

Egalet Corporation (EGLT)

Lowering Price Target to Reflect Egalet-001 Setback

MARKET DATA

Price	\$9.31
52-Week Range:	\$8.74 - \$19.85
Shares Out. (M):	14.7
Market Cap (\$M):	\$136.9
Average Daily Vol. (000):	40.0
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)	(\$3.24)
Previous FY		NC	NC	(\$3.13)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



MARKET OUTPERFORM | Price: \$9.31 | Target Price: \$13.00

INVESTMENT HIGHLIGHTS

Additional bioequivalence trial results confirm Egalet-001 setback; reiterate Market Outperform rating and lower price target on Egalet to \$13 from \$18. Egalet announced the results from a third bioequivalence trial comparing Egalet-001 to MS Contin. The results from the trial, evaluating a 15mg dose of Egalet-001, were in line with the previous trial for the 100mg dose, demonstrating that the bioequivalence standard was met for the AUC parameter, but not Cmax. Based on these results, we now view it as likely that an additional Phase 3 efficacy/safety trial will be required to support an NDA filing, and we now estimate NDA submission in mid-2016 vs. our prior assumption of 1H15. We lower our price target to reflect the extended timelines and increased clinical uncertainty. Our \$13 price target is derived through an unchanged sum-of-the-parts NPV analysis of Egalet-001 and Egalet-002.

Phase 3 pivotal trial likely required for mid-2016 NDA application. The company announced top-line data from study 067-EG-006, the third bioequivalence trial for Egalet-001, its abuse deterrent morphine tablet. Study 067-EG-006 was a single dose, open label, cross-over pharmacokinetic (PK) study of Egalet-001 15 mg vs. MS Contin 15 mg in 64 fasting subjects. Egalet-001 met the bioequivalence criteria (90% confidence interval of 80-125%) on the measure of AUC with a ratio of 95.12% (90% confidence interval of 91.01-99.42%). On the measure of Cmax, the ratio of Egalet-001 to MS Contin was 83.6%, and was within the range necessary for bioequivalence (80-125%); however, the 90% confidence interval was 78.99-88.47%, outside the lower bound for bioequivalence (90% confidence interval of 80-125%). Egalet-001 was well-tolerated, and no serious adverse events were reported. Management emphasized that five trials have now demonstrated a consistent AUC profile for Egalet-001, equivalent to MS Contin. Due to these results, we now view it as likely that a Phase 3 efficacy/safety trial will be required to support an NDA filing, and we now estimate the NDA submission in mid-2016.

Focus on FDA meeting and regulatory path forward. Management plans to hold a Type A meeting with the FDA in 4Q14 to discuss the viability of a bioequivalence path forward for Egalet-001, and if so, find out if additional PK studies are sufficient for registration. However, based on the mixed results from the bioequivalence trials, we believe a Phase 3 pivotal trial will be required to support FDA approval. On the call, management reiterated additional color on the Phase 3 trial, including that it will cost \$8-10 million to conduct and enroll ~300 patients with chronic lower back pain. The trial is planned to begin in 1Q15, with results expected by YE15. We note that this update does not affect Egalet's other programs, and there are no changes in the timing for Egalet-002, for which Egalet has already committed to conducting a Phase 3 trial. The NDA for Egalet-002 remains on track for filing in 1H16.

Updating model and valuation to reflect update. We are pushing back our expectation for the Egalet-001 launch by ~12 months, from the beginning of 2017 to the beginning of 2018, assuming NDA filing in mid-2016. We are also lowering our probability of success from 65% to 55%, in-line with our assumption for Egalet-002, to reflect the increased uncertainty with the program. We are not making any changes to our assumptions for peak market share of 8%, although we now project this to be achieved in 2023 vs. 2022 previously. These changes lower our NPV forecast for the asset by ~31%. We are also now including an assumed equity financing in 2015 vs. our previous assumption of 2016 to reflect the increased costs of the Egalet-001 development program. These additional shares (~4 million) are included in our price target calculation. Finally, we have updated our expense estimate to include the additional costs associated with the Phase 3 trial. While we have lowered our probability of success for Egalet-001, we continue to believe that the development plan remains low risk compared to NCE drug candidates.

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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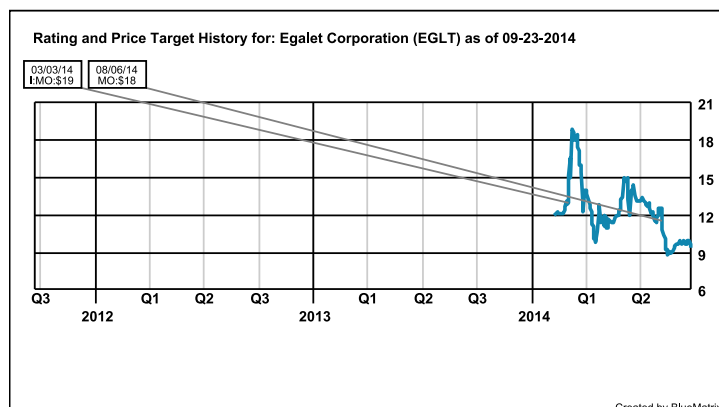
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MARKET OUTPERFORM	Buy	274	60.62%	Buy	274	60.62%	101	36.86%
MARKET PERFORM	Hold	138	30.53%	Hold	138	30.53%	20	14.49%
MARKET UNDERPERFORM	Sell	4	0.88%	Sell	4	0.88%	0	0%
COVERAGE IN TRANSITION		36	7.96%		36	7.96%	0	0%
TOTAL:		452	100%		452	100%	121	26.77%

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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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
Douglas Greiner	(212) 906-3525

Financial Processing & Outsourcing

David M. Scharf	(415) 835-8942
Douglas Greiner	(212) 906-3525

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 Infrastructure & 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
Ignatius Njoku	(415) 835-8960
Michael Wu	(415) 835-8996

Software

Patrick Walravens	(415) 835-8943
Peter Lowry	(415) 869-4418
Mathew Spencer	(415) 835-8930
Greg McDowell	(415) 835-3934
Rishi Jaluria	(415) 835-3961

Wireless & Cloud Computing Technologies

Alex Gauna	(415) 835-8998
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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