

Egalet Corporation (EGLT)

Initiating Coverage with a Market Outperform Rating; Differentiated Abuse-Deterrent Platform

MARKET DATA

Price	\$12.87
52-Week Range:	\$11.82 - \$13.67
Shares Out. (M):	14.7
Market Cap (\$M):	\$189.2
Average Daily Vol. (000):	92.0
Cash (M):	\$60
Cash/Share:	\$4.09
Enterprise Value (M):	\$129
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$12.87 | Target Price: \$19.00

INVESTMENT HIGHLIGHTS

We are initiating coverage on Egalet with a Market Outperform rating and \$19 price target. Egalet is a specialty pharmaceutical company focused on the development of abuse-deterrent opioids for the treatment of moderate-to-severe pain. In our view, the growing prescription drug abuse epidemic in the U.S. and heightened regulatory concern for products with abuse liability, provide a substantial opportunity for novel abuse-deterrent technologies. The company's lead development candidates are abuse-deterrent formulations of morphine and oxycodone, two of the most commonly prescribed opioids in the U.S. We believe that the company's proprietary abuse-deterrent technology can drive differentiated product offerings and we view the current clinical data as validation of large commercial opportunities. The company completed its IPO last month and we anticipate multiple clinical and regulatory catalysts in the coming 12-18 months that, in our opinion, could drive significant value. Our \$19 price target is derived through a sum-of-the-parts NPV analysis of Egalet-001 and Egalet-002.

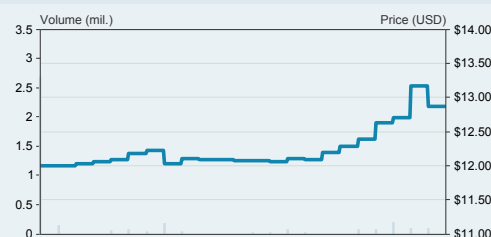
Egalet-001 has the potential to be the first-to-market, abuse-deterrent morphine tablet. Egalet's lead product, Egalet-001, is an oral, abuse-deterrent, extended release formulation of morphine. The product has demonstrated predictable pharmacokinetics and abuse-deterrent potential in initial studies. Egalet is initiating pivotal bioequivalence and clinical abuse-deterrence trials and we anticipate that an NDA will be filed in 4Q14. It has possible first-to-market advantage, and we see potential for substantial rebranding of the oral morphine market driven by the need for abuse-deterrent alternatives.

Egalet-002 addressing ER oxycodone market with potential to differentiate vs. current abuse-deterrent technologies. Egalet-002 is an oral, abuse-deterrent extended release formulation of oxycodone, which we expect to enter Phase 3 trials in 4Q14. We believe that Egalet's technology effectively addresses the primary method of abuse for oxycodone, crushing and snorting, and is differentiated from emerging abuse-deterrent products.

Abuse-deterrent technology has broad potential. We see potential application for Egalet's technologies with other opioid and non-opioid drugs, as well as combination products. We believe that this potential has been initially validated by a recent collaboration with Shionogi for hydrocodone-based candidates and anticipate that additional product candidates will be advanced into the clinic in 2014 and 2015.

Valuation based on sales of two lead candidates with conservative adoption assumptions. Our model and valuation include sales of Egalet-001 and Egalet-002. We project peak sales for these candidates of \$310MM and \$203MM, respectively, by 2030, when we assume patent expirations. We view our peak penetration assumptions, in the mid-to-high single-digit percentages for each product, as conservative, even taking into consideration the genericized market and potential for abuse-deterrent competition.

STOCK PRICE PERFORMANCE



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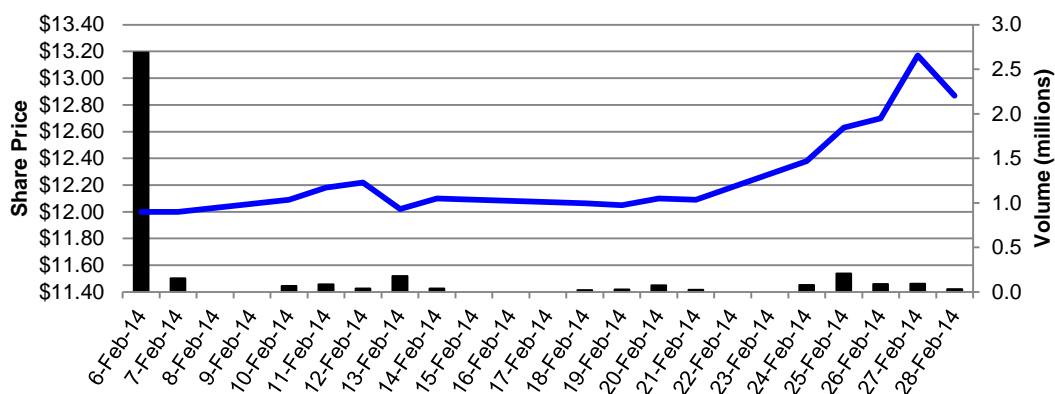
FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO JMP FACTS AND DISCLOSURES SECTION.

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-001 is slated to undergo pivotal bioequivalence studies in 1Q14, with a goal to file the NDA by YE2014, and Egalet-002 is expected to advance into a Phase 3 trial in 4Q14. Egalet also has a development collaboration and licensing agreement with Shionogi.

The company completed its IPO in February 2014 and concurrently completed a private placement with partner Shionogi, which together raised net proceeds of ~\$58MM. We believe the IPO proceeds provide sufficient cash to fund the company's lead development candidates, Egalet-001 and Egalet-002, through to regulatory approval in the U.S., as well as to establish commercial manufacturing capabilities for these products and advance additional programs that leverage the company's proprietary abuse-deterrent technology into the clinic.

FIGURE 1. EGLT Stock Chart



Source: Thompson Reuters, JMP Securities LLC

KEY UPCOMING MILESTONES

1H14	Egalet-001	Initiate pivotal bioequivalence and abuse-deterrence studies
1H14	Egalet-002	Initiate clinical abuse-deterrence studies
3Q14	Egalet-001	Complete bioequivalence and abuse-deterrence studies
4Q14	Egalet-001	NDA submission anticipated
4Q14	Egalet-002	Initiate Phase 3 safety trial

INVESTMENT THESIS

Specialty pharmaceutical company with a focus on novel abuse-deterrent drug delivery technology. Egalet has a proprietary drug delivery platform that enables drug formulations with abuse-deterrent features as well as the ability to customize and control release profiles. The platform is based on a plastic injection molding technology used in the manufacture of medical devices. The one-component system is used to produce tablets that consist of a hard matrix that is difficult to crush, grind, or dissolve and that controls the release of the active drug. The two-component system consists of a matrix similar to the one-component system, but is additionally surrounded by a water-impermeable, non-eroding hard shell made of polylactic acid that creates a cylinder, with the drug-containing matrix exposed at both ends. We believe that Egalet's drug delivery systems have the potential to enable differentiated abuse-deterrent, modified, and controlled-release formulations of drugs with large commercial opportunities. Additionally, we view the platform as having broad applicability.

Two significant opportunities in the multi-billion dollar U.S. opioid market. Egalet's lead product candidates, Egalet-001 and Egalet-002, are abuse-deterrent, extended-release oral formulations of commonly prescribed opioids for the treatment of pain. In 2013, the U.S. opioid market exceeded \$8bil in sales, with more than \$4bil, or ~15 million prescriptions, attributable to the long-acting opioid market that Egalet is addressing. Long-acting, morphine-based products and oxycodone-based products, the initial opportunities that Egalet is addressing, are the two most commonly prescribed, long-acting oral opioids. While there have been advances with abuse-deterrent opioid products (e.g., the approval of Purdue's abuse-deterrent oxycodone in April 2013), we believe there remains a substantial unmet need for improved technologies in this market.

Egalet-001 is an abuse-deterrent, extended-release, oral morphine formulation entering pivotal trials in the near term. In our view, initial pharmacokinetic trials have established the bioequivalence of Egalet-001 to MS-Contin, a currently approved, non-abuse-deterrent, oral morphine formulation. In our opinion, these clinical data support high predictive value of the company's technology demonstrated in pre-clinical models. Egalet intends to initiate pivotal bioequivalence trials and clinical abuse deterrence trials in 1Q14 with a NDA filing expected by YE2014. There are currently no commercially available, abuse-deterrent formulations of morphine; thus, there is a significant unmet need in this market. There are ~7.1 million prescriptions in the U.S. for non-abuse-deterrent, long-acting morphine products and we anticipate that Egalet-001 can achieve sales of ~\$310MM by 2030, assuming a peak penetration in the mid/high-single digit percentages.

Egalet-002 is an abuse-deterrent, extended-release, oral oxycodone formulation. The company has completed Phase 1 pharmacokinetic trials of Egalet-002 as well as initial abuse-deterrent studies. Additional abuse liability trials will be conducted in 2014 prior to the initiation of Phase 3 trials in 4Q14 and 1Q15. The NDA for Egalet-002 is expected to be filed in 1H16. The product's differentiated abuse-deterrent properties could confer advantages over currently available long-acting, abuse-deterrent oxycodone products. There are ~6.2 million prescriptions in the U.S. for long-acting oxycodone products and we anticipate that Egalet-002 can achieve sales of ~203MM by 2030.

Technology has broad applicability to drive emerging pipeline candidates and the Shionogi partnership further validates its value. We believe Egalet's abuse-deterrent, controlled-release drug delivery technology has broad applicability to opioid and non-opioid drugs. In November 2013, the company entered into a partnership with Shionogi to develop and commercialize abuse-deterrent, hydrocodone-based candidates using Egalet's proprietary technology. In addition, Egalet is developing a portfolio of pre-clinical, abuse-deterrent product candidates for the treatment of pain and in other indications and intends to select a third opioid product candidate (Egalet-003) to advance into clinical development in 2014.

Management has extensive experience in the CNS/pain space and a track record of M&A success. Members of the management team have been closely involved with the development and commercialization of several pain and central nervous system products, including Opana (oxymorphone), Zyprexa (olanzapine), and Prozac (fluoxetine). Moreover, CEO Robert Radie has a successful track record of M&A transactions in the biopharmaceutical space (e.g., Topaz Pharmaceuticals, Transmolecular, Prestwick Pharmaceuticals, Vicuron Pharmaceuticals).

VALUATION

We value Egalet based on the opportunity for Egalet-001 and Egalet-002 in the treatment of moderate-to-severe pain. Our \$19 price target is derived through a sum-of-the-parts NPV analysis of sales for both assets, as summarized in (Figure 2). Our full revenue models and accompanying descriptions can be found on pages 15-19 for Egalet-001 and pages 20-24 for Egalet-002. Note that while our valuation assumes the company commercializes both products through its own specialty sales force, we see potential for future commercial partnership agreements, especially in the case of Egalet-002.

We probability adjust our revenue projections to reflect clinical, regulatory, and commercial risks and apply a 15% discount rate to our NPV calculations to reflect the company's cost of capital. As summarized below, our price target reflects the ~14.7 million shares currently outstanding.

With a current market cap of ~\$180MM and enterprise value of ~\$120MM, we view EGLT as an attractive investment opportunity with multiple clinical catalysts over the coming 12 months and the potential for the company to receive FDA approval for its first product in 2015.

FIGURE 2. Egalet Sum-of-the-Parts NPV Valuation

	Peak revenue	Peak revenue year	Economics	Probability of success	Discount rate	NPV	NPV per share	Contribution
Egalet-001	310.5	2030	100%	65%	15%	190.9	\$13.02	69%
Egalet-002	202.6	2030	100%	55%	15%	86.6	\$5.91	31%
Price target							\$18.93	100%

Source: JMP Securities LLC

Capital Structure

Following the completion of the IPO, Egalet has ~14.7 million shares outstanding, not including the underwriters' option to purchase up to 525,000 additional shares. Additionally, there are warrants to purchase ~600,000 shares outstanding, 862,800 shares of restricted stock expected to be granted to management post-IPO, 817,200 shares to be reserved for issuance under equity incentive plans, and approximately 55,000 shares issuable upon the conversion of convertible bridge notes.

Balance Sheet

Egalet's pro forma cash position is estimated at approximately \$60MM. The company priced its initial public offering (IPO) of 4,200,000 shares of common stock on February 5, 2014, raising approximately \$50MM at \$12/share. Additionally, Egalet's partner Shionogi, purchased 1,250,000 shares of common stock at the IPO price in a concurrent private placement. Net proceeds of the offering and private placement were approximately \$58MM.

Intellectual property portfolio

As of December 31, 2013, Egalet's patent portfolio consisted of five issued or allowed patent applications with expiry dates ranging from 2022-2030. The issued patents related to the composition of matter or method of production for Egalet-002 and the fifth is related to a once-daily formulation of another oxycodone-based product candidate. The company has nine owned patent applications under active prosecution in the U.S. and 22 pending foreign patent applications. For Egalet-001, there is one pending patent application in the U.S. and one pending foreign patent application. For Egalet-002, there are three pending applications in the U.S. and four foreign pending patent applications. There are also five patent applications pending in the U.S. and 17 foreign pending patent applications pertaining to Egalet's technology platform.

Egalet owns all global rights to its lead clinical stage product candidates, Egalet-001 and Egalet-002, as well as to its technology platform.

Shionogi partnership

In November 2013, Egalet entered in to an exclusive, worldwide collaboration and license agreement with Shionogi for development of its abuse-deterrent, hydrocodone-based product candidates. Under the terms of the agreement, Egalet received a \$10MM upfront payment. Shionogi will assume all expenses incurred related to conducting clinical trials and preparing regulatory filings. If the candidates are approved, Egalet will be eligible to receive regulatory and sales milestones exceeding \$300MM. Additionally, Egalet would receive a mid-single digit to low-teens percentage royalty on net sales.

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.

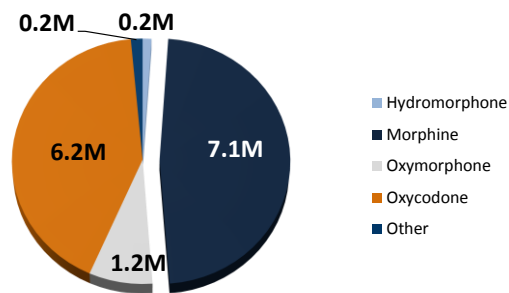
LARGE MEDICAL NEED AND MARKET OPPORTUNITY FOR ABUSE-DETERRENT OPIOIDS

Opioids are the most commonly prescribed drugs in the U.S. for the treatment of moderate-to-severe chronic pain and the current U.S. market exceeds \$8bil. Approximately 50% of this market is accounted for by long-acting opioids, representing approximately 15 million prescriptions annually. The most commonly prescribed long-acting opioids include morphine, oxycodone, oxymorphone, and hydromorphone (Figure 3).

FIGURE 3. Market Potential of Morphine and Oxycodone

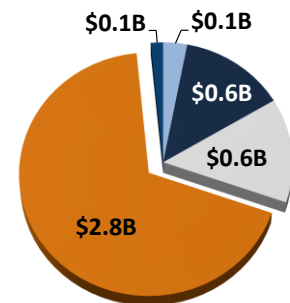
Long-Acting Opioid Prescriptions

14.8M U.S. prescriptions - 2012



Long-Acting Opioid Sales

\$4.1B in U.S. sales - 2012



- Morphine was the most widely prescribed long-acting opioid in the U.S. in 2012
 - Increased from 4.2 million Rx in 2007 to 7.1 million Rx in 2012
- Oxycodone was the highest selling long-acting opioid in the U.S. in 2012
 - Increased from \$1.0 billion in 2007 to \$2.8 billion in 2012

Sources: IMS Health, IMS NSP & NPA Audits. All stats are for the 12 months ended 9/30. SDI Vector One.

Source: Company reports

Opioid abuse epidemic

While these drugs provide effective pain relief, they are subject to abuse. Prescription drug abuse is an epidemic in the United States with over 35 million people using opioid and non-opioid pain killers recreationally. The CDC's National Center for Health Statistics has stated that drug-related deaths became the leading cause of accidental death in the United States in 2009, surpassing the number of deaths caused by automobile accidents, and the CDC estimates that 40% of these deaths are due to opioids.

According to a 2013 report by the American Journal of Managed Care, the costs associated with prescription drug abuse are estimated to be up to \$72.5 billion annually for public and private healthcare payers.

FDA guidance on abuse-deterrent opioids

Since the approval of Oxycontin in 1995 and emerging reports of overdose and death relating to the drug in the early 2000's, the FDA has taken multiple steps to address the issue of opioid abuse. These steps include introducing stronger warning language onto product labels, individual product and class-wide REMS, public meetings to discuss the risks of misuse and abuse, and the approval of the first generation of abuse-deterrent products. The first drug to be approved with abuse-deterrent measures was a formulation of Oxycontin, introduced in 2010. Importantly, the FDA has now issued draft guidelines for the development of opioid drug formulations with abuse-deterrent properties. We believe that these guidelines not only guide product development paths but also provide the framework for product labeling.

The draft guidance on abuse-deterrent opioids was published by the FDA in January 2013 and is specifically intended to inform the industry on the FDA's thinking about studies that should be conducted to demonstrate that an opioid formulation has abuse-deterrent properties, how those studies will be evaluated by the agency, and what labeling claims may be considered based on the results of the studies. The guidance document states that goals of abuse-deterrent approaches are to make product manipulation more difficult or to make the abuse of the manipulated product less attractive or rewarding.

The FDA provides a broad outline of the manners by which opioids can be abused and approaches to target these routes of abuse, including:

- Physical/chemical barriers
- Agonist/antagonist combinations
- Aversion techniques
- Delivery systems/prodrugs
- A combination of these methods

In order to evaluate abuse-deterrent product candidates, the FDA has outlined four categories of studies important in providing evidence of abuse potential, three are pre-approval. These categories are: 1) in vitro manipulation and extraction studies, 2) clinical pharmacokinetic trials, 3) clinical abuse potential trials, and 4) post-marketing studies to assess the in-market impact on actual abuse. Relating to clinical abuse potential trials, the FDA states in the guidance document that the extent of abuse deterrence should be understood in context to a comparator.

Regarding product labeling for an abuse-deterrent opioid formulation, the FDA has defined four general tiers of claims that enable the description of potential abuse-deterrent properties of a product candidate:

- Tier 1 - The product is formulated with physiochemical barriers to abuse
- Tier 2 - The product is expected to reduce or block effects of the opioid when the product is manipulated
- Tier 3 - The product is expected to result in a meaningful reduction in abuse
- Tier 4 - The product has demonstrated reduced abuse in the community

Source: FDA Guidance for Industry

Current abuse-deterrent formulations

Currently, the only abuse-deterrent oxycodone product available in the market is Purdue's OxyContin OP, approved in April 2013. This product replaced the previous abuse-deterrent OxyContin formulation, introduced in 2010, and was the first product approved after new FDA guidance was issued. Concurrent with the approval of this abuse-deterrent formulation, FDA determined that it was appropriate that the original OxyContin was withdrawn from the market. At the time of this approval, no generic formulations of the previous formulation of OxyContin were available and the FDA has stated that it will not accept or approve any generic applications that reference the original OxyContin.

A new formulation of Endo's Opana ER is designed to resist crushing relative to the original formulation. As such, Endo has also petitioned the FDA to facilitate the withdrawal of the original Opana ER formulation. However, in May 2013, the FDA determined that the original formulation of Opana ER should not be withdrawn from the market, citing that although the new formulation was resistant to crushing relative to the original formulation, it could still be abused through other forms of manipulation, including cutting, grinding, or chewing, as well as preparation for injection. Additionally, the FDA viewed post-marketing experience as inconclusive.

At this time, no available abuse-deterrent formulation of morphine exists in the marketplace in the United States. Pfizer's Embeda was the only abuse-deterrent morphine/naltrexone formulation previously approved by the FDA for moderate-to-severe pain. The drug, however, was removed from the market in 2011 due to potential fatalities if crushed and swallowed.


EGALET ABUSE-DETERRENT TECHNOLOGY ADDRESSES OPIOID ABUSE

Egalet's proprietary abuse-deterrent technology platform consists of two separate systems (Figure 4), a one-component system and a two-component system. We believe these systems can provide differentiated abuse-deterrent properties for a broad range of opioid drugs. Furthermore, we see potential for the application of the platform to combinations incorporating opioids and product formulations of additional drug classes.

The one-component system is used to produce tablets that contain a matrix which controls the release of the active pharmaceutical ingredient (API). The matrix erodes over time in the GI tract releasing the API as well as any or inactive excipients. The matrix produced using Egalet's proprietary injection molding technology. This technology has been validated, both from an efficacy/safety and regulatory perspectives, in several medical device implants and diagnostics; however, Egalet is the first company to combine injection molding technology with the production of oral pharmaceuticals. The injection molding technology contrasts to conventional compression methods used in other abuse-deterrent formulations on the market and in development. Furthermore, we view the technology as reproducible, scalable, and cost-efficient. While other pharmaceutical companies typically manufacture abuse-deterrent products using conventional compression methods, injection molding involves the simultaneous use of both pressure and heat to form tablets using a customized mold.

The two-component system consists of the same matrix that is used on the one-component system, and is surrounded by a water-impermeable, non-eroding hard shell of polylactic acid that forms a cylinder. The API containing matrix is exposed at both ends, but the shell limits the surface area that comes in contact with the GI tract. This allows the time release rate of the API to be calibrated. The shell also serves to make the tablet more difficult to grind or crush.

FIGURE 4. Egalet Abuse-Deterrent Technology

One-Component System	Two-Component System
<ul style="list-style-type: none">• Hard matrix• Addresses products abused primarily via injection• Extremely hard and resistant to crushing, grinding, chewing and smoking, in addition to injection• Used in manufacturing Egalet-001	<ul style="list-style-type: none">• Hard matrix with a shell• Addresses products abused primarily via crushing and snorting• Extremely hard and resistant to injection and smoking, in addition to crushing and snorting• Used in manufacturing Egalet-002
	

Source: Company reports

We believe that Egalet’s technology has the potential to enable best-in-class, abuse-deterrent products and product candidates. In our view, the technology provides opportunities to minimize the potential for extraction of the API by injection, snorting, smoking, and chewing. These features of Egalet’s abuse-deterrent technology are summarized in Figures 5 and 6, where we highlight how the technology is differentiated from competitors.

FIGURE 5. Egalet Technology Abuse-Deterrent Features

Egalet Abuse-Deterrent Feature	Type of Abuse Deterred	Advantages
Extremely Hard	Chew ing	The injection molding process and the combination of excipients allow Egalet to produce tablets that are difficult to crush using common techniques, including through the use of coffee grinders, graters, knives and blenders and through chew ing.
	Snorting	
	Injecting	
	Smoking	The hardness of the tablets also resists transformation into snortable or soluble powder.
Combustion Resistant	Smoking	The formulations cannot be easily smoked or vaporized and create an unpleasant, plastic-like odor when heated by using conventional household methods.
Gelling Effect	Injecting	The formulations contain gelling agents that form a highly viscous gel when attempting to dissolve in water or other common household solvents, making injection essentially impossible. The formulations exhibit resistance to extraction of the API from the matrix in water and other common household solvents.
Matrix Composition	Alcohol Dose-Dumping	Tablets do not accelerate the release of the API when combined with the consumption of alcohol as a result of the propensity of the matrix to dissolve less rapidly in the presence of less polar substances, such as alcohol, as compared to more polar substances, such as water.

Source: Company reports

FIGURE 6. Egalet Platform vs. Competitors

Features	Egalet	Hardness Approach (Intac, Opana, Oxycontin OP)	Microsphere (collegium, Oradur)	Combination (Antagonists, Irritants, Embeda, Acurox)
Oral Tablet	Y	Y	Y	Y
Deliver all dose ranged of existing products	Y	Y	N	N
Broad Platform	Y	N	N	N
No Crushing/Smoking/Chew ing	Y	N	N	N
No Exposure to Antagonist	Y	Y	Y	Y
Manufacturing	Y	Y	N	N
Stage of Development	Phase 3 ready	On the market	Phase 3	Withdraw n from market

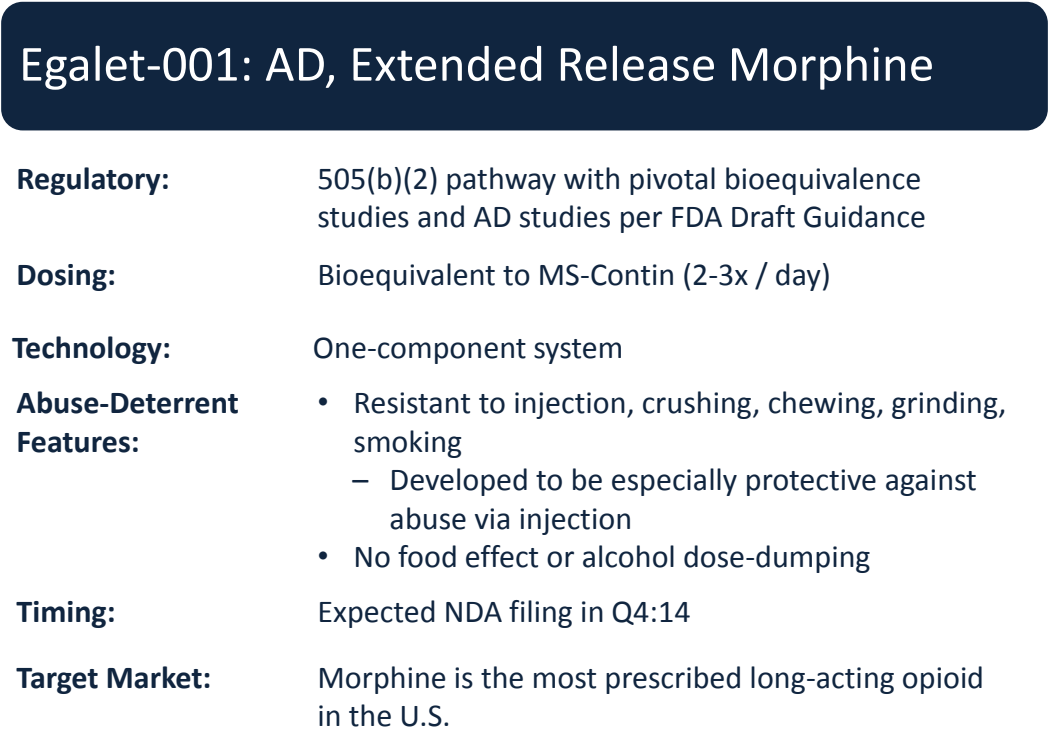
Source: Company reports

EGALET-001: ADDRESSES NEED FOR ABUSE-DETERRENT MORPHINE

Egalet-001 is an abuse-deterrent, extended-release (ER), oral formulation of morphine for the treatment of moderate-to-severe pain in patients who need to be on chronic opioid therapy (Figure 7). The tablets are made utilizing Egalet’s one-component, abuse-deterrent technology. At this time, there are three FDA approved, branded, long-acting, oral morphine products on the market: MS-Contin, Kadian, and Avinza. Generic forms of these drugs are also available. However, Egalet-001 could be the first approved, oral ER morphine product with abuse-deterrent properties.

To date, Egalet has completed two Phase 1 pharmacokinetic trials, in addition to pre-clinical abuse deterrence studies. These studies support the potential to demonstrate bioequivalence of Egalet-001 to MS Contin, and the potential for a differentiated abuse-deterrent profile. The company intends to initiate a pivotal bioequivalence trial for Egalet-001 in 1Q14 and to submit its NDA to the FDA during 4Q14.

FIGURE 7. Egalet-001 Product Profile



Source: Company reports

Planned pivotal studies

The pivotal development program for Egalet-001 includes trials to evaluate the product's bioequivalence and abuse-deterrence properties, as summarized in (Figure 8). We expect Egalet to initiate pivotal bioequivalence trials for Egalet-001 in 1Q14, comparing the product candidate to MS. Also in 1Q14, we expect the company to initiate additional abuse-deterrence studies, with the goal of obtaining abuse-deterrent claims for the product label.

FIGURE 8. Planned Bioequivalence and Abuse-deterrent Studies

Trial Type	# Patients	Description	Initiation Date	Data Readout
PK	24-30	15mg MS Contin, 15mg Egalet-001, under fasting conditions, single dose	1Q14	4Q14
Dose proportionality (<i>In Vitro</i>)	n/a	30mg, 60mg	1Q14	4Q14
PK	24-30	100mg MS Contin vs. 100mg Egalet-001, under fasting conditions, single dose and steady state	1Q14	4Q14
Abuse Deterrence Studies				
Tier 1 (<i>in vitro</i>)	n/a	Egalet-001 ability to resist crushing, dissolving, swallowing, snorting, and injecting.	1Q14	n/a
Tier 2 PK	15	PK Comparison of manipulated Egalet-001 vs. MS Contin	2Q14	n/a
Tier 3	30	Randomized, double-blind, placebo-controlled crossover study to compare the likeability of Egalet-001 and MS-Contin in experienced abusers	2Q14	n/a

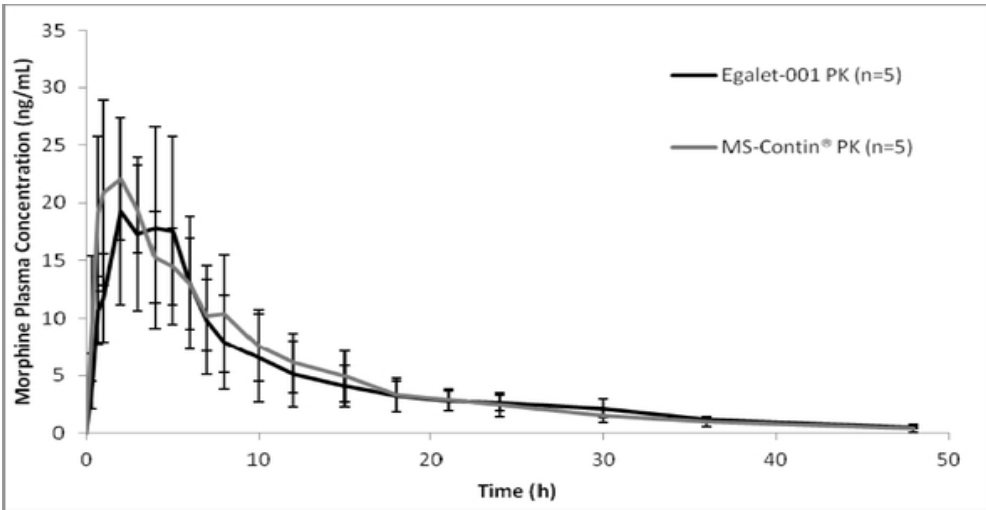
Source: Company reports

The company intends to commercialize a range of doses (15mg, 30mg, 60mg, and 100mg), in line with available morphine products. Per FDA guidance, the bioequivalence trial needs to establish that the C_{max} and AUC of Egalet-001 fall within the 80-125% range of the C_{max} and AUC of MS-Contin.

Completed pre-clinical and clinical trials to date

Egalet has completed two Phase 1 clinical trials of Egalet-001 in healthy subjects. For the first Phase 1, n=10 trial, the primary endpoint was PK profile similarity to MS Contin. API in the bloodstream was measured at 48 hours after administration of drug. Bioequivalence was established based on parameters, including the total concentration under the curve (AUC) and peak concentration (C_{max}). The result of this study shows that Egalet-001 has a PK profile similar to MS Contin (Figure 9).

FIGURE 9. PK Profiles: Egalet-001 vs. MS Contin



Source: Company reports

The second Phase I, n=30, standard crossover trial was also conducted to establish bioequivalence to MS Contin with primary endpoints of AUC and C_{max}. The concentration of API was measured in the bloodstream at 48 hours after administration of drug. The results of this trial also demonstrated bioequivalence of Egalet-001 to MS Contin (Figure 10).

FIGURE 10. Bioequivalence Profile of Egalet-001 vs. MS Contin

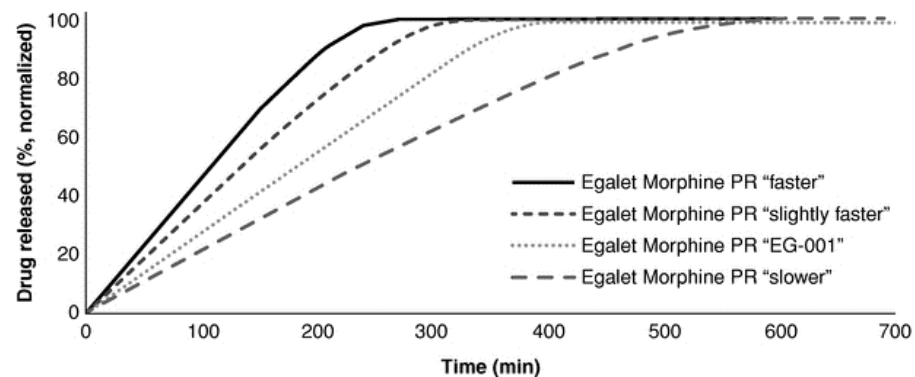
PK Parameter	Egalet-001	MS-Contin
AUC ₀₋₄ (ng/mL*h) ± one standard deviation (SD)	224 ± 53	236 ± 48
AUC _{0-∞} (ng/mL*h) ± SD	234 ± 56	244 ± 49
C _{max} (ng/mL) ± SD	25 ± 8	27 ± 8
T _{max} (h) [range]	3 [1-5]	1 [0-2]

Source: Company reports

Under FDA guidance, Egalet must establish that the AUC and C_{max} of Egalet-001 are within the 80-125% range similar to those of MS Contin, with a 90% confidence interval. The 90% intervals showed that Egalet-001 has an AUC between 91-98%, and a C_{max} between 80-99% as that of MS Contin, respectively. Maximum plasma concentration T_{max} was also measured. While the T_{max} for Egalet-001 was longer than that of MS Contin, it is in line with currently available morphine products.

Egalet also conducted an *in vitro* dissolution profile of Egalet-001, comparing it to blood concentrations of subjects in the trial, to establish consistency with the release profile seen in the pre-clinical setting. Egalet-001 was evaluated along with three other morphine formulations of varying release profile speed. The dissolution profile below (Figure 11) illustrates the percentage of each formulation released *in vitro*, over time. The C_{max} for the faster, slightly faster, Egalet-001, and slower formulations were 38ng/ml, 30ng/ml, 25ng/ml, 22ng/ml, respectively. Results suggest that Egalet-001 concentration levels may be predicted based on its *in vitro* dissolution profile, which, in turn, suggests that Egalet's technology will also be predictable in clinical trials.

FIGURE 11. Egalet-001 Dissolution Profile



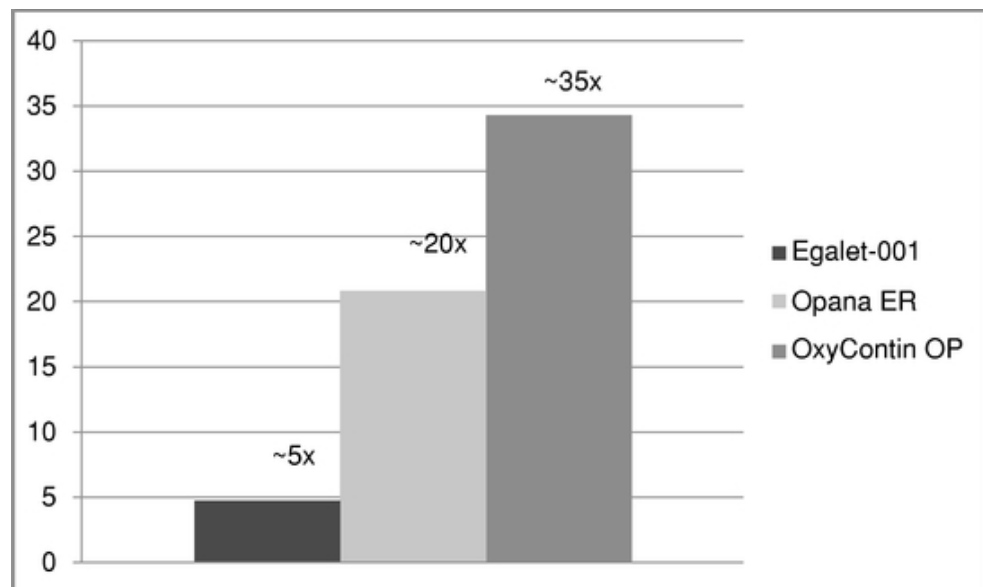
Source: Company reports

Based on results from the Phase 1 trials, Egalet expects to initiate pivotal bioequivalence trials in 1Q14 using MS Contin as the reference drug. The company will pursue the 502(2)(b) regulatory pathway and will follow FDA draft guidance in order to establish an abuse-deterrent label for its products. It expects to be able to file a NDA during 4Q14.

Pre-clinical, abuse-deterrence studies

Multiple pre-clinical studies of Egalet-001 have demonstrated its abuse-deterrent capacity. In one study, Egalet-001, OxyContin OP, and Opana ER tablets were ground up using a nutmeg grinder. Each drug's intact tablet and ground tablet particles were placed in water where the time it took to release 80% of the API was measured. The ground-up tablets of OxyContin ER and Opana ER have accelerated API release profiles, of 20x and 35x faster, respectively, when compared to their intact forms (Figure 12). Egalet-001, when ground, released API approximately 5x faster versus its intact tablet. These results show that is more difficult to release API from Egalet-001 than from OxyContin ER and Opana ER.

FIGURE 12. API Release Rate of Ground Tablets: Egalet-001 vs. Competitors



Source: Company reports

Another study was conducted to evaluate Egalet-001's abuse-deterrent properties against injection. Egalet-001, MS Contin, and OxyContin OP tablets were heated for up to 16 minutes in a microwave (i.e., crisping). They were then placed in 3ml of water, which is the maximum amount of solution an abuser would typically inject. The viscosity of the resulting solution was then measured by its ability to be drawn into a syringe. Egalet-001 was shown to be too viscous to inject after crisping, remaining above 2400cP (Figure 13).

FIGURE 13. Egalet-001 Not Injectable After Microwave Crisping

Crisping time, min (microwave oven, 900W)	Egalet-001 viscosity (3 mL water) cP	MS-Contin viscosity (3 mL water) cP	OxyContin OP viscosity (3 mL water) cP	Opana ER viscosity (3 mL water) cP
0 min	>2400	75	>2400	>2400
8 min	>2400	93	60	>2400
16 min	>2400	0	0	30

Source: Company reports

Commercial opportunity

As discussed above, Egalet-001 has the potential to be the first-to-market, abuse-deterrent oral ER morphine product. Moreover, based on the company's differentiated proprietary formulation technology and the pre-clinical and clinical data available to date, we believe the product could be the best-in-class should additional competitors emerge.

The market opportunity for oral ER morphine products is large, and according to data from IMS Health, more than seven million prescriptions are written annually for long-acting morphine products, including Avinza, Kadian, and MS-Contin, as well as for generics. The market is predominantly generic, with branded drugs accounting for less than 10% of total prescriptions. However, we believe that a novel product with compelling abuse-deterrent properties could result in substantial adoption.

Embeda (Pfizer) was the only abuse-deterrent morphine/naltrexone formulation previously approved by the FDA for moderate-to-severe pain. The drug, however, was removed from the market in 2011 due to potential fatalities if crushed and swallowed. At this time, there are no approved abuse-deterrent formulations of morphine available in the market.

Product differentiation

The most common approach to abuse of morphine-based drugs is by injection. When attempts are made to dissolve Egalet-001 in water or in other common solvents, the pill turns into a gel, rendering it impossible to inject. Egalet-001 is also designed to prevent alcohol dose dumping by slowing the release of the API in the presence of alcohol. This is unlike what is seen with some other morphine-based products, in which the release of the API is accelerated in the presence of alcohol. Whether a patient has consumed food or not has no effect on Egalet-001, which keeps pain relief consistent and increases the convenience factor for the patient. Egalet-001 is also unique in that, unlike many abuse-deterrent formulations, it does not contain opioid receptor antagonists. This reduces potential side-effects from additional API's and makes Egalet-001 the first of its kind.

Commercial strategy

The market for opioids and pain management is well defined. Approximately 6,500 high-prescribing physicians, including pain specialists and thought leaders, as well as high-prescribing primary care physicians account for approximately 50% of opioid prescriptions.

Egalet intends to commercialize Egalet-001 through its own specialty sales force, and out-license rights to the product in ex-U.S. geographies. We are confident in the company's ability to execute on a commercial launch based on its previous experience, which includes several pain and central nervous system drugs such as Opana, Zyprexa, and Prozac. The company is currently undertaking pre-commercialization activities including developing positioning, messaging focus, and initiatives with reimbursement organizations.

The company intends to launch Egalet-001 with approximately 50 sales professionals who will focus primarily on the approximately 5,000 board-certified, pain management physicians in the U.S. Additionally, the company intends to supplement its own sales force with a contract sales organization to broaden its coverage targeting primary care and internal medicine physicians who are high prescribers of pain management medicines.

In line with other pain management therapies, we would expect tier 3 reimbursement coverage for Egalet-001 at launch. However, given the focus by the FDA and broader political pressure, we expect the availability of abuse-deterrent technologies to drive rapid adoption even in a primarily generic market. Moreover, we point to the example of Purdue's Oxycontin OP where the FDA enabled the withdrawal of a non-abuse-deterrent product once an abuse-deterrent product was available.

Revenue model

There are ~7.1 million prescriptions in the U.S. for non-abuse-deterrent, long-acting morphine products in the U.S. We estimate that the market for these products will remain stable with growth in line with population growth. While we anticipate that Egalet will be the first approved abuse-deterrent oral ER morphine product, for the purpose of our revenue model, we conservatively anticipate multiple entrants to this market in coming years and project a peak penetration only in the high-single digit percentages.

Egalet has conducted market research on the potential pricing strategy of Egalet-001. The research surveyed 15 healthcare payers and results indicated that most payers (67%) expected Egalet-001 to be priced at par to current brands or with a price premium (27%) Branded drugs are priced at \$300-750 per month or ~\$5 per tablet. For Egalet's anticipated pricing strategy, we model Egalet-001 at approximately \$400 per month.

As shown in (Figure 14), we anticipate that Egalet-001 can achieve sales of ~\$310MM by 2030, assuming a peak penetration in the mid- to high-single digit percentages. We believe that there could be upside to our estimates if additional competition fails to enter the market or if the FDA takes measures to withdraw non-abuse-deterrent formulations from the market.

While we expect the company to pursue development and commercialization of Egalet-001 in other worldwide geographies, we note that the use of opioids outside of the U.S. is lower with a preference for non-opioid and multi-modal alternatives. As such, we do not include sales projections outside of the U.S. in our model at this time.

FIGURE 14. Egalet-001 Market Model

U.S. revenue estimates	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Long-acting morphine prescriptions	7,150,000	7,221,500	7,293,715	7,366,652	7,440,319	7,514,722	7,589,869	7,665,768	7,742,425	7,819,850	7,898,048	7,977,029	8,056,799	8,137,367	8,218,741	8,300,928	8,383,937	8,467,777	8,552,454
Population growth		1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
No. of Egalet-001 prescriptions					74,403	187,868	379,493	536,604	580,682	625,588	631,844	638,162	644,544	650,989	657,499	664,074	670,715	677,422	684,196
Egalet-001 market share					1.0%	2.5%	5.0%	7.0%	7.5%	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%
Price per prescription					\$400	\$412	\$424	\$437	\$450	\$464	\$478	\$492	\$507	\$522	\$538	\$554	\$570	\$587	\$605
Price increase						3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Gross sales (\$MM)					29.8	77.4	161.0	234.5	261.4	290.1	301.8	313.9	326.6	339.8	353.4	367.7	382.5	397.9	414.0
Gross-to-net adjustment					75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%
Egalet-001 net sales (\$MM)	0.0	0.0	0.0	0.0	22.3	58.1	120.8	175.9	196.1	217.6	226.3	235.5	244.9	254.8	265.1	275.8	286.9	298.4	310.5

Source: JMP Securities LLC

EGALET-002: ADDRESSES NEED FOR ABUSE-DETERRENT OXYCODONE

Egalet-002 is an abuse-deterrent, extended-release, oral formulation of oxycodone for the treatment of moderate-to-severe chronic pain. The product candidate incorporates Egalet's proprietary two-component, abuse-deterrent technology. The tablet is intended to be particularly resistant to crushing and snorting, which are known to be the most frequent methods of abusing oxycodone-containing drugs. It has also demonstrated the potential to be resistant to swallowing, snorting, and smoking as well as dissolving in order to inject the API.

The main ingredient in Egalet-002 is oxycodone, which was approved by the FDA in 1995 and has been in the market since 1996. Purdue currently has an abuse-deterrent formulation of oxycodone, marketed as Oxycontin OP. While the abuse-deterrent properties of Purdue's formulation have improved upon previous formulations, we still see potential for Egalet-002 to demonstrate a further differentiated profile.

Egalet plans to conduct two Phase 3 safety and efficacy clinical trials for Egalet-002, with the first expected to begin during 4Q14. The company will also conduct a safety and efficacy alcohol interaction trial during 2Q14. The company estimates filing a NDA for Egalet-002 in 1H16.

FIGURE 15. Egalet-002 Product Profile

Egalet-002: AD, Extended Release Oxycodone

Regulatory:	505(b)(2) pathway with two Phase 3 studies and AD studies per FDA Draft Guidelines
Dosing:	2x / day with improved PK profile
Technology:	Two-component system
Abuse-Deterrent Features:	<ul style="list-style-type: none">• Resistant to injection, crushing, chewing, grinding, smoking<ul style="list-style-type: none">– Developed to be especially protective against abuse via crushing and snorting• No food effect or alcohol dose-dumping
Timing:	Expected NDA filing in H1:16
Target Market:	Oxycodone is the highest selling long-acting opioid -- \$2.8B for the 12 mos. ended Sept 2012

14



Source: Company reports

Phase 3 development program

The company is planning to conduct two Phase 3 clinical trials for Egalet-002, designed to establish the safety and efficacy of the product candidate. The first Phase 3 is an n=300, multi-center, double-blind, placebo-controlled safety and efficacy trial for Egalet-002, in patients with moderate-to-severe lower back pain who require around-the-clock opioid therapy. The co-primary endpoints are reduced pain scores and reduced relief medication. The trial will have the following three parts:

- Baseline period of up to two weeks before administration of Egalet-002
- An open-label titration period of up to four weeks
- A double-blind, placebo-controlled treatment period of 12 weeks

This trial is expected to be initiated in 4Q14, with top-line results expected during 2H15.

The second Phase 3 will be an n=250, open-label, long-term safety trial. The primary endpoint will be to demonstrate safety of the tablet shell. Patients will be treated with Egalet-002 for either three months, six months, or twelve months. This trial will be initiated during 4Q14, with completion expected in 2H15.

In addition, a single-dose, alcohol interaction PK study will be conducted. Patients will be given a single Egalet-002 80mg tablet followed by 240ml of four liquid combinations consisting of plain water and water with alcohol in concentrations of 4%, 20%, and 40%. This study is slated to begin during 2Q14.

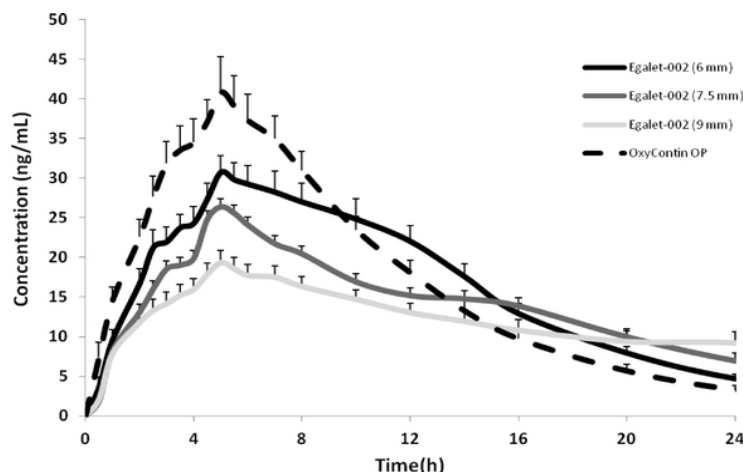
Anticipated clinical abuse-deterrence studies

Egalet also intends to conduct the following abuse-deterrent studies in accordance with FDA guidance.

- A Tier 1 *in vitro* study to evaluate an Egalet-002 tablet's ability to resist particle reduction and API extraction through crushing and then dissolving in addition to crushing, snorting, and injecting. The first part of this study has been completed. The second part will focus on its ability to resist extraction of the API when the tablet is suspended in various liquids.
- A Tier 2 abuse deterrence study to compare the PK profile of manipulated Egalet-002 vs. manipulated OxyContin OP. The study will enroll 45 healthy subjects, enrollment is expected to begin during 2Q14.
- A Tier 3 abuse deterrence study to compare the likeability of Egalet-002 vs. that of OxyContin OP. It will be a randomized, double-blind, placebo and comparator-controlled, crossover study. The study will enroll 45 experienced users with enrollment expected to begin during 3Q14.

Egalet-002 previous clinical trials

Egalet has completed three Phase 1 trials of Egalet-002. The first was an n=16, single-dose, crossover PK study. The primary endpoint was similarity to the PK profile of OxyContin OP, based on AUC and C_{max}. Three different sizes (6mm, 7.5mm, and 9mm) of a 40mg tablet and an OxyContin OP tablet were evaluated. As seen in Figure 16, all Egalet-002 tablets had lower peak-to-trough variability in API release profiles versus OxyContin OP.

FIGURE 16. Egalet-002 API Concentration in Bloodstream Over 24 hours

Source: Company reports

The second Phase 1 trial was an n=22, multiple-dose, crossover study conducted over a 5-day dosing period. The primary endpoint was also similarity to the PK profile of OxyContin OP, based on AUC and C_{max} . Results from this study also showed Egalet-002 to have lower variability in its API release profile versus OxyContin OP (Figure 17).

FIGURE 17. PK Profile of Egalet-002 vs. OxyContin OP

Steady State	Egalet-002	OxyContin OP	Percent improvement
C_{min} (ng/mL)	22	18	20%
C_{max} (ng/mL)	48	59	23%
AUC (ng/hr/mL)	1008	942	N/A
[range]	[687 - 1519]	[620 - 1782]	

Source: Company reports

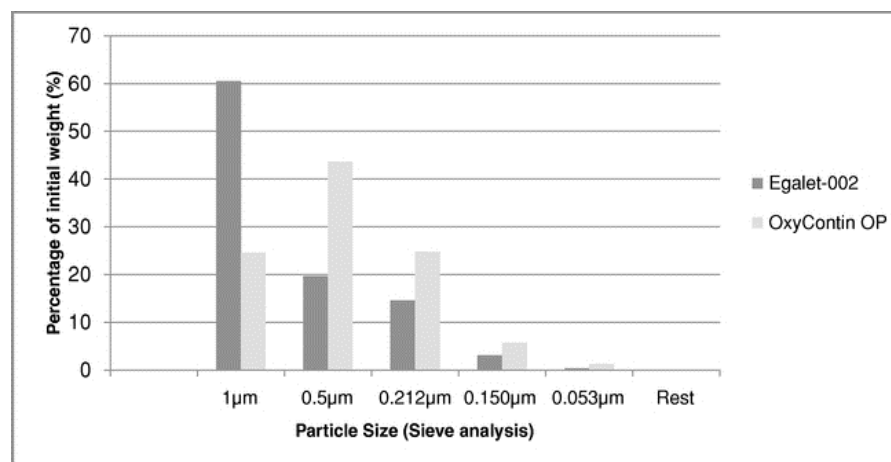
A third Phase 1 trial was conducted to evaluate Egalet-002 at doses of 10mg, 20mg, 40mg, and 80mg. The co-primary endpoints were dose proportionality and food effect. Only the 80mg arm was evaluated for food effect. Results of this trial confirmed linear dose proportionality across all doses. There was a minimal food effect consistent with that previously seen with OxyContin OP. Egalet believes this effect is related to Egalet-002's API, oxycodone, and not to its abuse-deterrent formulation.

Pre-clinical safety and abuse-deterrent studies

Pre-clinical studies were conducted in dogs to assess the safety of oral doses of PLA (polylactic acid), an inactive ingredient in the tablet's shell, as well as its degradation in the GI tract. Results showed no effect of PLA on the GI tract. There was no clinical toxicity and no gross or microscopic changes in the GI lymphoid tissue or any other organ. In another study, the fasted and fed states were simulated in artificial gastric fluid by incubating PLA granules in the fluid. Results from this study showed no degradation of PLA in the fluid and a minor (<0.0125%) breakdown of product in the fluid. Based on these studies, Egalet believes that the ingestion of PLA as part of a tablet is safe. PLA is already approved for use in medical devices such as implants and diagnostics.

Initial abuse-deterrent studies were conducted in accordance with FDA draft guidance. Tier 1 *in vitro* testing was done to compare Egalet-002 vs. OxyContin OP in the ease of reducing particle size, and the ease of attaining an injectable form of the tablet. For one study, five tablets each of Egalet-002 and OxyContin OP were put in a coffee grinder for 20 seconds. Afterwards, they were shaken for one minute and allowed to settle, then the particles were put on progressively smaller sieves ranging from a 1 μ m opening to a 0.053 μ m opening. The largest 1 μ m sieve captured 60% of the Egalet-002 tablet, letting 40% pass through the opening vs. capturing 24% of the OxyContin OP tablet, letting 76% pass through, attesting to the smaller particle size of the OxyContin OP tablet (Figure 18). Results of this study showed that the Egalet-002 tablet's size was not as easily manipulated vs. an OxyContin OP tablet.

FIGURE 18. Particle Reduction Sieve Analysis of Egalet-002 vs. OxyContin OP



Source: Company reports

Commercial opportunity

Extended-release oxycodone is one of the most commonly prescribed oral opioids in the U.S. According to data from IMS Health, there are more than six million oxycodone prescriptions written annually. If approved for the treatment of moderate-to-severe pain, Egalet-002 would compete directly with Purdue's abuse-deterrent OxyContin OP, extended-release product. At this time, there is no generic, abuse-deterrent oxycodone available in the market. There are, however, companies, such as Pfizer, that are developing abuse-deterrent oxycodone therapeutics, such as Remoxy and ALO-02, as well as Collegium who is developing Oxycodone DETERx (COL-003).

Product differentiation

We believe that Egalet's proprietary abuse-deterrent and extended-release technology can provide a superior product profile to Purdue's abuse-deterrent OxyContin OP and potentially a best-in-class product offering. Regarding abuse liability, crushing and snorting is the most common method of abusing or manipulating oxycodone-based products. The very hard exterior shell, in addition to the plastic matrix, that comprises the company's two-component, abuse-deterrent system is designed to address the potential for crushing. Furthermore, unlike other oxycodone drugs, Egalet-002's API release is slowed rather than speeded up in an alcohol solution.

Clinical data generated to date support a PK profile for Egalet-002 with a low peak-to-trough variability in dose concentration. We anticipate that consistent dose maintenance may result in fewer side effects versus OxyContin OP, more consistent pain relief and less use of rescue medication for breakthrough pain. We look to further data to support a superior PK/tolerability profile from the Phase 3 program. The PK profile of Egalet-002 remains comparable to those of peer drugs regardless of whether a patient has eaten or not before administration; therefore, there is no formulation-related food effect. In addition, the drug is designed to provide convenient dosing, along with consistent relief. Each tablet is intended for 2x per day dosing with 12-hour pain relief per dose.

Commercial strategy

As discussed above for Egalet-002, the market for opioids and pain management is well defined and the company intends to market its abuse-deterrent opioid products through its own specialty sales force of ~50 professionals. We believe that the approval of Egalet-002, which we believe would be the company's second product approval, will enable the company to leverage the sales and marketing infrastructure assembled for the launch of Egalet-001.

Revenue model

There are ~6.2 million prescriptions in the U.S. for long-acting oxycodone products and we anticipate that Egalet-002 can achieve sales of ~203MM by 2030 (see Figure 19). We estimate that Egalet will launch Egalet-002 at a price of \$475 per month, taking into consideration other branded long-acting opioid products, including OxyContin OP. We estimate that the product will be launched in 2017 and given the established market position of Purdue and the potential for additional competition, we project a peak market share of only 5%.

While we expect the company to pursue the development and commercialization of Egalet-001 in other worldwide geographies, we note that the use of opioids outside of the U.S. is lower, with a preference for non-opioid and multi-modal alternatives. As such, we do not include sales projections outside of the U.S. in our model at this time.

FIGURE 19. Egalet-002 Market Model

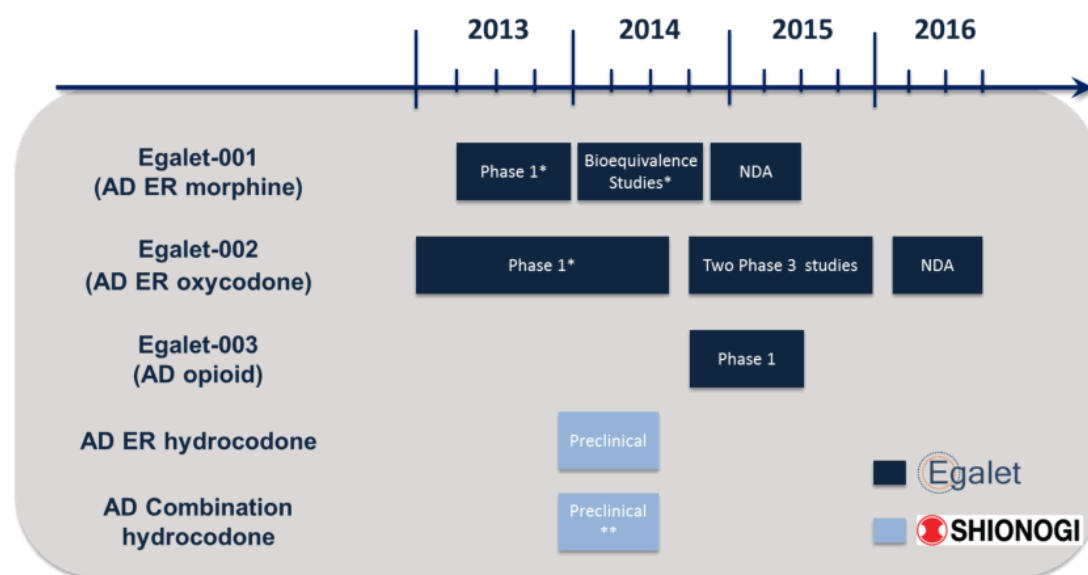
U.S. revenue estimates	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Long-acting morphine prescriptions	6,150,000	6,211,500	6,273,615	6,336,351	6,399,715	6,463,712	6,528,349	6,593,632	6,659,569	6,726,164	6,793,426	6,861,360	6,929,974	6,999,274	7,069,266	7,139,959	7,211,359	7,283,472	7,356,307
Population growth		1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
No. of Egalet-002 prescriptions						32,319	65,283	131,873	266,383	336,308	339,671	343,068	346,499	349,964	353,463	356,998	360,568	364,174	367,815
Egalet-001 market share						0.5%	1.0%	2.0%	4.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Price per prescription						\$500	\$515	\$530	\$546	\$563	\$580	\$597	\$615	\$633	\$652	\$672	\$692	\$713	\$734
Price increase							3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Gross sales (\$MM)				0.0	0.0	16.2	33.6	70.0	145.5	189.3	196.9	204.8	213.1	221.7	230.6	239.9	249.6	259.6	270.1
Gross-to-net adjustment				75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%
Egalet-002 net sales (\$MM)	0.0	0.0	0.0	0.0	0.0	12.1	25.2	52.5	109.2	141.9	147.7	153.6	159.8	166.2	172.9	179.9	187.2	194.7	202.6

Source: JMP Securities LLC

ADDITIONAL PIPELINE ASSETS

In addition to developing Egalet-001 and Egalet-002, the company is applying its abuse-deterrent technology to other APIs. Egalet-003 is an abuse-deterrent opioid formulation, currently in Phase 1 development for the treatment of moderate-to-severe pain. Egalet will seek to use the 505(b)(2) pathway for this asset as well. The company has two additional pre-clinical candidates in the pipeline. The first is an abuse-deterrent, extended-release hydrocodone, and the second is an abuse-deterrent, combination hydrocodone. Both of these are licensed to Shionogi for continued development and commercialization. The license agreement entitles Egalet to receive royalties from Shionogi.

FIGURE 20. Egalet Development Pipeline



* Upscaling of manufacturing/production is included in this timeline.
 ** Potential for multiple product candidates.

Source: Company reports

MANAGEMENT TEAM

Robert Radie – President and Chief Executive Officer

Mr. Radie is the President and Chief Executive Officer and a member of the board of directors, positions he has held since March 2012. From November 2010 to October 2011, Mr. Radie served as President and Chief Executive Officer of Topaz Pharmaceuticals Inc., a specialty pharmaceutical company acquired by Sanofi Pasteur in the fourth quarter of 2011. From March 2009 to November 2010, Mr. Radie served as President and Chief Executive Officer of Transmolecular, Inc., a biotechnology company developing cancer diagnostic and treatment products, after serving as a consultant to Transmolecular from December 2008 through March 2009. From September 2008 to December 2008, Mr. Radie was unemployed. From September 2007 to September 2008, Mr. Radie served as the Chief Business Officer of Prestwick Pharmaceuticals, Inc., a specialty pharmaceutical company. Before joining Prestwick, Mr. Radie served in senior management positions with a number of pharmaceutical and biotechnology companies, including Morphotek, Inc., Vicuron Pharmaceuticals, Inc. and Eli Lilly and Company. Mr. Radie has served as a director of Affinium Pharmaceuticals, Ltd., a specialty pharmaceutical company, since July 2012, and as a director of Horse Power For Life, a non-profit organization dedicated to improving the quality of life for individuals diagnosed with cancer, since 2007. Mr. Radie received his B.S. in Chemistry from Boston College.

Stan Musial - Chief Finance Officer

Mr. Musial has served as the Chief Financial Officer since April 2013. From June 2011 to March 2013, Mr. Musial was self-employed, acting as an independent consultant in the fields of financial management and accounting services. From January 2005 to May 2011, Mr. Musial served as Chief Financial Officer of Prism Pharmaceuticals, Inc., a specialty pharmaceutical and drug development company. Prior to joining Prism Pharmaceuticals, Mr. Musial was Vice President, Finance, and Chief Financial Officer for Strategic Diagnostics, Inc., a publicly held biotechnology company, from 2002 to 2004. Mr. Musial began his career with KPMG LLP, a professional services company. Mr. Musial received a B.S. in Accounting from the Pennsylvania State University and an M.B.A. from Temple University. He is a Certified Public Accountant in the Commonwealth of Pennsylvania.

Roland Gerritsen van der Hoop, M.D., Ph.D. – Chief Medical Officer

Dr. Gerritsen van der Hoop currently serves as Chief Medical Officer. As a consultant, Dr. Gerritsen van der Hoop is overseen directly by Mr. Radie, the company's Chief Executive Officer, and does not perform any policy-making functions. From March 2004 to August 2007, Dr. Gerritsen van der Hoop worked for Endo Pharmaceuticals as its Senior Vice President of Research and Development and Regulatory Affairs and from August 2003 to February 2004, he served as Endo's Group Vice President of Research and Development, Strategic Partners. Prior to working for Endo, Dr. Gerritsen van der Hoop served as Vice President of Research and Development and Chief Scientific Officer of Serologicals Corporation from 2002 to 2003, and as Chief Medical Officer and Senior Vice President of Research and Development of Solvay Pharmaceuticals from 1989 to 2002. He holds M.D. and Ph.D. degrees from the University of Utrecht.

Karsten Lindhardt, MSc, Ph.D. – Vice President Research and Development

Dr. Lindhardt has served as the Vice President, Research and Development since April 2011 and previously served as Senior Director of Portfolio Management and Alliance Manager from March 2010 to April 2011. From August 2008 to March 2010, Dr. Lindhardt served as the Director of Portfolio Management for predecessor Egalet A/S, and as a Project Manager from March 2008 to August 2008. Before joining Egalet A/S, Dr. Lindhardt served in management positions for Curalogic A/S and OSI Pharmaceuticals, and as a clinical pharmacologist for Ferring Pharmaceuticals and Novo Nordisk A/S. Dr. Lindhardt received a M.Sc. in Pharmacy and a Ph.D. in pharmaceutical development and pharmacology, each from the Royal Danish School of Pharmacy.

Source: Company website

FIGURE 21. Egalet Earnings Model (\$ thousands, except per share data)

(\$ in thousands 000's)	2011	2012	1Q:13	2Q:13	3Q:13	4Q:13E	2013E	1Q:14E	2Q:14E	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue																		
Egalet-001						0	0	0	0	0	0	0	0	22,321	58,051	120,781	175,908	196,069
Egalet-002						0	0	0	0	0	0	0	0	0	12,119	25,216	52,464	109,156
Other revenue	626	1,201	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Revenue	626	1,201	0	0	0	0	0	0	0	0	0	0	0	22,321	70,171	145,997	228,372	305,225
Cost of goods sold	0	0	0	0	0	0	0	0	0	0	0	0	0	3,348	10,526	21,900	34,256	45,784
Gross Profit	626	1,201	0	0	0	0	0	0	0	0	0	0	0	18,973	59,645	124,098	194,116	259,441
Operating expenses																		
R&D	4,466	4,256	1,073	1,073	1,073	1,095	4,315	1,171	1,253	1,341	1,435	5,201	7,802	9,362	10,298	11,328	12,461	13,707
G&A	2,068	2,241	1,074	1,074	1,074	1,096	4,319	1,151	1,208	1,269	1,332	4,959	12,398	37,195	42,774	47,051	49,404	51,874
Total Operating Expenses	6,534	6,497	2,148	2,148	2,148	2,191	8,634	2,322	2,462	2,610	2,767	10,160	20,200	46,557	53,072	58,379	61,865	65,581
Operating income (loss)	(5,908)	(5,296)	(2,148)	(2,148)	(2,148)	(2,191)	(8,634)	(2,322)	(2,462)	(2,610)	(2,767)	(10,160)	(20,200)	(27,584)	6,573	65,718	132,252	193,861
Interest expense	513	75	1,481	1,481	1,481	1,481	5,924	1,481	1,481	1,481	1,481	5,924	5,924	5,924	5,924	5,924	5,924	5,924
Loss on foreign currency exchange	36	27	38	38	38	0	113	0	0	0	0	0	0	0	0	0	0	0
Net Income Before Taxes	(6,457)	(5,398)	(3,666)	(3,666)	(3,666)	(3,672)	(14,671)	(3,803)	(3,943)	(4,091)	(4,248)	(16,084)	(26,124)	(33,508)	649	59,794	126,328	187,937
Income tax provision	0	0	0	0	0	0	0	0	0	0	0	0	0	0	227	20,928	44,215	65,778
Net income (loss)	(6,457)	(5,398)	(3,666)	(3,666)	(3,666)	(3,672)	(14,671)	(3,803)	(3,943)	(4,091)	(4,248)	(16,084)	(26,124)	(33,508)	422	38,866	82,113	122,159
EPS																		
Basic	(\$6.00)	(\$5.01)	(\$3.40)	(\$3.40)	(\$3.40)	(\$2.84)	(\$13.05)	(\$0.39)	(\$0.28)	(\$0.29)	(\$0.30)	(\$1.27)	(\$1.81)	(\$1.79)	\$0.02	\$2.00	\$4.14	\$6.03
Diluted	(\$6.00)	(\$5.01)	(\$3.40)	(\$3.40)	(\$3.40)	(\$2.84)	(\$13.05)	(\$2.93)	(\$0.28)	(\$0.29)	(\$0.30)	(\$3.80)	(\$1.81)	(\$1.79)	\$0.02	\$2.00	\$4.14	\$6.03
Weighted shares outstanding																		
Basic	1,077	1,077	1,077	1,077	1,077	1,292	1,131	9,691	14,000	14,070	14,140	12,975	14,423	18,712	19,086	19,468	19,857	20,254
Diluted	1,077	1,077	1,077	1,077	1,077	1,292	1,124	1,299	14,000	14,070	14,140	10,877	14,423	18,712	19,086	19,468	19,857	20,254

Source: Company reports and JMP Securities LLC

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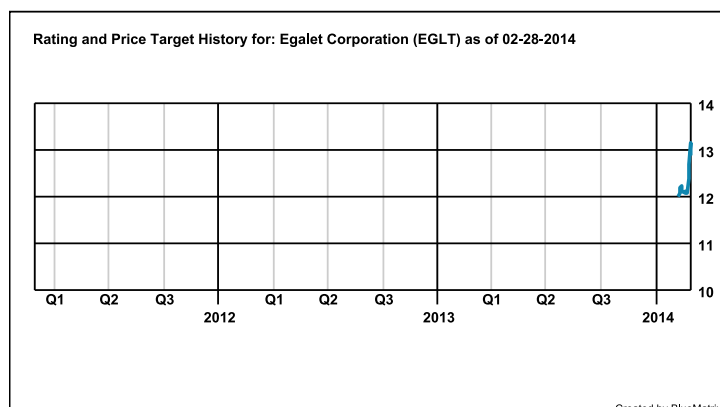
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MARKET OUTPERFORM	Buy	243	56.25%	Buy	243	56.25%	92	37.86%
MARKET PERFORM	Hold	138	31.94%	Hold	138	31.94%	18	13.04%
MARKET UNDERPERFORM	Sell	8	1.85%	Sell	8	1.85%	0	0%
COVERAGE IN TRANSITION		43	9.95%		43	9.95%	0	0%
TOTAL:		432	100%		432	100%	110	25.46%

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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