

## Specialty Pharmaceuticals

### Egalet Ltd.

#### (EGLT) - BUY

**Price:** **\$9.01**  
Fair Value Estimate: \$22.00  
52-Week Range: \$8.82-\$19.85  
Market Cap (MM): \$156  
Shr.O/S-Diluted (mm): 17.3  
Average Daily Volume: 34,892  
Dividend: NA  
Book Value: \$(4.69)

FYE: Dec	2013A	2014E	2015E
EPS:	\$(4.29)A	\$(3.24)E	\$(2.42)E
Prior EPS:		\$(2.74)	\$(2.15)
P/E:	NA	NA	NA

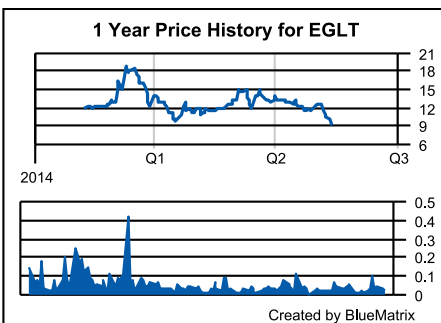
Quarterly EPS:

	2013A	2014E	2015E
Q1	\$(3.40)A	\$(1.34)A	\$(0.77)E
Q2	\$(3.40)A	\$(0.73)A	\$(0.68)E
Q3	\$(3.40)A	\$(0.71)E	\$(0.64)E
Q4	\$(0.35)A	\$(0.67)E	\$(0.37)E

FYE: Dec	2013A	2014E	2015E
Revenue (M):	\$0.0A	\$0.0E	\$6.0E

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: 2Q14 - Clarity in next Q for Egalet-001. Egalet-002 picks up the pace.

### INVESTMENT CONCLUSION:

EGLT announced 2Q14 results before the opening of the market yesterday reporting an EPS of (\$0.73) and revenue of \$490k. The EGLT story remains fully focused on the development story of Egalet-001, an extended-release abuse deterrent formulation of morphine which just last week announced split results in the 100mg bioequivalent (BE) study, hitting the endpoint of AUC, but missing on the upper-limit variability of Cmax. Data is expected in 3Q14 from the BE of the 15mg dose which will in turn dictate the clinical path forward for 001. In the meantime, management has made, in our opinion a smart decision to begin to push their second product candidate Egalet-002, extended-release abuse deterrent oxycodone through the needed clinical trials. Maintain Buy rating, \$22 fair value from \$26 based on increased discount rate.

### KEY POINTS:

- **2Q spending higher than expected:** Before the opening of the market yesterday, EGLT announced 2Q14 EPS of (\$0.73) compared to Janney estimate of (\$0.54) and cons. of (\$0.42). Though some amortized revenue, \$490k booked from Japanese partner Shionogi, which was a nice positive, R&D spend of \$7.3M and G&A spend of \$4.7M were both above estimates. With the adjustments to product development, we expect those levels to continue to significantly increase in the 2H14. EGLT finished out the quarter with \$69M in cash.
- **Two roads diverge for Egalet-001 in 3Q14:** Management will have some decisions to make come the top-line data from the 15mg bioequivalent study. The first option if top-line results are positive, is continuing the BE filing process with the data from the successful 60mg and 15mg. We believe that this is the most likely outcome and path forward. With this said however, even if the 15mg study has positive data, the FDA could come back and ask for additional data. This would delay time-to-market by ~12 months. If the 15mg study reads out as a split, like the 100mg, EGLT could choose to run an additional Phase 3. Though more costly and time consuming, a successful Phase 3 would generate product specific data and not just on a comparator. Again, the Phase 3 would push back time-to-market by about 12 months.
- **Condensing development for Egalet-002:** The second product candidate, Egalet-002 remains fully intact and management is condensing the clinical timeline. The required FDA abuse-deterrent studies are expected to be begin in 4Q14 with top-line data in late 2Q15. The two Phase 3 trials (safety & efficacy) are also slated to both initiate in 1Q15 with top-line data expected by end of year with the NDA filing in 1H16.
- **Increased risk on the Egalet-001 program \$22 FV from \$26:** Though we continue to like the long-term prospects of the EGLT story, we feel that the risk profile requires an adjustment. Though there is a clear path for Egalet-001 if the 15mg results are positive, we feel that the potential of the FDA to require additional clinical data is high enough to warrant a 5% increase in our discount rate. **We value US sales of Egalet products at \$20/share based on a 4x multiple of 2019 US sales of \$350M discounted 5 years at 35%. Our remaining \$2/shares value based on cash (end of 2014) and tech value.**

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

## EXHIBIT 1:

Egalet										
Quarterly income statement										
(\$000 except per share)	2012	2013A				2013A	2014E			
	Year	1QA	2QA	3QA	4QA	Year	1QE	2QA	3QE	4QE
<b>Revenues</b>										
Egalet-001: AD Morphine ER										
Egalet-002: AD Oxycodone ER										
Egalet-003: AD other opioid ER										
Collaborative R&D/Related Party	1,201						256	490		
<b>Total Revenue</b>	<b>\$1,201</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$256</b>	<b>\$490</b>	<b>\$0</b>	<b>\$0</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	-									
<b>Gross Margin</b>	<b>1,201</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>0</b>	<b>256</b>	<b>490</b>	<b>-</b>	<b>-</b>
Research and development	4,256	963	1,129	1,129	3,060	6,280	2,780	7,361	6,900	7,500
General and administrative	2,241	855	1,184	1,184	1,650	4,873	3,269	4,728	4,500	3,500
Total operating expenses	6,497	1,818	2,313	2,313	4,710	11,153	6,049	12,089	11,400	11,000
<b>Income (loss) from Operations</b>	<b>(5,296)</b>	<b>(1,818)</b>	<b>(2,313)</b>	<b>(2,313)</b>	<b>(4,710)</b>	<b>(11,153)</b>	<b>(5,793)</b>	<b>(11,599)</b>	<b>(11,400)</b>	<b>(11,000)</b>
Interest income (expense), net	(75)	-	(2,221)	(2,222)	(4,399)	(8,842)	(7,092)	4	5	5
FOREX loss	(27)	(22)	(46)	(46)	(77)	(190)	(4)	(40)	(25)	(25)
<b>Income (loss) before taxes</b>	<b>(5,398)</b>	<b>(1,796)</b>	<b>(4,580)</b>	<b>(4,580)</b>	<b>(9,186)</b>	<b>(20,185)</b>	<b>(12,889)</b>	<b>(11,635)</b>	<b>(11,420)</b>	<b>(11,020)</b>
Income tax exp (benefit)	-	-	-	-	-	22	35	16	15	15
<b>Net Income (Loss)</b>	<b>(5,398)</b>	<b>(1,796)</b>	<b>(4,580)</b>	<b>(4,580)</b>	<b>(9,186)</b>	<b>(20,207)</b>	<b>(12,924)</b>	<b>(11,651)</b>	<b>(11,435)</b>	<b>(11,035)</b>
<b>Earning per Share (EPS)</b>	<b>(\$4.18)</b>	<b>(\$1.39)</b>	<b>(\$4.25)</b>	<b>(\$0.63)</b>	<b>(\$0.88)</b>	<b>(\$15.64)</b>	<b>(\$1.34)</b>	<b>(\$0.73)</b>	<b>(\$0.71)</b>	<b>(\$0.67)</b>
<b>Adj EPS ex-1x &amp; non-cash items</b>										
Weighted avg. shares (000)	1,292	1,292	1,077	7,319	10,458	1,292	9,638	15,888	16,138	16,388
Fully diluted shares (000)							9,638	17,638	17,888	18,138

Source: Company reports and Janney estimates

Specialty Pharmaceuticals  
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## EXHIBIT 2:

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				
<b>Egalet-001: abuse deterrent morphine ER; 505(b)(2)</b>																																					
Phase 1										phase 1				data																							
Bioequivalence & PK studies														pk				data																			
Tier 1 Abuse-Deterrent Study														a-d stu				data																			
Tier 2 Abuse-Deterrent Study																		a-d study				data															
Tier 3 Abuse-Deterrent Study																		a-d study				data															
NDA filing																						NDA															
FDA approval & launch (expedited approval likely)																						FDA								LAUNCH							
<b>Egalet-002: abuse deterrent oxycodone ER; 505(b)(2)</b>																																					
Tier 1 abuse deterrent study														data																							
Tier 2 Abuse-Deterrent study																		a-d study				data															
Tier 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.

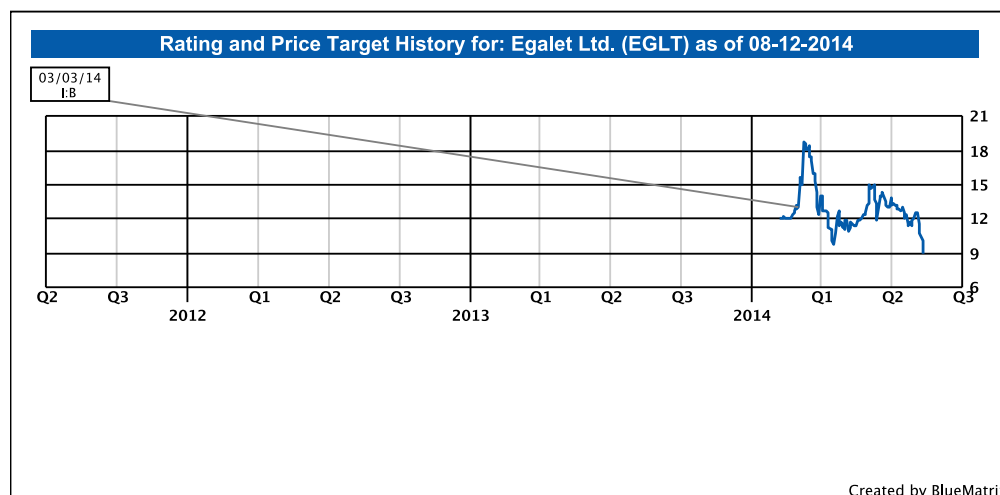
### **Definition of Ratings**

**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**



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### **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**

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.

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