Egalet Corporation (EGLT)

Spending Well-Controlled as Development Progress Continues

MARKET OUTPERFORM | Price: $6.49 | Target Price: $13.00

MARKET DATA

Price	$6.49
52-Week Range:	$3.81 - $19.85
Shares Out. (M):	14.7
Market Cap ($M):	$95.4
Average Daily Vol. (000):	14.0
Cash (M):	$60
Cash/Share:	$3.46
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	$0.3A	--
	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)**	**($2.87)**
Previous FY		NC	($3.70)	($3.24)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Looking to the initiation of Phase 3 trials for two lead development candidates in 1H15; reiterate Market Outperform rating and $13 price target on Egalet (EGLT). Egalet reported 3Q14 earnings results ahead of our and consensus estimates due to lower than expected operating expenses. The company ended the quarter with $60M in cash, which we view as sufficient to fund operations into 2016. The company is continuing its dialog with the FDA regarding the development path for Egalet-001, and at the same time, remains on-track to initiate Category 3 abuse-deterrent studies for Egalet-002 in 4Q14. We look to continued clinical progress in 2015, including advancement of both Egalet-001 and Egalet-002 into Phase 3 trials. Our $13 price target is derived through a sum-of-the-parts NPV analysis of Egalet-001 and Egalet-002.

Egalet-001 Phase 3 trial is on-track to initiate in 1Q15. Management remains in discussion with the FDA on the scope and design of a Phase 3 program for Egalet-001. It expects to receive FDA feedback by early 2015, and be in a position to begin a Phase 3 trial in 1Q15. This trial is still expected to cost ~$10-12M, and manufacturing of clinical trial material is already underway. In addition, the company continues to make progress with abuse-deterrent studies for Egalet-001, and data from Category 3 studies are anticipated in 1H15.

Egalet-002 Phase 3 pivotal trial expected in 1Q15. In 3Q14, management held an end of Phase 2 meeting with the FDA for Egalet-002, which it deemed successful. The company is on-track to initiate a Category 3 abuse-deterrent study for Egalet-002 in 4Q14, with results anticipated in mid-2015. It also reiterated its plan to initiate pivotal Phase 3 efficacy and safety trials for the candidate in 1Q15.

FDA meeting on abuse-deterrent formulations (ADF) highlights focus on medical need. We recently attended an FDA public meeting on abuse-deterrent opioids in which the agency expressed a high level of focus on and support for the development of ADF (abuse-deterrent formulations) opioids. This meeting highlighted the need for opioid ADFs, both for branded and generic products, continued advancement of development and labeling frameworks, as well as striking a balance between appropriate risk mitigation and patient access.

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3Q14 FINANCIAL SUMMARY

Egalet reported a 3Q14 net income loss of ($10.2M), above our estimate of ($12.7M) and consensus of ($12.1M), due to lower than expected operating expenses. The company reported revenue of $0.3M, above both our projection and consensus. Total operating expenses were $10.5M, below our estimate of $12.7M, driven by lower than expected R&D and SG&A costs. R&D expenses were $6.3M vs. our estimate of $7.9M, and SG&A expenses were $4.2M compared to our estimate of $4.8M. Cash totaled $59.7M as of September 30, 2014.

We have revised our model to include 3Q14 financial results and updated guidance as summarized in Figure 1.

FIGURE 1. 3Q14 Earnings Summary and Changes to Our Model

EGLT	3Q14			2014 est			2015 est		
	JMP est	Cons	Actual	JMP old	Cons	JMP new	JMP old	Cons	JMP new
Revenue	**0.0**	**0.0**	**0.3**	**0.7**	**0.6**	**1.1**	**0.0**	**1.5**	**0.0**
R&D	7.9		6.3	26.4		23.3	31.7		27.9
SG&A	4.8		4.2	17.7		16.5	21.3		19.8
Total operating expense	12.7		10.5	44.2		39.7	53.0		47.7
Net income (loss)	**(12.7)**	**(12.1)**	**(10.2)**	**(50.6)**	**(49.2)**	**(45.8)**	**(53.0)**	**(76.8)**	**(47.7)**
Shares outstanding (diluted)	16.0		16.2	14.4		14.5	16.4		16.6
EPS (diluted)	**($0.80)**	**($0.11)**	**($0.63)**	**($3.70)**	**($3.66)**	**($3.38)**	**(3.2)**	**(2.7)**	**($2.87)**

Source: JMP Securities LLC, Company reports

FDA CONVENES HEARING TO DISCUSS OPIOID ADFS

The FDA held the Development and Regulation of Abuse-Deterrent Opioids public meeting on October 30-31 in MD in order to discuss the challenges in development, manufacturing, and utilization of ADF (Abuse-Deterrent Formulations) of opioids, which are known as highly addictive painkillers. The meeting involved a panel discussion, public hearing, and companies that are developing brand name as well as generic opioids.

Overall observations noted during this meeting included:

- All opioids, including generics, should be ADF products
- ADF products are too diverse to have *in vitro* test standardization
- On product labeling, the FDA must balance patient needs with risks, to benefit the greatest number of people
- The FDA will take into consideration industry and patient perspectives on ADF products as the Draft Guidance documents evolve

All opioids should be ADF products. Due to the epidemic of abuse among prescription opioids, the FDA aims to transition existing opioids to ADF products. In addition, it is of the opinion that all opioids in development, including generics (which comprised 86% of prescriptions in 2013), should be manufactured in an abuse-deterrent formulation. While it is acknowledged that no ADF is 100% abuse deterrent, and that they are unlikely to change an addict's behavior, as they will simply switch to another opioid, including heroin, development of abuse-deterrent formulations are a priority for the FDA as studies have shown that they lower addiction rates and may prevent the advent of new addicts. It will be important to determine what percent reduction of addiction is meaningful as a standard benchmark.

ADF products are too diverse for *in vitro* test standardization. Since *in vitro* tests cannot be standardized for ADFs, they should be product-specific. Standardization, however, can play a role by having standardization based on product types (ER/IR, physical, antagonist) and specific common solvents can be required in all test batteries. The panel believes that *in vitro* testing must be done as it is important for opioids since they are highly soluble and easily transported in the body. In addition, *in vitro* is the least subjective type of test. We note that during one panel discussion, the point was made that *in vitro* testing is not sufficient, as preclinical data does not always translate to humans, and that human abuse liability studies should also be conducted. These can include observational studies in patient populations, epidemiology data, and post-marketing studies.

FDA labeling must balance risks vs. benefits to patients. Several patient advocates stressed their need for safe, effective and accessible opioid drugs. Prescription plans, price, and local availability are all important factors to consider. For example, too much red tape and barriers to access can cause elderly patients to go without medication for several days. Knowing that no abuse-deterrent is 100% effective, regarding labels, the FDA will aim to balance risks and benefits to patients. The FDA's main goal is to develop a product label that will ultimately benefit the greatest number of patients possible.

The FDA will consider input from industry and patients on evolving Draft Guidance. Many agreed that a date certain is needed when the market must convert existing opioids to ADF. The year 2020 was suggested. The following is an abbreviated summary of the different perspectives brought up to the committee which the FDA plans to take into account as it continues to develop the Draft Guidance for opioids.

- Companies developing Branded Opioids - ADF labeling is an incentive for development, conditional exclusivity would be another incentive, and reimbursement should be rewarded by payor.
- Companies developing Generic Opioids - Want to meet the same requirements as RLD (Reference Listed Drug), *in vitro* and some *in vivo* studies are needed depending upon the complexity of product, would like to see post-marketing data, generics rely on RLD to provide ADF data, so data not needed for generics.
- Payor perspective - Payors assume that the FDA has reviewed and validated the label, if ADF product should aim to deter abuse by oral misuse, which is a main route of abuse.
- Patient perspective - Patients implored the FDA to keep them in mind when developing Draft Guidance and reiterated their need for opioids with clear benefit, safety, and efficacy.

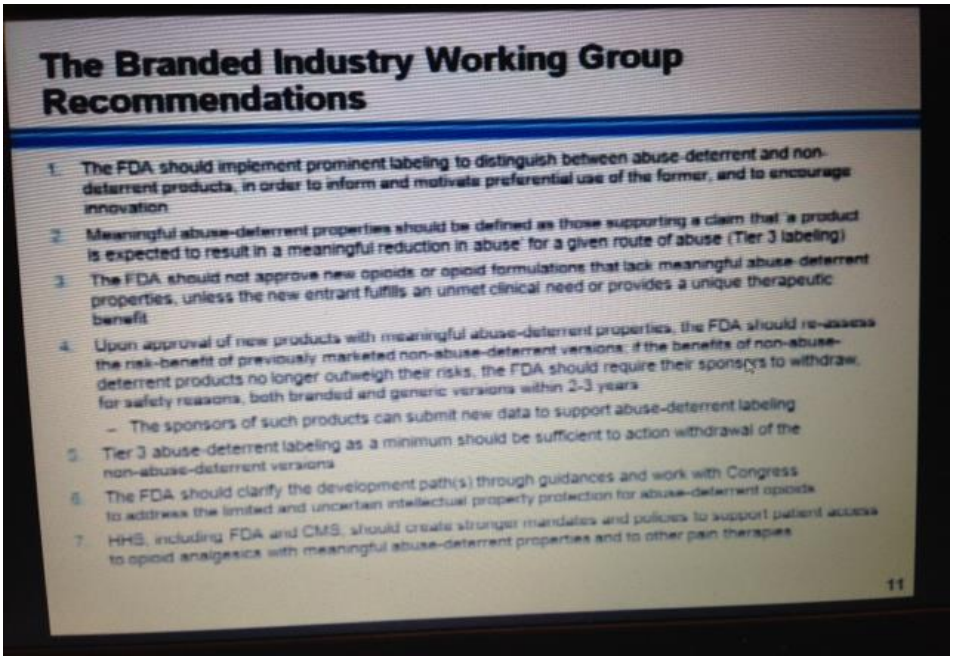
Potential for new opioid guidelines are not likely to impact Egalet's later stage development candidates. The meeting gathered input from industry, payors, and prescribers on how to address the health crisis of opioids abuse. There is agreement amongst all groups that further scientific study is needed. The FDA intends to consider and possibly incorporate the input to expand on the framework of the current Draft Guidance on opioids. There is no date set as to when the new guidance documents will be finalized, but it is expected that it will take several years to implement changes. At this time, we do not see an immediate impact on Egalet's ADF product candidates; however, earlier stage products such as Egalet-003 and their preclinical ADF hydrocodone candidates, may need to be developed under revised Draft Guidance.

FDA MEETING READ-THROUGHS TO EGALET

In our conversations with management, it acknowledges that there has been significant progress since the introduction of Draft Guidance for opioids in January 2013. It notes that cost is an important factor to be considered when making these drugs available to patients. Prescribing physicians are left to navigate payor and reimbursement issues and will often choose to prescribe the cheaper (i.e., generic) drug to their patients. A major point made by patient advocates at the meeting, and one that Egalet supports, is that the FDA must consider legitimate pain patients who rely on opioids to manage their chronic pain. The agency should not make it prohibitively difficult for pharmacies to stock opioid medications. As several patient stories illustrated, legitimate patients suffer when they cannot access their prescribed medications.

Importantly, Egalet was an active participant representing the Branded Industry Working Group at the FDA meeting. There was agreement that Category 1 data is not sufficient to enable an ADF label; therefore, clinical data needs to be generated to show meaningful abuse-deterrent properties, thus enabling a Tier 3 label. Management believes that there exists a, possibly long, regulatory path forward based on the current guidance. A decision or clarity on generic entrants with ADF is also still far away. We reiterate that it is the FDA's goal to get more ADFs on the market, or make all opioids switch to an ADF formulation. In our view, Egalet should have FDA support in the form of Draft Guidance and definitive feedback as it continues to develop its pipeline of abuse-deterrent opioids. Egalet was instrumental in developing and presenting the Branded Industry Working Group Recommendations to the FDA, as shown below.

FIGURE 2. Branded Industry Working Group Recommendations to the FDA



Source: FDA website

Egalet's technology is differentiated from competitors. There are now three opioids with ADF formulation. Two, Embeda (morphine and naltrexone), and Targiniq (oxycodone/naloxone) are extended release (ER) formulations, while OxyContin (oxycodone) is immediate release (IR). In October, the FDA approved an updated label to include abuse-deterrence (AD) studies for Pfizer's Embeda (morphine sulfate and naltrexone hydrochloride) extended-release oral capsules for oral and nasal routes. Embeda is indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment. Pfizer anticipates that Embeda will be available in the U.S. in early 2015. We note that morphine is most commonly abused by the iv route. As such, we believe that Egalet-001 is differentiated from Embeda in that it has an abuse-deterrent claim on iv use. Pfizer does not have this in its label for Embeda. In July, the FDA approved AD labeling for snorting and injecting for Purdue Pharma's Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride extended-release tablets). Targiniq is an extended-release/long-acting (ER/LA) opioid analgesic to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment. The drug is a combination agonist/antagonist, and when physically manipulated, the naloxone will act to block the effects of oxycodone. The FDA will require post-marketing studies for Targiniq to continue to evaluate abuse-deterrent properties, as well as the risk of misuse. Egalet's abuse-deterrent technology is focused on preventing physical manipulation of the product such as crushing, snorting, and injecting. It does not contain an antagonist to the opioid and therefore, its lead products are in a different abuse-deterrent category. OxyContin was approved in 2013 with AD labeling for the nasal and iv routes. Since then, an over 85% decrease in overdose deaths was seen, as well as reduced diversion. Heavy addicts, however, moved on to other opioids, including heroin, which is alarming, but does not negate the substantial medical need and potentially significant benefit of ADF products such as those being developed by Egalet.

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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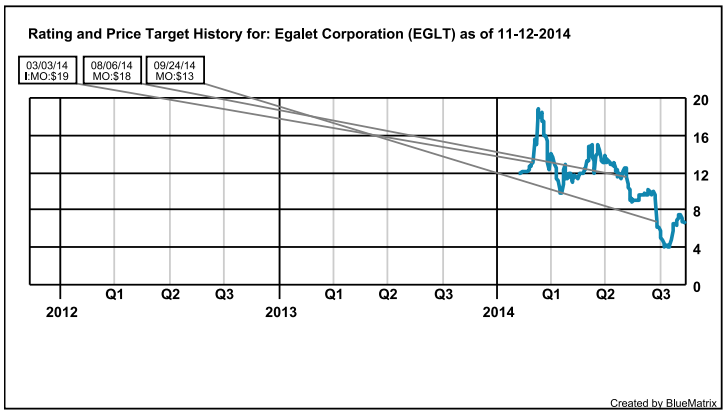
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	285	*61.03%*	Buy	285	*61.03%*	104	*36.49%*
MARKET PERFORM	Hold	141	*30.19%*	Hold	141	*30.19%*	15	*10.64%*
MARKET UNDERPERFORM	Sell	2	*0.43%*	Sell	2	*0.43%*	0	*0%*
COVERAGE IN TRANSITION		36	*7.71%*		36	*7.71%*	0	*0%*
TOTAL:		467	*100%*		467	*100%*	121	*25.91%*

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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