

Egalet Corporation (EGLT)

Looking to FDA Input on Egalet-001 Following Bioequivalence Setback

MARKET DATA

Price	\$11.77
52-Week Range:	\$9.54 - \$19.85
Shares Out. (M):	14.7
Market Cap (\$M):	\$173.0
Average Daily Vol. (000):	24.0
Cash (M):	\$78
Cash/Share:	\$4.49
Enterprise Value (M):	\$129
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$11.77 | Target Price: \$18.00

INVESTMENT HIGHLIGHTS

Bioequivalence uncertainty may result in delay to Egalet-001 timelines, however, our confidence in the probability of success remains; reiterate our Market Outperform rating on Egalet while lowering our price target from \$19 to \$18.

This morning, Egalet announced mixed results from two pivotal bioequivalence trials for Egalet-001, the company's abuse deterrent morphine candidate. The trials demonstrated that the FDA's criteria for bioequivalence were met with regards to the Area Under the Curve (AUC) endpoint, but not peak plasma concentration (Cmax). The company is exploring the optimal path forward for this development program, with scenarios including pursuing approval under the bioequivalence pathway for certain doses or conducting a pivotal efficacy trial. Conservatively, we have updated our model to assume a delay to approval of approximately 18 months which results in the decrease to our price target. However, we remain confident in the clinical benefit and utility that Egalet-001 provides, as well as the company's broader abuse deterrent formulation platform.

Consistent demonstration of bioequivalent AUC across multiple trials provides confidence in efficacy. Egalet has demonstrated in four trials that the AUC for Egalet-001 consistently achieves bioequivalence to MS Contin. Management noted on the conference call that it is well established that AUC is the most important PK measure for long-acting opioids with respect to predictive efficacy. We also note that results from Study 067-EG-004, announced today, support that there is no clinically relevant food effect with Egalet-001 which we view as an additional positive.

Cmax miss represents a speed bump, not a road block, in our view. The FDA's guidance for demonstrating bioequivalence includes a predefined range for the 90% confidence interval of Cmax to be within 80% to 125% of the reference drug. During the conference call, management provided additional color on the Cmax endpoint stating that while the mean Cmax was within the predefined range, the upper bound of the confidence interval exceeded the upper bound of the allowed range.

Looking to visibility on next steps based on FDA feedback. Management stated that it will leverage its priority status with the FDA to determine the optimal and fastest path forward for Egalet-001. One scenario is the potential to seek approval for the 60mg dose based on positive bioequivalence results from a previous trial. These data could later be supplemented with additional data for the 100mg dose, possibly including data from a pivotal efficacy trial. Management noted that ~90% of MS Contin prescriptions fall within 15mg-60mg, thus this represents a commercially viable strategy. Should the FDA require an efficacy trial prior to approval, we estimate that this would result in an ~18 month delay to approval and this conservative scenario is reflected in our updated

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

STOCK PRICE PERFORMANCE



price target. While the company did not speculate on the size or design of a possible efficacy trial, we do note that the company already plans to conduct a similar trial for Egalet-002.

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.

JMP FACTS AND DISCLOSURES

Analyst Certification:

The research analyst(s) who prepared this report does/do hereby certify that the views presented in this report are in accordance with my/our personal views on the securities and issuers discussed in this report. As mandated by SEC Regulation AC no part of my/our compensation was, is or will be directly or indirectly related to the specific views or recommendations expressed herein. This certification is made under the obligations set forth in SEC Regulation AC. Any other person or entity may not use it for any other purpose. This certification is made based on my/our analysis on the date of this report's publication. I/We assume no obligation to update this certification to reflect any facts, circumstances or events that may subsequently come to my/our attention. Signed Jason N. Butler

JMP Securities Disclosures:

JMP Securities currently makes a market in the security of Egalet Corporation

JMP Securities has received compensation for banking or other services rendered to Egalet Corporation in the past 12 months.

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.

JMP Securities Investment Opinion Definitions:

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.

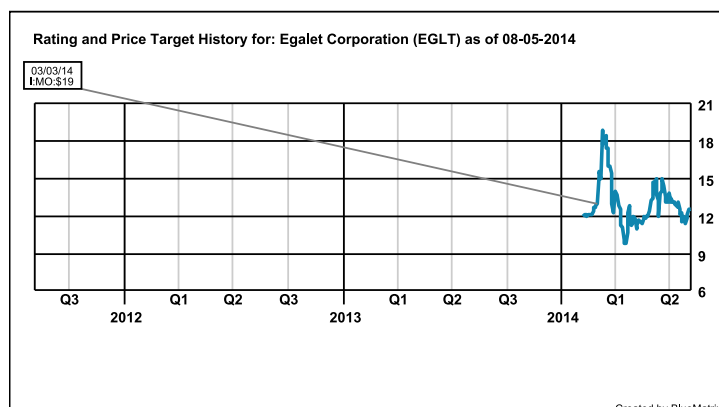
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of August 6, 2014)

JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
MARKET OUTPERFORM	Buy	266	60.05%	Buy	266	60.05%	98	36.84%
MARKET PERFORM	Hold	137	30.93%	Hold	137	30.93%	18	13.14%
MARKET UNDERPERFORM	Sell	4	0.90%	Sell	4	0.90%	0	0%
COVERAGE IN TRANSITION		36	8.13%		36	8.13%	0	0%
TOTAL:		443	100%		443	100%	116	26.19%

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.



JMP Disclaimer:

JMP Securities LLC (the "Firm") compensates research analysts, like other Firm employees, based on the Firm's profitability, which includes revenues from the Firm's institutional sales, trading, and investment banking departments as well as on the quality of the services and activities performed that are intended to benefit the Firm's institutional clients. These data have been prepared by JMP Securities LLC for informational purposes only and are based on information available to the public from sources that we believe to be reliable, but we do not guarantee their accuracy or completeness. Any opinions and projections expressed herein reflect our judgment at this date and are subject to change without notice. These data are neither intended nor should be considered as an offer to sell or a solicitation or a basis for any contract for the purchase of any security or other financial product. JMP Securities LLC, its affiliates, JMP Group LLC, Harvest Capital Strategies LLC, and their respective partners, directors, officers, and associates may have a long or short position in, may act as a market maker for, or may purchase or sell a position in the securities mentioned herein. JMP Securities LLC or its affiliates may be performing, have performed, or seek to perform investment banking, advisory, or other services and may have acted as manager or co-manager for a public offering of securities for any company mentioned herein. The reader should assume that JMP Securities LLC will solicit business from the company covered in this report. Members of our Sales and Trading Department provide oral and/or written market opinions and trading strategies to our clients that reflect their personal opinions about stocks that are the subject of the firm's research reports. Our research analysts discuss trading strategies with clients that sometimes reflect short-term expectations for the price of the securities that are the subject of research reports. These trading strategies are distinct from the analysts' fundamental rating for the stock, which is based upon the analysts' view compared to other stocks under coverage for the relevant time period. © Copyright 2014. All rights reserved by JMP Securities LLC. JMP Securities LLC is a member of FINRA, NASDAQ, and SIPC.

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

RESEARCH PROFESSIONALS

FINANCIAL SERVICES

Alternative Asset Managers

Devin Ryan	(212) 906-3578
Brian McKenna	(212) 906-3545

Commercial & Specialty Finance

Christopher York	(415) 835-8965
Hannah Kim, CFA	(415) 835-8962

Consumer Finance

David M. Scharf	(415) 835-8942
Jeremy Frazer	(312) 768-1796

Financial Processing & Outsourcing

David M. Scharf	(415) 835-8942
Jeremy Frazer	(312) 768-1796

Insurance

Matthew J. Carletti	(312) 768-1784
Christine Worley	(312) 768-1786

Investment Banks & Brokers

Devin Ryan	(212) 906-3578
Brian McKenna	(212) 906-3545

Mortgage Operating Companies

REITs: Agency, Hybrid, & Commercial Mortgage

Steven C. DeLaney	(404) 848-7773
Trevor Cranston, CFA	(415) 869-4431
Charter Robinson	(757) 613-8955
Benjamin Zucker	(212) 906-3529

HEALTHCARE

Biotechnology

Liisa A. Bayko	(312) 768-1785
Andrew Prigodich, PhD	(312) 768-1788
Bhumika Sharma, PhD	(312) 768-1795
Jason N. Butler, PhD	(212) 906-3505
Caroline Palomeque	(212) 906-3509
Michael G. King, Jr.	(212) 906-3520
Bryan Czyzewski, PhD	(212) 906-3577
Eric Joseph, PhD	(212) 906-3514

Healthcare Services & Facilities

Peter L. Martin, CFA	(415) 835-8904
Aaron Hecht	(415) 835-3963
Arthur Kwok	(415) 835-8908

Life Science Tools & Diagnostics

J. T. Haresco, III, PhD	(415) 869-4477
Marie T. Casey, PhD	(415) 835-3955

Medical Devices

J. T. Haresco, III, PhD	(415) 869-4477
Marie T. Casey, PhD	(415) 835-3955

Medical Devices & Supplies

David Turkaly	(212) 906-3563
John Gillings	(212) 906-3564

Specialty Pharmaceuticals

Oren G. Livnat, CFA	(212) 906-3566
Nazibur Rahman	(212) 906-3519

REAL ESTATE

Housing & Land Development

Peter L. Martin, CFA	(415) 835-8904
Aaron Hecht	(415) 835-3963
Bharathwajan Iyengar	(415) 835-3902

Lodging & Leisure

Robert A. LaFleur	(212) 906-3510
Whitney Stevenson	(212) 906-3538

Property Services

Mitch Germain	(212) 906-3546
Peter Lunenburg	(212) 906-3537

REITs: Healthcare, Residential, & Specialty

Peter L. Martin, CFA	(415) 835-8904
Aaron Hecht	(415) 835-3963
Arthur Kwok	(415) 835-8908

REITs: Office, Industrial, & Diversified

Mitch Germain	(212) 906-3546
Peter Lunenburg	(212) 906-3537

Residential Services

Peter L. Martin, CFA	(415) 835-8904
Aaron Hecht	(415) 835-3963
Bharathwajan Iyengar	(415) 835-3902

TECHNOLOGY

Communications Equipment & Internet Security

Erik Suppiger	(415) 835-3918
John Lucia	(415) 835-3920

Internet & Digital Media

Ronald V. Josey III	(212) 906-3528
Andrew Boone, CFA	(415) 835-3957
Michael Wu	(415) 835-8996

Software

Patrick Walravens	(415) 835-8943
Peter Lowry	(415) 869-4418
Greg McDowell	(415) 835-3934

Wireless & Cloud Computing Technologies

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

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