

## **Egalet Corp.**

EGLT: NASDAQ: US\$15.13

**BUY** 

John Newman - Canaccord Genuity Inc. (US)

Target: US\$20.00 JNewman@canaccordgenuity.com

212.389.8042

#### **COMPANY STATISTICS:**

Forecast Return:	53.4%
Market Cap (M):	US\$210.3
52-week Range:	11.82 - 13.92
Avg. Daily Vol. (000s):	78.0

### **EARNINGS SUMMARY:**

FYE Dec		2013E	2014E	2015E
Revenue (M):		0.0	10.0	7.8
EPS:		(1.11)	(1.51)	(1.53)
Revenue (M):	Q1	0.0A	10.0	0.0
	Q2	0.0A	0.0	0.0
	Q3	0.0A	0.0	2.5
	Q4	0.0	0.0	5.2
Total		0.0	10.0	7.8
EPS:	Q1	(2.13)A	0.28	(0.47)
	Q2	(2.29)A	(0.41)	(0.48)
	Q3	(4.28)A	(0.68)	(0.34)
	Q4	(0.30)	(0.71)	(0.09)
Total		(1.11)	(1.51)	(1.53)

#### **SHARE PRICE PERFORMANCE:**



Source: Interactive Data Corporation

## **COMPANY DESCRIPTION:**

Egalet is a specialty pharma company focused on developing abuse-deterrent formulated drugs, including opioids. Egalet is utilizing the FDA's 505(b)(2) pathway with the intent of shortening development timelines and cost.

All amounts in US\$ unless otherwise noted. Priced as of the close on March 4, 2014

## Life Sciences -- Specialty Pharmaceuticals

## ABUSE-DETERRENT PAIN DRUGS TARGET \$3.3B MARKET; INITIATE AT BUY, \$20 PT

## **Investment recommendation**

We view Egalet as a leader in the abuse-deterrent drug development space with two assets in the clinic targeting a lucrative combined \$3.3B market opportunity. We see upside based on expected FDA approval for the company's two lead assets, Egalet-001, an abuse-deterrent morphine, in H2/15, and Egalet-002, an abuse-deterrent oxycodone, in 2017.

## **Investment highlights**

- Abuse-deterrent morphine peak >\$150M, YE15 approval: We expect
  FDA approval for Egalet's abuse-deterrent morphine drug by YE15,
  with peak sales estimated at ~\$150M by 2024. Also, we expect
  entirely manageable competition from Embeda's-re-launch during
  Q2/14 due to four previous recalls and serious promotional
  violations.
- Oxycodone drug targets \$3B one-player market, no generics: Egalet's abuse-deterrent oxycodone could reach \$1.1B by 2027, given the \$3B one-player, 100% branded market, holding upside to shares. We value Egalet-002 at \$12 per share, adjusted by 35% based on stage of development, and ~\$25-55 based on partnered/non-partnered approval. Also, abuse-deterrence data vs. Purdue's Opana OP in 2014 could push shares higher.
- Platform applicable to other abuse-deterrence drugs: Egalet's abuse-deterrence technology platform could be applicable to other drug classes, such as Attention Deficit Hyperactivity Disorder (ADHD), adding additional value. ADHD is projected to reach >\$6B by 2018, and abuse is a major problem that carries heavy FDA scrutiny.

### **Valuation**

We value Egalet based on a probability-adjusted Net Present Value calculation for Egalet-001, Egalet-002 and cash. We model three possible scenarios for the company involving multiple partnership options for Egalet-002. We expect FDA approval for both Egalet-001 and 002. Our \$20 value is based on a \$6 value for Egalet-001, \$12 value for Egalet-002, and \$2 value for cash.

Canaccord Genuity is the global capital markets group of Canaccord Genuity Group Inc. (CF: TSX | CF.: LSE)

The recommendations and opinions expressed in this research report accurately reflect the Investment Analyst's personal, independent and objective views about any and all the Designated Investments and Relevant Issuers discussed herein. For important information, please see the Important Disclosures section in the appendix of this document.



## **TABLE OF CONTENTS:**

Investment thesis	3
Upcoming catalysts	4
Valuation – Establishing \$20 price target	6
Company overview	8
Risks to our outlook	8
Egalet-001, abuse-deterrent morphine – Estimate \$150M peak sales 2024	10
Embeda - \$75M run rate after 14 months encouraing	13
Bioequivalence enables short development timeline	15
Egalet-002 – abuse-deterrent oxycodone, estimate \$887m-\$1.1M peak 2027	18
\$3B single player market highly attractive	22
Egalet-002 – better abuse deterrence vs. market leader	22
OxyContin market likely branded long-term	23
Technology platform leverageable to other assets	24
FDA strongly favors abuse deterrence	25
Competitive landscape presents opportunity	28
Opioid abuse in the US	32
Management team	33
Financials	35



## **INVESTMENT THESIS**

We are initiating coverage of Egalet Corp. with a BUY rating and \$20 price target based on our expectation for FDA approval and robust revenues for the company's two abuse-deterrent opioid drugs. Egalet is a specialty pharma company focused on developing abuse-deterrent formulated drugs, including opioids, which should carry a higher barrier to entry than traditional formulations. Importantly, Egalet is utilizing the FDA's 505(b)(2) pathway, which could shorten development timelines and cost, thus lowering investor risk.

## Two abuse-deterrent products target combined \$3.3B market

Egalet is developing two abuse-deterrent opioid pain drugs: Egalet-001 (morphine), and Egalet-002 (oxycodone), both of which we expect to receive FDA approval. The market opportunity for each product seems attractive, and we estimate a \$300-400M available market for Egalet-001 and a \$3B opportunity for Egalet-002 (oxycodone). We expect FDA approval for Egalet-001 by YE 2015 and believe that revenues may surprise to the upside.

## Morphine product has \$150M peak sales potential, Embeda competition fully manageable

We expect Egalet-001 to garner meaningful market share upon expected launch in late 2015, driving share value. Egalet-001 is an abuse-deterrent formulation of morphine and utilizes a one-part formulation designed to resist abuse by preventing crushing, snorting, and injection. FDA will likely deem Egalet-001 bioequivalent to MS Contin, a previously approved oral, long-acting morphine product. We expect FDA approval for Egalet-001 based only on bioequivalence, studies without Phase 3 data, reducing time and cost.

Importantly, the Egalet-001 launch may fare better than Embeda, another abuse-deterrent form of morphine that was fully removed from the market due to formulation and stability issues in March 2011. Importantly, Embeda was on a ~\$75M annual run rate ~14 months after launch, but was heavily hindered by promotional violations and multiple recalls related to formulation and stability. Thus, Egalet-001 could fare better in the marketplace, and we predict ~\$150M peak sales by 2024. We expect Embeda to be re-introduced in Q2/14 but are skeptical with regard to market uptake due to four previous recalls and questions regarding physician comfort with the drug.

### Abuse-deterrent oxycodone could reach \$1B, no generics expected

Egalet-002 represents a significant upside driver, targeting a single-player (Purdue), 100% branded \$3B market for oxycodone, with no generics expected long term. Egalet-002 utilizes Egalet's two-part system, creating a higher barrier to abuse. We expect abuse-deterrence data for Egalet-002 during 2014 to drive shareholder value since the studies will be run head-to-head vs. Purdue's OxyContin OP, an FDA-approved abuse-deterrent formulation of oxycodone. We expect Egalet-002 to demonstrate better abuse-deterrence data versus Purdue's OxyContin OP, based on existing in-house mechanical manipulation data previously generated by Egalet. Better abuse-deterrence could result in a commercial advantage for Egalet-002 vs. OxyContin OP.



## Partnership validates technology, applicable to other drug classes

We also believe Egalet's injection molding technology platform has received additional validation due to a partnership with Shionogi for development of abuse-deterrent hydrocodone products. Shionogi made an upfront payment of \$10M to Egalet and also agreed to purchase \$15M of Egalet stock via a private placement concurrent with the completion of the recent initial public offering. Egalet will receive royalties on net product sales of all Shionogi compounds, with 100% of the R&D paid by Shionogi. Importantly, Egalet's technology could be applicable to other drug classes since the abuse deterrence is related to Egalet's matrix system and also Poly Lactic Acid shell, not the active ingredient. Specifically, Egalet's technology may be applied to Attention Deficit Hyperactivity Disorder (ADHD), a market with serious abuse concerns, predicted to exceed \$6B in the US by 2018.

## **UPCOMING CATALYSTS**

## Expect positive bioequivalence, abuse-deterrence data for Egalet-001 by Q3-Q4/14

We expect positive pivotal bioequivalence data for Egalet-001 (morphine) versus MS Contin by YE14, paving the way for NDA submission by YE14 and FDA approval in 2H15. Prior data demonstrate similar pK measures for both Cmax and AUC, leading us to believe upcoming pivotal bioequivalence data will also be successful. Bioequivalence with MS Contin, combined with abuse-deterrence properties that resist crushing and dissolving, satisfy a significant unmet need and should drive FDA approval (Figure 1).

We expect Tier II abuse-deterrence studies – testing abuse potential via manipulation – to return positive results during Q3-Q4/14, also supporting FDA approval. Importantly, Egalet's one-component hard matrix system prevents crushing, grinding, and, specifically, injecting. We also expect Tier III abuse-deterrence studies to produce positive data in Q3-Q4/14, in part because injection, the most common route of morphine abuse, should be nearly impossible.

## Anticipate FDA approval for Egalet-001 by H2/15

Our model assumes FDA approval for Egalet-001 during H2/15, which should significantly boost share value. Importantly, we do not believe that FDA will require any additional data beyond bioequivalence to MS Contin combined with Tier I, II, and III abuse-deterrent studies. Importantly, Egalet-001 is 100% owned by Egalet, with no royalties owed to a third party.

## Upside on Egalet-002 vs. OxyContin OP abuse deterrent, studies Q4/14

We anticipate positive abuse-deterrence data for Egalet-002 (oxycodone) compared head-to-head vs. OxyContin OP by Q4/14, leading to significant upside for the stock. Importantly, superior abuse-deterrence data for Egalet-002 vs. OxyContin OP would offer high clinical and commercial differentiation. Egalet expects Tier I, II and III abuse-deterrence data for Egalet-002 by Q4/14. We also expect positive data for an Egalet-002 alcohol extraction study and do not expect "dose-dumping" seen with OxyContin where alcohol results in rapid and dangerous drug uptake.

Event	Timing	Drug	Description	Effect	Importance	Notes	
Data	2Q14	Egalet-001	Tier 1 Abuse Deterrence results	<b>↑</b>	Moderate	Expect positive data supporting Tier 1 abuse deterrence given physiochemical performance of Egalet-001	
Data	3Q/4Q14	Egalet-001	Tier 2 and 3 Abuse Deterennce Results	<b>↑</b>	High	Expect positive data supporting Tier 2 and Tier 3 abuse deterrence given physiochemical performance of Egalet-001	
Data	4Q14	Egalet-002	Tier 2, Tier 3 Abuse Data, Alcohol Interaction Data	↑ Critical		Expect positive data <b>head-to-head design</b> vs. OxyContin OP should move stock	
Data	YE14	Egalet-001	Bioequivalence Data	Data    Critical		Expect positive data supporting bioequivalence	
Data	3Q15	Egalet-003	Phase 1 Data	1	Moderate	Safety Data for Egalet-003	
Data	4Q15	Egalet-002	Data for two Phase 3 studies	<b>↑</b>	Critical	Anticipate positive data supporting safet and efficacy	
FDA Decision	2H15	Egalet-001	PDUFA	<b>↑</b>	Critical	Expect approval given bioequivalence and unmet need for abuse-deterrent formulations of morphine	
FDA Decision	2H17	Egalet-002	PDUFA	<b>↑</b>	Critical	Expect approval given unmet need for abuse-deterrent formulation of oxycodor	

Source: Canaccord Genuity, Company presentations, SEC filings

## Phase 3 Egalet-002 data expected YE15

We expect positive Phase 3 data from two studies for Egalet-002 by YE15, offering a major catalyst for share appreciation. Egalet will conduct a full Phase 3 program for Egalet-002 since the two-component formulation system will be used. Importantly, abuse-deterrent data for Egalet-002 are expected by YE14 and could provide a critical indication of the product's approvability, especially in respect to abuse deterrence vs. OxyContin OP.



## **VALUATION - ESTIMATE \$20 PRICE TARGET**

We estimate a \$20 price target for Egalet shares based on a sum-of-the-parts probability-adjusted NPV analysis by product. We assume 100% commercialization for Egalet-001 and model three possible scenarios for Egalet-002: (1) 100% Egalet commercialization, (2) partnership based on an operating profit split, and (3) partnership involving an 8-18% net sales royalty. We assume probabilities of 20%, 55%, and 25% for the scenarios, giving our \$20 price target.

Figure 2: Egalet valuation

Product	Peak Sales (\$MM)	Peak Year	Current Value (\$MM)	Probability Adjustment	Value / Share	Scenario probability	Adjusted Value
Non-Partnered							
Egalet-001 (morphine)	162	2025	88	65%	\$6	20%	\$1
Egalet-002 (oxycodone)	886	2027	256	35%	\$18	20%	\$4
Equity Value					\$25	20%	\$5
Partnered							
Egalet-001 (morphine)	162	2025	88	65%	\$6	55%	\$3
Egalet-002 (oxycodone)	1112	2027	149	35%	\$11	55%	\$6
Equity Value					\$17	55%	\$9
Royalty							
Egalet-001 (morphine)	162	2025	88	65%	\$6	25%	\$2
Egalet-002 (oxycodone)	200	2027	109	35%	\$8	25%	\$2
Equity Value					\$14	25%	\$4
Total Equity Value							\$18
Net Cash (50% adj)							\$2
Value per share							\$20
Shares Outstanding (MM)							13.9
Risk-Free Rate	2.00%	, D					
Beta	1.30						
Risk Premium	8%	, D					
Discount Rate	12%	, D					
Effective Discount Rate 001	18%	, D					
Effective Discount Rate 002	24%	, D					

Figure 3: Comparable companies Company Ticker MKT Cap EΥ EV/Sales Price Nektar **NKTR** 1,782 1,685 11 \$14.18 9 Durect **DRRX** 161 143 \$1.45 Zogenix **ZGNX** 590 600 18 \$4.25 190 125 \$13.04 Egalet **EGLT** 

Source: Bloomberg; priced intraday 3/4/14. Sales are LTM.

<b>EV/Sales Comparables</b>			EV/Sale	es			
Company	<u>EV</u>	<u>LTM</u>	<u>2014E</u>	2015E	2016E	2017E	2018E
NKTR	1,685	11.2	8.0	6.0	6.7	5.2	3.3
DRRX	143	9.4	10.2	10.2	6.7	4.4	3.1
ZGNX	600	18.5	7.9	4.4	2.7	2.0	1.6
Average		13.0	8.7	6.9	5.4	3.9	2.6
Egalet	125		_	16.1	3.5	1.16	0.6

Source: Bloomberg; priced intraday 3/4/14.

Our analysis is based on peak sales projections for Egalet's two lead products – Egalet-001 and Egalet-002. We estimate peak sales for each product with a market build based on prescription data from Symphony Health. We then apply relevant COGS, R&D, and SG&A expenses to arrive at operating profit. Next, we subtract tax which we estimate at ~37%, to arrive at net profit. We assume Egalet will utilize non-operating loss carryforwards resulting in no tax for the first 1-2 years of product revenues. Last, we discount the net profit back to the present at 12%, which we derive from the Capital Asset Pricing Model (CAPM). Importantly, we utilize a 65% probability adjustment for Egalet-001 and a 35% probability adjustment for Egalet-002, resulting in effective discount rates of 18% and 24%, respectively. We also include a 50% probability adjusted value for net cash, as the company will burn cash until cash flow turns positive. (Figure 2).

## Egalet-001 (morphine) worth ~\$6 probability adjusted

We probability adjusted projected revenues for Egalet-001 by 65% based on anticipated positive results for bioequivalence data. We assume Egalet will commercialize Egalet-001 on its own, fielding a sales force of  $\sim$ 60 reps. We model peak sales of  $\sim$ \$150M by 2024 and probability adjust the resulting NPV by 65%. Importantly, assuming FDA approval, we estimate Egalet-001 is worth  $\sim$ \$10 to the stock.

### Egalet-002 (oxycodone) worth ~\$12 probability adjusted

Our estimates suggest a ~\$12 value for Egalet-002 based on peak sales of ~\$886-\$1.1B by 2027. We model three scenarios for Egalet-002: solo commercialization (20%), commercial partnership (55%), and commercial royalties (25%), which we used to find an expected value NPV. We assume slightly higher peak sales projections under a partnered scenario since the partner is likely to have a larger sales force marketing the products.

Our solo commercialization scenario is worth \$18, our commercial partnership scenario is worth \$11, and our royalty scenario is worth \$8. We remind investors that we apply a probability adjustment of ~35% to the NPV for each scenario. Assuming FDA approval for Egalet-002, the solo commercialization, partnership, and royalty scenarios would be worth \$56, \$36, and \$22, respectively.

## Net cash worth ~\$2, assuming 50% adjustment

We include a \$2 value for net cash in our valuation, which assumes a 50% probability adjustment, as the company will be burning cash in the near future. Egalet has  $\sim$ \$65M in cash at present and  $\sim$ 14M shares outstanding, resulting in a value of \$4 for net cash, which we then probability adjust by 50% to give the \$2 value.

## **COMPANY OVERVIEW**

Egalet is a clinical stage specialty pharmaceutical company focused on developing abuse-deterrent opioid and other drugs utilizing a 505(b)2 regulatory pathway. Egalet has two abuse-deterrent (AD) formulations – Egalet-001 (morphine) and Egalet-002 (oxycodone) – that prevent the crushing, grinding, combusting, and dissolution of its products.

Egalet-001 is an extended-release oral morphine formulation designed to be resistant to injection, the most common form of morphine abuse, as well as crushing, snorting, and extraction. Egalet-002 is an extended release oral oxycodone formulation particularly resistant to crushing, grinding, and snorting, the most common forms of oxycodone abuse. Egalet plans on filing an NDA for Egalet-001 in the first half of 2015 and an NDA for Egalet-002 in the first half of 2016.

Egalet plans to market Egalet-001 with a 50- to 60-person internal specialty sales force that will target pain specialists, followed by plans to target primary care physicians involving a salesforce increase or potential external partner. Manufacturing is currently outsourced to Halo Pharmaceuticals. Egalet will likely co-promote Egalet-002 utilizing its current sales force, as well as that of a potential partner, assuming FDA approval in 2016.

In addition, Egalet has partnered with Shionogi, a specialty pharmaceutical company, for development of abuse-deterrent formulations of hydrocodone. Egalet and Shionogi will develop hydrocodone-based products utilizing Egalet's abuse-deterrent 1 and 2 component systems. Under the agreement, Shionogi will pay for all development, commercialization and marketing expenses as well as pay Egalet development, commercialization, and sales milestones that could total up to \$450 million, in addition to tiered royalties on product sales. The agreement allows for up to 20 other hydrocodone-based products to be developed using Egalet's AD platform.

## **RISKS TO OUR OUTLOOK**

Risks to our rating and price target include the following: approval for Egalet-001 and Egalet-002 may be delayed or may never occur at all; total revenues, even with timely approvals, may be lower than our estimates; future litigation may delay or reduce total revenues.

Specifically, if the FDA does not allow Egalet to pursue approval for Egalet-001 through the Section 505(b)(2) pathway via bioequivalence to MS-Contin, the company may be forced to conduct Phase 3 studies resulting in increased costs, delayed revenue generation, and



more competition. Although current data seem to support bioequivalence vs. MS-Contin this does not guarantee similar results in future studies, which may result in FDA rejection and downside to our \$20 price target.

Egalet-001 and Egalet-002 also face competition from currently marketed non-abuse-deterrent products sold by Purdue, Pfizer, Endo, Actavis, Mallinkrodt, Watson, and others. Specifically, in the case of Egalet-001, >90% of the long-acting morphine market is help by low-cost generics, which may create a commercial challenge for Egalet-001. In addition, additional competitors are working towards bringing similar abuse-deterrent products to market – all of which may cause Egalet-001 and Egalet-002 to have lower peak sales than our estimates. Also, FDA guidance for development of generic abuse-deterrent drugs may surface earlier than our expectations, resulting in downside to the stock and our price target.

The planned reintroduction of Embeda, another abuse-deterrent long-acting morphine drug (Pfizer), may have a negative impact on the market opportunity for Egalet-001, resulting in downside to our price target. Embeda may be more readily accepted by doctors and be viewed as a better alternative versus Egalet-001, assuming approval. Also, Pfizer's marketing capability may be substantially higher than Egalet, resulting in higher than expected competition and limiting revenues for Egalet.

Also, legislation to remove non-abuse-deterrent opioid drugs from the market may never materialize, resulting in investor concern and potential downside to the share price. Even if legislation does materialize, it may be later than anticipated, allowing for lower priced generic versions of non-abuse-deterrent drugs to limit the market for Egalet-001 and 002. Our evaluation is based on the prior precedent of major changes to FDA policy being mandated by large but sometimes infrequent legislation such as the Affordable Care Act (ObamaCare).

Egalet may also face legal competition related to the entry of Egalet-001 and Egalet-002 to market. Several competitors currently in the space may undertake legal strategies to delay the launch of Egalet-001 and Egalet-002. These competitors have significantly greater resources at their disposal than Egalet and have more experience maneuvering the legal field. If they were to be successful in delaying or preventing the entry of Egalet's products to market this could result in meaningful downside to our price target and Egalet shares. Specifically, some may sue Egalet if Egalet-002 is approved, attempting to secure a preliminary injunction to stop Egalet's sale of drug into interstate commerce. We do not believe Purdue would be successful, as we do not view Egalet-002 as violating any of Purdue's issued patents. Importantly, the pK profile for Egalet-002 is substantially different than OxyCodone OP, which should avoid infringement of Purdue's patents. Also, Egalet-002's technology is different than Purdue's from an abuse-deterrence perspective, which should also favor Egalet-002.

From a financial standpoint, although Egalet currently has adequate cash on hand of ~\$65 per share, the company may require additional capital before the anticipated launch of Egalet-001 in the second half of 2015. An additional capital raise could pressure shares and result in downside to our \$20 price target.



# ABUSE-DETERRENT MORPHINE LIKELY \$150M PRODUCT BY 2024

We anticipate FDA approval for Egalet-001 (abuse-deterrent morphine) by YE 2015 and model peak sales of ~\$150M by 2024. We model Egalet-001 revenues based on share from retail data in four market segments, obtained from Symphony Health data (Bloomberg): (1) branded morphine prescriptions, (2) generic morphine prescriptions, (3) branded non-morphine long-acting opioids (Opana ER, Exalgo, etc), and (4) generic non-morphine long-acting opioids. We assume ~240,000 branded retail long-acting morphine prescriptions by 2024, ~7.3M generic long-acting morphine prescriptions, ~650,000 branded non-morphine long-acting prescriptions, and ~800,000 generic non-morphine prescriptions. Our model assumes a 14-24% market contraction for branded long-acting opioids during 2014 and 2015 followed by a 1% decline in 2016, no growth in 2017, and 1% growth from 2017 to 2020 (Figure 5). Our \$150M peak sales estimate is based on ~165,000 Egalet-001 prescriptions by 2024 and 15% prescription share. We also assume 5% price increases beginning in 2016. Importantly, we assume generic entry in 2026, although the barrier to generic entry is likely to be very high due to the abuse-deterrence properties for Egalet-001 and lack of FDA guidance for generic development.

We model a \$300-400M accessible market for Egalet-001 in 2024 based on \$200M from the branded market in 2024, \$93-190M from generic morphine based on a 1.5-3.0% share of ~7.2M prescriptions, \$6M from branded non-morphine high dose opioids based on a 1.5% share of ~615,000 prescriptions, and \$7M based on a 1.5% share from ~800,000 generic non-morphine high dose opioids.



Egalet-001 (morphine) (000s)	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Total Branded Retail Prescriptions (USC Code 02222)	1,151,011	1,070,440	1,016,918	986,411	976,547	976,547	976,547	976,547	976,547	976,547	976,547	976,547
% Growth YoY	88%	93%	95%	97%	99%	100%	100%	100%	100%	100%	100%	100%
Total Branded Morphine Sulfate Prescriptions	269,342	242,408	230,288	230,288	230,288	232,591	234,917	237,266	239,638	242,035	244,455	246,900
% Growth YoY	-20%	-10%	-5%	0%	0%	1%	1%	1%	1%	1%	1%	1%
Total Morphine Sulfate Generic Prescriptions	6,448,557	6,642,014	6,708,434	6,775,518	6,843,273	6,911,706	6,980,823	7,050,631	7,121,138	7,192,349	7,264,273	7,336,915
% Growth YoY	3%	3%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Branded Everthing Else	679,902	577,917	577,917	577,917	583,696	589,533	601,324	613,350	625,617	638,130	650,892	663,910
% Growth YoY	-30%	-15%	0%	0%	1%	1%	2%	2%	2%	2%	2%	2%
Generic Everything Else	392,910	510,783	612,939	674,233	707,945	729,183	743,767	758,642	773,815	789,291	805,077	821,179
% Growth YoY	338%	30%	20%	10%	5%	3%	2%	2%	2%	2%	2%	2%
Total Market	7,790,711	7,973,121	8,129,578	8,257,956	8,365,202	8,463,013	8,560,830	8,659,889	8,760,208	8,861,805	8,964,697	9,068,904
	2%	2%	2%	2%	1%	1%	1%	1%	1%	1%	1%	1%
% Egalet Share												
Branded Morphine Sulfate		2%	5%	8%	9%	12%	13%	14%	14%	15%	15%	16%
Generic Morphine Sulfate		0%	1%	1%	1%	1%	1% _	1% _	1% _	1% _	1% _	2%
Branded Everything Else		1%	1%	1%	2%	2%	2%	2%	2%	2%	3%	3%
Generic Everything Else		0%	0%	0%	1%	1%	1%	1%	1%	1%	1%	1%
Total Egalet Prescriptions	•	14,343	58,809	82,263	102,621	127,017	135,262	142,493	149,878	157,417	165,116	172,975
Cost Per Egalet Prescription		551	579	608	638	670	704	739	776	814	855	898
Total Egalet-001 Revenue		\$ 7.770	\$ 35,593	\$ 52,221	\$ 68.384	\$ 88.867	\$ 99,362	\$ 109.902	\$ 121,371	\$ 133,843	\$ 147,400 \$	162.128



## Comparator Embeda - \$75M run rate after 14 months encouraging

Importantly, Pfizer's Embeda was on a run rate of ~\$75M after only ~14 months on the market despite serious problems, suggesting higher potential for Egalet-001, which we believe should not have any of these issues. Embeda had serious stability issues and promotional violations that seriously hampered sales, yet the drug reached a \$75M run rate after only 14 months. Specifically, Pfizer recalled Embeda from the market on four separate occasions due to formulation issues, including three in 2010 and one in 2011 due to dissolution problems and naltrexone leakage. Embeda is an abuse-deterrent formulation of morphine formulated around a naltrexone core, where naltrexone is designed to neutralize the pain effect of morphine upon crushing.

We model a conservative launch ramp for Egalet-001 compared to Embeda, which was heavily hampered by formulation issues and promotional restrictions. As shown in Figure 6, we anticipate that Egalet-001 will gain ~4% market share four quarters after launch, compared to 7% for Embeda. Importantly, referencing Embeda may prove too conservative since the drug was recalled from the market four times and suffered from immediate FDA restrictions after launch, likely heavily dampening the launch trajectory. Egalet-001 could potentially enjoy a stronger launch trajectory, resulting in upside to our estimates.

Egalet-001 v Embeda Launch - % share 8% 7% 6% cent Market Share 5% 4% Embeda 3% Egalet-001 **Per** 2% 1% 0% 0 1 2 3 5 **Quarters Since Launch** 

Figure 6: Projected Egalet-001 vs. Embeda launch (share)

Source: Canaccord Genuity estimates, Bloomberg



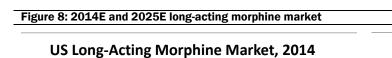
Figure 7: Projected Egalet-001 vs. Embeda launch (sales)

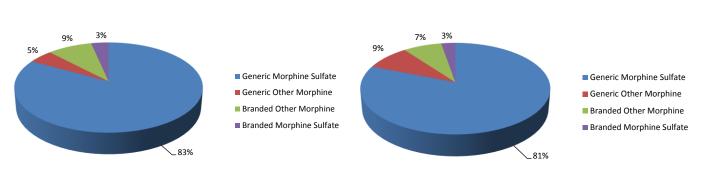
Source: Canaccord Genuity estimates, Bloomberg

## Long-acting morphine market attractive despite generics

The long-acting branded morphine market represents a  $\sim $300-400 \text{M}$  opportunity at present, an attractive opportunity for Egalet-001. Importantly, branded long-acting morphine makes up  $\sim 66\%$  of total long-acting morphine sales (branded+generic), even though branded drugs account for only  $\sim 6\%$  of total prescriptions. Thus, despite generic entry of MS Contin in 2009, the market still remains attractive for a branded entrant (Figure 8).

**US Long-Acting Morphine Market, 2025** 



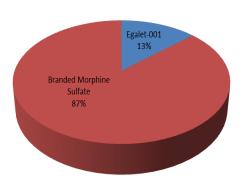


Source: Canaccord Genuity, Bloomberg

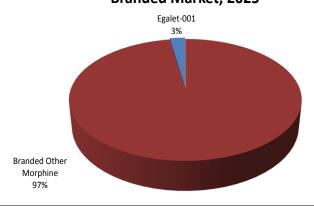


Figure 9: Estimates for branded morphine and non-morphine markets in 2025

Egalet-001 Market Share of Branded Morphine Sulfate Market, 2025

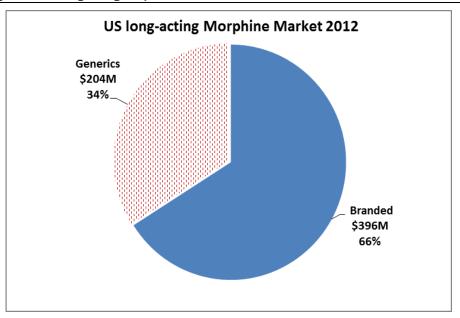


Egalet-001 Market Share of non-Morphine Branded Market, 2025



Source: Canaccord Genuity, Bloomberg

Figure 10: US long-acting morphine market 2012 - revenues



Source: Bloomberg, Egalet Company Presentations

There are three long-acting branded morphine products in the market at present, Kadian (Pfizer), Avinza (Actavis), and MS Contin, which has a generic alternative, but still garners some share as a branded product. Embeda was marketed between October 2009 and March 2011, but was withdrawn from the market. We expect Embeda to be re-introduced in Q2/14, but believe market uptake may be sluggish since the product has been withdrawn due to formulation issues on four prior occasions. Five versions of generic high dose morphine (MS Contin) currently garner ~90-95% prescription share, but branded sales make up 66% of dollar share.



## Bioequivalence data encouraging, enables short approval timeline

Egalet has produced encouraging bioequivalence data for Egalet-001 from two studies that should enable FDA approval. Egalet will utilize a 505(b)(2) pathway where the company can reference safety and efficacy data for the previously approved MS Contin in the Egalet-001 NDA filing. We also believe that the company can receive approval for Egalet-001 without running a full Phase 3 program but rather relying on bioequivalence to MS Contin which should be clearly demonstrated by YE14.

Egalet-001 has shown bioequivalence data with AUC and Cmax within 80-125% of the respective measures for MS-Contin, in each case within a confidence interval of 90%, suggesting a high chance of FDA approval. Egalet recently completed a pK study in n=30 healthy volunteers, with AUC of 224  $\pm$ 53 ng/mL\*hr for Egalet-001 vs. 236  $\pm$ 48 ng/mL\*hr for MS-Contin, and with Cmax of 25  $\pm$ 8 ng/mL vs. 27  $\pm$ 8 ng/mL for MS Contin (Figure 11). Importantly, although Tmax, or time to maximum plasma concentration of Egalet-001, was longer for Egalet-001 vs. MS Contin (3 vs. 1 hr); the observed Tmax for MS Contin is similar to other long-acting morphine drugs that are currently marketed. These data demonstrate bioequivalence for Egalet-001 vs. MS Contin, and should be sufficient for FDA approval.

Figure 11: Bioequivalence data for	r Egalet-001 to	<b>MS-Contin</b>
------------------------------------	-----------------	------------------

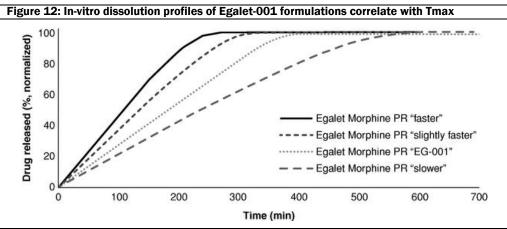
pK parameter	Egalet- 001	MS- Contin
$AUC_{0:t}(ng/mL^*h) \pm one standard$ deviation (SD)	224 ± 53	236 ± 48
$AUC_{0-\infty}(ng/mL^*h) \pm SD$	234 ± 56	244 ± 49
$C_{max}$ (ng/mL) ± SD	25 ± 8	27 ± 8
T <sub>max</sub> (h) [range]	3 [1-5]	1 [0-2]

Source: Egalet SEC Filings

## Additional formulation work for Egalet-001 reinforces technology

Egalet also showed the ability to increase or decrease the rate of dissolution for Egalet-001 via three other formulations, which correlated with changes in blood plasma levels, reaffirming the technology. Importantly, the Cmax for faster, slightly faster, Egalet-001, and slower formulations was 38, 30, 25, and 22 ng/mL, which correlated closely with dissolution times (Figure 12).





Source: Egalet SEC filings

## In-house abuse-deterrent data interesting

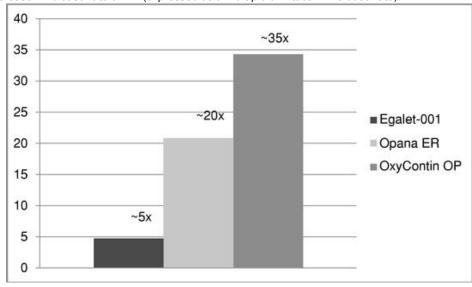
Egalet-001 has demonstrated superior abuse-deterrent data versus both Opana ER and OxyContin OP, via in-house studies, suggesting that upcoming clinical abuse-deterrent studies will be successful and support approval. Abuse deterrence has become a strong focus at FDA in recent years, and we expect that the agency will work closely with drug developers to introduce new abuse-deterrent products. Egalet conducted preclinical and inhouse studies to support Egalet-001's abuse-deterrent properties.

Preclinical work demonstrated that Egalet-001 forms a gel when dissolved in water or other common household solvents, preventing abuse by injection, which is the most common route of abuse. An in-house study also examined grinding Egalet-001, Opana ER, and OxyContin OP using a nutmeg grater, and time to release 80% of the API in water was compared. Egalet-001 demonstrated API release 5x faster than normal, versus 20x for Opena ER and 35x for OxyContin OP (Figure 13).



Figure 13: In-house abuse-deterrence data Egalet-001

Increase in release rate of API (expressed as a multiple of intact API release rate)



Source: Egalet SEC filings

Egalet also performed an in-house "crisping" study to evaluate resistance of Egalet-001 to abuse by injection, which produced strong results versus MS-Contin, OxyContin OP, and Opana ER. The crisping study involved heating Egalet-001, MS-Contin, OxyContin, and Opana ER tablets in a microwave for up to 16 minutes. The resulting substance was mixed with water and attempted to be drawn into a syringe in order to measure viscosity. Importantly, Egalet-001 demonstrated viscosity >2,400 centipose, a level which is impossible to inject at 0 min, 8 min, and 16 minute timepoints. Although OxyContin OP remained highly viscous at 0 minutes, viscosity dropped dramatically after 8 min of crisping. Also, Opana ER remained >2,400 centipose after 0 and 8 minutes of crisping, but showed only 30 centipose viscosity after 16 minutes of crisping (Figure 14).

Figure 14: Egalet in-house crisping study

Crisping time, min (microwave oven, 900W)	Egalet-001 viscosity (3mL water) cP	MS-Contin viscosity (3 mL water) cP	MS-Contin 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	60

Source: Egalet SEC filings

## Clinical abuse-deterrence data expected Q3-Q4/14

Egalet will conduct three separate abuse-deterrence studies for Egalet-001, which we expect to be successful and support FDA approval in 2H15. Tier I abuse-deterrence studies will evaluate Egalet-001's ability to withstand mechanical manipulation methods for abuse,

including particle size reduction, extraction through crushing or dissolving, as well as swallowing, snorting, and injecting. Tier II abuse-deterrence studies will follow to evaluate the pK properties of manipulated Egalet-001.

Tier III studies are arguably the most important of the abuse-deterrent trials, as they evaluate the "likeability" of Egalet-001 versus MS-Contin that is, how much abusers like the drug. The Tier III likeability study will be run in n=30 experienced abusers in a double blind, placebo-controlled and comparator crossover study. Low likeability for Egalet-001 versus MS-Contin would suggest a strong abuse-deterrent proposition to FDA. We expect that Egalet-001 will perform strongly versus MS Contin since injection of Egalet-001 has previously been shown to be nearly impossible based on in-house studies. Importantly, injection is the preferred route of morphine abuse.

# EGALET-002 – ANTICIPATE ~\$887M-\$1.1B PEAK SALES BY 2027

We expect FDA approval for Egalet-002, an abuse-deterrent formulation of oxycodone, for moderate-to-severe pain treatment by the second half of 2017, and model ~\$887M-\$1.1B peak sales by 2027. We view the \$3B single-player (Purdue) market as highly attractive and expect FDA approval, in part due to potentially superior abuse-deterrent properties versus OxyContin OP (Purdue). In addition, we do not anticipate competition from generic abuse-deterrent products until the FDA provides guidance on how to produce a generic abuse-deterrent oxycodone drug, which may not surface for some time. Also, FDA has declared that it will not approve generic versions of the non-abuse-deterrent version of OxyContin, since the drug was pulled from the market for safety reasons.

We model ~\$887M-\$1.1B U.S. peak sales for Egalet-002 by 2027 based on expected share from Purdue's long-acting abuse-deterrent oxycodone, OxyContin OP. We expect that Egalet-002 share will come mainly from branded high dose morphine, with minimal share from generics and non-morphine high dose drugs. Based on prescription and reported sales data, we assume 4.5M total retail prescriptions, and 661,000 institutional prescriptions for OxyContin OP by 2027.

## We assume three different scenarios for Egalet-002, with partnership being most likely

Possible scenarios include: (1) solo commercialization by Egalet, (2) Partnership with 50% operating profit split, and (3) partnership with royalty to Egalet. For our solo commercialization scenario, we model 25% retail and institutional share for Egalet-002 by 2027, resulting in ~1.7M prescriptions. For our two partnered scenarios, we assume a higher peak share of ~33% by 2027 due to a larger combined sales effort. Our model assumes Egalet-002 launch in 2017, even though Purdue could attempt to delay launch via litigation. We assume a price of \$450 per script for Egalet-002 at launch, and 5% annual price increases, resulting in a price of \$733 by 2027. Our resulting peak revenues are \$886M for Egalet-002 in 2027 for solo commercialization, and \$1.1B for partnered revenues (Figure 10).

Our partnering scenario involving royalties assumes an 8-18% tiered royalty, and assumes a partner would pay 100% of R&D and SG&A costs. We assume a tiered royalty beginning at  $\sim 8\%$  for Egalet-002 revenues < \$50M, 10% for revenues between \$50-100M, 12% for revenues between \$100-200M, 14% for revenues between \$200-400M, and 18% for revenues > \$400M.



Egalet-002 (\$000's)	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026
Total Retail Branded Rx Count	4,574,027	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287
% Growth yoy	98%	99%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Total Retail Generic Rx Count	43	44	44	45	45	46	46	46	47	47	48
% Growth yoy	102%	101%	101%	101%	101%	101%	101%	101%	101%	101%	1019
% Egalet Share of Branded		2%	5%	11%	16%	21%	22%	23%	23%	24%	249
% Egalet Share of Generic											
Number of Prescriptions		90,566	226,414	498,112	724,526	950,940	996,223	1,027,921	1,050,563	1,073,204	1,095,845
Cost Per Prescription		450	473	496	521	547	574	603	633	665	69
Egalet-002 Retail Revenue		40,755	106,981	247,126	377,428	520,143	572,158	619,881	665,211	713,525	765,007
	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026
Total Institutional Branded Rx Count	769,867	731,374	702,119	681,055	667,434	660,760	660,760	660,760	660,760	660,760	660,760
% Growth yoy	94%	95%	96%	97%	98%	99%	100%	100%	100%	100%	100%
% Egalet Share of Branded		2%	5%	11%	16%	21%	22%	23%	23%	24%	249
% Egalet Share of Generic											
Number of Prescriptions		14,627	35,106	74,916	106,789	138,760	145,367	149,992	153,296	156,600	159,904
Cost Per Prescription		250	263	276	289	304	319	335	352	369	38
Egalet-002 Institutional Revenue		3,657	9,215	20,649	30,906	42,166	46,382	50,251	53,926	57,842	62,016
Total Egalet-002 Revenue		44,411	116,196	267,774	408,334	562,309	618,540	670,132	719,137	771,367	827,023

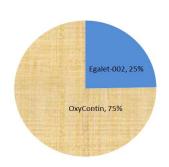
Source: Canaccord Genuity estimates

Figure 16: Long-acting US oxycodone market forecast, 2014 and 2027

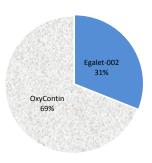
US Long-Acting Oxycodone Market, 2014

OxyContin 100%

US Long-Acting Oxycodone Market, 2027 - Solo-Commercialization



## US Long-Acting Oxycodone Market, 2027 Partnered Commercialization



Source: Canaccord Genuity estimates, Bloomberg

Figure 17: Egalet-002 scenarios 2 and 3:: commercial partnership, operating profit split, royalties

Oxycodone (Egalet-002) partnered	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Total Retail Branded Rx Count	4,574,027	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287	4,528,287
% Growth yoy	-2%	-1%	0%	0%	0%	0%	0%	0%	0%	0%
Total Retail Generic Rx Count	43	44	44	45	45	46	46	46	47	47
% Growth yoy	2%	1%	1%	1%	1%	1%	1%	1%	1%	1%
% Egalet Share of Branded % Egalet Share of Generic		3%	6%	12%	18%	23%	27%	28%	29%	30%
Number of Prescriptions		135,849	289,810	543,394	815,092	1,041,506	1,222,638	1,267,920	1,313,203	1,358,486
Cost Per Prescription		450	473	496	521	547	574	603	633	665
Egalet-002 Retail Revenue (\$000's)		61,132	136,935	269,592	424,607	569,681	702,193	764,611	831,514	903,196
	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Total Institutional Branded Rx Count	769,867	731,374	702,119	681,055	667,434	660,760	660,760	660,760	660,760	660,760
% Growth yoy	94%	95%	96%	97%	98%	99%	100%	100%	100%	100%
% Egalet Share of Branded % Egalet Share of Generic		3%	6%	12%	18%	23%	27%	28%	29%	30%
Number of Prescriptions		21,941	44,936	81,727	120,138	151,975	178,405	185,013	191,620	198,228
Cost Per Prescription		250	263	276	289	304	319	335	352	369
Total Institutional Revenue		5,485	11,796	22,526	34,769	46,182	56,924	61,984	67,407	73,218
Total Oxycodone Revenue		66,617	148,731	292,117	459,375	615,862	759,117	826,594	898,921	976,414
Partnership - operating profit split		4,382	56,422	144,563	251,608	349,720	451,613	500,468	553,079	609,700

Source: Canaccord Genuity estimates



## \$3B single player oxycodone market highly attractive

The \$3B oxycodone market is highly attractive based on its size and single player (Purdue, OxyContin OP). Egalet-002 should compete strongly with OxyContin OP on abuse deterrence, based on in-house data showing a more attractive pK profile and better abuse deterrence properties. The combination should generate significant upside for Egalet's share price, if approved.

Importantly, the market for OxyContin could continue to grow over time, assuming better abuse-deterrent formulations are introduced. Historically, OxyContin prescriptions have contracted slightly at a rate of ~3-5% per year, but abuse-deterrent options may slow or flatten this trend. Also, the lack of a generic drug suggests low additional downward pressure on OxyContin growth going forward. Also, the introduction of Egalet-002 might broaden the market somewhat if physicians feel more comfortable using Egalet-002 due to its abuse-deterrent properties.

We model a ~\$3B accessible market for Egalet-002 by 2027 based on ~\$3B in annual sales for Purdue's OxyContin OP in 2013, and assume moderate market contraction offset by similar price increases. We assume only a single competitor in Purdue, and no generic competition, since FDA will not approve generics for the non-abuse deterrent version of OxyContin, which has been removed from the market. We do not assume generic versions of Purdue's abuse-deterrent OxyContin OP since FDA has not yet issued guidance on abuse-deterrent generic drugs.

## Two-component system - high levels of abuse deterrence

Egalet-002 utilizes Egalet's two-component system, which is especially resistant to crushing, grinding, combustion, and dissolution, preventing injecting, smoking and snorting, and could offer a substantial improvement vs. OxyContin OP. In particular, early data suggest meaningfully better resistance to mechanical grinding and crushing as compared to OxyContin OP (Figure 18). Egalet's two-component system consists of a matrix similar to that in the one-component system, but is surrounded by a water-impermeable, non-eroding, cylindrical hard shell of poly-lactic acid (PLA) with the active pharmaceutical ingredient (API) exposed at both ends (Figure 19). The result is greater abuse deterrence, particularly to crushing and grinding, as well as controlled API release. The API surface area exposed to the GI tract is limited to the ends of the capsule, which minimizes dose dumping when taken with alcohol. Egalet-002's hard shell degrades into lactic acid over several months.



70 (3) 60 μμβ 50 | Egalet-002 | OxyContin OP | OxyContin OP | 1μm 0.5μm 0.212μm 0.150μm 0.053μm Rest | Particle Size (Sieve analysis)

Figure 18: Egalet-002 resistance to mechanical abuse

Source: Egalet company presentations, SEC filings

Figure 19: Egalet-002 two-component system control of dissolution

Source: Egalet company presentations, SEC filings

## FDA unlikely to ever approve generics for non-abuse-deterrent OxyContin

In 2013, the FDA approved reformulated abuse-deterrent OxyContin and Purdue subsequently withdrew the original OxyContin, which was deemed to be due to safety reasons; in effective, this permanently barred generics for the non-abuse-deterrent OxyContin. As a result, the FDA will no longer approve generic oxycodone that relies upon bioequivalence (and thus the approval of) original OxyContin. FDA is unlikely to approve generics for the current abuse-deterrent OxyContin (or other future abuse-deterrent oxycodone products) in the near term because of the difficulty in demonstrating similar



levels of abuse deterrence via Tier I, II, III, and IV studies. To demonstrate abuse deterrence, a drug must pass three tiers of studies. Tier I tests the physio-chemical properties of the drug (how the drug may be manipulated). Tier II tests the pK characteristics in the manipulated vs. impact state based on Tier I findings. In Tier III, recreational users are allowed to use the manipulated drug and are questioned on its "likeability" versus a positive control. Underscoring this difficulty is the <u>lack of guidance</u> the FDA has provided in developing abuse-deterrent oxycodone. Importantly, FDA could require generic drugs to demonstrate equivalent abuse potential in the community, which would be cost prohibitive and likely limit generic challenges.



# EGALET TECHNOLOGY PLATFORM LEVERAGEABLE TO OTHER ASSETS

Egalet's abuse-deterrence technology platform is non-specific to opioid based products and can be leveraged to add value in markets where abuse is a concern. Its products are "manufactured using a proprietary injection molding process in which the product is molded using pressure and heat." The result is "reproducible, scalable, and cost-efficient" and can be used to manufacture drugs with up to two APIs. Egalet has plans to initiate a Phase 1 study of Egalet-003, a potentially dual API oral opioid, in the first half of 2014.

## Egalet technology platform leverageable to other assets

Egalet's non-API-specific technology platform supports up to two APIs with different release rates, allowing for abuse-deterrent combination products. Egalet uses an injection molding process, like that utilized in manufacturing of medical implants and diagnostics, to create an efficient, flexible and scalable system. For example, the production of one-component and two-component matrices is done with the same machine. Egalet's recent partnership with Shionogi underscores the technology's abuse-deterrence properties and manufacturing process.

## Plastic injection molding highly efficient

Egalet manufactures its one- and two-component pill molds using a scalable plastic-injection molding process also used in medical device implants and diagnostics manufacturing. Egalet mixes a patented dry ingredient with the API at high heat to form a molten liquid, which is then injected into the pill mold. This two-step approach is highly efficient and flexible. Manufacturing equipment is sourced from Germany, and conducted by Halo Pharmaceuticals in New Jersey. Currently, one machine supplies drug for both clinical and abuse deterrence trials for Egalet-001 and Egalet-002.

## Other potential targets include ADHD, other pain drugs

Egalet has the capacity to advance abuse-deterrence for a number of indications involving schedule I or II narcotics including ADHD and other pain categories. The ADHD market is expected to exceed \$6B in annual US revenues by 2018, presenting an attractive commercial opportunity. Interestingly, Egalet has the capacity to administer up to two APIs using either its one- or two-component pill molds. API release rates are controlled by API surface area, allowing for both IR and ER production.

## Shionogi partnership offers additional validation

Egalet's Shionogi Partnership validates the Egalet platform and its ability to produce combinations of up to two APIs with similar or differing release rates. The partnership calls for the development of up to 20 hydrocodone-based abuse-deterrent products with Shionogi paying all development, manufacturing, and commercialization expenses. Milestones total up to \$450MM and tiered royalties from the mid-single to low teens.

## FDA STRONGLY FAVORS ABUSE DETERRENCE

FDA strongly favors abuse deterrence, based on public and written statements, which should improve Egalet's chances of approval for both Egalet-001 and 002. Importantly, FDA guidance issued in early 2013, combined with numerous FDA advisory committee meetings, offers clarity to the development of abuse-deterrent opioids, and reinforces the agency's desire to address the growing problem of prescription pain drug abuse.

## FDA guidance suggests desire to remove non-abuse-deterrent long-acting opioids from market

FDA's stance on abuse deterrence could improve Egalet's chances of approval for both Egalet-001 and 002, lowering approval risk. Importantly, FDA issued guidance on development of abuse-deterrent opioids in early 2013, which signals the agency's desire to eventually remove non-abuse-deterrent long-acting products from the market. FDA wants companies to generate data showing less abuse with abuse-deterrent products before the agency moves to remove non-abuse-deterrent long-acting opioids from the market. In addition, FDA could eventually remove non-abuse-deterrent products from the market.

Importantly, FDA specifically states in the 2013 guidance that: "One potentially important step towards the goal of creating safer opioid analgesics has been the development of opioids that are formulated to deter abuse. FDA considers the development of these products a high public health priority." This statement provides evidence for FDA's desire to replace current non-abuse-deterrent pain drugs with harder to abuse abuse-deterrent forms.

## Abuse-deterrent labeling claims offer important commercial benefit

Most importantly, FDA outlined requirements for obtaining specific labeling claims for abuse deterrence in its 2013 guidance for opioids, offering a significant commercial benefit. The agency outlined four different types of claims available to manufacturers, termed Tier I-IV. The tiers are described as: (I) Formulation with Physiochemical Barriers to Abuse, (II) Expected to reduce or block the effect of the opioid when product is manipulated, (III) Product is expected to result in a meaningful reduction in abuse, and most importantly, (IV) Product has demonstrated reduced abuse in the community. In general FDA has asked for cumulative data for all categories, for example, if a manufacturer desires a Tier III claim, the agency would desire data to support a Tier I and II claim as well.

Importantly, once a large number of abuse-deterrent opioid products are approved <u>and</u> demonstrate a reduction of abuse in the community via Phase 4 studies, FDA could push for removal of non-abuse-deterrent opioid drugs. The removal of non-abuse-deterrent opioids would significantly expand the commercial opportunity for all abuse-deterrent opioids, including Egalet-001 and -002.

## Generic Opana ER approval suggests high FDA standards, not distraction from eventual generic removal.

FDA's approval of a generic, non-abuse-deterrent Opana ER reflects FDA's desire for robust abuse-deterrence data, and still supports the long-term desire to remove non-abuse-deterrent generic pain drugs from the market. Importantly, Endo Pharmaceuticals

developed an abuse-deterrent formulation of its long-acting pain drug Opana ER, received FDA approval, and then removed the non-abuse-deterrent formulation from the market. Endo had hoped that with the removal of the non-abuse-deterrent formulation of Opana ER, FDA would not approve generic versions of the drug. However, the agency did approve generic versions of the non-abuse-deterrent version of Opana ER, which was due to subpar abuse deterrence technology, based on written FDA statements.

Endo requested that FDA determine that the withdrawal of the original non-abuse-deterrent Opana ER was due to safety reasons in order to block generic entry, but FDA disagreed, citing inadequate abuse deterrence data. In the final denial of a Citizen's Petition lodged by Endo, FDA claimed that "The available data do not support Endo's conclusions regarding purported safety advantages of OPR relative to OP." The agency specifically noted that data from in vitro and pharmacokinetic studies show that Opana OPR's (abuse-deterrent formulation) extended release features can be compromised, causing the product to "dose dump" when subjected to other forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.

The agency also noted that Opana OPR can be prepared for snorting using commonly available tools and methods, and that the drug can be readily prepared for injection. In fact, FDA stated that certain data suggest that Opana OPR can *more easily* be prepared for injection than the non-abuse-deterrent formulation.

Most importantly, FDA cited inconclusive post-marketing data for Opana OPR in terms of potential for lower abuse, which could be critical to FDA's desire to remove non-abuse-deterrent drugs from the market. FDA noted the data showed only one or two quarters following introduction of Opana OPR, and suffered from additional deficiencies such that it was not possible to draw meaningful conclusions.

## Zohydro approval result of development before abuse-deterrence center focus at FDA

Some investors may also cite FDA's approval of non-abuse-deterrent Zohydro (long-acting hydrocodone) as contrary to a desire to remove non-abuse-deterrent drugs from the market, but Zohydro was developed under FDA guidance prior to abuse deterrence. Therefore FDA's approval may have been in response to positive safety and efficacy data for Zohydro despite a negative vote from an FDA advisory panel. Zohydro development was undertaken before revised FDA thinking on abuse-deterrent opioids, and therefore FDA ruled on Zohydro under prior considerations. However, Zogenix, which manufacturers Zohydro, has partnered with Paladin in Canada to develop an abuse-deterrent version of Zohydro. It is our strong belief that Zogenix will remove the non-abuse-deterrent form of Zohydro from the market assuming approval of an abuse-deterrent form, based on an "understanding" with FDA.

## OxyContin - no generics now, none expected

FDA will never approve a non-abuse-deterrent version of OxyContin, based on written, public statements, preserving a branded \$3B market for OxyContin. FDA approved an abuse-deterrent formulation of OxyContin, called OxyContin OP, manufactured by Purdue on April 5, 2010, after which Purdue withdrew the older formulation from the market. Importantly, FDA determined that the original formulation of OxyContin was withdrawn from the market for safety reasons. As a result, the agency will not accept or approve any abbreviated new drug applications (generics) that rely on the approval of these products (non-abuse-deterrent OxyContin), effectively keeping the market 100% branded.

FDA has had a long and unpleasant history with Purdue Pharma and OxyContin, resulting in its extreme sensitivity around OxyContin abuse. OxyContin was originally approved on December 12, 1995, and launched in 1996, with an indication for "management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." FDA later realized that this label was too broad. Purdue's aggressive marketing campaign resulted in broad use. In addition, labeling language that suggested OxyContin had lower abuse potential likely also caused problems in terms of higher prescribing patterns, resulting in more abuse.

Notably, the year 2000 marked initial reports of OxyContin abuse and diversion, involving crushing of tablets, inhalation, and injection. Abuse involved teenagers, recreational drug users, and pain patients, with the Appalachian states, Maine, and Ohio being heavily affected. During 2001, Purdue contacted FDA to discuss the problems and discontinued its 160 mg tablet. As a result, FDA initiated a risk management plan in August 2001 involving (1) education and outreach, (2) labeling, (3) surveillance, and (4) intervention. FDA also instituted label changes involving a narrower label and a boxed warning. The agency also removed the language associated with the Controlled Release formulation that might suggest lower abuse potential.

During 2002, an advisory committee met to discuss opioids, including abuse, and determined that abuse of opioid analgesics is a considerable public health problem. However, the committee also noted that opioids are an important part of pain management and that any Risk Management Program attempting to restrict opioids may prevent appropriate use.

September 2003 marked a public discussion regarding Risk Management Programs for modified-release products, and the abuse potential and Risk Management Program for Palladone. Key conclusions regarding an appropriate Risk Management Program were reached including surveillance of misuse, abuse, and diversion, and also the assessment of the Risk Management Program's impact on opioid prescribing practices.

FDA met again in May 2008 to specifically discuss OxyContin reformulation in terms of tamper resistance, adequacy of test methods, impact on abuse, misuse and diversion, changes to the product label, and a Risk Management Program. The advisory committee concluded that the available data were not at all adequate to support tamper-resistance claims, and that inclusion of new physiochemical properties in the label may result in false security and adversely impact addiction and overdose. Importantly, FDA was visibly dissatisfied with Purdue's work to date and not pleased with the company's presentation.

Finally, FDA met in November 2008 to discuss Remoxy XRT, an abuse-deterrent version of OxyContin, and the data suggesting reduced risk and abuse, determining again that the data were not adequate to support tamper-resistance claims. The agency also determined that properties described in the label may result in false security and adversely impact addiction and overdose.

The totality of FDA's interactions regarding OxyContin suggest that the agency has a strong desire to reduce abuse, and views abuse-deterrent formulations as very attractive. Importantly, Egalet-002 may convincingly address FDA's desire to reduce oxycodone abuse.



## COMPETITIVE LANDSCAPE PRESENTS OPPORTUNITY

The competitive landscape for Egalet-001 (morphine) and Egalet-002 (oxycodone) seems attractive, especially since Egalet-002 will be targeting a \$3B single player market. We estimate the branded long-acting morphine market at ~\$350M in 2013, and the branded long-acting oxycodone market at \$3B. Although other companies are developing abuse-deterrent formulations of oxycodone and oxymorphone, Egalet's abuse-deterrent technology could be superior in most cases. We expect that Egalet-001 and Egalet-002 will gain meaningful market share due to differentiation based on differentiating abuse deterrence properties.

## **Current branded morphine competition manageable**

Egalet-001 (assuming approval) will face competition from three branded long-acting morphine products and multiple generic versions of MS Contin, and we assume meaningful share gains for Egalet (Figure 14). Branded products include Actavis' Kadian, Pfizer's Avinza, and Purdue's MS Contin, which still has a small amount of branded sales even though generics are available. Importantly, although generic MS Contin currently holds ~95% of the prescription market share, branded drugs still hold ~80% of the total dollar share, creating a meaningful opportunity for Egalet-001. We assume that the branded market for long-acting morphine remains flat going forward, since the overall long-acting morphine market has grown in recent years, but the % of branded prescriptions has decreased.

			Market sh	are - 2013		
Drug	API	Company	% prescriptions	% dollars	Revenue	(est.) (\$M)
Kadian	morphine sulfate	Actavis	1.0%	36%	\$	96
Avinza	•	Pfizer	2.0%	40%	\$	106
MS-Contin		Purdue	0.3%	6%	\$	15
Embeda		Pfizer	0.0%	0%	\$	-
generic MS-Contin		6 generics	0.0%	19%	\$	50
Total		-			\$	268
Total branded			3.3%	81.3%	\$	218

Source: Bloomberg, FDA, Company presentations

## Multiple Embeda recalls suggest hampered re-launch

We expect Pfizer to re-introduce Embeda to the market during 2Q14, although uptake may be hampered by four previous recalls and additional promotional violations. Embeda is an extended-release form of morphine surrounding a naltrexone core. If the drug is crushed and the naltrexone core is broken, the naltrexone will neutralize the pain-reducing effect of morphine.

Investors may view Embeda as the most appropriate gauge of market opportunity for Egalet-001, but the launch was severely hampered and, in our view, under-represents the true market opportunity. Importantly, Embeda was recalled on four separate occasions, which likely severely hampered market uptake. Specifically, Embeda was recalled in March 2010, May 2010, November 2010, and March 2011 (Figure 15).



Interestingly, the final recall involved 106,113 bottles in commerce, and marked a full market withdrawal.

Recall Date	Bottles	Reason for recall
March 23, 2010	44,184	Failed dissolution testing for Morphine Sulfate during stability testing
May 10, 2010		Failed dissolution testing for Morphine Sulfate during stability testing
November 1, 2010	3,651	Two lots out of specification (dissolution testing)
March 10, 2011	106,113	Impurities/Degradation Products: Stability data do not support the acceptance criteria for related compounds through the product's labeled expiry

Source: www.fda.gov

Doctors are likely to be highly skeptical regarding product supply upon Embeda's planned relaunch in 2Q14. Also, physicians may be concerned about the potential for additional naltrexone leakage as seen in early 2011. Finally, many physicians could be more comfortable with a simpler abuse deterrence formulation such as Egalet-001, which does not involve a second active pharmaceutical ingredient (API) of naltrexone, but contains only morphine sulfate.

Pfizer claims it has solved the formulation issues for Embeda for the re-launch in 2Q14. However, we are skeptical regarding the commercial viability of the product at this point in time. Additional formulation issues may surface, and it seems likely that physicians will also be skeptical of additional potential supply issues.

### Embeda promotional violations should not be overlooked

Promotional violations by King Pharmaceuticals had a serious negative impact on Embeda sales, and are unlikely to impact Egalet-001 in a similar fashion. FDA withheld full promotional materials for Embeda for at least **five months** post approval due to serious concerns regarding misleading promotional violations, which likely substantially suppressed commercial uptake. Although King was able to market to specialists during the period, spillover likely affected the entire Embeda prescribing base.

Importantly, FDA held a teleconference on August 17, 2009, only four days after Embeda's approval, to voice serious concerns regarding two Embeda video releases that completely omitted the potential risk of fatality as described in the Black Box for the drug. FDA also noted that King's video advertisements implied that Embeda was useful in a broader range of conditions or patients than demonstrated by clinical data.



Due to non-compliance by King, FDA then issued a warning letter in October 2009, only two months after the drug's approval. The letter again warned King regarding the improper video release Link to FDA letter. FDA noted misleading claims for Embeda, including the idea that Embeda may reduce drug likeability and euphoria, which was not an approved labeled claim. Interestingly, FDA noted a prior conversation with King on March 19, 2009, prior to Embeda's approval where the agency noted similar concerns communicated to King. These concerns included claims and presentations that imply abuse resistance and decreased likeability with Embeda, not supported by substantial evidence.

The letter also requested that King submit a written response before October 23, 2009 with a complete listing of the promotional materials that were discontinued for Embeda as a result of the August 2009 teleconference and the FDA warning letter. The agency also requested a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed to the audience(s) that received the violative promotional materials. Consequently, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) withheld King's full marketing materials for the drug for some time.

We do not expect Egalet-001 to experience any of the launch issues that Embeda encountered during its product launch. Our statement is based on simpler, well-established plastic molding technology for Egalet-001, and lessons learned from King's promotional missteps with FDA. Importantly, we also believe that Egalet CEO Robert Radie's past experience in pharmaceutical sales will strengthen launch execution for Egalet-001 and increase the chances of positive results.

## Abuse-deterrent pipeline crowded, but few standouts

Our research suggests that there are approximately 13 abuse-deterrent products in development, but few that stand out in terms of available clinical data, with only two products that would compete head-to-head with Elaget-001 and four products that would compete head-to-head with Egalet-002. The other seven products in development involve different APIs or lower dosage immediate release, including Acura's oxycodone IR and hydrocodone/acetaminophen combination, Mallinckrodt's oxycodone/acetaminophen combination and hydrocodone/acetaminophen combination, and Zogenix's abuse-deterrent hydrocodone combination.

The two products that may compete with Egalet-001 are Pfizer's Embeda, and PharmacoFore's PF329 hydromorphone product. As discussed previously, Pfizer plans to re-launch Embeda in 2Q14, but we have doubts regarding stability after four prior recalls. Also, numerous promotional violations occurred during the initial Embeda launch, which will likely result in more careful and measured promotion. PharmacoFore's PF329 is early in development with little known about the compound. PF329 appears to be a prodrug of hydromorphone, which may be resistant to chemical extraction and active drug release, but clinical studies in line with FDA guidance have not yet been reported (Figure 16 --- are we sure figure numbers are right? IE no duplicates).



Figure 22: Abuse-deterrent long-acting morphine pipeline

## Abuse-deterrent long-acting morphine competitive pipeline

Company	API	Drug	Stage
Pfizer	morphine sulfate/naltrexone	Embeda	re-launch 2Q14
Signature Therapeutics	hydromorphone ER	PF329	Phase 2

Source: SEC filings, Canaccord Genuity

The competitive landscape for long-acting oxycodone is more crowded, but key abuse deterrence data have not yet surfaced for all of the competitors. The most advanced candidate is arguably Pain Therapeutics' Remoxy, but the drug has shown stability issues, which will likely require reformulation and additional large Phase 3 trials. Pfizer is in charge of clinical development and believes it can rectify the stability issues by modifying an inactive excipient and bridging to prior efficacy data, but we do not believe this will be acceptable to FDA. Collegium's COL-003 is an interesting drug, which relies on a waxy coating around small oxycodone drug particles. The drug could prove interesting, but we are skeptical as to whether the simple capsule formulation will show enough resistance to mechanical forms of abuse. Also, we are unclear as to whether the waxy coating might produce digestion issues. Pfizer's ALO-02 recently showed positive Phase 3 data in terms of efficacy, but key abuse deterrence data are not yet available. Also, the addition of naltrexone may translate into a commercial disadvantage versus other drugs that contain only the single oxycodone active ingredient (Figure 17, 18).

Figure 23: Abuse-deterrent long-acting oxycodone pipeline

## Abuse-deterrent long-acting oxycodone competitive pipeline

Company	API	Drug	Stage
Pain Therapeutics	oxycodone ER	Remoxy	Phase 3
Collegium	oxycodone ER	COL-003	Phase 3
Pfizer	oxycodone/naltrexone	ALO-02	Phase 3
KemPharm	oxycodone ER prodrug	KP-606	preclinical
Signature Therapeutics	oxycodone ER prodrug	PF619	preclinical

Source: SEC filings, Canaccord Genuity



Figure 24: Other a	Figure 24: Other abuse-deterrent drugs in pipeline								
Other Abuse-deterrent opioids in development									
Company	API	Drug	Stage						
Acura	oxycodone IR hydrocodone/acetaminophen IR	Acuracet	formulation/stability						
Mallinckrodt	oxycodone/acetaminophen hydrocodone/acetaminophen	MNK-795 MNK-155	FDA action 2Q14						
Zogenix	hydrocodone	Zohydro	formulation						

Source: SEC filings, Canaccord Genuity

## OPIOID ABUSE IN THE US - A SERIOUS ISSUE

Americans only constitute 4.6% of the world population, yet consume over 80% of the global opioid supply. From 1997 to 2007, average US sales of opioids per person increased from 74 milligrams to 369 milligrams, a 500% increase. In 2011, over 480,000 opioid-related emergency room visits occurred resulting in over 14,000 deaths, or roughly 3% per visit. In 2007, societal costs of opioid abuse were estimated at \$55.7 billion, with healthcare costs accounting for \$25 billion of this.

Data from the Substance Abuse and Mental Health Services Administration show a high, steady growth rate of OxyContin abuse in the US. In 2004 there were 615,000 *new* nonmedical users of OxyContin and 3.1 million nonmedical lifetime users. By 2008, the number of *new* nonmedical users grew to 1.5 million. Correspondingly, the number of OxyContin-related emergency room visits more than doubled from 41,000 in 2004 to 105,000 in 2008. In 2012, OxyContin-related emergency room visits reached over 150,000, posing a large and growing burden to our health system. Oxycodone ER usage (also known as OxyContin) results in more emergency room visits than any other form of oxycodone usage. In 2008, 70 of every 10,000 prescriptions filled resulted in an emergency visit, more than 40% higher than the next leading oxycodone form, oxycodone single-ingredient instant release.

Responding to the rapid growth rate, the FDA banned generic long-acting oxycodone in 2010. OxyContin-related emergency room visit growth rates have slowed dramatically since then, but are still rising. The FDA is likely encouraged by this partial early success and willing to engage further abuse-deterrent oxycodone, and opioid based pain killers.

Morphine-related emergency room visits increased over 146% from 14,000 in 2004 to 35,000 in 2011.



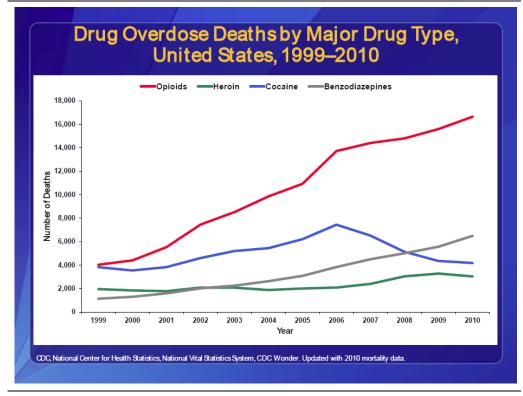


Figure 25: Drug overdose deaths by drug type, US, 1999-2010

# MANAGEMENT TEAM – STRONG MARKETING, OPERATING, AND R&D EXPERIENCE

## Robert Radie - President and CEO

Mr. Radie is 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 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 the company, Dr. Gerritsen van der Hoop is overseen directly by CEO Robert Radie, 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 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 May 2010 to April 2011. From August 2008 to May 2010, Dr. Lindhardt served as the director of portfolio management for the company's 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, Prosidion Ltd. 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 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, 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.

## **FINANCIALS**

We do not anticipate Egalet to generate meaningful revenue until 2015 with the launch of Egalet-001. We anticipate revenues to increase substantially with the launch of Egalet-002 in 2017 and continue through 2028 when we expect patent expiration. Egalet currently has no debt, and cash on hand of roughly \$65 million with a projected burn rate of ~\$29 million in 2014. We anticipate Egalet will raise cash through equity financing in 2015, 2016, and 2017, when we forecast the company will break even.

The company has a low share count of ~14M, with 600,000 shares issuable upon exercise of warrants. The company also has ~862,000 shares of restricted stock for executives, and 817,200 shares reserved for future issuance. We do not anticipate a near-term debt raise as the company will not be sustainably cash flow positive in the near term. Egalet is likely to book milestone payments from its partnership with Shionogi, which we do not include in our model. Egalet's amortization and depreciation expense are both likely to increase over time as the company may secure approval and listing of additional patents and also purchase additional assets related to manufacturing.



Income Statement (\$000's)	<u>2013E</u>	Mar-14E	Jun-14E	Sep-14E	Dec-14E	<u>2014E</u>	<u>2015E</u>	<u>2016E</u>	<u>2017E</u>	<u>2018E</u>	<u>2019E</u>	2020E
Total revenues		10,000				10,000	7,770	35,593	96,632	184,580	356,641	507,696
Cost of goods sold		.,				.,	1,162	5,339	13.529	23,995	46,363	60,923
Gross profit	0	10,000		•	•	10,000	6,608	30,254	83,104	160,584	310,278	446,772
Operating expenses												
Research & development												
Egalet-001	1,187	1,800	2,100	2,100	2,000	8,000	800	840	798	638	638	638
Egalet-002	371	48	48	3,400	3,600	7,096	12,000	1,800	900	900	900	900
Other Clinical and Preclinical	1,288	1,250	1,250	1,250	1,250	5,000	5,000	5,500	6,849	18,112	48,959	76,094
Personnel Related	1,431	365	372	379	386	1,503	1,578	1,735	2,083	2,499	2,999	3,599
R&D	4,277	3,463	3,770	7,129	7,236	21,599	19,378	9,875	10,630	22,150	53,496	81,231
Egalet-001							5,625	16,500	17,160	17,846	18,560	19,303
Egalet-002							0,020	10,000	37,500	43,125	49,594	57,033
General & administrative	4,475	1.389	1.659	1.929	2.199	7.175	8.075	8.883	10,659	13.324	16,655	20,818
SG&A	4,475	1,389	1,659	1,929	2,199	7,175	13,700	25,383	65,319	74,295	84,809	97,154
	,	,,	,,	-,	_,	7,175	,		19,326	64,603	124,825	177,693
Total expenses	8,752	4,852	5,429	9,058	9,435	28,774	33,078	35,258	75,949	96,445	138,305	178,385
Depreciation & amortization	433	213	307	401	495	1,416		5,192	6,787	7,674	7,420	8,571
EBITDA	(8,752)	5,148	(5,429)	(9,058)	(9,435)	(18,774)	(26,470)	(5,004)	7,155	64,140	171,973	268,387
Operating income	(9,185)	4,935	(5,736)	(9,459)	(9,930)	(20,189)	(26,470)	(10,196)	368	56,466	164,553	259,816
	( ,		, , , , , , , , , , , , , , , , , , ,	, , ,	, ,	(20,189)		, , ,				
Interest income												
Interest expense		-	-	-	-	-	-	-	-	=	-	-
Other expense / (income), net		1,000	50	50	50	1,150	200	200	200	200	200	200
Interest & other	6,272	1,000	50	50	50	1,150	200	200	200	200	200	200
Taxes							-	-	62	20,818	60,811	96,058
Tax rate							37%	37%	37%	37%	37%	37%
Net income - GAAP	(15,457)	3,935	(5,786)	(9,509)	(9,980)	(21,339)	(26,670)	(10,396)	106	35,447	103,543	163,558
Net income - Adjusted	(15,404)	3,935	(5,786)	(9,509)	(9,980)	(21,339)	(26,670)	(10,396)	106	35,447	103,543	163,558
GAAP EPS	(\$1.11)	\$0.28	(\$0.41)	(\$0.68)	(\$0.71)	(\$1.51)	(\$1.53)	(\$0.54)	\$0.01	\$1.65	\$4.64	\$7.05
Adjusted EPS excl. options expense	(\$1.11)	\$0.28	(\$0.41)	(\$0.68)	(\$0.71)	(\$1.51)	(\$1.53)	(\$0.54)	\$0.01	\$1.65	\$4.64	\$7.05
Diluted shares outstanding	13,902	13,902	13,972	14,041	14,112	14,112	17,441	19,340	20,614	21,438	22,296	23,187





Figure 27: Egalet Balance Sheet

Balance Sheet												
	2013E	Mar-14E	Jun-14E	<u>Sep-14E</u>	Dec-14E	<u>2014E</u>	2015E	2016E	<u>2017E</u>	<u>2018E</u>	2019E	2020
Assets												
Cash and Cash Equivalents	5,530	62,640	55,185	44,099	32,636	32,636	49,356	59,249	60,251	85,241	176,519	327,0
Related Party Receivable	32	32	32	32	32	32	32					
Accounts Receivable							-					
Prepaid Expenses	1,822	1,822	1,822	1,822	1,822	1,822	3,422	4,278	5,347	6,684	8,354	10,4
Other Receivables	395	415	435	457	480	480	583	642	706	776	854	ę
Other Current Assets												
Total Current Assets	7,779	64,908	57,474	46,410	34,970	34,970	53,394	64,168	66,303	92,701	185,727	338,3
	-					-	-					
Property and Equipment, net	1,912	3,199	4,392	5,491	6,497	6,497	9,581	16,389	21,602	25,928	30,508	33,9
Intangible Assets	205	205	205	308	308	308	400	400	400	400	400	4
Deposits and Other Assets	27	27	27	27	27	27	27	27	27	27	27	
Total Long-term Assets	2,144	3,431	4,624	5,826	6,831	6,831	10,008	16,816	22,029	26,355	30,935	34,
Total Assets	9,923	68,339	62,098	52,236	41,801	41,801	63,402	80,984	88,332	119,055	216,662	372,
Liabilities												
Related Party Senior Convertible debt, net	-					-	-					
Related Party Subordinated Covertible debt, net	-					-	-					
Accounts Payable	1,505	753	753	753	753	753	1,553	1,863	2,236	2,683	3,219	3,8
Accrued Expenses	622	311	311	311	311	311	611	733	880	1,056	1,267	1,
Other Current Liabilities	107	107	107	107	107	107	107	107	107	107	107	
Deferred Revenue	-					-	-					
Total Current Liabilities	2,234	1,171	1,171	1,171	1,171	1,171	2,271	2,703	3,222	3,846	4,593	5,4
Total School Calabilities	2,20	.,	.,	.,	,,	.,	2,2.1	2,100	O,EEE	0,010	1,000	- 0,
Total Long-term Liabilities				-	-	-	-	-	-		-	
Convertible Preferred Shares												
Convertible Series A-1 Preferred		-	-	-	-							
Convertible Series A-2 Preferred		-	•	-	-							
Convertible Series B Preferred		-	•	-	-							
Convertible Series B-1 Preferred		-	-	-	-							
Total Convertible Preferred Shares	-	-	-	-	-	-	-	-	-	-	-	
Par Value of Stock												
Additional Paid-In Capital		56,000	-	-	-			31,000	11,000	-	-	
Accumulated other comprehensive income												
Deficit Accumulated	7,689	11,169	60,927	51,066	40,631	40,631	61,131	47,281	74,109	115,210	212,069	367,
Shareholders Equity	-	56,000	-	-	-	-	-	31,000	11,000	-	-	
Total Long-term Liabilities and Shareholders Equity	2,234	57,171	1,171	1,171	1,171	1,171	2,271	33,703	14,222	3,846	4,593	5,



Figure	28: Ega	let Cash	Flow St	atement
--------	---------	----------	---------	---------

Cash Flows Statement	<u>2013E</u>	<u>Mar-14E</u>	<u>Jun-14E</u>	<u>Sep-14E</u>	<u>Dec-14E</u>	<u>2014E</u>	<u>2015E</u>	<u>2016E</u>	<u>2017E</u>	<u>2018E</u>	<u>2019E</u>	2020E
Net Income (loss)	(15,457)	3,935	(5,786)	(9,509)	(9,980)	(21,339)	(26,670)	(10,396)	106	35,447	103,543	163,558
D&A	433	213	307	401	495	1,416	2,916	5,192	6,787	7,674	7,420	8,571
Loss on Asset Disposal	-					-	-					
Write-off of related party receivable	-					-	-					
Amortization of beneficial conversion feature and deferred financing fees	-					-	-					
Noncash Interest	4,263	-	-	-	-	-	-					
Related Party Receivable	2					-	-					
Accounts Receivable	-	-	-	-	-	-	-					
Prepaid Expenses	(1,147)	(456)	(456)	(456)	(456)	(1,822)	(4,022)	(4,278)	(5,347)	(6,684)	(8,354)	(10,443)
Other Receivables	(59)	(20)	(21)	(22)	(23)	(85)	(103)	(58)	(64)	(71)	(78)	(85)
Other Current Assets	(75)	-	-	-	-	-	-	-	-	-	-	-
Deposits and other assets	(2)					-	-	-	-	-	-	-
Accounts Payable	97	(753)	-	-	-	(753)	800	311	373	447	537	644
Accrued Expenses	41	(311)	-	-	-	(311)	300	122	147	176	211	253
Other Current Liabilities	90	-	-	-	-	-	-	-	-	-	-	-
Deferred Revenue	-	-	-	-	-	-	-	-	-	-	-	-
	-					-	-					
	-					-	-					
Cash Flow From Operating Activities	(11,814)	2,610	(5,955)	(9,585)	(9,963)	(22,894)	(26,780)	(9,107)	2,001	36,990	103,278	162,498
Purchase of PP&E		(1,500)	(1,500)	(1,500)	(1,500)	(6,000)	(6,000)	(12,000)	(12,000)	(12,000)	(12,000)	(12,000)
Proceeds from the sale of property and equipment						- 1	-					
						-	-					
Cash Flow From Investing Activities	(1,322)	(1,500)	(1,500)	(1,500)	(1,500)	(6,000)	(6,000)	(12,000)	(12,000)	(12,000)	(12,000)	(12,000)
Cash Flow Flohi lilvesting Activities	(1,322)	(1,500)	(1,500)	(1,500)	(1,500)	(0,000)	(0,000)	(12,000)	(12,000)	(12,000)	(12,000)	(12,000)
Proceesd from Issuance of Common Stock		56,000				56,000	49,500	31,000	11,000	-	-	-
Proceeds from Issuance of convertible debt						-	-	-				
Repayment of lease financing Obligations						-	-					
Payment of deferred financing fees						-	-					
Payment of Lender Fees						-	-					
Proceeds from Sale of Series B Preferred						-	-					
						-	-					
Cash Flow From Financing Activitise	14,902	56,000	-	-	-	56,000	49,500	31,000	11,000	-	-	-
Effect of Foreign Currency Translation	360											
Increase in Cash and Cash Equivalents	2,126	57,110	(7,455)	(11,085)	(11,463)	27,106	16,720	9,893	1,001	24,990	91,278	150,498
Cash and CE at beg of period	3,404	5,530	62,640	55,185	44,099	5,530	32,636	49,356	59,249	60,251	85,241	176,519
Cash and CE at end of period	5,530	62,640	55,185	44,099	32,636	32,636	49,356	59,249	60,251	85,241	176,519	327,017



## **APPENDIX: IMPORTANT DISCLOSURES**

## **Analyst Certification:**

Each authoring analyst of Canaccord Genuity whose name appears on the front page of this research hereby certifies that (i) the recommendations and opinions expressed in this research accurately reflect the authoring analyst's personal, independent and objective views about any and all of the designated investments or relevant issuers discussed herein that are within such authoring analyst's coverage universe and (ii) no part of the authoring analyst's compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by the authoring analyst in the research.

Analysts employed outside the US are not registered as research analysts with FINRA. These analysts may not be associated persons of Canaccord Genuity Inc. and therefore may not be subject to the NASD Rule 2711 and NYSE Rule 472 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

### **Compendium Report:**

If this report covers six or more subject companies, it is a compendium report and Canaccord Genuity and its affiliated companies hereby direct the reader to the specific disclosures related to the subject companies discussed in this report, which may be obtained at the following website (provided as a hyperlink if this report is being read electronically) <a href="https://disclosures.canaccordgenuity.com/EN/Pages/default.aspx">https://disclosures.canaccordgenuity.com/EN/Pages/default.aspx</a>; or by sending a request to Canaccord Genuity Corp. Research, Attn: Disclosures, P.O. Box 10337 Pacific Centre, 2200-609 Granville Street, Vancouver, BC, Canada V7Y 1H2; or by sending a request by email to disclosures@canaccordgenuity.com. The reader may also obtain a copy of Canaccord Genuity's policies and procedures regarding the dissemination of research by following the steps outlined above.

#### **Site Visit:**

An analyst has not visited the material operations of Egalet Corp.

## **Distribution of Ratings:**

Global Stock Ratings (as of 31 December 2013)

Coverage Universe								
Rating	#	%	IB Clients %					
Buy	564	57.0%	38.1%					
Speculative Buy	47	4.7%	42.6%					
Hold	325	32.8%	11.4%					
Sell	50	5.1%	6.0%					
_	990*	100.0%						

<sup>\*</sup>Total includes stocks that are Under Review

## Canaccord Genuity Ratings System:

**BUY:** The stock is expected to generate risk-adjusted returns of over 10% during the next 12 months. **HOLD:** The stock is expected to generate risk-adjusted returns of 0-10% during the next 12 months. **SELL:** The stock is expected to generate negative risk-adjusted returns during the next 12 months. **NOT RATED:** Canaccord Genuity does not provide research coverage of the relevant issuer.

"Risk-adjusted return" refers to the expected return in relation to the amount of risk associated with the designated investment or the relevant issuer.

## **Risk Qualifier:**

**SPECULATIVE:** Stocks bear significantly higher risk that typically cannot be valued by normal fundamental criteria. Investments in the stock may result in material loss.

### Canaccord Genuity Research Disclosures as of 4 March 2014

Company	Disclosure
Egalet Corp.	1A, 2, 3, 5, 7

- The relevant issuer currently is, or in the past 12 months was, a client of Canaccord Genuity or its affiliated companies. During this period, Canaccord Genuity or its affiliated companies provided the following services to the relevant issuer:
  - A. investment banking services.
  - ${\bf B}.$  non-investment banking securities-related services.
  - C. non-securities related services.
- In the past 12 months, Canaccord Genuity or its affiliated companies have received compensation for Corporate Finance/Investment Banking services from the relevant issuer.
- 3 In the past 12 months, Canaccord Genuity or any of its affiliated companies have been lead manager, co-lead manager or co-manager of a public offering of securities of the relevant issuer or any publicly disclosed offer of securities of the relevant issuer or in any related derivatives.
- Canaccord Genuity acts as corporate broker for the relevant issuer and/or Canaccord Genuity or any of its affiliated companies may have an agreement with the relevant issuer relating to the provision of Corporate Finance/Investment Banking services.

- 5 Canaccord Genuity or one or more of its affiliated companies is a market maker or liquidity provider in the securities of the relevant issuer or in any related derivatives.
- In the past 12 months, Canaccord Genuity, its partners, affiliated companies, officers or directors, or any authoring analyst involved in the preparation of this research has provided services to the relevant issuer for remuneration, other than normal course investment advisory or trade execution services.
- 7 Canaccord Genuity or one or more of its affiliated companies intend to seek or expect to receive compensation for Corporate Finance/Investment Banking services from the relevant issuer in the next six months.
- 8 The authoring analyst, a member of the authoring analyst's household, or any individual directly involved in the preparation of this research, has a long position in the shares or derivatives, or has any other financial interest in the relevant issuer, the value of which increases as the value of the underlying equity increases.
- The authoring analyst, a member of the authoring analyst's household, or any individual directly involved in the preparation of this research, has a short position in the shares or derivatives, or has any other financial interest in the relevant issuer, the value of which increases as the value of the underlying equity decreases.
- Those persons identified as the author(s) of this research, or any individual involved in the preparation of this research, have purchased/received shares in the relevant issuer prior to a public offering of those shares, and such person's name and details are disclosed above.
- A partner, director, officer, employee or agent of Canaccord Genuity or its affiliated companies, or a member of his/her household, is an officer, or director, or serves as an advisor or board member of the relevant issuer and/or one of its subsidiaries, and such person's name is disclosed above.
- As of the month end immediately preceding the date of publication of this research, or the prior month end if publication is within 10 days following a month end, Canaccord Genuity or its affiliated companies, in the aggregate, beneficially owned 1% or more of any class of the total issued share capital or other common equity securities of the relevant issuer or held any other financial interests in the relevant issuer which are significant in relation to the research (as disclosed above).
- As of the month end immediately preceding the date of publication of this research, or the prior month end if publication is within 10 days following a month end, the relevant issuer owned 1% or more of any class of the total issued share capital in Canaccord Genuity or any of its affiliated companies.
- **14** Other specific disclosures as described above.

"Canaccord Genuity" is the business name used by certain wholly owned subsidiaries of Canaccord Genuity Group Inc., including Canaccord Genuity Inc., Canaccord Genuity Limited, Canaccord Genuity Corp., and Canaccord Genuity (Australia) Limited, an affiliated company that is 50%-owned by Canaccord Genuity Group Inc.

The authoring analysts who are responsible for the preparation of this research are employed by Canaccord Genuity Corp. a Canadian broker-dealer with principal offices located in Vancouver, Calgary, Toronto, Montreal, or Canaccord Genuity Inc., a US broker-dealer with principal offices located in New York, Boston, San Francisco and Houston, or Canaccord Genuity Limited., a UK broker-dealer with principal offices located in London (UK) and Dublin (Ireland), or Canaccord Genuity (Australia) Limited, an Australian broker-dealer with principal offices located in Sydney and Melbourne.

The authoring analysts who are responsible for the preparation of this research have received (or will receive) compensation based upon (among other factors) the Corporate Finance/Investment Banking revenues and general profits of Canaccord Genuity. However, such authoring analysts have not received, and will not receive, compensation that is directly based upon or linked to one or more specific Corporate Finance/Investment Banking activities, or to recommendations contained in the research.

Canaccord Genuity and its affiliated companies may have a Corporate Finance/Investment Banking or other relationship with the issuer that is the subject of this research and may trade in any of the designated investments mentioned herein either for their own account or the accounts of their customers, in good faith or in the normal course of market making. Accordingly, Canaccord Genuity or their affiliated companies, principals or employees (other than the authoring analyst(s) who prepared this research) may at any time have a long or short position in any such designated investments, related designated investments or in options, futures or other derivative instruments based thereon.

Some regulators require that a firm must establish, implement and make available a policy for managing conflicts of interest arising as a result of publication or distribution of research. This research has been prepared in accordance with Canaccord Genuity's policy on managing conflicts of interest, and information barriers or firewalls have been used where appropriate. Canaccord Genuity's policy is available upon request. The information contained in this research has been compiled by Canaccord Genuity from sources believed to be reliable, but (with the exception of the information about Canaccord Genuity) no representation or warranty, express or implied, is made by Canaccord Genuity, its affiliated companies or any other person as to its fairness, accuracy, completeness or correctness. Canaccord Genuity has not independently verified the facts, assumptions, and estimates contained herein. All estimates, opinions and other information contained

in this research constitute Canaccord Genuity's judgement as of the date of this research, are subject to change without notice and are provided in good faith but without legal responsibility or liability. Canaccord Genuity's salespeople, traders, and other professionals may provide oral or written market commentary or trading strategies to our clients and our proprietary trading desk that reflect opinions that are contrary to the opinions expressed in this research. Canaccord Genuity's affiliates, principal trading desk, and investing businesses may make investment decisions that are inconsistent with the recommendations or views expressed in this research.

This research is provided for information purposes only and does not constitute an offer or solicitation to buy or sell any designated investments discussed herein in any jurisdiction where such offer or solicitation would be prohibited. As a result, the designated investments discussed in this research may not be eligible for sale in some jurisdictions. This research is not, and under no circumstances should be construed as, a solicitation to act as a securities broker or dealer in any jurisdiction by any person or company that is not legally permitted to carry on the business of a securities broker or dealer in that jurisdiction. This material is prepared for general circulation to clients and does not have regard to the investment objectives, financial situation or particular needs of any particular person. Investors should obtain advice based on their own individual circumstances before making an investment decision. To the fullest extent permitted by law, none of Canaccord Genuity, its affiliated companies or any other person accepts any liability whatsoever for any direct or consequential loss arising from or relating to any use of the information contained in this research.

#### For Canadian Residents:

This research has been approved by Canaccord Genuity Corp., which accepts sole responsibility for this research and its dissemination in Canada. Canadian clients wishing to effect transactions in any designated investment discussed should do so through a qualified salesperson of Canaccord Genuity Corp. in their particular province or territory.

## For United States Residents:

Canaccord Genuity Inc., a US registered broker-dealer, accepts responsibility for this research and its dissemination in the United States. This research is intended for distribution in the United States only to certain US institutional investors. US clients wishing to effect transactions in any designated investment discussed should do so through a qualified salesperson of Canaccord Genuity Inc. Analysts employed outside the US, as specifically indicated elsewhere in this report, are not registered as research analysts with FINRA. These analysts may not be associated persons of Canaccord Genuity Inc. and therefore may not be subject to the NASD Rule 2711 and NYSE Rule 472 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

## For United Kingdom and European Residents:

This research is distributed in the United Kingdom and elsewhere Europe, as third party research by Canaccord Genuity Limited, which is authorized and regulated by the Financial Conduct Authority. This research is for distribution only to persons who are Eligible Counterparties or Professional Clients only and is exempt from the general restrictions in section 21 of the Financial Services and Markets Act 2000 on the communication of invitations or inducements to engage in investment activity on the grounds that it is being distributed in the United Kingdom only to persons of a kind described in Article 19(5) (Investment Professionals) and 49(2) (High Net Worth companies, unincorporated associations etc) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended). It is not intended to be distributed or passed on, directly or indirectly, to any other class of persons. This material is not for distribution in the United Kingdom or elsewhere in Europe to retail clients, as defined under the rules of the Financial Conduct Authority.

## For Jersey, Guernsey and Isle of Man Residents:

This research is sent to you by Canaccord Genuity Wealth (International) Limited (CGWI) for information purposes and is not to be construed as a solicitation or an offer to purchase or sell investments or related financial instruments. This research has been produced by an affiliate of CGWI for circulation to its institutional clients and also CGWI. Its contents have been approved by CGWI and we are providing it to you on the basis that we believe it to be of interest to you. This statement should be read in conjunction with your client agreement, CGWI's current terms of business and the other disclosures and disclaimers contained within this research. If you are in any doubt, you should consult your financial adviser. CGWI is licensed and regulated by the Guernsey Financial Services Commission, the Jersey Financial Services Commission and the Isle of Man Financial Supervision Commission. CGWI is registered in Guernsey and is a wholly owned subsidiary of Canaccord Genuity Group Inc.

## For Australian Residents:

This research is distributed in Australia by Canaccord Genuity (Australia) Limited ABN 19 075 071 466 holder of AFS Licence No 234666. To the extent that this research contains any advice, this is limited to general advice only. Recipients should take into account their own personal circumstances before making an investment decision. Clients wishing to effect any transactions in any financial products discussed in the research should do so through a qualified representative of Canaccord Genuity (Australia) Limited. Canaccord Genuity Wealth Management is a division of Canaccord Genuity (Australia) Limited.

## For Singapore Residents:

This research is distributed pursuant to 32C of the Financial Advisers under an arrangement between each of the Canaccord Genuity entities that publish research and Canaccord Genuity Singapore Pte. Ltd who are an exempt financial adviser under section 23(1)(d) of the Financial Advisers Act. This research is only intended for persons who fall within the definition of accredited investor, expert investor or institutional investor as defined under section 4A of the Securities and Futures Act It is not intended to be distributed or passed on, directly or indirectly, to any other class of persons. Recipients of this report can contact Canaccord Genuity Singapore Pte. Ltd. (Contact Person: Tom Gunnersen's tel # is +852 3919 2561) in respect of any matters arising from, or in connection with, the [analyses or report].

## For Hong Kong Residents:

This research is distributed in Hong Kong by Canaccord Genuity (Hong Kong) Limited who is licensed by the Securities and Futures Commission. This research is only intended for persons who fall within the definition of professional investor as defined in the Securities and Futures Ordinance. It is not intended to be distributed or passed on, directly or indirectly, to any other class of persons. Recipients of this report can contact Canaccord Genuity (Hong Kong). Ltd. (Contact Person: Tom Gunnersen's tel # is +852 3919 2561) in respect of any matters arising from, or in connection with, the research.

### Additional information is available on request.

Copyright © Canaccord Genuity Corp. 2014. – Member IIROC/Canadian Investor Protection Fund Copyright © Canaccord Genuity Limited 2014. – Member LSE, authorized and regulated by the Financial Conduct Authority.

Copyright © Canaccord Genuity Inc. 2014. - Member FINRA/SIPC

Copyright © Canaccord Genuity (Australia) Limited 2014. – Participant of ASX Group, Chi-x Australia and of the NSX. Authorized and regulated by ASIC.

All rights reserved. All material presented in this document, unless specifically indicated otherwise, is under copyright to Canaccord Genuity Corp., Canaccord Genuity Limited, Canaccord Genuity Inc. or Canaccord Genuity Group Inc. None of the material, nor its content, nor any copy of it, may be altered in any way, or transmitted to or distributed to any other party, without the prior express written permission of the entities listed above.