Egalet Corp.

EGLT : NASDAQ : US$9.68

BUY

Target: US$20.00

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COMPANY STATISTICS:

Forecast Return:	107%
Market Cap (M):	US$167
52-week Range:	8.74 - 19.85
Avg. Daily Vol. (000s):	33.1

EARNINGS SUMMARY:

FYE Dec		2013A	2014E	2015E
P/Sales:		--	224.3x	21.5x
P/E:		NM	NM	NM
Revenue (M):	Q1	0.0	0.3A	0.0
	Q2	0.0	0.5A	0.0
	Q3	0.0	0.0	2.5
	Q4	0.0	0.0	5.2
Total		0.0	0.7	7.8
EPS:	Q1	(2.12)	(1.34)A	(0.43)
	Q2	(2.28)	(0.73)A	(0.44)
	Q3	(4.34)	(0.76)	(0.32)
	Q4	(0.67)	(0.78)	(0.08)
Total		(1.45)	(3.42)	(1.27)

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

PHARMACOKINETIC ANALYSIS PREDICTS SUCCESS OF EG-001 15 MG BIOEQUIVALENCE

Investment highlights

High probability of bioequivalence success with EG-001 15 mg due to PK analysis

We expect positive results for the EGLT-001 15mg bioequivalence study, with upside for the stock. Opioid PK profiles become unpredictable at higher doses, reflected in the failure of bioequivalence with EG-001 100 mg dose recently. However, data from Kaiko et al show lower doses have a more linear, predictable PK profile, a plus for EGLT-001 15 mg with data expected during September 2014.

15 mg and 60 mg dose represent 90% of market share, positive

Importantly, the 15 and 60mg morphine doses represent ~90% of the market, suggesting commercial viability for EGLT-001. The 60 mg dose was already found to be bioequivalent, and we believe positive results for the 15mg dose should enable successful commercialization if approved.

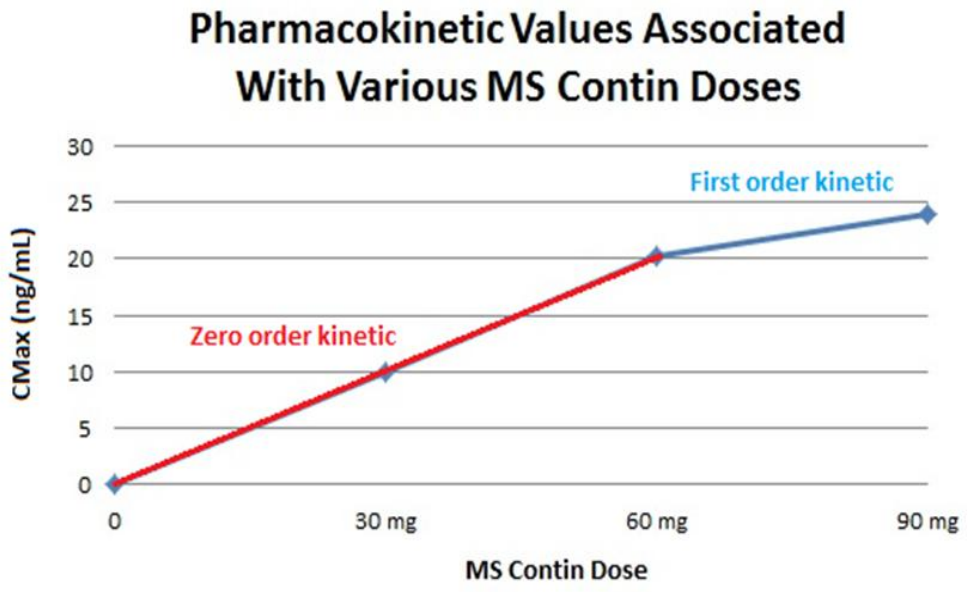
Physicians seeking opioid deterrent formulation, likely high uptake by cancer pain specialists

After consulting with numerous pain specialists at the recent NCCN Annual Congress meeting, the demand for an abuse deterrent opioid formulation is especially high in the cancer population. Physicians emphasized that compared to non-cancer pain with average morphine doses of 23.7 mg (Macey TA 2011), cancer patients take an average of 115 mg with a high duration of about 5.2 ± 8.6 months (Freud T 2013), representing a risk for abuse. Additionally, these physicians state 10-20% of their patients are suspicious of abuse, a problem that will drive product uptake of abuse deterrent opioids.

PHARMACOKINETIC EVALUATION SHOWS DIFFERENT KINETIC PROFILES OF MS CONTIN AT HIGHER DOSES

Kaiko et al. reported pharmacology studies of MS Contin in 15, 30, 60, and 100 mg tablets, which showed significant differing pharmacokinetic (PK) profiles of the drug at different doses, giving us confidence that EG-001 will hit bioequivalence with the lower 15 mg dose even though the drug was not bioequivalent at the 100 mg dose (Kaiko R et al. Cancer. 1989). According to the graph below, between 30 and 60 mg doses, the PK of MS Contin exhibits zero order kinetics where increasing the dose two-fold from 30 mg to 60 mg increased the Cmax in a linear fashion (10 ng/mL for 30 mg and 20.2 ng/mL for 60 mg). However, at higher doses of 90 mg, the PK of MS Contin changes to first order kinetic and the Cmax plateaus instead of falling into a linear slope (24 ng/mL). This reflects the erratic pharmacology of all opioids exhibiting first order kinetics at high doses due to variability from absorption, distribution, metabolism, and excretion in the human body (Allen L. et al, J Clin Pharmacol. 1982).

Figure 1: PK profile of various MS Contin doses



Source: Kaiko R et al. Cancer. 1989, Canaccord Genuity

Figure 2: PK Values with 30, 60, and 100 mg doses

TABLE 1. Pharmacokinetic Values (Mean ± SE) Associated With Single Doses of MS Contin 30 mg Tablets (Reference Drug) *Versus* MS Contin 15, 60, and 100 mg Tablets

	Reference	Test agent	*P* (significance)	Power 1-beta
Study 1*				
AUC (0, 24) (ng/ml × hr)	55.8 ± 3	57.5 ± 3	0.5 (NS)	0.61
C_{max} (ng/ml)	10.0 ± 0.4	10.8 ± 0.4	0.2 (NS)	0.87
T_{max} (hr)	2.1 ± 0.1	1.8 ± 0.1	0.1 (NS)	0.57
Study 2†				
AUC (0, 24) (ng/ml × hr)	140.3 ± 6	135.4 ± 6	0.5 (NS)	0.89
C_{max} (ng/ml)	20.2 ± 0.8	20.2 ± 0.8	0.5 (NS)	0.93
T_{max} (hr)	2.3 ± 0.2	2.5 ± 0.2	0.5 (NS)	0.27
Study 3‡				
AUC (0, 24) (ng/ml × hr)	183.5 ± 13	169.6 ± 13§	0.04	0.99
C_{max} (ng/ml)	24 ± 2	23.2 ± 2	0.5 (NS)	0.46
T_{max} (hr)	2.2 ± 0.3	1.9 ± 0.1	0.2 (NS)	0.26

AUC: area under the plasma morphine *versus* time curve; C_{max}: maximum morphine concentration; T_{max}: time of maximum morphine concentration.

* Reference: 1 × 30 mg; test agent: 2 × 15 mg.

† Reference: 2 × 30 mg; test agent: 1 × 60 mg.

‡ Reference: 3 × 30 mg; test agent: 1 × 100 mg.

§ Value adjusted to total dose of 90 mg.

Source: Kaiko R et al. Cancer. 1989

With this phenomenon in mind, the results of the EG-001 trial mirrored the kinetics of the drug itself. EG-001 60 mg was bioequivalent in both AUC and Cmax to MS Contin 60 mg since the drug is still undergoing zero order metabolism, while the higher 100 mg fell above the Cmax reference range of MS Contin as the PK became less predictable at higher doses. Because lower doses of opioids have more stable kinetics, we are confident that the 15 mg dose of EG-001 will be bioequivalent to the 15mg dose of MS Contin. We remind investors that because the 15 and 60 mg dose represents nearly 90% of the morphine market, we see the likelihood of bioequivalence with 15 mg to be high and the two doses alone may be enough to drive market share.

Figure 3: Egalet Valuation

Product	Peak Sales ($MM)	Peak Year	Current Value ($MM)	Probability Adjustment	Value / Share	Scenario probability	Adjusted Value
Non-Partnered							
Egalet-001 (morphine)	162	2025	91	65%	$7	20%	$1
Egalet-002 (oxycodone)	886	2027	257	35%	$18	20%	$4
Equity Value					**$25**	**20%**	**$5**
Partnered							
Egalet-001 (morphine)	162	2025	91	65%	$7	55%	$4
Egalet-002 (oxycodone)	1112	2027	145	35%	$10	55%	$6
Equity Value					**$17**	**55%**	**$9**
Royalty							
Egalet-001 (morphine)	162	2025	91	65%	$7	25%	$2
Egalet-002 (oxycodone)	200	2027	111	35%	$8	25%	$2
Equity Value					**$15**	**25%**	**$4**
Total Equity Value							$18
Net Cash (50% adj)							$2
Value per share							**$20**
Shares Outstanding (MM)							13.9

Risk-Free Rate	2.00%
Beta	1.30
Risk Premium	7%
Discount Rate	12%

Source: Canaccord Genuity Estimates

Figure 4: Egalet income statement

Income Statement ($000's)	2013A	Mar-14A	Jun-14A	Sep-14E	Dec-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Total revenues	**0**	**256**	**490**	**-**	**-**	**746**	**7,770**	**35,593**	**96,632**	**184,580**	**356,641**	**507,696**	**672,211**	**739,911**
Cost of goods sold							1,162	5,339	13,529	23,995	46,363	60,923	80,665	88,789
Gross profit	**0**	**256**	**490**	**-**	**-**	**746**	**6,608**	**30,254**	**83,104**	**160,584**	**310,278**	**446,772**	**591,546**	**651,121**
Operating expenses														
Research & development														
Egalet-001	1,187	1,800	2,100	2,100	2,000	8,000	800	840	798	638	638	638	638	638
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	6,849	18,112	48,959	76,094	101,697	111,665
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**	**19,378**	**9,875**	**10,630**	**22,150**	**53,496**	**81,231**	**107,554**	**118,386**
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			**19,326**	**64,603**	**124,825**	**177,693**	**107,554**	**110,987**
Total expenses	**11,153**	**6,049**	**12,089**	**12,170**	**12,590**	**32,507**	**33,903**	**36,165**	**77,038**	**97,806**	**140,006**	**180,512**	**220,751**	**244,977**
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)**	**(24,725)**	**(5,911)**	**6,066**	**62,778**	**170,272**	**266,260**	**370,795**	**406,144**
Operating income	**(11,153)**	**(5,793)**	**(11,599)**	**(12,170)**	**(12,590)**	**(42,152)**	**(24,725)**	**(11,220)**	**(808)**	**55,104**	**162,852**	**257,689**	**361,795**	**396,694**
Interest income			4											
Interest expense	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)	(24,525)	(11,020)	(608)	55,304	163,052	257,889	361,995	396,894
Taxes	22	35	16				-	-	-	20,315	60,181	95,271	133,790	146,703
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)**	**(24,525)**	**(11,020)**	**(608)**	**34,990**	**102,871**	**162,618**	**228,205**	**250,191**
GAAP EPS	**($1.45)**	**($1.34)**	**($0.73)**	**($0.76)**	**($0.78)**	**($3.42)**	**($1.27)**	**($0.52)**	**($0.03)**	**$1.49**	**$4.22**	**$6.41**	**$8.65**	**$9.12**
Adjusted EPS excl. options expe	**($1.45)**	**($1.34)**	**($0.73)**	**($0.76)**	**($0.78)**	**($3.42)**	**($1.27)**	**($0.52)**	**($0.03)**	**$1.49**	**$4.22**	**$6.41**	**$8.65**	**$9.12**
Diluted shares outstanding - GAAP														
Diluted shares outstanding	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
Pro Forma Shares														

Source: Company reports, Canaccord Genuity

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 lll 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 ~$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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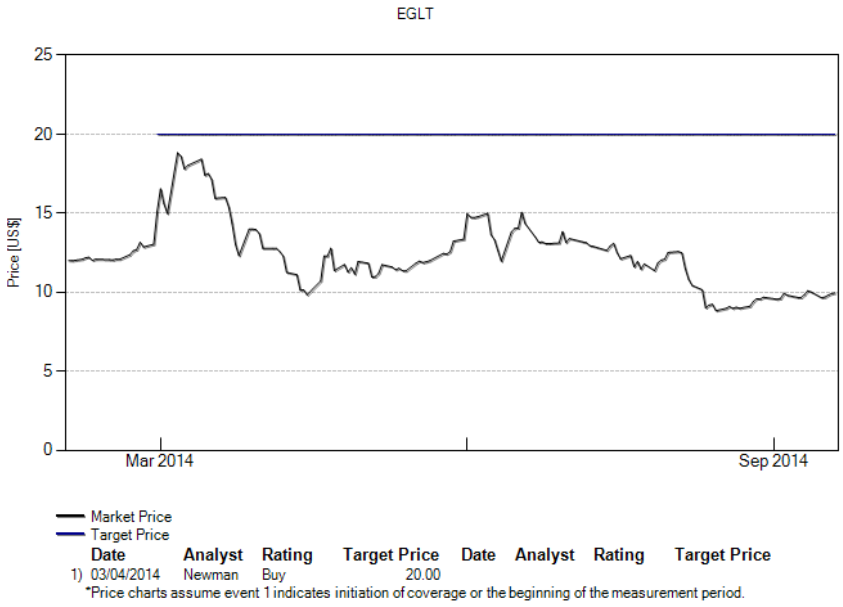
Site Visit: An analyst has not visited the material operations of Egalet Corp.

Price Chart:*



Date	Analyst	Rating	Target Price	Date	Analyst	Rating	Target Price
1) 03/04/2014	Newman	Buy	20.00				

*Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

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(as of 3 July 2014)

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Speculative Buy	49	5.0%	55.1%
Hold	290	29.5%	13.1%
Sell	41	4.2%	7.3%
	984	100.0%	

*Total includes stocks that are Under Review

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