

Toda to Observe	Annual EPS	Target		
Today's Changes	2015E (\$2.05) from (\$1.27)	\$10.00 from \$20.00		

# **Egalet Corp.**

EGLT: NASDAQ: US\$9.31

BUY

**Target: US\$10.00** ↓

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#### **COMPANY STATISTICS:**

Forecast Return:	7%
Market Cap (M):	US\$161
52-week Range:	8.74 - 19.85
Avg. Daily Vol. (000s):	33.1

#### **EARNINGS SUMMARY:**

FYE Dec		2013A	2014E	2015E
P/Sales:		NM	215.7x	NM
P/E:		NM	NM	NM
Revenue (M):	Q1	0.0	0.26A	0.0
	Q2	0.0	0.49A	0.0
	Q3	0.0	0.0	0.0
	Q4	0.0	0.0	0.0
Total		0.0	0.75	0.0
EPS:	Q1	(2.12)	(1.34)A	(0.53)
	Q2	(2.28)	(0.73)A	(0.55)
	Q3	(4.34)	(0.76)	(0.54)
	Q4	(0.67)	(0.78)	(0.44)
Total		(1.45)	(3.42)	(2.05)

#### **SHARE PRICE PERFORMANCE:**



Source: Interactive Data Corporation

#### **COMPANY DESCRIPTION:**

Egalet is a specialty pharma company focused on developing abuse-deterrent formulated drugs, including opioids. Egalet is utilizing the FDA's 505(b)(2) pathway with the intent of shortening development timelines and cost.

All amounts in US\$ unless otherwise noted.

# Life Sciences -- Specialty Pharmaceuticals

# 15 MG BIOEQUIVALENCE MISS, EXPECT FULL PH 3 FOR MORPHINE, LOWERING TARGET TO \$10

# **Investment highlights**

# EGLT-001 15 mg misses Cmax bioequivalence

EGLT-001 15mg did not demonstrate bioequivalence to the 15mg MS Contin dose, with Cmax outside the 90% confidence interval with 78.99 to 88.47% (reference range 80-125%). Although AUC was within bioequivalence criteria, the miss on Cmax will likely delay the NDA filing for EGLT-001 until mid-2016.

# FDA meeting 4014, expect full Phase 3 program for EGLT-001

EGLT will meet with the FDA during 4Q14 to discuss bioequivalence data for 15, 60, and 100mg ELGT-001 vs. MS Contin, and we expect a full Phase 3 program will be required. Egalet estimates n=300 patients in a back pain study, 15 months needed to complete, at a cost of ~\$8-10M.

## EGLT-002 targets \$2-3B single player oxycodone market

We continue to estimate ~\$886M peak sales for EGLT-001, an abuse deterrent oxycodone. Importantly, head-to-head abuse deterrent data for EGLT-002 vs. Purdue's Oxycontin OP are expected 2Q15. EGLT-002 will involve a full Phase 3 program, as previously established. Company guidance remains on track for data readout by YE15.

# Lowering price target to \$10 on longer timelines

We are lowering our price target to \$10 based on a longer timeline to potential EGLT-001 approval. We have lowered the probability of approval for EGLT-001 to 10% from 65%. We have also removed cash from our valuation. EGLT-001 is now worth <\$1 in our valuation, EGLT-002 makes up  $\sim$ \$10 of our valuation.

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23 September 2014

Income Statement (\$000's)	<u>2013A</u>	Mar-14A	Jun-14A	<u>Sep-14E</u>	Dec-14E	<u>2014E</u>	<u>2015E</u>	<u>2016E</u>	<u>2017E</u>	<u>2018E</u>	<u>2019E</u>	<u>2020E</u>	<u>2021E</u>	<u>2022E</u>
Total revenues	0	256	490	-	-	746	-		65,494	151,515	321,547	470,416	632,611	697,844
Cost of goods sold						7		-	9,169	19,697	41,801	56,450	75,913	83,741
Gross profit	0	256	490	•	-	746	-	•	56,325	131,818	279,746	413,966	556,697	614,103
Operating expenses														
Research & development														
Egalet-001	1,187	1,800	2,100	2,100	2,000	8,000	9,282	9,746	9,259	7,407	7,407	7,407	7,407	7,407
Egalet-002	371	48	3,400	3,400	3,600	10,448	12,000	1,800	900	900	900	900	900	900
Other Clinical and Preclinical	1,288	567	1,489	1,250	1,250	4,556	5,000	5,500	(5,037)	7,376	36,926	63,361	88,592	98,166
Personnel Related	1,431	365	372	379	386	1,503	1,578	1,735	2,083	2,499	2,999	3,599	4,318	5,182
R&D	6,280	2,780	7,361	7,129	7,236	24,507	27,860	18,782	7,204	18,182	48,232	75,267	101,218	111,655
Egalet-001							5,625	16,500	17,160	17,846	18,560	19,303	20,075	20,878
Egalet-002									37,500	43,125	49,594	57,033	65,588	75,426
General & administrative	4,873	3,269	4,728	5,041	5,353	8,000	8,900	9,790	11,748	14,685	18,356	22,945	27,534	30,288
SG&A	4,873	3,269	4,728	5,041	5,353	8,000	14,525	26,290	66,408	75,656	86,510	99,281	113,197	126,591
						18,391			13,099	53,030	112,541	164,646	101,218	104,677
Total expenses	11,153	6,049	12,089	12,170	12,590	32,507	42,385	45,072	73,612	93,838	134,742	174,547	214,415	238,247
Depreciation & amortization		242	336	430	524	1,532		5,309	6,874	7,674	7,420	8,571	9,000	9,450
EBITDA	(11,153)	(5,551)	(11,263)	(11,740)	(12,066)	(40,620)	(39,792)	(45,072)	(17,287)	37,980	145,003	239,419	342,283	375,856
Operating income	(11,153)	(5,793)	(11,599)	(12,170)	(12,590)	(42,152)	(39,792)	(50,380)	(24,162)	30,306	137,584	230,848	333,283	366,406
Interest income			4											
Interest ex pense	8,842	(7,092)	-	-	- "	(7,092)	-	-	-	-	-	-	-	-
Other expense / (income), net	190	•		50	50	100	200	200	200	200	200	200	200	200
Interest & other	9,032	(7,092)	4	50	50	(6,992)	200	200	200	200	200	200	200	200
Gain on foreign currency exchange		4	(40)											
Pre-tax income		(12,881)	(11,635)	(12,120)	(12,540)	(49, 176)	(39,592)	(50, 180)	(23,962)	30,506	137,784	231,048	333,483	366,606
Taxes	22	35	16				-	-	-	11,139	50,832	85,340	123,241	135,496
Tax rate							37%	37%	37%	37%	37%	37%	37%	37%
Net income - GAAP	(20,207)	(12,916)	(11,651)	(12,120)	(12,540)	(49,227)	(39,592)	(50,180)	(23,962)	19,367	86,952	145,708	210,242	231,110
GAAP EPS	(\$1.45)	(\$1.34)	(\$0.73)	(\$0.76)	(\$0.78)	(\$3.42)	(\$2.05)	(\$2.37)	(\$1.06)	\$0.83	\$3.56	\$5.74	\$7.97	\$8.42
Adjusted EPS excl. options expe	(\$1.45)	(\$1.34)	(\$0.73)	(\$0.76)	(\$0.78)	(\$3.42)	(\$2.05)	(\$2.37)	(\$1.06)	\$0.83	\$3.56	\$5.74	\$7.97	\$8.42
Diluted shares outstanding - GAAP Diluted shares outstanding Pro Forma Shares	13,902	9,638	15,888	15,967	16,047	14,385	19,271	21,206	22,555	23,457	24,395	25,371	26,386	27,441

Source: Company reports, Canaccord Genuity estimates





Figure 2: Egalet Valuation

Product	Peak Sales (\$MM)	Peak Year	Current Value (\$MM)	Probability Adjustment	Value / Share	Scenario probability	Adjusted Value
Non-Partnered							
Egalet-001 (morphine)	112	2025	6	10%	\$0	20%	\$0
Egalet-002 (oxycodone)	886	2027	228	35%	\$16	20%	\$3
Equity Value					\$17	20%	\$3
Partnered							
Egalet-001 (morphine)	112	2025	6	10%	\$0	55%	\$0
Egalet-002 (oxycodone)	1112	2027	126	35%	\$9	55%	\$5
Equity Value					\$10	55%	\$5
Royalty							
Egalet-001 (morphine)	112	2025	6	10%	\$0	25%	\$0
Egalet-002 (oxycodone)	200	2027	99	35%	\$7	25%	\$2
Equity Value					\$8	25%	\$2
Total Equity Value							\$10
Net Cash (50% adj)							\$0
Value per share							\$10
Shares Outstanding (MM)							13.9
Risk-Free Rate	2.00%						
Beta	1.30						
Risk Premium	8%						
Discount Rate	13%						

Source: Canaccord Genuity estimates



#### **Investment risks**

Risks to our rating and price target include the following:

Approval for Egalet-001 and Egalet-002 may be delayed or may never occur at all: If the FDA does not allow Egalet to pursue approval for Egalet-001 through the Section 505(b)(2) pathway via bioequivalence to MS-Contin, the company may be forced to conduct Phase Ill studies resulting in increased costs, delayed revenue generation, and more competition.

Total revenues, even with timely approvals, may be lower than our estimates: Egalet-001 and Egalet-002 face competition from currently marketed non-abuse-deterrent products, while the planned reintroduction of Embeda, another abuse-deterrent long-acting morphine drug (Pfizer) may have a negative impact on the market opportunity for Egalet-001. Also, legislation to remove non-abuse-deterrent opioid drugs from the market may never materialize, resulting in investor concern

Future litigation may delay or reduce total revenues. Several competitors currently in the space may undertake legal strategies to delay the launch of Egalet-001 and Egalet-002. These competitors have significantly greater resources at their disposal than Egalet and have more experience maneuvering the legal field.

From a financial standpoint, although Egalet currently has adequate cash on hand  $\sim$ \$65, the company may require additional capital before the anticipated launch of Egalet-001 in the second half of 2015. An additional capital raise could pressure shares.



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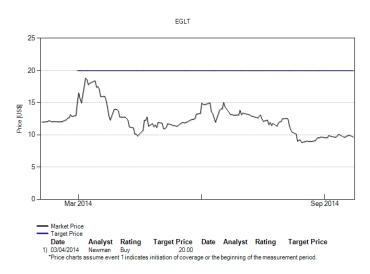
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An analyst has not visited the material operations of Egalet Corp.

# Price Chart:\*



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Coverage Universe							
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<sup>\*</sup>Total includes stocks that are Under Review

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