

Chiara Russo crusso@janney.com

617-557-2984

Egalet Ltd.
EGLT - BUY
August 6, 2014

### Specialty Pharmaceuticals

## Egalet Ltd. (EGLT) - BUY

Price:	\$12.50
Fair Value Estimate:	\$26.00
52-Week Range:	\$9.54-\$19.85
Market Cap (MM):	\$216
Shr.O/S-Diluted (mm):	17.3
Average Daily Volume:	33,444
Dividend:	NA
Book Value:	\$(4.69)

FYE: Dec 2013A 2014E 2015E EPS: \$(4.29)A \$(2.74)E \$(2.15)E Prior EPS: NC \$(2.07) P/E: NA NA NA

#### Quarterly EPS:

Ql	\$(3.40)A	\$(1.34)A	(0.60)E					
Q2	\$(3.40)A	(0.54)E	\$(0.56)E					
Q3	\$(3.40)A	\$(0.50)E	\$(0.63)E					
Q4	(0.35)A	(0.63)E	\$(0.37)E					
FYE: Dec	2013A	2014E	2015E					
Revenue (M):	\$0.0A	\$0.0E	\$8.0E					
Ouarterly Revenue (M):								

Q1	\$0.0A	\$0.0A	
Q2	\$0.0A	\$0.0E	
Q3	\$0.0A	\$0.0E	
Q1 Q2 Q3 Q4	\$0.0A	\$0.0E	



Equity Research
FLASH Note

# EGLT: Mixed Results on Bioequivalent Study of 001 Down but Far from Out

#### **KEY POINTS:**

- Mixed results from the bioequivalent (BE) study of Egalet-001: EGLT announced this morning the top-line results from their BE study of Egalet-001 (abuse-deterrent morphine) at the 100mg dose compared to MS Contin. In both fed and fasted studies, Egalet-001 met bioequivalence to MS Contin in AUC (amount of drug that reaches the system) but was outside the upper-limit range for Cmax (peak concentration), which means that more drug was present than compared to MS Contin.
- What are the positives?: The positives are that even with the miss on Cmax, the studies did indicate bioequivalence in AUC, which has been consistent across not just the 100mg dose but also the 60mg dose. The study also demonstrated that there should be no clinically relevant food effect and that safety was not issue with no serious adverse events reported.
- What are the negatives? To state the obvious, the miss on Cmax is a negative for the 100mg dose. Though on the follow-up call, management mentioned the possibility of continuing on with a BE filing for the 100mg, we do not believe the FDA will support that. Another option is a full Phase 3 trial instead of the BE filing, but we feel that running a full P3 trial is not a risk that management is willing to undertake.
- What are the next steps? In 3Q14, the bioequivalent studies for the 15mg dose will read out. If positive, we feel that EGLT will look to file on the success of the 60mg and 15mg doses, which could leave the 4Q14 NDA timeline for Egalet-001intact. Management, due to their Fast Track designation will be able to get in front of the FDA sooner rather than later to discuss the potential paths forward, but ultimately the decision will not be made until 3Q14 catalyst.
- NET: Though a solid jab to the program, Egalet-001 is far from down. The 15mg and 60mg doses are still viable for a year-end filing and Egalet-002 remains intact and on track.
- Maintain Buy rating, \$26 fair value down from \$30: We are adjusting our fair value based on revenue revisions from the expected loss of the 100mg dose. We value US sales of Egalet products at \$24/share based on a 4x multiple of 2019 US sales of \$350M discounted 5 years at 30%. Our remaining \$2/shares value based on cash (end of 2014) and tech value.

Research Analyst Certifications and Important Disclosures are on pages 2 - 3 of this report

#### 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.

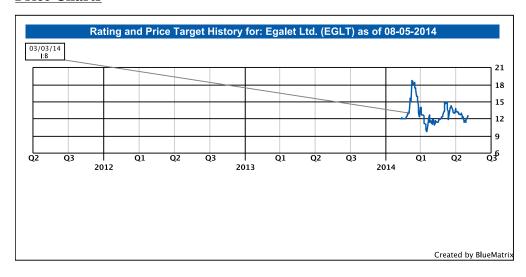
#### **Definition of Ratings**

**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

IB Serv./Past 12 Mos.

Rating	Count	Percent	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**

Janney Montgomery Scott LLC, is a U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the New York Stock Exchange, the Financial Industry Regulatory Authority and the Securities Investor Protection Corp.

This report is for your information only and is not an offer to sell or a solicitation of an offer to buy the securities or instruments named or described in this report. Interested parties are advised to contact the entity with which they deal or the entity that provided this report to them, should they desire further information. The information in this report has been obtained or derived from sources believed by Janney Montgomery Scott LLC, to be reliable. Janney Montgomery Scott LLC, however, does not represent that this information is accurate or complete. Any opinions or estimates contained in this report represent the judgment of Janney Montgomery Scott LLC at this time and are subject to change without notice.

Investment opinions are based on each stock's 6-12 month return potential. Our ratings are not based on formal price targets, however, our analysts will discuss fair value and/or target price ranges in research reports. Decisions to buy or sell a stock should be based on the investor's investment objectives and risk tolerance and should not rely solely on the rating. Investors should read carefully the entire research report, which provides a more complete discussion of the analyst's views. Supporting information related to the recommendation, if any, made in the research report is available upon request.