

# **Egalet Corporation (EGLT)**

End-of-Phase 2 Meeting Provides Input on Egalet-002 Development Program

MARKET DATA	
Price 52-Week Range:	\$8.84 \$8.82 - \$19.85
Shares Out. (M):	14.7
Market Cap (\$M):	\$129.9
Average Daily Vol. (000):	14.0
Cash (M):	\$69
Cash/Share:	\$4.02
Enterprise Value (M):	\$129
LT Debt (M):	\$0
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	\$0.0	\$0.3A	
	2Q	\$0.0	\$0.5A	-
	3Q	\$0.0	\$0.0	-
	4Q	\$0.0	\$0.0	
	FY	\$0.0	\$0.7	\$0.0
EPS	1Q	(\$1.39)	(\$1.34)A	-
	2Q	(\$3.40)	(\$0.73)A	-
	3Q	(\$3.40)	(\$0.80)	-
	4Q	(\$7.13)	(\$0.83)	-
	FY	(\$15.64)	(\$3.70)	(\$3.13)
Source: Company re	eports a	nd JMP Securitie	s LLC	



MARKET OUTPERFORM | Price: \$8.84 | Target Price: \$18.00

## **INVESTMENT HIGHLIGHTS**

Egalet-002 development on track following completion of end-of-Phase 2 meeting with the FDA; reiterate Market Outperform rating and \$18 price target on Egalet.

This morning, Egalet announced that it has completed an end-of-Phase 2 meeting with the FDA for Egalet-002, its abuse-deterrent candidate for oxycodone. The company stated that the FDA provided guidance on clinical development as well as the manufacturing process for Egalet-002. We continue to anticipate that Category 2/3 abuse deterrent trials for Egalet-002 will begin in 4Q14, with the first pivotal Phase 3 efficacy trial expected to start in 1Q15. Phase 3 results are expected in 2H15. Our \$18 price target is derived through a sum-of-the-parts NPV analysis of Egalet-001 and Egalet-002.

#### FDA interactions provide input into manufacturing process and clinical program.

The FDA reviewed Egalet's chemistry, manufacturing and CMC as well as clinical development plans for Egalet-002. Egalet reached an agreement with the FDA on its CMC strategy and was given input into the design of the Phase 3 efficacy and safety trials. This guidance will allow Egalet to advance the product into Category 2/3 abuse deterrent trials and the pivotal Phase 3 program. We continue to believe that Egalet's technology effectively addresses the primary method of abuse for oxycodone, crushing and snorting, and is differentiated from emerging abuse-deterrent products.

Phase 3 pivotal program expected to begin in 1Q15. Egalet is pursuing FDA approval of Egalet-002 via the 505(b)(2) pathway and intends to complete two Phase 3 clinical trials as well as abuse-deterrence studies, in line with FDA guidance. The first Phase 3 is an n=300, multi-center, double-blind, placebo-controlled trial in patients with moderate-to-severe lower back pain who require around the clock opioid therapy. The co-primary endpoints are reduced pain scores and reduced relief medication. The second Phase 3 will be an n=250, open-label, long-term safety trial in which patients will be treated with Egalet-002 for either three months, six months, or twelve months.

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## **Company Description**

Egalet Ltd. (Nasdaq: EGLT) is a specialty pharmaceutical company, headquartered in Malvern, PA., primarily focused on the development of novel, oral, abuse-deterrent, opioid pain products. These tamper-resistant opioid candidates are based on the company's proprietary, patented platform technology. Egalet has two lead clinical development programs; Egalet-001, an abuse-deterrent, extended-release, oral formulation of morphine for moderate-to-severe pain, and Egalet-002, an abuse-deterrent, extended-release, oral formulation of oxycodone, also for moderate-to-severe pain. Egalet also has a development collaboration and licensing agreement with Shionogi.

#### **Investment Risks**

Clinical risk. Egalet may not be successful in the full development and launch of its product candidates. There may be dosing, efficacy, or safety issues related to product candidates undergoing clinical trials that could preclude continued development. In addition, there may be manufacturing issues including challenges with the scale-up to commercial quantities. Any of these issues could pose a risk to success.

Regulatory risk. The company's potential regulatory filing for its NDA may not receive approval from the FDA or ex-U.S. agencies. If the FDA does not determine that a product candidate is sufficiently bioequivalent to approved drugs, or if the FDA does not allow Egalet to file under Section 505(b)(2), the approval pathway will likely take longer and cost significantly more. If approved, a mandatory REMS (Risk Evaluation and Mitigation Strategy) program may be required that may deter usage or slow the commercial launch trajectory, either of which would reduce the chances of reaching projected sales.

Competitive risk. Given the competitive landscape in the biotechnology space, another company may come out with a more efficacious, less expensive product that could take away significant market share from Egalet's products. This would challenge the company's ability to achieve the milestones contained in the collaboration agreement with Shionogi and sales sufficient to generate royalties under that agreement. There is a risk that the patent holder of the approved drugs that are included in Egalet's products may file a patent infringement suit against an Egalet product and the company would then need to spend money in defense fees. In addition, the 505 (2)(b) regulatory pathway makes Egalet susceptible to a competitor filing an ANDA for a generic candidate with the FDA.

Financial risk. Egalet currently gets revenue from feasibility and collaboration agreements. It does not yet have product revenues and may not reach profitability if there are any issues commercializing its product candidates. The company has a history of operational losses due to research and development expenses as well as operational expenses. These expenses are expected to continue to incur in the near future. We anticipate that Egalet will likely need to raise funds in the future to continue operations.

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JMP Securities was manager or co-manager of a public offering of securities for Egalet Corporation (EGLT) in the past 12 months, and received compensation for doing so.

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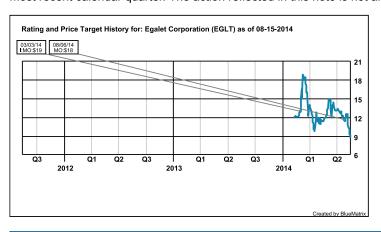
Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months. Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months. Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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							# Co's Receiving IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	267	60.00%	Buy	267	60.00%	98	36.70%
MARKET PERFORM	Hold	138	31.01%	Hold	138	31.01%	18	13.04%
MARKET UNDERPERFORM	Sell	4	0.90%	Sell	4	0.90%	0	0%
COVERAGE IN TRANSITION		36	8.09%		36	8.09%	0	0%
TOTAL:		445	100%		445	100%	116	26.07%

# **Stock Price Chart of Rating and Target Price Changes:**

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar guarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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