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Zacks Small-Cap Research

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EyeGate Pharmaceuticals (EYEG-NASDAQ)

EYEG: Cataract Surgery Phase II Topline Data: Efficacy Signal Despite Miss to Primary Endpoint

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 $4.50/share.

Current Price (02/20/18)	$0.60
Valuation	**$4.50**

OUTLOOK

EyeGate announced top-line results of its phase IIb study evaluating the safety and efficacy of EGP-437 in patients which underwent cataract surgery. While results showed that the primary endpoints were not met, details within the data indicate that there was a positive treatment effect. We should know more when the full data is analyzed and released. While statistical significance was not reached on the co-primary endpoints, both secondary measures did show statistical significance (p=0.0096 on mean change in ACC at Day 7 and p=0.0149 on mean change in pain score at Day 1). Given the efficacy signals in the phase IIb topline results we are treating the miss on the primary endpoint as a delay (as opposed to failure) to our previously anticipated timeline for eventual commercialization of EGP-437 for post-cataract surgery. While we still incorporate a 70% haircut to revenues to represent risk of regulatory or commercial failure, we have delayed forecasted launch from 2019/2020 to 2020/2021. Despite the delay, as modeled early-years revenue (excluding development milestones) has been rather benign, the change has nominal impact on our DCF-calculated valuation of EYEG.

SUMMARY DATA

52-Week High	**$3.90**
52-Week Low	**$0.50**
One-Year Return (%)	**-61.08**
Beta	**2.91**
Average Daily Volume (sh)	**422,824**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**13**
Insider Ownership (%)	**25**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0 A	235 A	274 A	160 A	669 A
2017	185 A	148 A	75 A	0 E	408 E
2018					6980 E
2019					8086 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.31 A	-$0.46 A	-$0.36 A	-$0.38 A	-$1.51 A
2017	-$0.28 A	-$0.28 A	-$0.24 A	-$0.26 E	-$1.05 E
2018					-$0.61 E
2019					-$0.43 E

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

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Cataract Surgery Phase II Topline Data: Efficacy Signal Despite Miss to Primary Endpoint

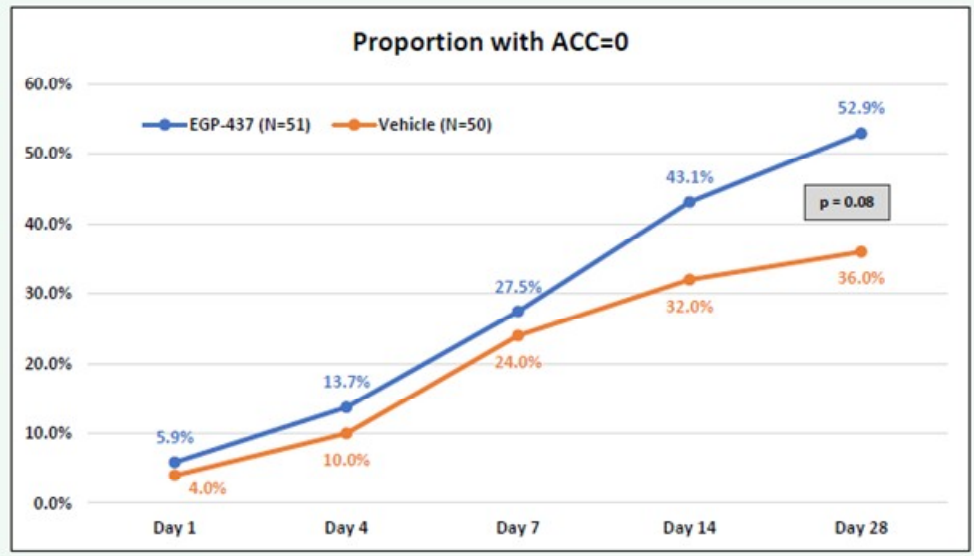
Earlier this month EyeGate announced top-line results of its phase IIb study evaluating the safety and efficacy of EGP-437 in patients which underwent cataract surgery with implantation of a monofocal posterier chamber intra-ocular lens (IOL). Primary efficacy endpoint is the proportion of subjects with an anterior chamber (AC) cell count of zero at Day 7 and the proportion of subjects with pain score of zero at Day 1. Secondary endpoints are change in mean ACC on Day 7 and change in mean pain score on Day 1.

Final enrollment was 106 patients (of which 101 were evaluable) across seven U.S. trial sites. Subjects were randomized immediately after surgery to either EGP-437 (iontophoresis with 40 mg/mL dexamethasone phosphate) (n=51) or placebo (iontophoresis with 100 mM sodium citrate solution) (n=50). Evaluations were completed at Days 0, 1, 4, 7, 14 and 28.

While top-line results showed that the primary endpoints were not met, details within the data indicate that there was a positive treatment effect. We should know more when the full data is analyzed and released. EYEG noted in their February 5th press release that while statistical significance was not reached on the co-primary endpoints, that both secondary measures did show statistical significance (p=0.0096 on mean change in ACC at Day 7 and p=0.0149 on mean change in pain score at Day 1).

In addition, and also supporting the theme of a positive treatment effect of EGP-437, was that a greater percentage of placebo patients required rescue by Day 14 and, unlike EGP-437 patients, rescues continued in the placebo arm between Day 14 and Day 28. And finally, throughout the study and on every evaluation day, a greater proportion of treatment patients had ACC of 0 as compared to placebo patients and this separation continued to grow from Day 7 until the final evaluation on Day 28 (chart below). We think this divergence over time is particularly compelling. EYEG also notes that EGP-437 safety profile was favorable with no SAEs reported.

Efficacy Favors EGP-437 At Every Time Point



SOURCE: EyeGate Feb 2018 Presentation

Our Comments…

While the full data is still being analyzed, based on our discussion with management, it appears that results may have been influenced by a greater than anticipated proportion of patients in the placebo arm having little to no post-surgical inflammation. While speculation, we think it is possible that recent advances in surgical procedures may play a part in lower rates of inflammation. Regardless, just one day after surgery 48% of placebo patients had either no inflammation (i.e. ACC = 0) or mild inflammation (mild inflammation if typically considered to ACC < 10). This included 4% of the placebo group that had no inflammation. Further analysis indicated that had these patients been excluded from the study that there would have been an even greater separation of treatment vs. placebo on the primary endpoint of ACC = 0 at Day 7 – potentially enough to reach statistical significance.

Next steps….
While we do not expect any definitive decisions as it relates to next steps until after final data analysis, we think topline results suggest compelling enough evidence to warrant continuation of the EGP-437 cataract surgery clinical program. Clearly clinical trial design modifications should be considered. Management noted that they expect to conduct a follow-on phase II study with randomization occurring on Day 1 (as opposed to Day 0) in order to better ascertain the severity of inflammation. I doing so, that may help to mitigate the proportion of patients with little-to-no inflammation (and which would likely not need anti-inflammatory therapy).

Randomizing on Day 1 instead of Day 0 post-surgery is consistent with design of pivotal trials supporting NDA applications of certain of the FDA-approved drugs indicated for the treatment of inflammation as a result of cataract surgery with IOC-implantation. That includes Xibrom (bromfenac 0.09% BID), Durezol (difluprednate 0.05% QID) and Lotemax (loteprednol 0.5% QID).

Other potential trial design changes that we think may be reasonable for EYEG to consider in order to further improve on efficacy towards reaching statistical significance include potentially extending the primary endpoint to Day 14 (i.e. timepoint of greater ACC=0 separation) and maybe increasing total enrollment (although certain other design changes might mean that increased enrollment may not be necessary). Similar to the choice of which day to randomize, we think FDA is likely to be open to considering other modifications to trial design. For context (and as an example), in different pivotal drug trials FDA has allowed the ACC=0 primary endpoint to be evaluated at days 7, 8, 14 or 15.

Model updates
Given the efficacy signals in the phase IIb topline results we are treating the miss on the primary endpoint as a delay (as opposed to failure) to our previously anticipated timeline for eventual commercialization of EGP-437 for post-cataract surgery. While we still incorporate a 70% haircut to revenues to represent risk of regulatory or commercial failure, we have delayed forecasted launch from 2019/2020 to 2020/2021. Despite the delay, as modeled early-years revenue (excluding development milestones) has been rather benign, the change has nominal impact on our DCF-calculated valuation of EYEG.

The stock price has been almost cut in half since the cataract surgery topline data was announced. We think the sell-off is overdone as we do believe that there is still a viable path for an FDA cataract surgery indication. Additionally, the extent of the sell-off suggests the market was valuing cataract surgery at approximately the same as anterior uveitis, OBG and the rest of the company's pipeline, combined – which is wildly divergent with our estimates.

Uveitis Topline Data Expected Q2
In mid-December EYEG announced that the phase III pivotal trial evaluating EGP-437 for the treatment of uveitis reached 75% enrollment. Management continues to expect topline data to be announced sometime in Q2. Given that this study is expected to act as the backbone for an FDA filing seeking a uvieits indication, we are highly anticipating the study results. Assuming positive, we think this could also represent the next potential inflection point in the share price.

VALUATION

Our model incorporates the following assumptions:

Anterior Uveitis Indication:
- 80% probability of successful FDA approval/clearance and launch for anterior uveitis indication. All modeled milestones and royalties related to anterior uveitis are initially discounted by 20% (i.e. 1 – 0.80) to account for risk of regulatory or commercialization failure
- EYEG begins to book revenue related to AU milestones in 2018
- Receipt of FDA approval/clearance and launch in 2019 or 2020 and receipt of regulatory milestones as well as additional development milestones up until then
- $300 cost per application x 3 applications (per clinical trial protocol) = $900/patient. Cost increases at rate of inflation

- U.S. market size of ~110k, increasing at the rate of population growth. Less than 1% penetration through 2020, mid-single digit penetration by 2023/2024 and 10% in 2026/2027 (the out-year in our 10-yr DCF model)

Cataract Surgery Indication:
- Following the announcement that Valeant will license rights for the cataract surgery indication we moved our probability of successful FDA approval/clearance and launch for cataract surgery indication up from 15% to 30%. All modeled milestones and royalties related to cataract surgery are initially discounted by 70% to account for risk of regulatory or commercialization failure
- As we had noted in prior updates, we felt that the cataract surgery could be the indication which the risk discount could be reduced the most significantly in the near term. Additional positive clinical data could prompt another reduction to the haircut
- Receipt of development milestones began in 2017
- Receipt of FDA approval/clearance and launch in 2020 or 2021 and receipt of regulatory milestones as well as additional development milestones up until then
- $300 cost per application x 2 applications (per clinical trial protocol) = $600/patient. Cost increases at rate of inflation
- U.S. market size of ~1.1M, increasing at the rate of population growth. Less than 1% penetration in 2020/2021, mid-single digit penetration by 2022/2023 and 15% in 2026/2027

Jade's Pipeline
- 50% probability of successful FDA approval/clearance of OBG
- Out-licenses to major ophthalmology-focused company such as Allergan, Novartis or Bausch+Lomb for 20% of net revenues
- U.S. launch in 2019, single digit penetration through 2022/2023
- Annual U.S. market for initial indication of ~$125M
- Currently do not model other indications for OBG or for other of Jade's candidates. This will be updated with news flow

DCF Currently Values EYEG at $4.50/Share, Progression Through Clinicals Should Push Value Higher…

Given the efficacy signals in the cataract surgery phase IIb topline results we are treating the miss on the primary endpoint as a delay (as opposed to failure) to our previously anticipated timeline for eventual commercialization of EGP-437 for post-cataract surgery. While we still incorporate a 70% haircut to revenues to represent risk of regulatory or commercial failure, we have delayed forecasted launch from 2019/2020 to 2020/2021. Despite the delay, as modeled early-years revenue (excluding development milestones) has been rather benign, the change has nominal impact on our DCF-calculated valuation of EYEG.

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The above assumptions 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 $4.50/share (updated from $5.00/share). While our target price represents attractive upside to the current share price, our calculated value should appreciate further on progression of EGP-437 and Jade's pipeline through clinical trials in any of the indications as this would positively affect (i.e. decrease) our risk discounts.

FINANCIAL MODEL

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

	2016 A	Q1A	Q2A	Q3A	Q4E	2017 E	2018 E	2019 E
Milestones & Royalties	$0	$0	$0	$0	$0	$0	$6,980	$8,086
Collaboration Revenue (Jade, Gov't grants)	$669	$185	$148	$75	$0	$408	$0	$0
Total Revenues	$669.2	$184.5	$148.3	$74.7	$0.0	$407.5	$6,979.8	$8,085.8
YOY Growth	-	-	-36.8%	-72.8%	-100.0%	-39.1%	1612.8%	15.8%
Cost of Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.00	$0.0	$0.0
Gross Income	$669.2	$184.5	$148.3	$74.7	$0.0	$407.5	$6,979.8	$8,085.8
Gross Margin	-	-	-	-	-	-	-	-
R&D	$8,422.5	$1,815.0	$2,262.2	$3,176.0	$3,262.0	$10,515.2	$13,105.0	$11,339.0
% R&D	1258.5%	983.6%	1525.5%	4251.9%	#DIV/0!	2580.3%	187.8%	140.2%
SG&A	$5,593.6	$1,289.1	$1,212.9	$1,038.8	$1,248.0	$4,788.9	$6,216.0	$6,958.0
% SG&A	835.8%	698.6%	817.9%	1390.7%	#DIV/0!	1175.1%	89.1%	86.1%
Operating Income	($13,346.8)	($2,919.6)	($3,326.8)	($4,140.1)	($4,510.0)	($14,896.5)	($12,341.2)	($10,211.2)
Operating Margin	-1994.3%	-1582.2%	-2243.4%	-5542.6%	#DIV/0!	-3655.4%	-176.8%	-126.3%
Total, other income (exp)	$3.4	($0.0)	($0.1)	($0.3)	$0.0	($0.4)	$0.0	$0.0
Pre-Tax Income	($13,343.4)	($2,919.7)	($3,326.9)	($4,140.4)	($4,510.0)	($14,896.9)	($12,341.2)	($10,211.2)
Taxes	$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%
Net Income	($13,343.4)	($2,919.7)	($3,326.9)	($4,140.4)	($4,510.0)	($14,896.9)	($12,341.2)	($10,211.2)
YOY Growth	-	-	-	-	-	-	-	-17.3%
Net Margin	-	-	-	-	-	-	-	-
EPS	($1.51)	($0.28)	($0.28)	($0.24)	($0.26)	($1.05)	($0.61)	($0.43)
YOY Growth	-44.0%	-10.3%	-39.6%	-33.9%	-30.3%	-30.7%	-41.8%	-28.7%
Diluted Shares O/S	8,834	10,456	12,067	17,205	17,205	14,233	20,250	23,500

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