

Egalet Corporation (EGLT)

NDA Filing Remains on Track for 4Q14

MARKET DATA	
Price 52-Week Range: Shares Out. (M): Market Cap (\$M): Average Daily Vol. (000): Cash (M): Cash/Share: Enterprise Value (M):	\$11.43 \$9.54 - \$19.85 14.7 \$168.0 15.0 \$78 \$59.97 \$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	\$0.0				
	3Q	\$0.0	\$0.0	-			
	4Q	\$0.0	\$0.0				
	FY	\$0.0	\$0.3	\$0.0			
EPS	1Q	(\$1.39)	(\$1.34)A	-			
	2Q	(\$3.40)	(\$0.96)	-			
	3Q	(\$3.40)	(\$0.97)	-			
	4Q	(\$7.13)	(\$0.99)	-			
	FY	(\$15.64)	(\$4.26)	(\$4.74)			
Source: Company reports and JMP Securities LLC							



MARKET OUTPERFORM | Price: \$11.43 | Target Price: \$19.00

INVESTMENT HIGHLIGHTS

Egalet-001 NDA filing remains on track for 4Q14; reiterate our Market Outperform rating and \$19 price target on Egalet. The company reported 1Q14 earnings below our and consensus estimates due to higher than expected expenses. Egalet ended 1Q14 with cash of \$77.5MM and we believe this is enough to fund through the approval and launch of Egalet-001. The company remains on track to complete bioequivalence studies and to submit an NDA for Egalet-001 in 4Q14. In addition, it has ramped manufacturing in preparation for a projected 2H15 launch. We continue to believe Egalet-001 could be the first approved, abuse-deterrent, long-acting morphine on the market. Our \$19 price target is derived through a sum-of-the-parts NPV analysis of Egalet-001 and Egalet-002.

Clinical progress in support of an abuse-deterrent label. As previously reported, positive results of the Egalet-001 category 1, abuse-deterrent study demonstrated abuse-deterrent properties of Egalet-001 vs. MS Contin. The company has initiated the second part of the category 1 studies and results are expected during 2Q14. Also during 2Q14, Egalet expects to initiate category 2 and 3, pharmacokinetic and clinical abuse-potential studies for Egalet-001. These studies are being conducted to support an abuse-deterrent label in accordance with FDA draft guidance. Prior to the NDA filing, the company expects to participate in a pre-NDA meeting with the FDA. For Egalet-002, the company plans to initiate category 2 and 3 abuse deterrence studies during 3Q14 and a pivotal Phase 3 trial in 4Q14.

Prelaunch preparations underway. The company is ramping manufacturing capabilities and completed a tech transfer from its manufacturing facility in Denmark to Halo Pharmaceuticals in NJ, its contract manufacturing partner. This has increased production of batches to 60x previous capacity in preparation for commercial supply of Egalet-001. Additionally, the company has 50-60 sales reps ready to reach out to ~5,000 U.S. pain specialists, and stated that within 12-18 months it will also look for a partner that has a footprint in primary care.

Early stage on deck for clinical development. Egalet plans to initiate a Phase 1 clinical trial for Egalet-003, the company's third opioid abuse-deterrent product candidate in 1Q15. The company continues to evaluate the technical feasibility, commercial opportunity, and competitive landscape for this product candidate.



1Q14 FINANCIAL SUMMARY

Egalet reported a 1Q14 net income loss of (\$12.9MM), below our estimate of (\$9.4MM) and consensus of (\$0.6MM), due to higher than expected operating expenses. The company did not report any revenue, in line with our projection, while consensus looked for \$3.3MM in revenue. Total operating expenses were \$6MM, above our estimate of \$5MM, driven by higher than expected SG&A costs due to the hiring of personnel, a stock compensation plan and costs associated with completing the IPO. R&D expenses were \$2.8MM vs. our estimate of \$3.3MM and SG&A expenses were \$3.3MM compared to our estimate of \$1.7MM. Cash and cash equivalents totaled \$77.5MM as of March 31, 2014.

We have revised our model to include 1Q14 financial results and updated guidance as summarized in Figure 1.

FIGURE 1. 1Q14 Earnings Summary and Changes to Our Model

EGLT	1Q14			2014 est			2015 est		
	JMPest	Cons	Actual	JMP old	Cons	JMP new	JMP old	Cons	JMP new
Revenue	0.0	3.3	0.3	0.0	3.3	0.3	0.0	3.9	0.0
R&D	3.3		2.8	14.5		12.3	21.8		19.7
SG&A	1.7		3.3	7.5		13.5	18.7		20.2
Total operating expense	5.0		6.0	22.0		25.8	40.5		40.0
Net income (loss)	(9.4)	0.6	(12.9)	(39.6)	(35.3)	(54.0)	(58.1)	(28.8)	(68.3)
Shares outstanding (diluted)	1.3		9.6	10.9		13.0	14.4		14.4
EPS (diluted)	(\$7.24)	(\$0.09)	(\$1.34)	(\$9.39)	(\$1.79)	(\$4.26)	(4.0)	(1.7)	(\$4.74)

Source: JMP Securities LLC, Company reports

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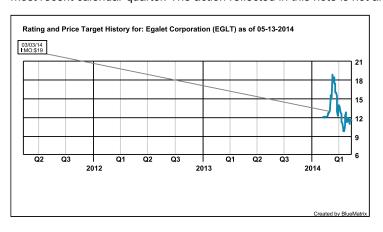
Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months. Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months. Market Underperform (MU): JMP Securities expects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

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		# Co's	%		# 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	254	57.99%	Buy	254	57.99%	98	38.58%
MARKET PERFORM	Hold	136	31.05%	Hold	136	31.05%	17	12.50%
MARKET UNDERPERFORM	Sell	5	1.14%	Sell	5	1.14%	0	0%
COVERAGE IN TRANSITION		43	9.82%		43	9.82%	0	0%
TOTAL:		438	100%		438	100%	115	26.26%

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 quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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Egalet Corporation (EGLT)



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