

#### Specialty Pharmaceuticals

Price:	\$6.53
Fair Value Estimate:	\$14.00
52-Week Range:	\$3.81 - \$19.85
Market Cap (MM):	\$113
Shr.O/S-Diluted (mm):	17.3
Average Daily Volume:	38,001
Book Value:	\$(4.69)
Dividend:	NA
Cash/Share:	\$(0.73)
FCF Yield:	(5.7)%
Debt/Cap:	235%

FYE: Dec	2013A	2014E	2015E
EPS:	\$(4.29)A	\$(3.12)E	\$(2.67)E
Prior EPS:		\$(3.31)	NC
Consensus	NM	-3.52	-2.49
P/E Ratio:	NA	NA	NA

#### Quarterly EPS:

Q1	\$(3.40)A	\$(1.34)A	\$(0.83)E
Q2	\$(3.40)A	\$(0.73)A	\$(0.68)E
Q3	\$(3.40)A	\$(0.63)A	\$(0.61)E
Q4	\$(0.35)A	\$(0.65)E	\$(0.58)E
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#### Quarterly Revenue (M):

Q1	\$0A	\$0A	
Q2	\$0A	\$0A	
Q3	\$0A	\$0A	
Q4	\$0A	\$0E	
Year:	\$0A	\$0E	\$0E

November 12, 2014

# Egalet Ltd.

(EGLT) - BUY

# EGLT: Clinical Programs Advancing - 2015 The Year of the Phase 3

#### PORTFOLIO MANAGER BRIEF

EGLT announced 3Q14 earnings with EPS of (\$0.63), above Janney estimate of (\$0.71), consensus of (\$0.77). Management remains focused on the clinical progress of Egalet-001 and -002, with Category 3 abuse-deterrent data slated for 1H15 and mid-2015 which should be incrementally positive. However, 2015 will be the year of the Phase 3 with EGLT expected to initiate three Phase 3 trials in 1Q15. Though necessary, we feel the current timelines for the Phase 3s are ambitious, but we will hold of judgment until management provides more detail.

#### **ANALYST NOTES**

- 3Q14 Financial Review Lower Spending...for now: Before the open of the market, EGLT announced 3Q14 results with EPS of (\$0.63) above both Janney estimate (\$0.71) and consensus (\$0.77). R&D and G&A spending was less than expected coming in at \$6.3M and \$4.2M, respectively. We expect these figures to remain flat going into 4Q14 and then significantly increase going into 1Q15. EGLT finished out the quarter with \$59.7M in cash.
- Clinical Timelines: 2015 will be an exciting year for EGLT with multiple data point from the Category 3 abuse-deterrent studies in both Egalet-001 and Egalet-002 as well as the initiation of three Phase 3 trials.

•	Product Candidate	Event	Initiation	Expected Data
	Egalet-001	Category 3 AD Study	4Q14	1H15
	Egalet-001	Phase 3	1Q15	1H16
	Egalet-002	Category 3 AD Study	4Q14	mid-2015
	Egalet-002	Two Phase 3 trials	1Q15	1H16

# FDA Wildcard - Category 3 Hurdles :

• The FDA has asked EGLT to "raise the bar" in terms of "breaking" its technology in the Category 3 AD studies, asking for a little more effort and stronger methods than previously guided. EGLT believes that this is for two reasons: 1) inexperience with this kind of technology and 2) straight-up curiosity. An abuse-deterrent label is still a moving target so it's not surprising that the FDA is looking at these new products on an individual basis as well as a framework.

#### FDA Wildcard - BE Path Forward :

• Another wildcard in the game is that EGLT management has approached the FDA for guidance on the potential of a bioequivalent path forward, which was



- their original intention with Egalet-001. Though we believe that the technical argument of "same of similar" will fall on deaf ears, there is the outside possibility that the FDA will ask for an additional clinical study. This would be a very significant event for the name; however; we feel that the Phase 3 for Egalet-001 is here to stay.
- Maintain Buy rating, \$14 FV: We are maintaining our Buy rating. We currently value Egalet-001 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.

#### **INVESTMENT THESIS**

EGLT has two product candidates heading into Phase 3 clinical trials: Egalet-001 which is an abuse-deterrent (AD)extended-release formulation of morphine and Egalet-002 which is an abuse-deterrent extended-release formulation of oxycodone. EGLT's proprietary Guardian technology is unique in the AD space using plastic injection molding technology to create an extremely hard matrix pill. EGLT plays in the long-lasting opioid space with morphine and oxycodone making up 13.3M and 14.8M of the extended-release Rxs written in the US in 2012. With AD opioids a current hot topic with legislatures and the FDA, if approved Egalet-001 and -002 could take meaningful market share.

#### ISSUES TO CONSIDER

Key Issue	Our Position	Timing	Impact
Will the three Phase 3 trials be successful?	This is, of course a tough question to answer and we are going to reserve our judgment until we get more clarity around trial design, number of sites, who the CROs are and final timelines. Historically, 1 out 3 pain trails fail, but there always exceptions to the rule.	12-24 Months	+ 0 -
Is the technology truly differentiating?	Absolutely. Yes, there are other approved AB opioids on the market (Embeda, Targiniq, Opana ER) however, Egalet-001 and -002 will be unique in that the physical properties of their pills are exceptional which should be demonstrated in the AD study data.	6-12 Months	+ 0 -
Are they an acquisition target?	We feel that there is the potential for a company to target EGLT for an acquisition if they have successful Phase 3 data. We do not believe that acquisition would come anytime before that.	12-24 Months	+ 0 -

#### FIVE-YEAR VALUATION

Historical Multiples - Premium to Comps							
Current vs 5 yr Average Historical Premium		5 Yr Historical I	Premium Range	Implied @ Hist Avg			
Metric	Current	Low	High	Average	Multiple Price (USD)		
Current Price					\$6.53		
NTM/PE	N/A	N/A	N/A	N/A	N/A		
NTM EV/EBITDA	-6.9x	N/A	N/A	N/A	N/A		
NTM EV/FCF	N/A	N/A	N/A	N/A	N/A		
NTM EV/REV	210.7x	210.7x	210.7x	210.7x	\$53.93		
Price/Book	1.8x	1.1x	3.9x	2.7x	\$9.75		

#### **EXHIBIT 1:**

	2012		201	3A		2013A		2014	1E		2014E
(\$000 except per share)	Year	1QA	2QA	3QA	4QA	Year	1QE	2QA	3QE	4QE	Year
Revenues											
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	346	350	
Total Revenue	\$1,201	\$0	\$0	\$0	\$0	\$0	\$256	\$490	\$346	\$350	\$1,442
Expenses:	ψ1,201		Ψ0	Ψ0	Ψ0	40	<u> </u>	Ψ-100	ΨΟ-1Ο	ΨΟΟΟ	ψ1,11 <u>2</u>
Cost of Revenue (COGS)											
Gross Margin	1,201	-	-	-	-	0	256	490	346	350	1,442
Research and development	4,256	963	1,129	1,129	3,060	6,280	2,780	7,361	6,346	6,500	22,987
General and administrative	2,241	855	1,184	1,184	1,650	4,873	3,269	4,728	4,194	4,500	16,691
Total operating expenses	6,497	1,818	2,313	2,313	4,710	11,153	6,049	12,089	10,540	11,000	39,678
Income (loss) from Operations	(5,296)	(1,818)	(2,313)	(2,313)	(4,710)	(11,153)	(5,793)	(11,599)	(10,194)	(10,650)	(38,236
Interest income (expense), net	(75)	-	(2,221)	(2,222)	(4,399)	(8,842)	(7,092)	4	5	5	(7,078
FOREX loss	(27)	(22)	(46)	(46)	(77)	(190)	4	(47)	46	(25)	(22
Income (loss) before taxes	(5,398)	(1,796)	(4,580)	(4,580)	(9,186)	(20,185)	(12,881)	(11,642)	(10,143)	(10,670)	(45,336
Income tax exp (benefit)	-	-	-	-	-	22	35	16	(35)	15	31
Net Income (Loss)	(5,398)	(1,796)	(4,580)	(4,580)	(9,186)	(20,207)	(12,916)	(11,658)	(10,178)	(10,685)	(45,437
Earning per Share (EPS)	(\$4.18)	(\$1.39)	(\$4.25)	(\$0.63)	(\$0.88)	(\$15.64)	(\$1.34)	(\$0.73)	(\$0.63)	(\$0.65)	(\$3.12
Adj EPS ex-1x & non-cash items	. ,	,	,		,	, ,	. ,	,	,	,	
Weighted avg. shares (000)	1,292	1,292	1,077	7,319	10,458	1,292	9,638	15,888	16,207	16,457	14,547
Fully diluted shares (000)	1						9,638	17,638	17,957	18,207	15,860

Source: Company reports and Janney estimates

Specialty Pharmaceuticals
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#### **EXHIBIT 2:**

Egalet Quarterly variance analys	is				
(000's except per share)	3Q13A	3Q14A	3Q14E	Variance	% Y/Y
Product Revenues	\$0	\$0	\$0	\$0	N/A
Collaborative / milestones	0	346	0	346	N/A
Total Revenue	\$0	\$346	\$0	\$346	N/A
COGS	0	0	0	0	N/A
Gross Profit	0	346	0	346	N/A
SG&A Expense	1,184	4,194	4,500	3,010	254%
R&D Expense	1,129	6,346	6,900	5,218	462%
Operating Income	(2,313)	(10,194)	(11,400)	(7,882)	341%
Int. inc. (expense), net	(2,222)	5	5	2,227	-100%
FOREX loss	(46)	46	(25)	92	-201%
Other (exp) gain, net	2			(2)	-100%
Pretax Income	(4,580)	(10,143)	(11,420)	(5,563)	121%
Income Tax exp (benefit)	0	(35)	15	(35)	N/A
Net income (loss)	(4,580)	(10,178)	(11,435)	(5,598)	122%
1x items & non-cash exp	0	0	0	0	N/A
Adj NI ex-1x/non cash	0	0	0	Ō	N/A
Weighted avg. shares (000)	7,319	16,207	16,138	8,887	121%
Fully diluted shares (000)				0	N/A
Earning per Share (EPS) Adj EPS ex-1x & non-cash	(\$0.63) \$0.00	(\$0.63) \$0.00	(\$0.71) \$0.00	(\$0.00) \$0.00	0% N/A

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.

# <u>Definition of Ratings</u>

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 9/30/14

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Rating	Count	Percent	Count	Percent
BUY [B]	169	52.81	24	14.20
NEUTRAL [N]	150	46.88	18	12.00
SELL [S]	1	0.31	0	0

<sup>\*</sup>Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.

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#### Other Disclosures

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