	$3,933.5
Enterprise Value	$202.0
Debt	$83.0
Cash	$71.7
Equity Value	**$190.7**
Estimated Share Price	**$4.0**
Estimated Share Price (Fully Diluted)	**$4.0**
Implied Terminal Multiple	7.8x

																			$2,127.6
	($31.2)	($83.8)	($98.4)	($102.6)	($105.4)	($22.2)	$6.7	$30.2	$60.2	$93.4	$128.7	$161.7	$204.3	$238.4	$254.4	$264.5	$266.7	$268.9	$2,398.7

FourWorld
CAPITAL MANAGEMENT

Appendix C: H.R. 4679 & H.R. 4683

I

115TH CONGRESS
1ST SESSION

H. R. 4679

To amend title XVIII of the Social Security Act to provide for improvements to coverage and payment under the Medicare program for new drugs, devices, and technology.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 18, 2017

Mr. REED (for himself and Mr. REICHERT) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend title XVIII of the Social Security Act to provide for improvements to coverage and payment under the Medicare program for new drugs, devices, and technology.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Ensuring Equal Access to Treatments Act of 2017".

SEC. 2. COVERAGE AND PAYMENT FOR NEW DRUGS, DEVICES, AND TECHNOLOGY UNDER THE MEDICARE PROGRAM.

(a) IMPROVEMENTS TO NTAP PAYMENT ADJUSTMENT UNDER THE INPATIENT PROSPECTIVE PAYMENT SYSTEM.—

(1) PAYMENT FOR COSTS OF NEW TECHNOLOGIES.—With respect to hospital discharges occurring on or after October 1, 2018, for which payment is made under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)), in calculating the amount of the additional payment for a new medical service or technology under paragraph (5)(K) of such section with respect to such a discharge, the Secretary of Health and Human Services shall apply section 412.88 of title 42, Code of Federal Regulations—

(A) as if the reference to "50 percent" each place it appears in such section were a reference to "75 percent"; and

(B) as if paragraph (b) of such section did not include "Unless a discharge case qualifies for outlier payment under § 412.84.".

(2) REVISION TO THE COST THRESHOLD.—Section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) is amended—

(A) in clause (ii)—

(i) in subclause (I), by striking ''75 percent'' each place it appears and inserting ''50 percent''; and

(ii) in subclause (II), by striking ''not less than two years and not more than three years'' and inserting ''five years''; and

(B) in clause (iii), by striking ''International Classification of Diseases, 9th Revision, Clinical Modification (''ICD–9–CM'')'' and inserting ''International Classification of Diseases, 10th Revision, Clinical Modification (''ICD–10–CM'')''.

(3) REVISION TO THE COMMENCEMENT OF THE PERIOD FOR COLLECTION OF COST DATA FOR NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(ii)(II) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(ii)(II)) is amended by inserting ''the later of the date that is the date of the clearance or approval by the Commissioner of Food and Drugs of the service or technology or'' after ''beginning on''.

(4) PERMITTING APPEALS OF NTAP DETERMINATIONS.—

(A) IN GENERAL.—Section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

''(x)(I) An individual or entity that submits an application for additional payment under this subparagraph for a new technology shall be entitled to administrative review of an adverse determination by the Secretary with respect to such application.

''(II) The Secretary shall establish a process for administrative review for purposes of subclause (I). Under such process, administrative review shall be conducted by the Departmental Appeals Board of the Department of Health and Human Services. Under such process, the Departmental Appeals Board shall complete administrative review within 90 days of the date of receipt of the request for such review.''.

(B) CONFORMING AMENDMENT.—Section 1886(d)(7)(B) of such Act (42 U.S.C. 1395ww(d)(7)(B)) is amended by inserting ''but not including a denial by the Secretary of an application for additional payment under paragraph (5)(K)'' after ''paragraph (4)(D)''.

(5) REQUIRING NEW DRG CODES FOR NEW TECHNOLOGIES COMING OFF OF NEW TECHNOLOGY

ADD-ON.—Section 1886(d)(5)(K)(ii)(IV) of such Act (42 U.S.C. 1395ww(d)(5)(K)(ii)(IV)) is amended by striking "or existing".

(6) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—Section 1886(d)(5) of such Act (42 U.S.C. 1395ww(d)(5)) is amended by adding at the end the following new subparagraph:

"(M) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

"(i) IN GENERAL.—The total of the additional payments made under subparagraphs (K) and (L) for covered services furnished for discharges in a fiscal year (as estimated by the Secretary before the beginning of the fiscal year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered services furnished for discharges in that fiscal year. If this clause is first applied to less than a full fiscal year, the previous sentence shall apply only to the portion of such fiscal year.

"(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable

percentage'' for fiscal year 2019 and each subsequent fiscal year, is a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

''(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a fiscal year that the amount of the additional payments under subparagraphs (K) and (L) for the fiscal year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause (i), the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that fiscal year (or portion thereof) in order to ensure that the aggregate additional payments under subparagraphs (K) and (L) (as so estimated) do not exceed such limit.''.

(7) EFFECTIVE DATE.—The amendments made by paragraphs (2), (3), (4), (5), and (6) shall take effect on the date of the enactment of this Act and shall apply with respect to hospital discharges occur-

ring on or after October 1, 2018, for inpatient hospital services for which payment is made under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww).

(b) IMPROVEMENTS TO PAYMENT ADJUSTMENT UNDER THE MEDICARE OUTPATIENT PROSPECTIVE PAYMENT SYSTEM FOR CERTAIN DRUGS AND DEVICES ELIGIBLE OR PREVIOUSLY ELIGIBLE FOR PASS-THROUGH.—

(1) REQUIRING SEPARATE AMBULATORY PAYMENT CLASSIFICATION FOR CERTAIN DRUGS AND DEVICES PREVIOUSLY ELIGIBLE FOR PASS-THROUGH PAYMENTS.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended—

(A) in paragraph (2)—

(i) in subparagraph (G), by striking "and" at the end;

(ii) in subparagraph (H), by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following new subparagraph:

"(I) the Secretary shall create additional groups of covered OPD services that classify separately procedures and services that employ medical devices and drugs described in a sub-

paragraph of paragraph (22), in accordance with such paragraph."; and

(B) by adding at the end the following new paragraph:

"(22) SEPARATE ADDITIONAL PAYMENT GROUPS FOR CERTAIN DRUGS AND DEVICES PREVIOUSLY ELIGIBLE FOR PASS-THROUGH PAYMENTS.—For purposes of paragraph (2)(I), the following shall apply:

"(A) IN GENERAL.—For payments under this subsection for services furnished on or after January 1, 2020, the Secretary shall, in accordance with subparagraph (B), create additional groups of covered OPD services to classify separately from other covered OPD services the following:

"(i) EXISTING PASS-THROUGH DRUGS AND DEVICES.—Medical devices and drugs that met the requirements of paragraph (6)(A)(iv) and were receiving payment under paragraph (6) by reason of satisfying such requirements beginning on or after the date of enactment of this paragraph.

"(ii) RETIRED PASS-THROUGH DRUGS AND DEVICES.—Medical devices and drugs that had met the requirements of paragraph (6)(A)(iv) and were receiving payment under paragraph (6) by reason of satisfying such requirements before the date of enactment of this paragraph but after January 1, 2010.

"(B) CONSIDERATIONS.—In carrying out subparagraph (A), the Secretary shall—

"(i) bundle procedures and services that employ a device to which such subparagraph applies with all relevant diagnostic tests and surgical procedures, as applicable;

"(ii) bundle procedures and services that employ a drug, with respect to which payment is not made on or after the date specified in subparagraph (A) in accordance with the methodology under section 1847A and to which such subparagraph applies, with all relevant diagnostic tests and surgical procedures, as applicable; and

"(iii) include such relevant diagnostic tests and surgical procedures in more than

one group created under such subparagraph, as necessary.".

(2) REVISION TO PASS-THROUGH PERIOD UNDER OPPS.—Section 1833(t)(6) of the Social Security Act (42 U.S.C. 1395l(t)(6)) is amended—

(A) in subparagraph (B)(iii), by striking "at least 2 years, but not more than 3 years" and inserting "5 years"; and

(B) in subparagraph (C)(i), by striking "at least 2 years, but not more than 3 years" and inserting "5 years".

(3) APPEALS PROCESS.—Section 1833(t)(6) of the Social Security Act (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

"(F) APPEALS PROCESS.—

"(i) IN GENERAL.—An individual or entity that submits an application for additional payment under this paragraph for a new technology shall be entitled to administrative review of an adverse determination by the Secretary with respect to such application.

"(ii) PROCESS.—The Secretary shall establish a process for administrative re-

view for purposes of clause (i). Under such process, administrative review shall be conducted by the Departmental Appeals Board of the Department of Health and Human Services. Under such process, the Department official involved shall complete administrative review within 90 days of receipt of a request for such review.''.

(4) EFFECTIVE DATE.—The amendments made by paragraphs (2) and (3) shall take effect on the date of enactment of this Act and shall apply with respect to items and services furnished on or after January 1, 2020.

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I

115TH CONGRESS
1ST SESSION

H. R. 4683

To amend title XVIII of the Social Security Act to revise the NTAP period under the Medicare inpatient prospective payment system and the pass-through period under the Medicare outpatient prospective payment system.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 19, 2017

Mr. REICHERT (for himself, Ms. DELBENE, Mrs. MCMORRIS RODGERS, Ms. SEWELL of Alabama, and Mrs. WATSON COLEMAN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend title XVIII of the Social Security Act to revise the NTAP period under the Medicare inpatient prospective payment system and the pass-through period under the Medicare outpatient prospective payment system.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. REVISION TO NTAP PERIOD UNDER IPPS AND PASS-THROUGH PERIOD UNDER OPPS FOR NEW DRUGS AND DEVICES.

(a) REVISION TO NTAP PERIOD UNDER IPPS.—Section 1886(d)(5)(K)(ii)(II) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)(ii)(II)) is amended by striking "not less than two years and not more than three years" and inserting "five years".

(b) REVISION TO PASS-THROUGH PERIOD UNDER OPPS.—Section 1833(t)(6) of the Social Security Act (42 U.S.C. 1395l(t)(6)) is amended—

(1) in subparagraph (B)(iii), by striking "at least 2 years, but not more than 3 years" and inserting "5 years"; and

(2) in subparagraph (C)(i), by striking "at least 2 years, but not more than 3 years" and inserting "5 years".

○

Appendix D: OMIDRIA Is Replaceable and Made from Generic Ingredients

OMIDRIA is a combination of two drugs that have been around for over 100 years combined – phenylephrine and ketorolac. Phenylephrine is a potent vasoconstrictor first used in ocular studies in the 1930s.[35] It is used by ophthalmologists in eye-drop form to maintain pupil dilation during eye surgery. Pupil dilation allows the surgeon greater access and visibility during a lens replacement procedure. The typical dosage of phenylephrine ophthalmic is 1 to 2 gtts (drops) per eye before surgery or 2 to 4 drops in a typical ocular surgery.[36] For the retail consumer, a 2mL bottle of generic phenylephrine ophthalmic solution costs $37.[37] There are approximately 20 gtts per 1 mL, so a 2mL bottle contains 40 drops - enough to last ten procedures.

The second component is ketorolac, a nonsteroidal anti-inflammatory drug (NSAID) first developed by Syntex Corp (acquired by Roche) in 1989 and approved by the FDA in eye drop form in 1992. Traditionally ketorolac was prescribed for post-operative use as an anti-inflammatory and pain reducer, whereby the patient would use up to 4 drops per day for 2 to 4 weeks. The FDA approved a preservative-free ophthalmic solution from Allegan, called *Acuvail*, for use with cataract surgeries in 2009. This study showed that when applied starting one day prior to surgery, instances of inflammation and pain were reduced.[38] For the retail consumer, 3mL bottle, containing 60 drops, of generic ketorolac ophthalmic solution costs $42[39] - enough to last 15 procedures.

Studies have shown that the use of NSAIDs drops prevent pupil constriction during surgery.[40] The main value of the Omeros studies for OMIDRIA seems to be that using a combination of a pupil dilator (like phenylephrine) and an anti-inflammatory (like ketorolac) could be more effective at maintaining a dilated pupil than using either in isolation. Since the vast majority of ophthalmologists already use a pupil dilator (epinephrine, phenylephrine, tropicamide, or cyclopentolate) with great success, the incremental value is in using ketorolac contemporane ously. While the ophthalmologists we consulted rarely used ketorolac, they stated that the claimed benefits were likely achievable by applying 1 to 2 drops of ketorolac just prior to surgery and/or having the patient apply 1 to 2 drops the day before surgery. The Omeros study suggests adding the combination to the Balanced Salt Solution (BSS) (the irrigation solution used in cataract surgeries) for use intracamerally (inside the eye chamber) has additional benefits. However, ophthalmologists already utilize additives to the BSS in order to achieve necessary pupil dilation that can be compounded by specialty pharmacies for less than $30 per vial. We contacted two 503B compounding labs, who quoted a price of $26 for a vial of Behndig's intracameral dilation solution (cyclopentolate 0.1%, phenylephrine 1.5%, and lidocaine 1%) and a price of $28 for *epi-Shugarcaine* solution (epinephrine 0.025% and lidocaine 0.75% in fortified balanced salt solution). These prices did not reflect volume

[35] Heath, P. Neosynephrin Hydrochloride: Some Uses and Effects in Ophthalmology. Archives of Ophthalmology 16:839 (Nov.) 1936.
[36] Hamilton, R. (2017). Tarascon Pocket Pharmacopoeia 2017 Deluxe Lab-Coat Edition. p. 382
[37] Pricing from www.drugs.com as of January 24, 2018
[38] "FDA Approves Ketorolac Solution to Treat Cataract Surgery Pain and Inflammation." July 24, 2009. https://www.medscape.com/viewarticle/706455
[39] Hamilton, R. (2017). Tarascon Pocket Pharmacopoeia 2017 Deluxe Lab-Coat Edition. p. 383
[40] Chang DF, Braga-Mele R, Mamalis N, Masket S, Miller KM, Nichamin LD, Packard RB, Packer M, for the ASCRS Cataract Clinical Committee. ASCRS white paper: Clinical review of intraoperative floppy-iris syndrome. J Cataract Refract Surg 2008; 34:2153–2162. Available at: http://www.ascrs.org/sites/default/files/resources/JCRS%20IFIS%20White%20Paper%2012-08.pdf.

discounts, which would drive them down even further. We have spoken to several surgeons at multiple ASCs and received feedback that these compounds are perfectly acceptable substitutes for OMIDRIA, which, according to these surgeons, would need to be repriced to ~$30 in order to compete with compounded alternatives.

Omeros discerned that while the components of OMIDRIA had been previously approved by the FDA for topical ocular use, neither drug had been approved for intracameral (i.e. inside the eye chamber) applications (uses inside of the anterior eye cavity). In short, OMIDRIA approval for intracameral use gives surgeons the ability to circulate a constant concentration of phenylephrine and ketorolac inside the eye during surgery, maintaining a consistently dilated iris throughout the procedure. The surgeons we consulted characterized the clinical benefits of OMIDRIA as mild at best, but not worth much, if any, additional cost over available alternatives.