

Specialty Pharmaceuticals

Egalet Ltd.

(EGLT) - BUY

Price: **\$12.87**
Fair Value Estimate: \$30.00
52-Week Range: \$11.82-\$13.67
Market Cap (MM): \$189
Shr.O/S-Diluted (mm): 14.7
Average Daily Volume: NA
Dividend: NA
Book Value: \$(4.69)

FYE: Dec	2013A	2014E	2015E
EPS:	\$(4.29)A	\$(1.75)E	\$(2.50)E
Prior EPS:		NC	NC
P/E:	NA	NA	NA

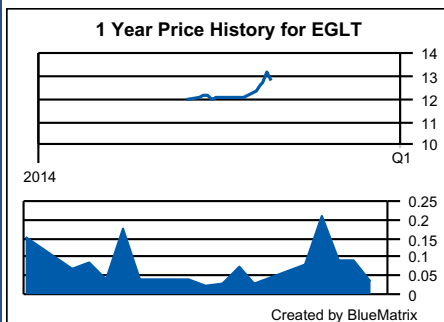
Quarterly EPS:

	2013A	2014E	
Q1	\$(3.40)A	\$(0.34)E	--
Q2	\$(3.40)A	\$(0.36)E	--
Q3	\$(3.40)A	\$(0.39)E	--
Q4	\$(0.35)A	\$(0.65)E	--

FYE: Dec	2013A	2014E	2015E
Revenue (M):	\$0.0A	\$0.0E	\$8.0E

Quarterly Revenue (M):

	2013A	2014E	
Q1	\$0.0A	\$0.0E	--
Q2	\$0.0A	\$0.0E	--
Q3	\$0.0A	\$0.0E	--
Q4	\$0.0A	\$0.0E	--



Equity Research
Basic Report

Initiate with a BUY rating, \$30 FV: Safer Opioids Through Better Technology

INVESTMENT CONCLUSION:

We are initiating coverage on Egalet (EGLT) with a Buy rating and a \$30 fair value. EGLT is a specialty pharmaceutical company focused on the development and commercialization of abuse-deterrent oral products for the treatment of pain using their proprietary technology platform. The two product candidates consist of the powerful and highly prescribed opioids morphine and oxycodone both in an extended-release, abuse-deterrent formulations. With the rise of prescription drug abuse, particularly in opioids over the last decade, regulating agencies are taking steps to encourage abuse-resistant/ abuse-deterrent formulations. EGLT is pursuing the easier-to-market 505(b)(2) filing strategy for both products, with a bioequivalence study for Egalet-001 starting in 1Q14 with data read out by the end of the year. We believe that EGLT is at an inflection point, and we value the company at \$30/share based on a sum of the parts.

KEY POINTS:

- **Positioned in the “sweet spot” of opioid deterrence.** Following the recent approval of abuse-deterrent Oxycontin OP from Purdue and Opana TRF (tamper resistant formulation) from Endo International, there is a clear path at the FDA for approving abuse-deterrent opioid products, but that wasn't the case just a few years ago. Even more compelling was the decision by the FDA in 2013 to deny generic equivalents to Purdue's Oxycontin OP, highlighting the clear medical need for additional options to curb the epidemic of opioid abuse.
- **Drugs target a significant markets.** Both Egalet-001 and Egalet-002 are targeting the long-acting opioid market. Opioids remain the most prescribed pain medication in the US. According to IMS data, for the last 12 months ending September 2012, long-lasting opioids were prescribed 14.8 million times in the US, generating approximately \$4.1B in sales. Long-acting morphine is the most commonly prescribed opioid with about half of the market at 7.1M prescriptions generating \$560M in sales (heavily generic). Oxycodone is right behind morphine, in terms of prescriptions, at 6.2M but Oxycodone sells \$2.8B as there is less generic competition.
- **More straightforward path to FDA approval.** EGLT plans to utilize the 505(b)(2) regulatory pathway with both Egalet-001 and Egalet-002 as both morphine and oxycodone are well known products. This should mean an accelerated path to FDA approval with a series of bio-equivalence and safety trials. The pivotal PK study for Egalet-001 is expected to initiate in 1Q14 with NDA submission 4Q14. Egalet-002 is expecting to initiate the first of two Phase 3 safety and efficacy and PK trials in 4Q14 (due to the hard shell abuse-deterrent technology) as well as an abuse-deterrent study in 1Q14. The NDA for Egalet-002 is expected in 1H16.
- **Initiate with a Buy rating, \$30 FV.** Our fair value is derived from a sum-of-the-parts with the US sales of Egalet abuse-deterrent opioids at \$28/share based on a 4x multiple of 2019 US sales of \$475M discounted 5 years at 30%. Our remaining \$2/share value is based on cash (end 2014) and technology value.

Research Analyst Certifications and Important Disclosures are on pages 16 - 18 of this report

Summary and Investment Thesis

We are initiating coverage on Egalet (EGLT) with a Buy rating and a \$30 fair value. EGLT is a specialty pharmaceutical company focused on the development and commercialization of abuse-deterrent oral products for the treatment of pain using their proprietary technology platform. The two product candidates consist of the powerful and highly prescribed opioids morphine and oxycodone both in an extended-release, abuse-deterrent formulations. With the rise of prescription drug abuse, particularly in opioids over the last decade, regulating agencies are taking steps to encourage abuse-resistant/ abuse-deterrent formulations. We believe that Egalet-001(abuse-deterrent morphine) could be a \$125M product by 2018 and Egalet-002 (abuse-deterrent oxycodone) could be \$110M by 2018. EGLT is pursuing the easier-to-market 505(b)(2) filing strategy for both products, with a bioequivalence study for Egalet-001 starting in 1Q14 with data read out by the end of the year. Egalet-002 will start two Phase 3 trials in 4Q14. With the ability to expand to other potential active ingredients and opioids and with the potential of becoming a commercial stage biotech in 2H15, we believe that EGLT is an in inflection point and we value the company at \$30/share based on a sum of the parts.

Top Three Reasons to Own EGLT:

- 1) Positioned in the “sweet spot” of opioid deterrence.** Following the recent approval of abuse-deterrent Oxycontin OP from Purdue and Opana TRF (tamper resistant formulation) from Endo International there is a clear path at the FDA for approving abuse-deterrent opioid products, where that wasn't the case just a few years ago. Even more compelling was the decision by the FDA in 2013 to deny generic equivalents to Purdue's Oxycontin OP, highlighting the clear medical need for additional options to curb the epidemic of opioid abuse.
- 2) Drugs target a significant markets.** Both Egalet-001 and Egalet-002 are targeting the long-acting opioid market. Opioids remain the most prescribed pain medication in the US. According to IMS data, for the last 12 months ending September 2012, long-lasting opioids were prescribed 14.8 million times in the US, generating approximately \$4.1B in sales. Long-acting morphine is the most commonly prescribed opioid with about half of the market at 7.1M prescriptions generating \$560M in sales (heavily generic). Oxycodone is right behind morphine, in terms of prescriptions, at 6.2M but Oxycodone sells \$2.8B as there is less generic competition.
- 3) More straightforward path to FDA approval.** EGLT plans to utilize the 505(b)(2) regulatory pathway with both Egalet-001 and Egalet-002 as both morphine and oxycodone are well known products. This should mean an accelerated path to FDA approval with a series of bio-equivalence and safety trials. The pivotal PK study for Egalet-001 is expected to initiate in 1Q14 with NDA submission 4Q14. Egalet-002 is expecting to initiate the first of two Phase 3 safety and efficacy and PK trials in 4Q14 (due to the hard shell abuse-deterrent technology) as well as an abuse-deterrent study in 1Q14. The NDA for Egalet-002 is expected in 1H16.

Upcoming potential catalysts

EXHIBIT 1

Event	Expected Timing
Egalet-002 Tier 1 Abuse-Deterrent Study	1Q14
Egalet-001 Tier 2 Abuse-Deterrent Study	2Q14
Egalet-001 Tier 3 Abuse-Deterrent Study	2Q14
Egalet-002 Tier 2 & 3 Abuse Deterrent Study	2Q14
Egalet-002 Phase 1 crossover doses	3Q14
Egalet-001 Bioequivalence & PK studies	4Q14
Egalet-001 NDA filing	4Q14/1Q15

Source: Janney estimates

Valuation

We value EGLT at \$30/share fair value based on a sum-of-the-parts. We value the US sales of Egalet abuse-deterrent opioids at \$28/share based on a 4x multiple of 2019 US sales of \$475M discounted 5 years at 30%. Our remaining \$2/share value is based on cash (end 2014) and technology value.

EXHIBIT 2

Sum-of-the-parts value: EGLT		
Segment	Valuation (000's)	Per share value
Egalet AD opioids	\$511,725	\$28.0
Cash (end '14) & tech value	\$29,450	\$2.0
SUM	\$541,175	\$30
Shares out '14E (000)		18,170

Source: Janney estimates

Company Description:

Egalet (EGLT) is a specialty pharmaceutical company that is focused on the development and commercialization of proprietary, abuse-deterrent oral products for the treatment of chronic pain and other potential indications. The abuse-deterrent characteristics make the two current product candidates, Egalet-001 and Egalet-002 resistant to crushing and grinding, making the drugs difficult to snort, smoke or inject as well as dissolve in alcohol. As these products use commonly prescribed opioids, EGLT will be utilizing the FDA's 505(b)(2) regulatory pathway to take advantage of a faster and more cost effective drug approval process.

EGLT has two product candidates in late-stage development. The first is Egalet-001, an extended-release, abuse deterrent oral morphine formulation for the treatment of pain. Egalet-001 is expected to initiate a bioequivalence in 1Q14 with data read out by the end of the year as well as two abuse-deterrent studies with data in 2Q14. An NDA is expected 4Q14/1Q15. We project Egalet-001 could be a \$125M product by 2018.

The second product is Egalet-002, an extended-release, abuse deterrent oral formulation of oxycodone in a two-component system, a hard matrix surrounded by a polylactic acid hard shell. Egalet-002 expected to initiate two Phase 3 safety and efficacy trials in 4Q14. We project that Egalet-002 could generate \$110M in sales by 2018.

Egalet-001 (Morphine)

The lead product candidate is Egalet-001, an abuse-deterrent extended release, oral morphine formulation for chronic pain. This product consists of a hard matrix that controls the release of the active pharmaceutical ingredient (API), in this case morphine, over time as the matrix erodes in the GI tract of the patient.

These tablets are produced via an injection molding, not the traditional compression method. This one-component system is resistant to crushing, in order to swallow, snort or smoke, and dissolving in order to inject, and is designed to deter abuse by injection in particular, which is the most common method of abuse of morphine-based products.

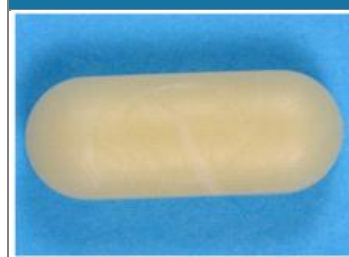
Egalet-002 (Oxycodone)

The second product candidate is Egalet-002. Much like Egalet-001, this too is an abuse deterrent extended release oral formulation for chronic pain. However, Egalet-002 is an oxycodone product and has a two-component system, utilizing the hard matrix from Egalet-001 but then adding an additional hard shell made of polylactic acid which is a thermoplastic aliphatic polyester created from renewable resources that degrades into lactic acid in the body. Egalet-002 not only has abuse-deterrent properties but also demonstrates lower peak-to-trough concentration variability in drug exposure.

The Egalet Technology Platform:

The Egalet platform is unique in the business as it uses injection-molding, via pressure and heat to create its tablets. This is the same technology that is used to manufacture certain medical devices such as implants and diagnostics and is reproducible and most importantly scalable and cost-efficient. The technology also allows EGLT to tailor release profiles by changing the composition of the matrix as well as the

EXHIBIT 3 – Egalet-001



Source: company presentation

EXHIBIT 4 – Egalet-002

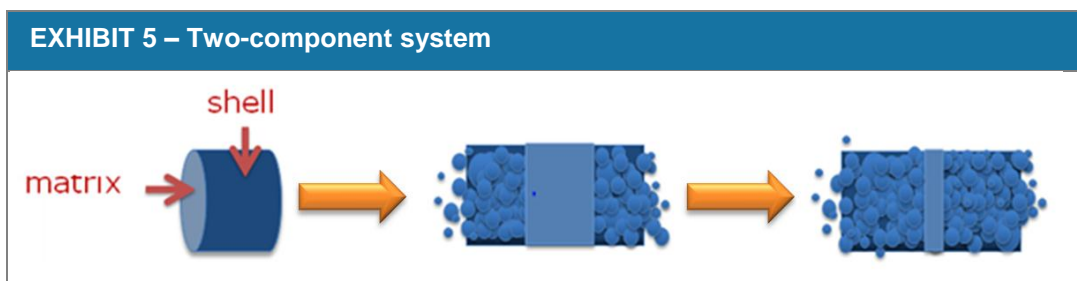


Source: company presentation

amount of surface area exposed to create immediate release (IR), extended release (ER) or sustained release (SR) profiles.

The one-component system: The one-component system is utilized in the Egalet-001 production. The system produces a tablet that consists of a matrix that controls the release of the API, in this case morphine as well as other inactive agents. This matrix erodes in the GI tract, thus releasing the API. The one-component system is resistant to crushing which makes it resistant to abuse via swallowing, snorting, smoking or dissolving and also possesses a gelling effect which is designed in particular to deter abuse from injection.

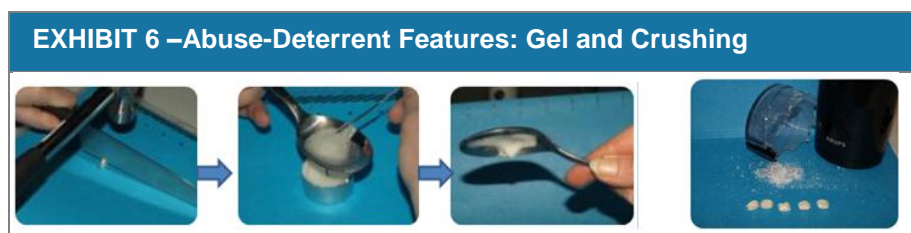
The two-component system: The second two-component system utilizes the hard matrix of the first system but is surrounded by a water-impermeable, non-eroding cylindrical hard shell made of PLA. This system allows the API matrix to have limited surface area exposure. This, in turn slows down its erosion in the GI tract. Once the API matrix erodes from the shell, the shell degrades over several months into lactic acid, a natural chemical found in the body.



Source: company presentation

Abuse-Deterrent Features:

According to the CDC, opioids and their derivatives are the most abused prescription drug in the US. Abusers are usually looking to accelerate the concentration of drug in the bloodstream which intensifies their effects. One of the easiest forms of opioid abuse is physical tampering of the medications such as crushing. Crushing allows the drug to be snorted, smoked or dissolved for injection. EGLT technology, however, offers unique features to curtail these methods of abuse.



Source: company presentation

EGLT Technology Feature	Description	Abuse Method Targeted
Extreme Hardness	<ul style="list-style-type: none"> • Difficult to grind into a powder • Not easily crushed or chewed 	Snorting
Difficult to Extract	<ul style="list-style-type: none"> • Dissolves poorly in domestic solvents • Slow to dissolve in water 	Snorting Ingestion
Difficult to Melt	<ul style="list-style-type: none"> • High melting temperature • Heating creates foul, plastic odor 	Ingestion Injection
Combustion-Resistant	<ul style="list-style-type: none"> • Drug vapor not released from matrix • Burning creates a foul, plastic odor 	Smoking

What is the Market?

Both Egalet-001 and Egalet-002 are targeting the long-acting opioid market. Opioids remain the most prescribed pain medication in the US. According to IMS data, for the last 12 months ending September 2012, long-lasting opioids were prescribed 14.8 million times in the US, generating approximately \$4.1B in sales.

Of that market, long-acting morphine is the most commonly prescribed opioid with about half of the market at 7.1M prescriptions generating \$560M in sales. Currently there are only three branded products presenting 66.4% of sales but only 11.1% (~788,000) of prescriptions. If approved, Egalet-001 should capture significant share of the branded market. We model sales at \$125M in 2018.

Oxycodone is right behind morphine, in terms of prescriptions, coming in at 6.2M in the 12-months ending September 2012. However, Oxycodone is the market leader in sales of long-acting opioids with \$2.8B as the oxycodone market has less generic competition. If approved, Egalet-002 should capture a significant share of this branded market. We model sales at \$110M in 2018

Current Regulatory Environment:

According to the CDC, in 2009 drug-related deaths (40% of which involved opioids) became the leading cause of accidental death in the US, surpassing that of car accident. Death from opioid analgesic were more than cocaine and heroin combined.

Due to the rise in abuse of these medications coupled with the cost of abuse to both public and private healthcare payors, the regulators took notice. In July of 2012, the STOPP (Stop Tampering of Prescription Pills) Act was introduced. The Act requires a shift to abuse-deterrent (AD) products for controlled substances like opioids with the removal of non-AD products.

In January 2013, the FDA outlined the regulatory pathway for the approval of drugs with abuse-deterrent claims on their label and in April it denied the approval of generic Oxycotin as the generic formulation did not have the abuse-deterrent features of the 2010 reformulated version. Continuing the trend, in September 2013, the FDA announced that it intends to change the labeling on all approved ER and long-acting opioids. This change would effectively limit the use of these drugs to patients who have pain severe enough to require daily, around-the-clock, long-term pain management. Lastly, in October of 2013, the FDA announced that it would be formally requesting that Vicoden be reclassified from a schedule III controlled substance so that of the more restrictive schedule II, sighting the high incidence of abuse.

A Faster Path to Approval Through 505(b)(2) Trails

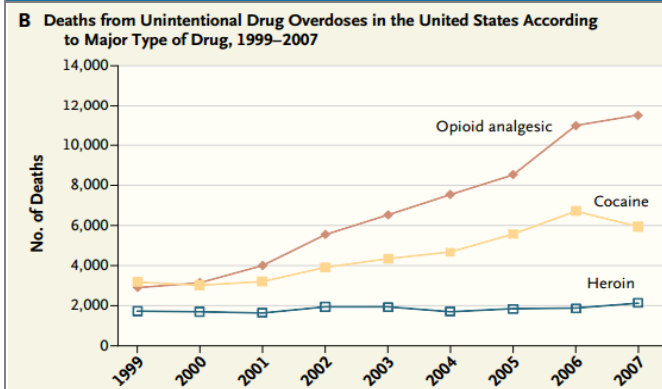
EGLT plans to utilize the 505(b)(2) regulatory pathway with both Egalet-001 and Egalet-002 as both morphine and oxycodone are well known products. This should mean an accelerated, less expensive path to FDA approval. EGLT is not required to run expensive and time consuming phase 3 trials, but rather a series of bio-equivalence and safety trials. The pivotal PK study for Egalet-001 is expected to initiate in 1Q14 with NDA submission 4Q14. Egalet-002 is expecting to initiate the first of two Phase 3 safety and efficacy and PK trials in 4Q14 as well as an abuse-deterrent study in 1Q14. The NDA for Egalet-002 is expected in 1H16.

Clinical Trial Data: Egalet-001

Egalet-001 Clinical Program: EGLT's product candidate Egalet-001 has completed several clinical phase 1 trials as well as several abuse-deterrence studies.

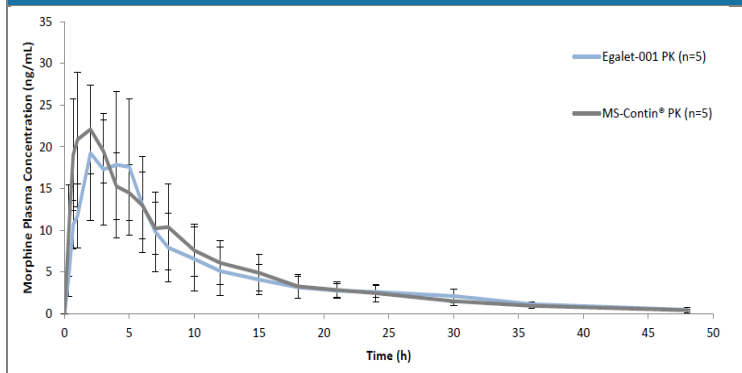
Egalet-001 completed a Phase 1 trial with a primary endpoint of similarity to the pharmacokinetic (PK) profile of MS-Contin. The standard bioequivalence parameters are total concentration, expressed as the area under the curve or (AUC) and peak concentrations,

EXHIBIT 7 – Deaths from Unintentional Drug OD



Source: NEJM, Data from National Vital Stats System, CDCP

EXHIBIT 8 – Egalet-001 PK Profile similar to MS-Contin



Source: company presentation

EXHIBIT 9 – PK 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 presentation

expressed as C_{max}. The results of this 10 participant trial as shown by the graph below, demonstrate that Egalet-001 has a similar PK profile to MS-Contin in concentration of API in the bloodstream for 48 hours after administration.

A second Phase 1 PK trial to evaluate Egalet-001 compared to MS-Contin has also been completed. This study involved 30 healthy participants and was conducted using a standard crossover design with AUC and C_{max} as primary endpoints.

In order to demonstrate bioequivalence under FDA guidance, EGLT must establish that the AUC and C_{max} of Egalet-001 are within a 80-125% range of the same measures of MS-Contin, in each case with a 90%

confidence interval. In this trial, the 90% confidence intervals indicated that Egalet-001 had an AUC of between 91% and 98% of that of MS-Contin and a C_{max} of between 82% and 99% of MS-Contin. These results successfully met the FDA guidance for bioequivalence between Egalet-001 and MS-Contin.

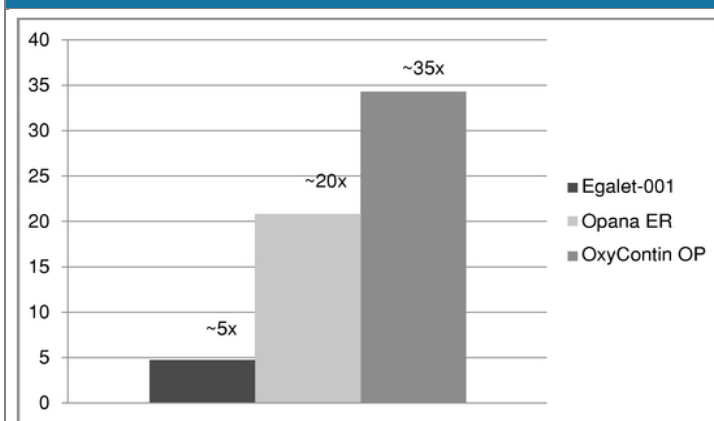
Egalet-001 Preclinical Abuse-Deterrence Studies:

EGLT has also completed several in-house studies of the abuse-deterrent features of Egalet-001 particularly that of injection as it is the most common form of abuse for morphine. Another form of abuse is manipulation via dissolution in water and other common household solvents.

The in-house study had participants attempt to grind Egalet-001, OxyContin OP and Opana ER into smaller particles and then take the remaining tablet and particles and place them in water. The amount of time for 80% of API to be released was then measured. The OxyContin and the Opana ER particles both showed accelerated release profiles compared to their intact forms whereas as Egalet-001 particles released at ~5X the rate of the intact form. This study will have to be confirmed via a third-party in order to support the inclusion of abuse-deterrent claims on the label.

A second in-house study evaluated Egalet-001 for abuse by injection. In this study Egalet-001, MS-Contin and OxyContin OP were placed in a microwave and heated for up to 16 minutes. The resulting substance was then mixed with a small amount of water, typical for injection. The solution was then drawn into a syringe in order to measure viscosity of the liquid. Egalet-001 remained highly viscous at 2400cP which is the limit of what can be measured as a form that is too viscous to be injected. Centipoise (cP) is the common measurement of viscosity. Egalet-001 at 2400 cP is quite gelatinous compared to room temperature water, which has a cP of 1. The chart below shows the results.

EXHIBIT 10 – Increase in Release Rate of API



Source: company presentation

EXHIBIT 11 – Egalet-001 Viscosity in Crisping Study

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 presentation

Egalet-001: The Path Forward:

In order to submit the NDA for approval, Egalet-001 still needs to complete several more clinical trials that establish that the C_{max} and the AUC will fall within the 80%-125% range of the C_{max} and the AUC of MS-Contin. These intended trials are as follows:

- PK trial comparing single-dose 15mg MS-Contin with single dose 15mg Egalet-001 under fasting conditions
 - N=24 to 30 patients
 - Initiate 1Q14 with data 4Q14
- PK trial comparing single-dose and steady-state 100mg MS-Contin with 100mg Egalet-001 under fasting conditions
 - N=24 to 30 patients
 - Initiate 1Q14 with data 4Q14
- PK trial comparing 100mg MS-Contin with 100mg Egalet-001 under fed conditions
 - N=24 to 30 patients
 - Initiate 1Q14 with data 4Q14
- In vitro dose proportionality trials of 30 and 60mg doses.
 - Initiate 1Q14 with data 4Q14

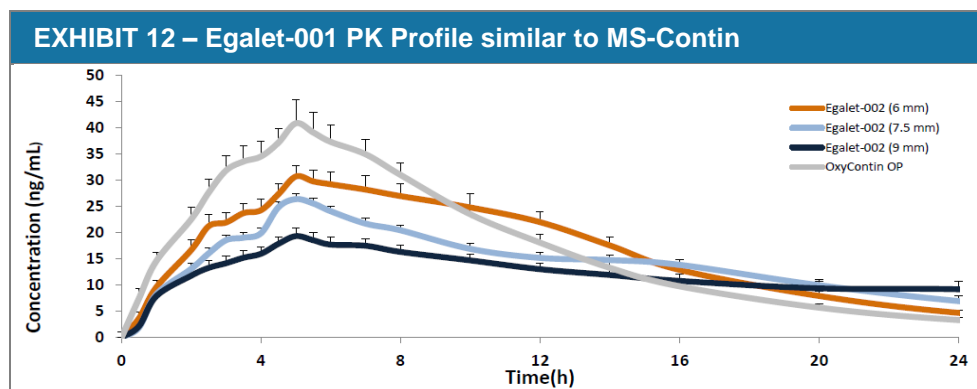
The other critical piece to the success of Egalet-001 is to perform the abuse-deterrent studies consistent with the FDA guidelines. EGLT believes the following three studies are necessary in order to file for abuse-deterrence.

- Tier 1 in vitro studies to test Egalet-001's ability to resist a broad range of common methods of abuse such as particle size reduction or extraction through crushing or dissolving and common methods of intake such as swallowing, snorting and injecting.
 - Initiate 1Q14
- A tier 2 abuse deterrence study comparing PK characteristics of manipulated Egalet-001 and manipulated MS-Contin
 - N=15 patients
 - Initiate 2Q14
- A tier 3 randomized, double-blind, placebo-controlled and comparator controlled crossover study to compare the likeability of Egalet-001 and MS-Contin.
 - N=30 experienced patients
 - Initiate 2Q14

Clinical Trial Data: Egalet-002

Egalet-002 Clinical Program: EGLT's product candidate Egalet-002 has also completed three clinical phase 1 trials as well as several abuse-deterrence studies.

The first phase 1 PK trial was a single-dose, crossover study looking at three different sizes of 40mg Egalet-002 tablet, 6mm, 7.5mm and 9mm compared to OxyContin OP. The study compared their relative in vivo release profiles of 16 patients with the primary endpoint being similarity to the PK profile of OxyContin based on C_{max} and the AUC over 24 hours. Each formulation showed differences in release profile with all three Egalet-002 showing lower peak-to-trough variability.



Source: company presentation

A second phase 1 trial involved multiple-doses and was a crossover study with 22 patients covering a dosage period of five days with similar PK endpoints of OxyContin OP. From this trial, results were consistent with the single dose study and the 6mm formulation was selected as it was consistent with the twice-daily dosing schedule of OxyContin OP. A summary of the two trials is below:

EXHIBIT 13 – Egalet-002 Demonstrated Improved PK Profile to OxyContin OP

Steady State BID	Egalet-002	OxyContin OP	% Improvement
C_{min}^+	22	18	20↑
C_{max}^+	48	59	23↓
AUC * [range]	1008 [687-1519]	942 [620-1782]	N/A

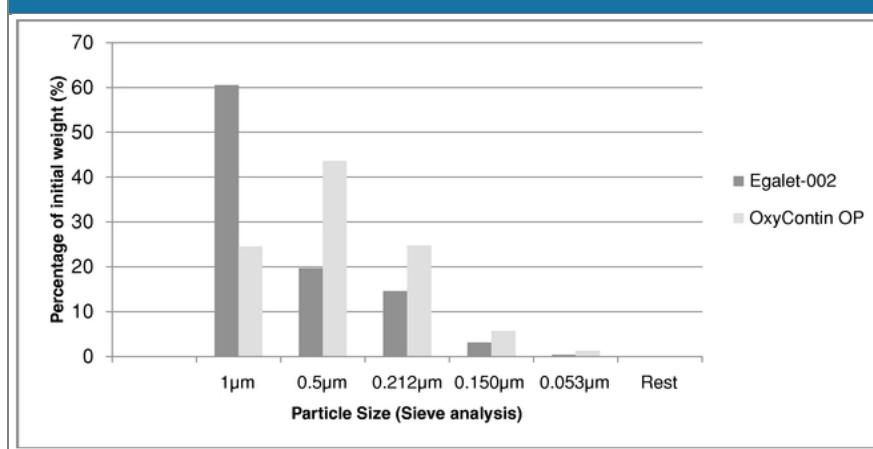
Source: company presentation +ng/mL *ngxh/mL

The third completed trial measured dose proportionality and food effect by looking at the 10, 20, 40 and 80mg doses of Egalet-002 combined with a food-effect arm for the 80mg dose. Egalet-002 showed linear dose proportionality across the full dose range. Food effect was observed, but it was minimal and mirrored results from previous OxyContin studies.

Egalet-002 Preclinical Abuse-Deterrence Studies:

As per the FDA draft guidance, a third party was commissioned to conduct a tier 1 in vitro test of Egalet-002 to compare the ease of achieving particle size reduction of Egalet-002 and OxyContin OP through the use of conventional tools as well as manipulation into an injectable form. With the aid of a coffee grinder, 5 tablets of each Egalet-002 and OxyContin OP were milled in the grinder for 20 seconds and sieved for measurement. Egalet-002 only lost 40% to the first sieve 1um opening while 60% of the tablet did not pass through. In contrast, only 24% of the OxyContin was captured in the first sieve with 76% of the tablet was small enough to pass through. See the chart below.

EXHIBIT 14 – Egalet-002 Superior to OxyContin OP in Tampering



Source: company presentation

Egalet-002: The Path Forward:

Based on feedback from the FDA, Egalet-002 will need to complete several more clinical trials.

- Phase 3 randomized, double-blind, placebo-controlled efficacy and safety trial for the analgesic management of 300 patients with moderate to severe chronic lower back pain requiring around-the-clock opioid therapy
 - Endpoints: reduced pain scores and potentially reduced relief medication
 - Trial design: a baseline period of up to two weeks prior to administration of Egalet-002 40mg, an open-label titration period of up to four weeks and a double-blind placebo-controlled treatment period of 12 weeks

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- Initiate 1Q15 with data 2H15
 - Phase 3 open-label, long-term safety trial in which up to 250 patients will be treated with Egalet-002 for either one year, six months or three months in order to demonstrate the safety of the shell
 - Initiate 4Q14
 - A single-dose, alcohol-interaction PK study in which subjects will ingest an Egalet-002 80mg tablet followed by 240ml of four liquid combinations: water with no alcohol and water with alcohol concentrations of 4%, 20% and 40%.
 - Initiate 2Q14

The other critical piece to the success of Egalet-002 is to perform the abuse-deterrent studies consistent with the FDA guidelines. EGLT believes the following three studies are necessary in order to file for abuse-deterrence.

- Tier 1 in vitro studies to test Egalet-002's ability to resist a broad range of common methods of abuse such as particle size reduction or extraction through crushing or dissolving and common methods of intake such as swallowing, snorting and injecting.
 - Initiate 1Q14
- A tier 2 abuse deterrence study comparing PK characteristics of manipulated Egalet-002 and manipulated OxyContin OP
 - N=45 patients
 - Initiate 2Q14
- A tier 3 randomized, double-blind, placebo-controlled and comparator controlled crossover study to compare the likeability of Egalet-002 and OxyContin.
 - N=45 experienced patients
 - Initiate 3Q14

Potential for Other Products: Egalet-003

EGLT's proprietary technology platform has the potential to become more broadly used with additional types of pharmaceutical products. This unique drug delivery platform allows for a flexibility that can be applied to administration of other commonly abused APIs, including combination products.

Based on preclinical development, EGLT intends to select a third abuse-deterrent, opioid product candidate, Egalet-003. Selection and the initiation of Phase 1 clinical studies are expected in 2014 with EGLT seeking regulatory approval through the same Section 505(b)(2) pathway as Egalet-001 and Egalet-002.

Management

Robert Radie, President and CEO – 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 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 Financial Officer – Mr. Musial has served as 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.

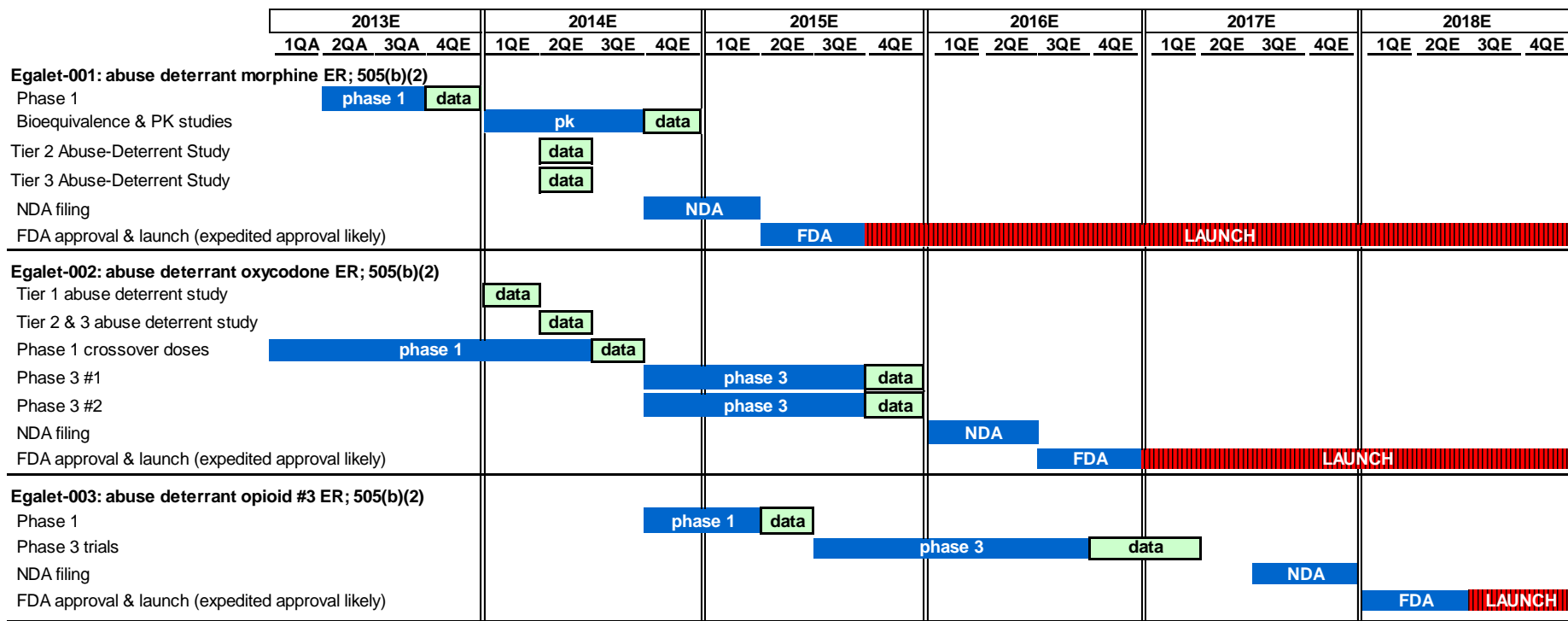
Roland Gerritsen van der Hoop, M.D., PH.D., Chief Medical Officer – Dr. Gerritsen van der Hoop currently serves as chief medical officer. As a consultant to Egalet, Dr. Gerritsen van der Hoop is overseen directly by Mr. Radie, the chief executive officer, and does not perform a policy making-function. 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 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 of Research and Development – Dr. Lindhardt has served as 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 our 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.Sci. in Pharmaceutics and a Ph.D. in pharmaceutical development and pharmacology, each from the Royal Danish School of Pharmacy.

Mark Strobeck, PH.D., Chief Business Officer – Dr. Strobeck is the chief business officer, a position he has held since January 2014, and previously served as an adviser to Egalet from June 2012 to December 2013. From January 2012 to December 2013, Dr. Strobeck served as president and chief executive officer and a director of Corridor Pharmaceuticals, Inc. From December 2010 to October 2011, Dr. Strobeck served as chief business officer of Topaz Pharmaceuticals Inc., a specialty pharmaceutical company acquired by Sanofi Pasteur in the fourth quarter of 2011. From June 2010 to November 2010 and October 2011 to January 2012, Dr. Strobeck worked as a consultant. From January 2008 to May 2010, Dr. Strobeck served as chief business officer of Trevena, Inc., a pharmaceutical company. Prior to joining Trevena, Dr. Strobeck held management roles at GlaxoSmithKline, SR One Limited and EuclidSR Partners, L.P. Dr. Strobeck currently serves on the board of directors of Horse Power For Life, a non-profit organization dedicated to improving the quality of life for individuals diagnosed with cancer, a position he has held since 2012. Dr. Strobeck received his B.S. in biology from St. Lawrence University and his Ph.D. in pharmacology from the University of Cincinnati, and completed his post-doctoral fellowship at the University of Pennsylvania.

Egalet

Clinical development trial timelines



Source: Company reports and Janney estimates

Specialty Pharmaceuticals
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Egalet

Quarterly income statement

	2012 Year	2013E				2013E Year	2014E				2014E Year
		1QA	2QA	3QA	4QE		1QE	2QE	3QE	4QE	
(\$000 except per share)											
Revenues											
Egalet-001: AD Morphine ER											
Egalet-002: AD Oxycodone ER											
Egalet-003: AD other opioid ER											
Collaborative R&D	1,201										
Total Revenue	\$1,201	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Expenses:											
Cost of Revenue (COGS)	-										
Gross Margin	1,201	-	-	-	-	0	-	-	-	-	0
Research and development	4,256	1,073	1,073	1,073	1,075	4,295	3,250	3,500	3,600	8,000	18,350
General and administrative	2,241	1,074	1,074	1,074	1,075	4,298	2,250	2,450	2,800	3,000	10,500
Total operating expenses	6,497	2,148	2,148	2,148	2,150	8,593	5,500	5,950	6,400	11,000	28,850
Income (loss) from Operations	(5,296)	(2,148)	(2,148)	(2,148)	(2,150)	(8,593)	(5,500)	(5,950)	(6,400)	(11,000)	(28,850)
Interest income (expense), net	(75)	(1,481)	(1,481)	(1,481)	(1,500)	(5,943)					0
FOREX loss	(27)	(38)	(38)	(38)	(40)	(153)					0
Income (loss) before taxes	(5,398)	(3,666)	(3,666)	(3,666)	(3,690)	(14,689)	(5,500)	(5,950)	(6,400)	(11,000)	(28,850)
Income tax exp (benefit)	-	-	-	-	-						
Net Income (Loss)	(5,398)	(3,666)	(3,666)	(3,666)	(3,690)	(14,689)	(5,500)	(5,950)	(6,400)	(11,000)	(28,850)
Earning per Share (EPS)	(\$5.01)	(\$3.40)	(\$3.40)	(\$3.40)	(\$0.35)	(\$4.29)	(\$0.34)	(\$0.36)	(\$0.39)	(\$0.65)	(\$1.75)
Adj EPS ex-1x & non-cash items											
Weighted avg. shares (000)	1,077	1,077	1,077	1,077	10,458	3,422	16,120	16,370	16,620	16,870	16,495
Fully diluted shares (000)							17,568	18,120	18,370	18,620	18,170

Specialty Pharmaceuticals

Source: Company reports and Janney estimates

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Egalet

Annual income statement

(\$000 except per share)	2013E	2014E	2015E	2016E	2017E	2018E	Comments
Revenues							
Egalet-001: AD Morphine ER			\$8,000	\$40,000	\$91,000	\$125,000	FDA approval mid-2015
Egalet-002: AD Oxycodone ER				0	85,000	110,000	phase 3 data 4Q15, 1Q17 launch
Egalet-003: AD other opioid ER					0	15,000	phase 3 starts 2H15
Total Revenue	\$0	\$0	\$8,000	\$40,000	\$176,000	\$250,000	
Expenses:							
Cost of Revenue (COGS)	-	-	2,000	4,800	17,600	25,000	
Gross Margin	-	-	6,000	35,200	158,400	225,000	
R&D	4,295	18,350	34,050	33,000	35,000	40,000	
G&A	4,298	10,500	21,600	29,750	34,500	41,000	120 person sales force
Total op exp	8,593	28,850	55,650	62,750	69,500	81,000	
Inc/(loss) from Ops	(8,593)	(28,850)	(49,650)	(27,550)	88,900	144,000	
Int income (exp), net	(5,943)	-	-	-	-	-	
Other expenses, net	(153)	-	-	-	-	-	
Inc/(loss) before taxes	(14,689)	(28,850)	(49,650)	(27,550)	88,900	144,000	
Income tax exp (benefit)	-	-	-	-	-	21,600	
Net Income (Loss)	(\$14,689)	(\$28,850)	(\$49,650)	(\$27,550)	\$88,900	\$122,400	
Earning per Share	(\$4.29)	(\$1.75)	(\$2.50)	(\$1.30)	\$3.40	\$4.20	
Weighted avg. shares (000)	3,422	16,495	19,870	21,120	22,620	24,121	
Fully diluted shares (000)	-	18,170	22,620	24,120	26,120	29,121	
Cash (\$000)	\$6,767	\$42,900	\$37,520	\$11,870	\$103,470	\$228,645	

Source: Company reports and Janney estimates

Specialty Pharmaceuticals
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Egalet

Balance sheet

(\$000's except per share)	2013E	2014E	2015E	2016E	2017E	2018E
ASSETS						
Current assets						
Cash and cash equivalents	6,767	42,900	37,520	11,870	103,470	228,645
Total current assets	9,767	55,400	56,270	38,620	138,720	273,145
PP&E	1,500	1,500	1,750	2,500	3,000	3,750
Intangible asset						
Total Assets	14,767	61,400	63,270	46,870	148,970	285,395
LIABILITIES						
Total current liabilities	15,849	16,500	18,000	22,000	26,500	32,500
Total liabilities	30,806	32,000	36,000	44,500	54,150	67,950
Shareholders Equity						
Common	11	15	20	20	25	25
Additional paid-in-capital	11,506	86,116	133,631	136,281	139,826	140,051
Other comp income	325					
Accumulated deficit	(27,881)	(56,731)	(106,381)	(133,931)	(45,031)	77,369
Total shareholders' equity	(16,039)	29,400	27,270	2,370	94,820	217,445
Total liabilities & net worth	14,767	61,400	63,270	46,870	148,970	285,395

Source: Company reports and Janney estimates

Egalet

Statement of cash flows

(\$000's except per share)	2013E	2014E	2015E	2016E	2017E	2018E
Operating Activities						
Net Income (Loss)	(\$14,689)	(\$28,850)	(\$49,650)	(\$27,550)	\$88,900	\$122,400
Adjustments:						
Depreciation and Amortization	325	350	400	400	450	525
Noncash interest	4,750	5,000	5,000	5,000	5,000	5,000
Changes in assets and liabilities	(1,125)	(8,849)	(4,750)	(4,000)	(4,000)	(3,250)
Net cash from operations	(10,739)	(32,349)	(49,000)	(26,150)	90,350	124,675
Investing Activities						
Purchase of equipment	(800)	(1,000)	(1,500)	(2,000)	(2,000)	(2,500)
Net cash from investing	(800)	(1,000)	(1,500)	(2,000)	(2,000)	(2,500)
Financing Activities						
Issuance of common stock		54,482	45,120	2,500	3,250	3,000
Shionogi share purchase		\$15,000				
Proceeds from convertible debt	15,000					
Payment lender fees	(98)					
Net cash from financing	14,902	69,482	45,120	2,500	3,250	3,000
Net change in cash	3,363	36,133	(5,380)	(25,650)	91,600	125,175
Cash at beginning of year	3,404	6,767	42,900	37,520	11,870	103,470
Cash at end of year	6,767	42,900	37,520	11,870	103,470	228,645

Source: Company reports and Janney estimates

RISKS TO FAIR VALUE ESTIMATE:

Exogenous events could impact our outlook. We believe that pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often our conclusions are drawn from early-stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

IMPORTANT DISCLOSURES

Research Analyst Certification

I, Jim Molloy, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Egalet Ltd. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Egalet Ltd. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Egalet Ltd. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Egalet Ltd. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

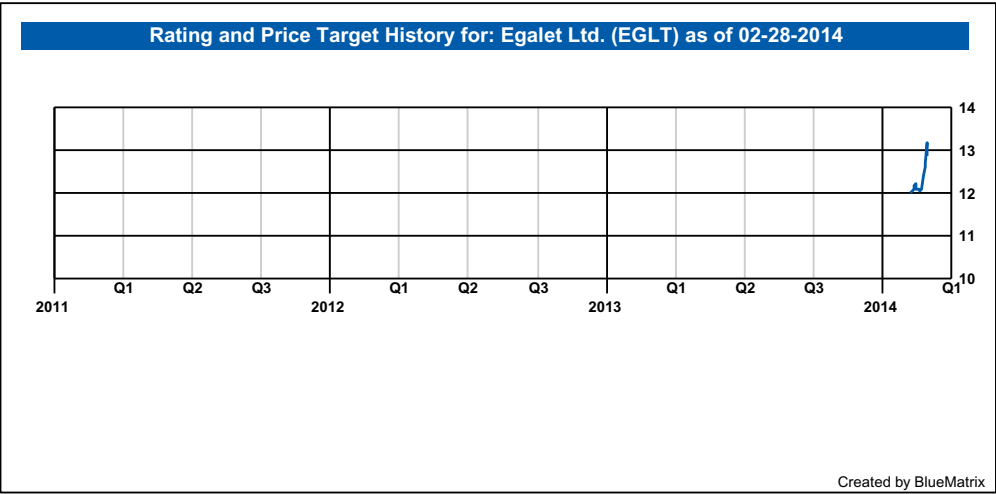
Definition of Ratings

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 12/31/13

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	247	53.00	30	12.10
NEUTRAL [N]	211	45.50	13	6.20
SELL [S]	7	1.50	0	0.00

***Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.**

Other Disclosures

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