

# **Egalet Corporation (EGLT)**

Abuse-Deterrent Platform Validated by FDA Guided Liability Study

MARKET DATA	
Price	\$6.11
52-Week Range: Shares Out. (M):	\$3.81 - \$19.85 17.3
Market Cap (\$M):	\$105.7
Average Daily Vol. (000): Cash (M):	20.0 \$60
Cash/Share:	\$3.45
Enterprise Value (M):	\$129
LT Debt (M):  Source: Thomson Reuters and JMP Securities LLC	\$0

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	\$0.0	\$0.3A	
	2Q	\$0.0	\$0.5A	
	3Q	\$0.0	\$0.3A	
	4Q	\$0.0	\$0.0	
	FY	\$0.0	\$1.1	\$0.0
EPS	1Q	(\$1.39)	(\$1.34)A	-
	2Q	(\$3.40)	(\$0.73)A	
	3Q	(\$3.40)	(\$0.63)A	
	4Q	(\$7.13)	(\$0.68)	
	FY	(\$15.64)	(\$3.38)	(\$3.75)



MARKET OUTPERFORM | Price: \$6.11 | Target Price: \$13.00

# **INVESTMENT HIGHLIGHTS**

Positive Egalet-001 abuse-liability results reinforce differentiated product profile; reiterate our Market Outperform rating and \$13 price target on Egalet (EGLT). This morning, Egalet announced positive top-line results from a Category 3 abuse liability study for Egalet-001. Results from this trial demonstrated that the potential for abuse with Egalet-001 was significantly reduced vs. MS Contin, the currently available non-abuse deterrent, extended release morphine product. In our view, these results support the abuse-deterrent properties (and likely representation thereof in a potential product label) of Egalet-001 and, more broadly, for Egalet's Guardian technology. We look to further visibility on the path to approval for Egalet-001 in 1Q15 as a key near-term, value-driving catalyst. Our \$13 price target is derived through a sum-of-the-parts NPV analysis of Egalet-001 and Egalet-002, with recent product acquisitions that represent potential upside to our current assumptions.

Category 3 studies show that when physically manipulated, Egalet-001 retains its abuse-deterrent characteristics. The Category 3 study was a single-center, randomized, double-blind, four-way crossover study evaluating the abuse potential of oral Egalet-001 versus MS Contin in 38 non-dependent, recreational opioid users. The study compared the relative abuse potential of intact and manipulated formulations of Egalet-001 versus manipulated MS Contin. On the primary endpoint of drug liking as measured by Emax, the score for manipulated Egalet-001 was significantly lower than the Emax for manipulated MS Contin (p < 0.007). Furthermore, there was no difference in preference for intact vs. manipulated Egalet-001, supporting that Egalet-001 retains its abuse-deterrent properties after extensive manipulation. We believe these results build upon the Category 1 studies and we look to additional detail on planned Phase 3 studies that are slated to begin in 1Q15 and additional abuse-deterrent studies in 2015.

Jason N. Butler, PhD jbutler@jmpsecurities.com (212) 906-3505



# **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 on 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.

January 23, 2015 2



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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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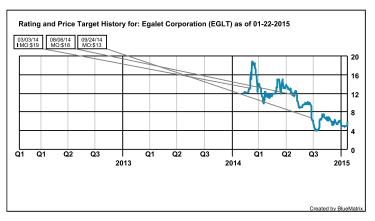
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		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	288	64.14%	Buy	288	64.14%	99	34.38%
MARKET PERFORM	Hold	151	33.63%	Hold	151	33.63%	20	13.25%
MARKET UNDERPERFORM	Sell	7	1.56%	Sell	7	1.56%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL:		449	100%		449	100%	121	26.95%

## **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.

January 23, 2015 3





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Jeffrey H. Spurr Director of Research (415) 835-3903

# **RESEARCH PROFESSIONALS**

#### **FINANCIAL SERVICES**

Alternative Asset Managers		Medical Devices & Supplies	
Devin Ryan	(212) 906-3578	David Turkaly	(212) 906-3563
Brian McKenna	(212) 906-3545	John Gillings	(212) 906-3564
		Curacialty, Dhammanayticala	
Commercial & Specialty Finance	(445) 005 0005	Specialty Pharmaceuticals	(040) 000 0500
Christopher York	(415) 835-8965	Oren G. Livnat, CFA	(212) 906-3566
Hannah Kim, CFA	(415) 835-8962	Nazibur Rahman	(212) 906-3519
Canadan Financa		DEAL ESTATE	
Consumer Finance	(445) 025 0042	REAL ESTATE	
David M. Scharf	(415) 835-8942	Hausing 9 Land Davelanment	
Douglas Greiner	(212) 906-3525	Housing & Land Development Peter L. Martin, CFA	(445) 025 0004
Figure 1-1 Burner 1 and 0 Outs according			(415) 835-8904
Financial Processing & Outsourcing	(445) 005 0040	Aaron Hecht	(415) 835-3963
David M. Scharf	(415) 835-8942	Bharathwajan Iyengar	(415) 835-3902
Douglas Greiner	(212) 906-3525	Ladalan O Lalauna	
		Lodging & Leisure	(040) 000 0540
Insurance		Robert A. LaFleur	(212) 906-3510
Matthew J. Carletti	(312) 768-1784	Whitney Stevenson	(212) 906-3538
Christine Worley	(312) 768-1786		
		Property Services	
Investment Banks & Brokers		Mitch Germain	(212) 906-3546
Devin Ryan	(212) 906-3578	Peter Lunenburg	(212) 906-3537
Brian McKenna	(212) 906-3545		
		REITs: Healthcare, Residential, & Speci-	
Mortgage Operating Companies		Peter L. Martin, CFA	(415) 835-8904
REITs: Agency, Hybrid, & Commercial N	lortgage	Aaron Hecht	(415) 835-3963
Steven C. DeLaney	(404) 848-7773	Arthur Kwok	(415) 835-8908
Trevor Cranston, CFA	(415) 869-4431		
Charter Robinson	(757) 613-8955	REITs: Office, Industrial, & Diversified	
Benjamin Zucker	(212) 906-3529	Mitch Germain	(212) 906-3546
<b>,</b>	( ,	Peter Lunenburg	(212) 906-3537
HEALTHCARE		-	
		Residential Services	
Biotechnology		Peter L. Martin, CFA	(415) 835-8904
Liisa A. Bayko	(312) 768-1785	Aaron Hecht	(415) 835-3963
Masha Chapman	(415) 835-8944	Bharathwajan Iyengar	(415) 835-3902
Bhumika Sharma, PhD	(312) 768-1795	, , ,	, ,
Jason N. Butler, PhD	(212) 906-3505	TECHNOLOGY	
Michael G. King, Jr.	(212) 906-3520		
Bryan Czyzewski, PhD	(212) 906-3577	Communications Infrastructure & Interr	net Security
,,_,,	(= 1=) 111 1111	Erik Suppiger	(415) 835-3918
Healthcare Services & Facilities		John Lucia	(415) 835-3920
Peter L. Martin, CFA	(415) 835-8904		, ,
Aaron Hecht	(415) 835-3963	Internet & Digital Media	
Arthur Kwok	(415) 835-8908	Ronald V. Josey III	(212) 906-3528
/ utilal revole	(110) 000 0000	Andrew Boone, CFA	(415) 835-3957
Life Science Tools & Diagnostics		Ignatius Njoku	(415) 835-8960
J. T. Haresco, III, PhD	(415) 869-4477	Michael Wu	(415) 835-8996
Marie T. Casey, PhD	(415) 835-3955		( )
Marie 1. Oddey, 1 11D	(+10) 000-0000	Software	
Medical Devices		Patrick Walravens	(415) 835-8943
J. T. Haresco, III, PhD	(415) 869-4477	Peter Lowry	(415) 869-4418
Marie T. Casey, PhD	(415) 835-3955	Mathew Spencer	(415) 835-8930
Marie 1. Casey, FIID	(710) 000-0800	Greg McDowell	(415) 835-3934
		Rishi Jaluria	(415) 835-3961
		เมื่อแเงสเนแส	( <del>+</del> 13) 033-380 1
		Wireless & Cloud Computing Technolog	nies
		Alex Gauna	(415) 835-8998

# **ADDITIONAL CONTACTS**

Thomas R. Wright Director of Equities (212) 906-3599 Dan Wychulis Director of Institutional Sales (617) 235-8530

Alex Gauna

**600 Montgomery Street, Suite 1100** San Francisco, CA 94111 www.jmpsecurities.com

(415) 835-8998