

Specialty Pharmaceuticals

Egalet Ltd.

(EGLT) - BUY

Price: **\$9.31**
Fair Value Estimate: \$14.00
52-Week Range: \$8.74-\$19.85
Market Cap (MM): \$161
Shr.O/S-Diluted (mm): 17.3
Average Daily Volume: 34,055
Dividend: NA
Book Value: \$(4.69)

FYE: Dec	2013A	2014E	2015E
EPS:	\$(4.29)A	\$(3.31)E	\$(2.67)E
Prior EPS:		\$(3.24)	\$(2.42)
P/E:	NA	NA	NA

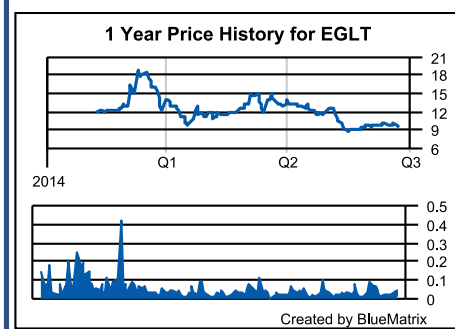
Quarterly EPS:

	2013A	2014E	2015E
Q1	\$(3.40)A	\$(1.34)A	\$(0.83)E
Q2	\$(3.40)A	\$(0.73)A	\$(0.68)E
Q3	\$(3.40)A	\$(0.71)E	\$(0.61)E
Q4	\$(0.35)A	\$(0.73)E	\$(0.58)E

FYE: Dec	2013A	2014E	2015E
Revenue (M):	\$0.0A	\$0.0E	\$0.0E

Quarterly Revenue (M):

	2013A	2014E	2015E
Q1	\$0.0A	\$0.0A	--
Q2	\$0.0A	\$0.0E	--
Q3	\$0.0A	\$0.0E	--
Q4	\$0.0A	\$0.0E	--



Equity Research
Note

EGLT: With delay and added Phase 3 risk, lowering FV to \$14

INVESTMENT CONCLUSION:

EGLT announced the bioequivalent (BE) results from its 15mg fasted-state 64-subject trial of Egalet-001 compared to MS Contin. Similar to the 100mg dose results that were announced last month, the 15mg dose also had split results. Egalet-001 met bioequivalence to MS Contin in area under the curve (AUC) but was outside the lower-limit confidence interval for Cmax (peak concentration), which means that less drug was present than compared to MS Contin. Though management plans to schedule a meeting with the FDA in 4Q14 to discuss potential faster pathways forward, we believe that EGLT will have to run a successful Phase 3 trial in order to get Egalet-001 approved. This now delays the program 15-18 months with an NDA filing in mid-2016 with potential launch now in 1H17. We have adjusted the risk metrics and potential revenues from Egalet-001 and we are adjusting our fair value to \$14, down from \$22 and maintaining our Buy rating.

KEY POINTS:

- **Bioequivalence is off the table for 001:** Though management will most likely meet with the FDA in 4Q14, we believe that the technical argument of "same or similar" will fall on deaf ears. Though 5 clinical studies have shown that Egalet-001 has consistent AUC compared to MS Contin, the recent misses both above and below the 90% confidence interval for Cmax will not compel the FDA to give EGLT an easy shot on goal, even if the PK profile of morphine is known to be wonky. The Phase 3 is here to stay.
- **R&D just got Real & Daunting:** EGLT R&D has their hands full. Not only are they planning to initiate a Phase 3 in Egalet-001 in 1Q15, but also two Phase 3 trials in Egalet-002 as well as continuing the 002 category 2/3 abuse deterrent studies. Though Dr. Dayno and Dr. Lindhardt have fine pedigrees, we don't envy their jobs for the next 15-18 months. Pulling together three large successful Phase 3 trials in the pain space is a daunting task for even the most seasoned professional. We view the additional Phase 3 for the 001 program as a risk-on event.
- **New potential commercial timeline reduces outlook:** With the Phase 3 trial now inserted into the commercial timeline for 001, we will see a delay to market. Our initial projected timeline was an NDA submission in 1Q15 with launch in early 2016. Management has guided the NDA submission to mid-2016 which pushes back potential commercialization to 1H17. Our estimated sales in 2019 have been adjusted from \$125M to \$94M.
- **Maintain Buy rating, \$14FV (down from \$22):** We are maintaining our Buy rating as we still see value in the morphine product and the Egalet-002 program remains unchanged. We currently value Egalet-002 at \$9/share based on 2019 predicted sales of \$130M discounted back 5 years at 30%, Egalet-002 at \$4/share based on 2019 predicted sales of \$94M discounted back 5 years at 40% with \$1/share of cash (end 2014) and tech value.

Research Analyst Certifications and Important Disclosures are on pages 3 - 4 of this report

EXHIBIT 1:

Sum-of-the-parts value: EGLT		
Segment	Valuation (000's)	Per share value
Egalet AD opioids	\$58,661	\$4.0
Cash (end '14) & tech value	\$16,762	\$1.0
SUM	\$210,087	\$14
Shares out '14E (000)		15,825

Source: Janney estimates

EXHIBIT 2:

Egalet									
Revenue model									
(\$000 except per share)	2015E				2015E	2016E	2017E	2018E	2019E
	1QA	2QA	3QA	4QA	Year	Year	Year	Year	Year
Egalet-001: AD Morphine ER					\$0	\$0	\$22,500	\$59,000	\$94,000
growth Y-Y								162%	59%
Egalet-002: AD Oxycodone ER							\$42,000	\$89,000	\$125,000
growth Y-Y								112%	40%
TOTAL Egalet opioid sales					\$0	\$0	\$64,500	\$148,000	\$219,000
growth Y-Y								129%	48%

Source: Company reports and Janney estimates

EXHIBIT 3:

Egalet										Egalet																																							
Clinical development trial timelines																																																	
2013A				2014E				2015E				2016E				2017E				2018E																													
1QA	2QA	3QA	4QA	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE																										
Egalet-001: abuse deterrent morphine ER; 505(b)(2)																																																	
Phase 1																																																	
Bioequivalence & PK studies										pk										data																													
Tier 1 Abuse-Deterrent Study										a-d study										data																													
Tier 2 Abuse-Deterrent Study										a-d study										data																													
Tier 3 Abuse-Deterrent Study										a-d study										data																													
Phase 3 - lower back pain										FDA										phase 3										data																			
NDA filing																				NDA																													
FDA approval & launch (expedited approval likely)																														FDA										LAUNCH									
Egalet-002: abuse deterrent oxycodone ER; 505(b)(2)																																																	
Tier 1 abuse deterrent study										data																																							
Tier 2/3 Abuse-Deterrent study										a-d study										data																													
Phase 1 crossover doses										phase 1										data																													
Phase 3 #1 - safety																				phase 3										data																			
Phase 3 #2 - efficacy																				phase 3										data																			
NDA filing																				NDA																													
FDA approval & launch (expedited approval likely)																				FDA										LAUNCH																			

Source: Company reports and Janney estimates

IMPORTANT DISCLOSURES

Research Analyst Certification

I, Chiara Russo, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Egalet Ltd. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Egalet Ltd. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Egalet Ltd. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Egalet Ltd. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

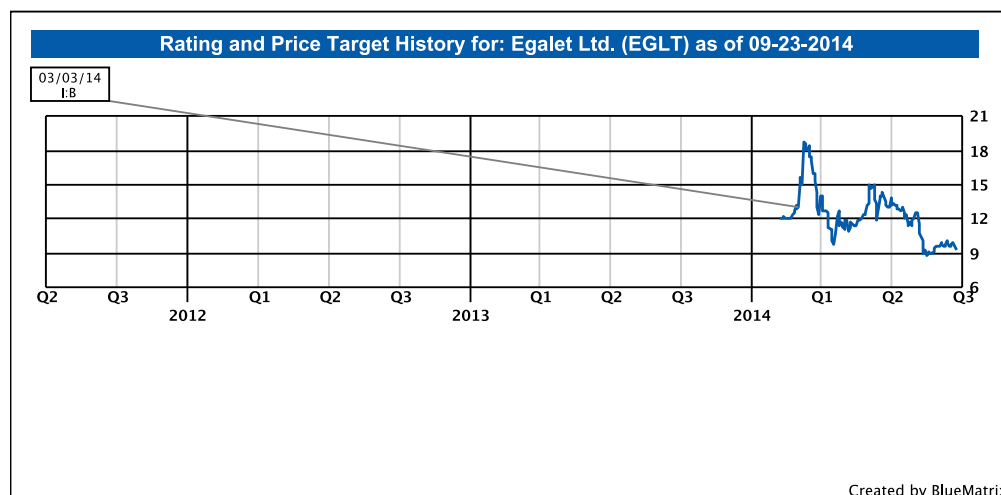
Definition of Ratings

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 6/30/14

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	207	53.80	53	25.60
NEUTRAL [N]	176	45.70	28	15.90
SELL [S]	2	0.50	0	0.00

***Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.**

Other Disclosures

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