Zacks Small-Cap Research

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EyeGate Pharma (EYEG-NASDAQ)

EYEG: Positive Post-Cataract Surgery Interim Results. Pivotal Study Could Initiate By Year-End

The detailed assumptions in our Valuation section along with other inputs in our DCF including a 10% discount rate and 2% terminal growth rate, results in a current DCF-generated valuation of approximately $6/share.

Current Price (06/02/16)	$3.56
Valuation	**$6.00**

OUTLOOK

EYEG is a pre-revenue stage company engaged in the development of drugs and drug delivery devices for diseases of the eyes. Their novel iontophoresis drug delivery platform offers a much less burdensome and non-invasive solution to current standard of care for diseases of the eye. Phase 3 pivotal study in anterior uveitis now enrolling – if positive will support NDA filing. Launch could happen by 2018. Out-licensing agreement recently consummated with Valeant/Bausch+Lomb. Clinicals in other indications also enrolling, which could eventually expand the label and respective target market size. Recent Jade acquisition brings complementary, de-risked pipeline. Our DCF model, which incorporates indication-specific risk adjustments to account for potential clinical or regulatory failure for each of the three programs, currently values the shares at approximately $6. While representing attractive upside to the current share price, our calculated value should appreciate further on progression through clinical trials of EGP-437 as well as Jade's pipeline.

SUMMARY DATA

52-Week High	**$20.00**
52-Week Low	**$1.59**
One-Year Return (%)	**-23.56**
Beta	**2.74**
Average Daily Volume (sh)	**45,727**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 E	0 E	0 E	0 E
2017					0 E
2018					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$3.23 A	-$0.24 A	-$0.19 A	-$0.35 A	-$2.70 A
2016	-$0.31 A	-$0.37 E	-$0.41 E	-$0.44 E	-$1.53 E
2017					-$1.56 E
2018					-$1.54 E

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

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WHAT'S NEW…

Positive Cataract Surgery Top-Line Results…
Yesterday (6/1) EyeGate announced positive top-line results from its ongoing phase Ib/IIa post-cataract surgery clinical trial. The recently initiated study will enroll up to 50 patients (recently increased from up to 20 patients) which have undergone unilateral cataract extraction and implantation of a monofocal intraocular lens. Patients are separated into five cohorts (10 patients each); three dosing ranges (4.0 mA-min, 9.0 mA-min and 14.0 mA-min) with the two highest doses at two different treatment schedules (on day 0, day 1 and day 2 or day 0, day 1 and day 4). All three doses have the potential to add another treatment on day 7. (Note that the dose design was recently updated from that still listed on clinicaltrials.gov ID: NCT02571556 of a single patient cohort receiving 4.0 mA-min at 1.5 mA on days 0 and 7). Primary endpoint is the proportion of subjects with ACC count of zero on day 14. Secondary efficacy endpoint is the proportion of subjects with a pain score of zero on Day 7.

While the interim results announcement did not include specific data, the study investigator notes that, "The majority of subjects treated to-date in the two higher dose cohorts have displayed clinically relevant reductions in anterior chamber cell count (ACC) with little to no pain, and no steroid related increase in intraocular pressure (IOP) by 2 weeks". Additionally, the press release discloses that "A positive response was observed in the majority of the patients, with some patients in 9.0 and 14.0 mA-min cohorts presenting with ACC of zero at day 14 and others presenting with trace ACC levels. Additionally, all subjects experienced low pain throughout the duration of the trial."

This certainly sounds encouraging, particularly given the lack of an obvious efficacy signal from the company's prior cataract surgery study which, unlike the current study, treated patients before they underwent cataract surgery and only used the lowest of the current studies' dose. As a reminder, EYEG conducted a phase II study (clinicaltrials.gov ID: NCT01602068) with EGP-437 combination treatment in cataract surgery which completed in 2013. They decided to apply EGP-437 treatment (4.0 mA-min at 1.5 mA) one day prior to surgery in order to avoid putting the delivery device directly on a post-surgery open wound. Primary endpoint was proportion of subjects with ACC count of zero on day 7 (primary endpoint of current study is ACC of zero at day 14). While we were unable to find the detailed results in the public domain, EYEG has noted that "the surgical procedure eliminates or washes out any remaining drug product from the ocular tissue that becomes inflamed post-surgery" - presumably indicating that the study failed to meet the efficacy endpoint.

So by treating post- (as opposed to prior to) surgery and at higher doses the current study hopes to eliminate the wash-out issue and improve upon efficacy. These top-line results seem to suggest that may be happening. A potential drawback to applying treatment immediately following surgery is related pain – this interim announcement also suggests that pain has not been an issue – also an obvious positive result.

The other (lower dose) cohorts in the ongoing study continue to enroll which we think could be completed as soon as within the next few weeks. Additional data could be available shortly afterwards and should provide greater insight into the effectiveness of the EGP-437 combo therapy. And depending on the data, we think it could be a catalyst to moving EYEG's share price. If subsequent results remain positive (EYEG may conduct a subsequent small study to determine optimal dose and treatment schedule), we think EYEG may be able to move directly to phase 3 – which could initiate as early as later this year or early next. Given that targeted tissues (i.e. iris and ciliary body) with post-cataract surgery are similar to those with anterior uveitis (which has the most supporting evidence of efficacy to-date), we think cataract surgery may be able to move through later stage/pivotal studies fairly swiftly.

3.6 million cataract surgeries are performed in the U.S. every year. Target market for EyeGate's therapy may more likely be a sub-segment of this. Inclusion criteria of the ongoing clinical study requires implantation of monofocal intraocular lens. This represents ~30% of the aggregate cataract surgery market or ~1.1 million people, making it the largest market (by far) of EYEG's current focused programs and approximately 10x as large as anterior uveitis. As such, an eventual post-cataract surgery indication would be a highly attractive and potentially highly profitable market for EYEG.

FINANCIAL MODEL

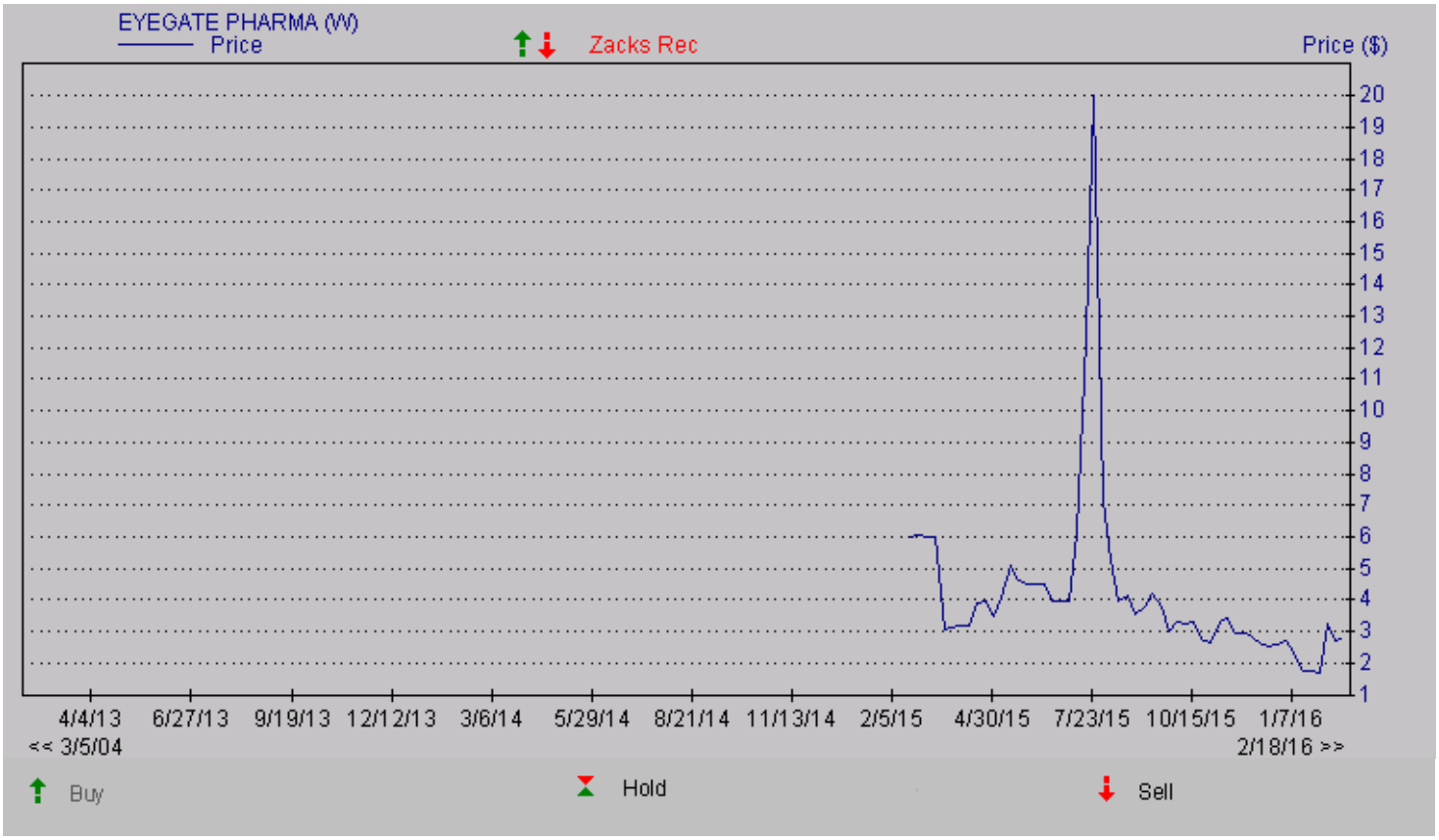
EyeGate Pharmaceuticals Inc. (figures in 000s of $)

	2015 A	Q1 A	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Legacy Eyegate									
Anterior Uveitis									
Probability reaches market	-	-	-	-	-	80%	80%	80%	80%
U.S. Market Size	-	-	-	-	-	110,000	112,200	114,444	116,733
Penetration %	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	0.7%
Number of patients	-	-	-	-	-	**0**	**0**	**343**	**817**
EYEG Royalty rate	-	-	-	-	-	8%	8%	8%	8%
Cost per procedure	-	-	-	-	-	$900	$923	$946	$969
Revenue (millions) w/haircut	-	-	-	-	-	**$0.00**	**$0.00**	**$20.78**	**$50.69**
Milestones w/ haircut	-	-	-	-	-	**$0.00**	**$4,000.00**	**$5,600.00**	**$2,800.00**
AU Total Revenue	-	-	-	-	-	**$0.0**	**$4,000.0**	**$5,620.8**	**$2,850.7**
Macular Edema									
Probability reaches market	-	-	-	-	-	50%	50%	50%	50%
U.S. Market Size	-	-	-	-	-	660,000	673,200	686,664	700,397
Penetration %	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Number of patients	-	-	-	-	-	**0**	**0**	**0**	**0**
EYEG Royalty rate	-	-	-	-	-	8%	8%	8%	8%
Cost per procedure	-	-	-	-	-	$900	$923	$946	$969
Revenue (millions) w/haircut	-	-	-	-	-	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Milestones w/ haircut	-	-	-	-	-	**$0.00**	**$1,250.00**	**$1,250.00**	**$2,500.00**
ME Total Revenue	-	-	-	-	-	**$0.0**	**$1,250.0**	**$1,250.0**	**$2,500.0**
Cataract Surgery									
Probability reaches market	-	-	-	-	-	15%	15%	15%	15%
U.S. Market Size	-	-	-	-	-	1,100,000	1,122,000	1,144,440	1,167,329
Penetration %	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	1.7%
Number of patients	-	-	-	-	-	**0**	**0**	**2,289**	**19,845**
EYEG Royalty rate	-	-	-	-	-	8%	8%	8%	8%
Cost per procedure	-	-	-	-	-	$600	$615	$630	$646
Revenue (millions) w/haircut	-	-	-	-	-	**$0.00**	**$0.00**	**$17.31**	**$153.87**
Milestones w/ haircut	-	-	-	-	-	**$0.00**	**$375.00**	**$750.00**	**$525.00**
CS Total Revenue	-	-	-	-	-	**$0.0**	**$375.0**	**$767.3**	**$678.9**
Product Sales/Royalites	-	-	-	-	-	$0.0	$0.0	$38.1	$204.6
Dvlpmnt / Reg Milestones	-	-	-	-	-	$0.0	$5,625.0	$7,600.0	$5,825.0
Jade's Pipeline									
JDE-003 (Corneal Repair)									
Probability reaches market	-	-	-	-	-	50%	50%	50%	50%
U.S. Market Size	-	-	-	-	-	125,000	127,500	130,050	132,651
Penetration %	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10%	3.0%
Number of patients	-	-	-	-	-	**0**	**0**	**1,301**	**3,980**
EYEG Royalty rate	-	-	-	-	-	20%	20%	20%	20%
Cost per procedure	-	-	-	-	-	$450	$461	$473	$485
Revenue (millions) w/haircut	-	-	-	-	-	**$0.00**	**$0.00**	**$61.49**	**$192.85**
Milestones w/ haircut	-	-	-	-	-	**$0.00**	**$0.00**	**$0.00**	**$0.00**
Corneal Repair Total Revenue	-	-	-	-	-	**$0.0**	**$0.0**	**$61.5**	**$192.8**
Total Milestones		**$1,178**	-	-	-	**$1,178**	**$5,625**	**$7,600**	**$5,825**
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$99.6	$397.4
YOY Growth	-	-	-	-	-	-	-	-	*299.1%*
Cost of Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.00	$0.0	$0.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$99.6	$397.4
Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$2,717.1	$914.0	$1,367.0	$1,712.0	$1,944.0	$5,937.0	$7,518.0	$7,855.0	$8,110.0
%R&D	-	-	-	-	-	-	-	*7888.4%*	*2040.8%*
SG&A	$3,960.5	$1,528.8	$1,715.0	$1,722.0	$1,894.0	$6,859.8	$7,430.0	$7,782.0	$8,012.0
%SG&A	-	-	-	-	-	-	-	*7815.1%*	*2016.1%*
Operating Income	($6,677.6)	($2,442.8)	($3,082.0)	($3,434.0)	($3,838.0)	($12,796.8)	($14,948.0)	($15,537.4)	($15,724.6)
Operating Margin	-	-	-	-	-	-	-	-	-
Total, other income (exp)	($1,710.4)	$0.3	$0.0	$0.0	$0.0	$0.3	$0.0	$0.0	$0.0
Pre-Tax Income	($8,388.0)	($2,442.4)	($3,082.0)	($3,434.0)	($3,838.0)	($12,796.4)	($14,948.0)	($15,537.4)	($15,724.6)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($16,615.2)	($2,442.4)	($3,082.0)	($3,434.0)	($3,838.0)	($12,796.4)	($14,948.0)	($15,537.4)	($15,724.6)
YOY Growth	-	-	-	-	-	-	-	-	*1.2%*
Net Margin	-	-	-	-	-	-	-	-	-
EPS	($2.70)	($0.31)	($0.37)	($0.41)	($0.44)	($1.53)	($1.56)	($1.54)	($1.50)
YOY Growth	*-70.7%*	*-90.4%*	*52.4%*	*116.0%*	*25.1%*	*-43.1%*	*1.6%*	*-1.2%*	*-2.7%*
Diluted Shares O/S	6,164	7,847	8,350	8,400	8,800	8,349	9,600	10,100	10,500

Brian Marckx, CFA

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