

Specialty Pharmaceuticals

Egalet Ltd.

(EGLT) - BUY

Price: **\$12.94**

Fair Value Estimate: \$30.00

52-Week Range: \$9.54-\$19.85

Market Cap (MM): \$224

Shr.O/S-Diluted (mm): 17.3

Average Daily Volume: 35,244

Dividend: NA

Book Value: \$(4.69)

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

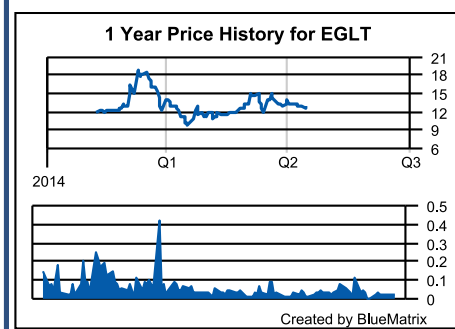
Quarterly EPS:

Q1	\$(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	\$(0.30)E

FYE: Dec	2013A	2014E	2015E
Revenue (M):	\$0.0A	\$0.0E	\$8.0E

Quarterly Revenue (M):

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



Equity Research
FLASH Note

Positive Category 1 AD trial for Egalet-001

EGLT timeline remains tight, but executable

KEY POINTS:

- **Positive top-line data from Category 1 abuse-deterrent study:** Yesterday morning EGLT announced positive results from the independent lab Category 1 abuse-deterrent study of Egalet-001, an abuse-deterrent, extended-release oral morphine formulation. The Category 1 study demonstrated that the formulation was extremely resistant to crushing and grinding with household tools and, due to its gelling effect, could not be injected.
- **Pushing the envelop on Egalet-001 NDA timeline:** By management's own admission, EGLT has an aggressive timeline for 001. The Category 1 data was expected in 2Q14. but over-shooting that by 15 days isn't exactly a deal breaker. Management has stated that both the Category 2 (PK) & Category 3 (experienced user manipulation - likability) studies initiated at the end of June. Results are expected in very early 4Q14 with the NDA expected to be filed by the end of that quarter, possibly in 1Q15.
- **Still positive that 001 will hit on all deadlines:** Though running two AD trials at once, we remain positive that the read-outs will remain on track as these are not overly complicated trials and they do not require large participant numbers. With the turn around from data read-out to NDA in 4Q14, we believe that EGLT is showing confidence in their product by currently being in the process of drafting the NDA documents.
- **Looking ahead to Egalet-002 timeline:** Egalet-002 is the second product candidate, an abuse-deterrent, extended-formulation of oxycodone. This formulation is also going for the abuse-deterrent label and will have to provide data from all three category studies as guided by the FDA. Data from the Category 1 is expected in 3Q14. Again, EGLT management is taking an aggressive timeline as they not only have to provide abuse-deterrent data, but due to the formulation, they also must run a full Phase 3 safety and efficacy program. We expect the NDA to be filed in the late 2Q16/ early 3Q16.
- **We remain positive on the Phase 3 Egalet-002 prospects:** The Egalet-002 formulation involves an added physical barrier to manipulation in the form of a non-eroding polylactic acid (PLA) hard shell. This hard-shell is not digested, but once the active pharmaceutical is released, the empty shell is simply excreted. Dosed 2x daily, with an opioid that slows GI motility, obstruction could be a safety concern. However, several marketed products use a PLA "ghost tablet" delivery system including the popular ADHD drug, Concerta. In looking at precedence of past trials coupled with the positive animal toxicity studies, it is our opinion that Egalet-002 should read-out positive Phase 3 data.
- **Maintain Buy rating, \$30 fair value:** We value US sales of Egalet products at \$28/share based on a 4x multiple of 2019 US sales of \$475M 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 3 - 4 of this report

Egalet																								
Clinical development trial timelines																								
	2013A				2014E				2015E				2016E				2017E							
	1QA	2QA	3QA	4QA	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE			
Egalet-001: abuse deterrant morphine ER; 505(b)(2)																								
Phase 1	phase 1				data																			
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											
NDA filing													NDA											
FDA approval & launch (expedited approval likely)													FDA											
Egalet-002: abuse deterrant oxycodone ER; 505(b)(2)																								
Tier 1 abuse deterrant 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			
Egalet-003: abuse deterrant opioid #3 ER; 505(b)(2)																								
Phase 1									phase 1				data											
Phase 3 trials													phase 3				data							
NDA filing																					NDA			
FDA approval & launch (expedited approval likely)																								

Source: Company reports and Janney estimates

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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.

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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.

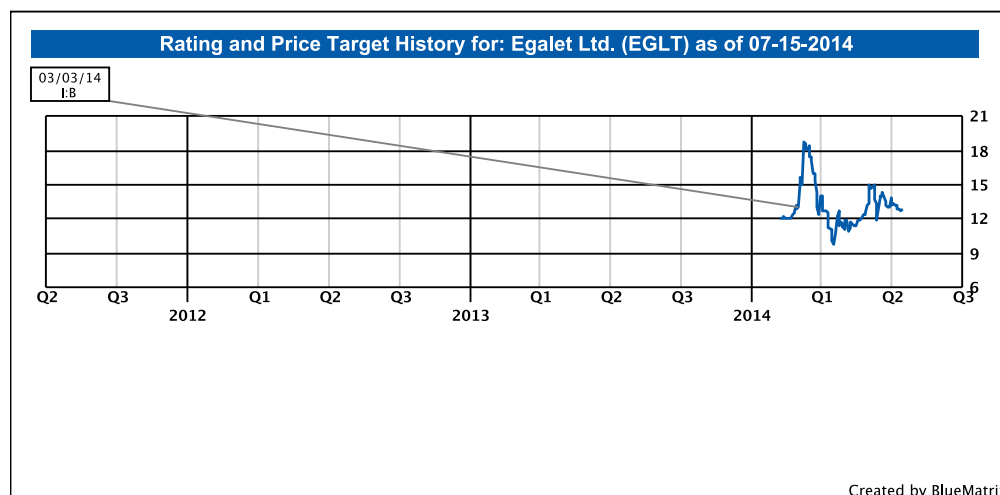
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BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

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.**

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