

### **Egalet Corp.**

EGLT: NASDAQ: US\$16.83

BUY

**Target: US\$20.00** 

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#### **COMPANY STATISTICS:**

Forecast Return:	55.4%
Market Cap (M):	US\$252.3
52-week Range:	11.82 - 13.67
Avg. Daily Vol. (000s):	78.0

#### **EARNINGS SUMMARY:**

FYE Dec		2013E	2014E	2015E	
Revenue (M):		0.0	10.0	7.8	
EPS:		(1.11)	(1.51)	(1.53)	
Revenue (M):	Q1	0.0	10.0	0.0	
	Q2	0.0	0.0	0.0	
	Q3	0.0	0.0	2.5	
	Q4	0.0	0.0	5.2	
Total		0.0	10.0	7.8	
EPS:	Q1	(2.13)	0.28	(0.47)	
	Q2	(2.29)	(0.41)	(0.48)	
	Q3	(4.28)	(0.68)	(0.34)	
	Q4	(0.30)	(0.71)	(0.09)	
Total		(1.11)	(1.51)	(1.53)	

#### **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**

# ELITE PHARMA BIOEQUIVALENCE DATA NOT A CONCERN

#### ELI-200 bioequivalence data vs. Embeda not a concern

We do not view recent bioequivalence data for ELI-200 as a competitive concern, as Egalet's '001 morphine formulation is likely more resistant to abuse. Elite Pharmaceuticals released data this morning showing bioequivalence for ELI-200, an abuse-deterrent morphine versus a comparator (likely Embeda), from a single-dose, open-label, partially randomized study involving n=80 subjects based on Cmax and AUC. Elite plans on filing an NDA by YE14, but we expect important abuse-deterrence data (YE14) to be less favorable vs. Egalet-001.

#### Naltrexone encapsulation less attractive to physicians

Adding naltrexone to morphine for ELI-200 is unlikely to be attractive to physicians, especially after Pfizer removed Embeda from the market due to naltrexone leakage. Egalet-001, by contrast, contains only morphine, which we believe will be more familiar to doctors. Importantly, any unintentional naltrexone leakage neutralizes the effect of morphine and other pain agents.

#### Elite Pharma's technology raises IP questions

Elite's bioequivalence approach to what is likely Embeda may face patent challenges from Pfizer, as Embeda's patents may cover naltrexone encapsulation by morphine, preventing FDA approval for ELI-200. Also, FDA may require full clinical studies for ELI-200 given the morphine / naltrexone combination, significantly delaying NDA filing and potential FDA approval.

#### Continue to anticipate positive bioequivalence data for Egalet-001 in 2014

We expect positive bioequivalence and abuse-deterrence data for Egalet-001 by YE14, which should drive the stock higher. Also, we expect better abuse-deterrent data for Egalet-001 vs. ELI-200. In addition, we expect important abuse-deterrence data for Egalet-002, an abuse-deterrent formulation of OxyContin, vs. Purdue's OxyContin by YE14, which should be a major drive for shares. Demonstrating better abuse-deterrence data for Egalet-002 head-to-head vs. OxyContin could signal a major commercial advantage for Egalet, and move shares higher in 2014.

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5 March 2014

#### **Valuation**

Our \$20 price target for Egalet shares is based on a sum-of-the-parts probability-adjusted NPV analysis by product. We assume 100% commercialization for Egalet-001 and model three possible scenarios for Egalet-002: (1) 100% Egalet commercialization, (2) partnership based on an operating profit split, and (3) partnership involving an 8-18% net sales royalty. We assume probabilities of 20%, 55%, and 25% for the scenarios, giving our \$20 price target

#### **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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**Site Visit:** 

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

#### Price Chart:\*



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Coverage Universe					
D-4	и	0/	IB Clients		
Rating	#	%	%		
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_	990*	100.0%			

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

### Daily Letter | 4

5 March 2014

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Company	Disclosure
Egalet Corp.	1A, 2, 3, 5, 7

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