Egalet Corporation (EGLT)

No Surprises in 4Q13 as Clinical Development Remains on Track

MARKET OUTPERFORM | Price: $15.25 | Target Price: $19.00

MARKET DATA

Price	$15.25
52-Week Range:	$11.82 - $19.85
Shares Out. (M):	14.7
Market Cap ($M):	$224.2
Average Daily Vol. (000):	44.0
Cash (M):	$72
Cash/Share:	$4.92
Enterprise Value (M):	$143
LT Debt (M):	$0

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013E	2014E	2015E
Revenue ($M)	1Q	$0.0	$0.0	--
	2Q	$0.0	$0.0	--
	3Q	$0.0	$0.0	--
	4Q	$0.0	$0.0	--
	FY	**$0.0**	**$0.0**	**$0.0**
EPS	1Q	($3.40)A	($2.93)	--
	2Q	($3.40)A	($0.28)	--
	3Q	($3.40)A	($0.29)	--
	4Q	($2.84)	($0.30)	--
	FY	**($13.05)**	**($3.80)**	**($1.81)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Clinical progress and 2014 catalysts for Egalet-001 and -002 abuse-deterrent pain products remain on track; reiterate Market Outperform rating and $19 price target on Egalet. Egalet reported 2013 earnings below our and consensus estimates due to higher than expected expenses. The company ended 2013 with cash of $15.7MM, which together with ~$65MM proceeds from the company's IPO in January 2014, and simultaneous private placement with Shionogi, should be sufficient to fund operations through the approval and launch of Egalet-001. We look to multiple pipeline catalysts in 2014, including the NDA submission of Egalet-001 in 4Q14, as well as initiation of a pivotal Phase 3 trial for Egalet-002, both of which assets have been granted fast-track status by the FDA and which, in our view, appropriately address the FDA's abuse-deterrent guidelines. Our $19 price target is derived through a sum-of-the-parts NPV analysis of Egalet-001 and Egalet-002.

Progressing to NDA filing for Egalet-001 in 2014. Egalet-001 is an abuse-deterrent, extended-release, oral morphine formulation that is designed to specifically deter abuse by injection. Results from a confirmatory PK study from January 2014 demonstrated bioequivalence to MS Contin. Pivotal bioequivalent studies were initiated in March 2014, while Egalet anticipates completing the first phase of category 1 abuse deterrence studies for Egalet-001 in 1Q14, followed by initiation of category 2 and 3 abuse deterrence studies in 2Q14. The company reiterated guidance to submit the NDA for Egalet-001 in 4Q14. In our view, the product has a possible first-to-market advantage, and we see potential for rebranding of the oral morphine market.

Initiation of Pivotal Phase 3 trial slated for 4Q14. Egalet-002 is an oral, abuse-deterrent, extended-release formulation of oxycodone. The company plans to initiate the second phase of category 1 abuse-deterrence studies for Egalet-002 in 2Q14, followed by the initiation of category 2 and 3 abuse deterrence studies in 3Q14. In 4Q14, the company anticipates initiating its pivotal Phase 3 trial for Egalet-002 and aims to file the NDA in 1H16. We continue to believe that Egalet's technology effectively addresses the primary method of abuse for oxycodone, crushing and snorting, and is differentiated from current and emerging abuse-deterrent products.

Early-stage pipeline to be progressed into clinical development. Egalet anticipates initiating a Phase 1 clinical trial for Egalet-003, the company's third opioid abuse-deterrent product candidate, in early 2015.

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FY 2013 FINANCIAL SUMMARY

Egalet reported FY 2013 net income loss of ($20.2MM), below our estimate of ($14.7MM) and consensus estimates of ($13.7MM), due to higher than expected operating expenses and interest expense. The company did not report any revenue, in line with our projection, while consensus looked for $2.5MM in revenue. Total operating expenses were $11.2MM, above our estimate of $8.6MM, driven by higher than expected R&D and SG&A costs. R&D expenses were $6.3MM vs. our estimate of $4.3MM, and SG&A expenses were $4.9MM compared to our estimate of $4.3MM. Cash and cash equivalents totaled $15.7MM as of December 31, 2013.

We have updated our model to include 2013 financial results and updated guidance as summarized in Figure 1.

FIGURE 1. 2013 Earnings Summary and Changes to Our Model

EGLT	2013 est			2014 est		
	JMP est	Cons	Actual	JMP old	Cons	JMP new
Revenue	**0.0**	**2.5**	**0.0**	**0.0**	**3.9**	**0.0**
R&D	4.3		6.3	5.2		14.5
SG&A	4.3		4.9	5.0		7.5
Total operating expense	8.6		11.2	101.6		22.0
Net income (loss)	**(14.7)**	**(13.7)**	**(20.2)**	**(16.1)**	**(34.6)**	**(39.6)**

Source: JMP Securities LLC, Company reports

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.

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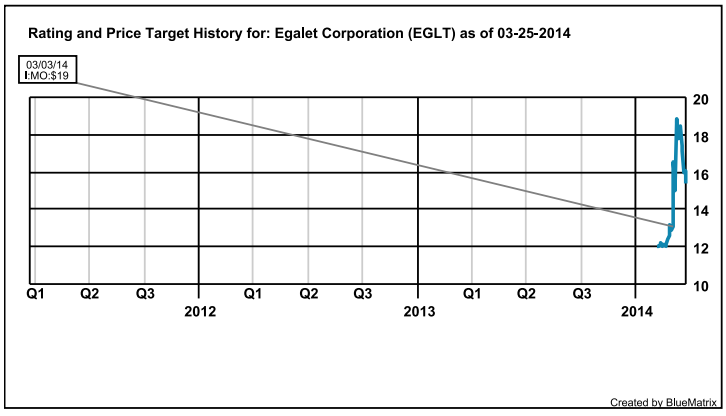
MARKET OUTPERFORM	Buy	250	*57.34%*	Buy	250	*57.34%*	99	*39.60%*
MARKET PERFORM	Hold	136	*31.19%*	Hold	136	*31.19%*	15	*11.03%*
MARKET UNDERPERFORM	Sell	7	*1.61%*	Sell	7	*1.61%*	0	*0%*
COVERAGE IN TRANSITION		43	*9.86%*		43	*9.86%*	0	*0%*
TOTAL:		436	*100%*		436	*100%*	114	*26.15%*

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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