

Egalet Corp  
Form 424B4  
February 07, 2014

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Filed Pursuant to Rule 424(b)(4)  
Registration No. 333-191759

**PROSPECTUS**

**4,200,000 Shares**

**Common Stock**

**\$12.00 per share**

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This is the initial public offering of Egalet Corporation. We are selling 4,200,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price is \$12.00 per share.

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol "EGLT."

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be eligible for reduced public company reporting requirements. See "Summary Implications of Being an Emerging Growth Company."

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**Investing in our common stock involves risks. See "Risk Factors" beginning on page 13.**

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|                                  | <b>Per Share</b> | <b>Total</b>  |
|----------------------------------|------------------|---------------|
| Public offering price            | \$ 12.00         | \$ 50,400,000 |
| Underwriting discount(1)         | \$ 0.84          | \$ 3,528,000  |
| Proceeds, before expenses, to us | \$ 11.16         | \$ 46,872,000 |

(1) See "Underwriting" beginning on page 145 for additional information regarding underwriting compensation.

Shionogi Limited, our collaborator, has agreed to purchase 1,250,000 shares of our common stock in a separate private placement concurrent with the completion of this offering at a price per share equal to the initial public offering price. The sale of such shares will not be registered under the Securities Act of 1933, as amended. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

Our existing stockholders have agreed to purchase an aggregate of 833,333 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

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We have granted the underwriters a 30-day option to purchase up to 630,000 additional shares of common stock to cover over-allotments on the same terms and conditions set forth above.

The underwriters expect to deliver the shares on or about February 11, 2014.

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*Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.*

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**Stifel**

**JMP Securities**

**Canaccord Genuity**

**Janney Montgomery Scott**

The date of this prospectus is February 5, 2014.

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**Until and including March 2, 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.**

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You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with information different from that after paragraph contained in this prospectus. We are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

For investors outside the United States: neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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**PROSPECTUS SUMMARY**

*This summary highlights certain information about us and this offering contained elsewhere in this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including "Risk Factors" beginning on page 13 and the financial statements and related notes included in this prospectus.*

Unless the context indicates otherwise, as used in this prospectus, the terms "Egalet," "we," "us," "our," "our company" and "our business" refer both to Egalet Corporation and Egalet Limited on a consolidated basis giving effect to the Share Exchange discussed under "Summary Our Corporate Information." "Egalet US" refers to Egalet Corporation and "Egalet UK" refers to Egalet Limited. The Egalet logo is our trademark and Egalet is our registered trademark. All other trade names, trademarks and service marks appearing in this prospectus are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this prospectus, appear with the trade name, trademark or service mark notice and then throughout the remainder of this prospectus without the trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

**Overview**

**Our Company**

We are a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent oral products for the treatment of pain and in other indications. Using our proprietary technology platform, we have developed a pipeline of clinical-stage, opioid-based product candidates in tablet form that are specifically designed to deter abuse by physical and chemical manipulation while also providing the ability to tailor the release of the active pharmaceutical ingredient, or API.

Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation in development for the treatment of moderate to severe pain. There are currently no commercially available abuse-deterrent formulations of morphine, and we believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. We have completed our Phase 1 clinical trials of Egalet-001 and we plan to initiate pivotal trials to establish the bioequivalence of Egalet-001 to MS-Contin®, a currently approved oral morphine formulation, in the first quarter of 2014 and submit a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in the fourth quarter of 2014.

Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release, oral oxycodone formulation in development for the treatment of moderate to severe pain. We believe that Egalet-002, if approved, will have advantages over commercially available, long-acting, abuse-deterrent oxycodone products due to its differentiated abuse-deterrent properties and a pharmacokinetic, or PK, profile that demonstrates low peak-to-trough concentration variability in drug exposure. We have conducted Phase 1 trials of Egalet-002 and have completed initial abuse deterrence studies in compliance with the FDA draft guidance. We plan to initiate the first of two Phase 3 trials for Egalet-002 in the fourth quarter of 2014 and to submit an NDA to the FDA in the first half of 2016.

In November 2013, we entered into a collaboration and license agreement with Shionogi Limited, or Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. Shionogi will be responsible for all expenses associated with the development of these product candidates and is responsible for the completion of all clinical trials necessary to support NDA filings for the product candidates. Under the terms of the agreement, Shionogi made an upfront payment to us of \$10.0 million.

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We are eligible to receive additional payments upon the achievement of specified regulatory and sales-based milestones. These milestone payments may exceed \$300 million in the aggregate if multiple product candidates are approved. If any products are approved for marketing, we are also eligible to receive royalties at percentage rates ranging from the mid-single digits to the low-teens on net sales of licensed products.

IMS Health, or IMS, a healthcare information firm, estimates that total U.S. sales of analgesic narcotics, or opioids, for therapeutic purposes were \$8.3 billion for the 12 months ended September 30, 2012. Of this total opioid market, long-acting opioids accounted for approximately \$4.1 billion in total sales on 14.8 million prescriptions. Egalet-001 and Egalet-002 will target this long-acting opioid market. Long-acting morphine-based products and oxycodone-based products are the two most commonly prescribed long-acting, oral opioids, with over 13.3 million prescriptions in the aggregate resulting in sales of \$3.4 billion in the United States for the 12 months ended September 30, 2012.

Drug-related deaths, 40% of which involved the use of opioids in 2008 according to the National Center for Health Statistics, became the leading cause of accidental death in the United States in 2009, surpassing deaths caused by automobile accidents, according to a 2011 report by the U.S. Centers for Disease Control and Prevention. A 2011 research report prepared by the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services, or SAMHSA, estimated that nearly 35 million Americans have used prescription pain relievers, including opioid-containing drugs, for non-prescription purposes at least once in their lifetime. The total costs of prescription drug abuse were estimated to be up to \$72.5 billion annually for public and private healthcare payors in the United States, according to a 2013 report in the American Journal of Managed Care.

Prescription medications, particularly opioids, are prone to being abused through physical and chemical manipulation for the purpose of increasing drug concentration in the bloodstream in order to accelerate and intensify their effects. Common methods of manipulating medications in pill or tablet form include crushing in order to swallow, snort or smoke, and dissolving in order to inject. Our product candidates are specifically designed to deter these common methods of abuse, as well as to prevent alcohol dose dumping, which is the acceleration of the release of the API by consuming alcohol at the same time.

In reaction to the increasing costs and other consequences of widespread prescription opioid abuse, the U.S. government and a number of state legislatures have introduced, and in some cases have enacted, legislation and regulations intended to encourage the development and adoption of abuse-deterrent forms of pain medications. In January 2013, the FDA issued draft guidance that for the first time outlined a regulatory pathway for the approval of drugs with abuse-deterrent claims in their product label. In addition to our planned clinical trials for Egalet-001 and Egalet-002, we are currently conducting abuse deterrence studies with both product candidates in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product labels.

We plan to seek U.S. regulatory approval of Egalet-001 and Egalet-002 pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act, or Section 505(b)(2), which permits companies to rely upon the FDA's previous findings of safety and effectiveness for an approved product, such as morphine and oxycodone. If either of our clinical-stage product candidates achieves regulatory approval, we intend to establish our own specialty sales force to market the product in the United States by targeting physicians specializing in pain management. To supplement our internal U.S. sales force, we intend to contract with third parties to access sales representatives who target primary care and internal medicine physicians in the United States.

Our technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple APIs with similar or different release profiles. In addition to our two clinical-stage product candidates and the preclinical hydrocodone-based product candidates licensed to Shionogi, we are developing a portfolio of preclinical, abuse-deterrent product

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candidates for the treatment of pain and in other indications. We exclusively own the rights to Egalet-001, Egalet-002 and our technology platform.

Members of our management team have substantial experience in product development, manufacturing, clinical development, regulatory affairs and sales and marketing and have been closely involved with the development and commercialization of several pain and central nervous system products, including Opana®, Zyprexa® and Prozac®. We believe this experience will help us to successfully develop and commercialize our abuse-deterrent product candidates.

**Our Abuse Deterrence Technology Platform**

We have created two distinct drug delivery systems, each with novel abuse-deterrent features and the ability to control the release profile of the API. Our one-component system is used to produce tablets, such as Egalet-001, that consist of a hard matrix that is difficult to crush, grind or dissolve and that also controls the release of the API. The matrix, which contains the API as well as inactive agents known as excipients, erodes over time in the gastrointestinal, or GI, tract, releasing the API. Our two-component system is used to produce tablets, such as Egalet-002, that consist of a matrix similar to the matrix that is a part of our one-component system, but that is surrounded by a water-impermeable, non-eroding, hard shell made of polylactic acid that creates a cylinder, with the API-containing matrix exposed at both ends. The shell serves to limit the portion of the matrix's surface area that is exposed to the GI tract, which allows us to tailor the release rate of the API and makes it even more difficult to crush or grind the tablet, thereby enhancing its abuse-deterrent properties.

We use an injection molding technology that is used in the manufacture of medical devices, including implants and diagnostics, to create our matrix and shell. We believe that we are the first company to combine standard pharmaceutical production with plastic injection molding to produce orally delivered pharmaceutical products.

We believe that our systems offer the following advantages:

*Abuse Deterrence.* Abusers often seek to accelerate the absorption of opioids into the bloodstream by crushing in order to swallow, snort or smoke, or dissolving in order to inject, the drug. Tablets produced using our systems have physical and chemical barriers intended to deter these common methods of abuse. Using our systems, we have produced oral formulations of morphine and oxycodone that are difficult to crush, grind or vaporize, and that also resist dissolution into an injectable form by becoming gelatinous in the presence of water and other common household solvents. We believe that tablets made using our proprietary technology deter the most common methods of manipulating opioids for the purpose of abuse.

*Ability to Tailor Release.* In our tablets, the API is integrated into the matrix, which makes it difficult for abusers to extract quickly. However, when the tablet is exposed to GI fluids, the matrix erodes, thereby releasing the API. Using our technology, we can change the amount and composition of the polymer used to create the matrix formulation and can vary the surface area of the matrix exposed to the GI tract. By varying the matrix composition and surface area, we can control the rate of erosion of the matrix and the rate of release of the API which allows us to develop products with immediate release, or IR, extended release, or ER, and sustained release, or SR, profiles.

*Broad Applicability.* Our technology can also be used to develop other abuse-deterrent products with other APIs, as well as combination products containing two APIs that can be released at the same or different rates. We have developed prototypes and conducted feasibility studies of these combination products, both independently and in collaboration with major pharmaceutical companies.

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**Our Product Candidates**

***Egalet-001***

Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation. Egalet-001 utilizes our proprietary one-component system, which allows the development of customized ER profiles. Egalet-001 consists of an approved and well-characterized drug substance, morphine sulfate, together with inactive ingredients deemed safe for chronic oral use. Morphine-based products, including MS-Contin, have been available in the U.S. market for many years and have a well-established safety profile. All ingredients in Egalet-001 are present in approved drug products on the U.S. market. We are developing Egalet-001 for administration two to three times a day.

According to IMS, long-acting morphine was the most commonly prescribed long-acting opioid in the United States for the 12 months ended September 30, 2012 with sales of approximately \$560 million on 7.1 million prescriptions. We believe that Egalet-001, if approved, would provide patients and physicians with the following benefits when compared to existing morphine-based products:

*Abuse-deterrent features:* Egalet-001 is designed to resist the most common methods of abuse, including crushing in order to swallow, snort or smoke, and dissolving in order to inject. Egalet-001 uses our one-component system, which is designed to enhance the deterrence of abuse by injection in particular, which is the most common method of abuse of morphine-based products.

*No alcohol dose dumping:* Egalet-001 slows the release of the API in the presence of alcohol, contrary to the effects seen with some other morphine-based products, in which the release of the API is accelerated in the presence of alcohol.

*No food effect:* The PK profile of Egalet-001 is similar to that of other long-acting morphine formulations with or without the presence of food. This feature provides more consistent pain relief, as well as improved patient convenience.

*Morphine only:* Egalet-001 has the potential to be the first abuse-deterrent, ER morphine product that does not contain opioid-receptor antagonists. Abuse-deterrent products with antagonists include additional APIs that may have adverse effects.

*Convenient dosing:* Egalet-001 offers patients the option of a convenient two to three times daily dosing regimen, thereby increasing the likelihood of patient adherence. We intend to make Egalet-001 in 15, 30, 60 and 100 mg doses, which are consistent with currently available morphine formulations.

*Consistent relief:* Two to three times a day dosing can offer around-the-clock pain relief. Egalet-001, with its ER profile, is designed to provide consistent relief of moderate to severe chronic pain over an eight- or 12-hour period per dose.

We plan to seek approval of Egalet-001 under the FDA's Section 505(b)(2) approval pathway, and as a result we believe that Egalet-001 should have an accelerated path to approval if we are able to establish bioequivalence. We have completed our Phase 1 clinical trials of Egalet-001 and plan to initiate pivotal trials of Egalet-001 in the first quarter of 2014 to establish its bioequivalence to MS-Contin. We also plan to conduct additional abuse deterrence studies in the first quarter of 2014, in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product label. We intend to rely on the FDA's previous conclusions of safety with respect to MS-Contin, and we do not expect that any additional preclinical safety studies will be required for our formulation. Based on the expected timing of our studies and trials, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2014.

***Egalet-002***

Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release, oral oxycodone formulation. Egalet-002 utilizes our proprietary two-component system, which allows the development of





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customized ER profiles. Egalet-002 consists of an approved and well-characterized drug substance, oxycodone hydrochloride, together with inactive ingredients deemed safe for chronic oral use. Oxycodone-based products, including OxyContin OP®, have been available in the United States for many years and have a well-established safety profile. All ingredients in Egalet-002 have been used in approved drug products in the U.S. market, other than polylactic acid, or PLA, an inactive substance contained in the shell.

Oxycodone-based products are the market leader in sales among long-acting opioids in the United States. IMS estimates that U.S. sales of long-acting oxycodone totaled approximately \$2.8 billion for the 12 months ended September 30, 2012 on approximately 6.2 million prescriptions. We believe that Egalet-002, if approved, would provide patients and physicians with the following benefits when compared to existing oxycodone-based products:

*Abuse-deterrent features:* Egalet-002 was developed to address the most common methods of abuse, including crushing in order to swallow, snort or smoke, and dissolving in order to inject. Egalet-002 uses our two-component system, which is designed to enhance the deterrence of abuse by crushing and snorting in particular, which is the most common method of manipulating oxycodone-based products for the purpose of abuse.

*PK profile:* We believe that Egalet-002 provides less peak-to-trough concentration variability in drug exposure when compared to OxyContin OP, which we believe will result in Egalet-002 having fewer side effects and providing better and more consistent pain relief, resulting in reduced use of rescue medication to treat breakthrough pain.

*No alcohol dose dumping:* Egalet-002 slows the release of the API in the presence of alcohol, contrary to the effects seen with other oxycodone products.

*No formulation-related food effect:* The PK profile of Egalet-002 is similar to that of other long-acting oxycodone formulations in the presence of food.

*Consistent relief and convenient dosing:* Egalet-002, with its ER profile, is designed to provide consistent relief of moderate to severe chronic pain for a 12-hour period per dose. Egalet-002 permits twice-daily dosing, consistent with currently available oxycodone formulations, to provide around-the-clock pain relief. We intend to make Egalet-002 in 10, 20, 40 and 80 mg doses, which are consistent with currently available oxycodone formulations.

We plan to seek approval of Egalet-002 under the Section 505(b)(2) approval pathway, and as a result we believe that Egalet-002 could have an accelerated path to approval. We have conducted Phase 1 trials of Egalet-002 and have completed initial abuse deterrence studies in compliance with the FDA draft guidance. We plan to initiate the first of two Phase 3 safety and efficacy trials of Egalet-002 in the fourth quarter of 2014, as well as an alcohol interaction trial in the second quarter of 2014, which have been designed to demonstrate the safety and efficacy of Egalet-002 and a PK profile that exhibits low peak-to-trough concentration variability in drug exposure. In addition to the safety and efficacy trials, we intend to initiate additional abuse deterrence studies in the first quarter of 2014, in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product label. Based on the expected timing of our studies and trials, we anticipate submitting an NDA for Egalet-002 in the first half of 2016.

***Preclinical Programs***

We have developed prototypes, conducted feasibility studies and are exploring additional applications of our technology, both on our own and in collaboration with major pharmaceutical companies, to develop single-agent and combination products for indications other than pain in which potential for abuse exists. We have completed initial research and development efforts on 13 potential product candidates. In November 2013, we entered into a collaboration and license agreement with Shionogi for the development

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and potential commercialization of abuse-deterrent hydrocodone-based product candidates using our technology.

Based on preclinical development we have performed, we intend to select a third abuse-deterrent, opioid product candidate, to be designated Egalet-003, based on a number of factors, including market opportunity and competitive dynamics. Once selected, we intend to initiate clinical trials in 2014 with this product candidate. We plan to also seek regulatory approval for this product candidate under the Section 505(b)(2) approval pathway.

**Our Strategy**

Our goal is to be a leading specialty pharmaceutical company focused on the development, manufacture and commercialization of abuse-deterrent pharmaceutical products. Our strategy for achieving this goal is to:

*Develop and obtain FDA approval for Egalet-001 as an abuse-deterrent morphine product for the treatment of moderate to severe pain.* We are developing Egalet-001 to treat moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We intend to demonstrate bioequivalence to MS-Contin and plan to submit an NDA in the fourth quarter of 2014.

*Develop and obtain FDA approval for Egalet-002 as an abuse-deterrent oxycodone product for the treatment of moderate to severe pain.* We are developing Egalet-002 to treat moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We intend to demonstrate safety, efficacy and a PK profile that exhibits low peak-to-trough concentration variability in drug exposure and plan to submit an NDA in the first half of 2016.

*Commercialize Egalet-001 and Egalet-002.* If either of our clinical-stage product candidates achieve regulatory approval, we intend to establish our own specialty sales force to market the product in the United States by targeting physicians specializing in pain management. To supplement our internal U.S. sales force, we intend to contract with third parties to access sales representatives who target primary care and internal medicine physicians in the United States. We will seek to license the development and commercial rights to our products outside the United States to a third-party organization that has an established track record of success in commercializing pain products outside the United States.

*Leverage our proprietary technology platform to develop additional product candidates and create out-licensing opportunities.* We plan to employ our technology to develop additional abuse-deterrent products containing APIs other than morphine and oxycodone. In addition, we will seek to out-license our proprietary technology in areas outside of our current focus, such as for abuse-deterrent combination products, and in therapeutic areas beyond the treatment of pain. For example, we entered into a collaboration and license agreement with Shionogi, wherein we granted Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology.

**Risks Related to Our Business**

Our ability to implement our business strategy is subject to numerous risks and uncertainties. As an early-stage pharmaceutical company, we face many risks inherent in our business and our industry generally. You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," prior to making an investment in our common stock. These risks include, among others, the following:

we currently generate no revenue and may never become profitable;

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we may require additional capital to fund our operations, and if we fail to obtain the necessary financing, we may be unable to complete the development and commercialization of our product candidates;

our success is primarily dependent on the regulatory approval and commercialization of Egalet-001 and Egalet-002, our lead product candidates, and an abuse-deterrent formulation of hydrocodone under our agreement with Shionogi;

we and our collaborator are subject to regulatory approval processes that are lengthy, time-consuming and unpredictable, and we or our collaborator may not obtain approval for any of our product candidates from the FDA;

our ability to market and promote any approved products as abuse-deterrent will be determined by the FDA-approved labeling for such products;

our product candidates contain controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to significant government regulation;

we face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do;

we and our collaborator depend on the performance of third parties, including contract research organizations and manufacturers, to conduct our preclinical studies and clinical trials, and if they do not successfully carry out their contractual duties or meet expected deadlines, we or our collaborator may not be able to obtain regulatory approval for or commercialize our product candidates;

we currently have no sales or marketing capabilities and, if we are unable to develop our own sales and marketing capabilities or enter into strategic alliances with marketing partners, we may not be successful in commercializing our product candidates;

we may be unable to recruit or retain key personnel, including our senior management team; and

it is difficult and costly to protect our intellectual property rights.

**Concurrent Private Placement**

Shionogi Limited, our collaborator, has agreed to purchase 1,250,000 shares of our common stock in a separate private placement concurrent with the completion of this offering at a price per share equal to the initial public offering price. The sale of such shares will not be registered under the Securities Act of 1933, as amended. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

**Our Corporate Information**

Egalet US was incorporated in Delaware in August 2013 and prior to this offering had nominal assets and no operations. Egalet UK, formed in July 2010, currently owns all of our assets and operations and acquired them in July 2010 from Egalet A/S, which was founded under the laws of Denmark. Egalet A/S is a shareholder of Egalet UK. In November 2013, all of the issued and outstanding ordinary and preferred shares of Egalet UK were exchanged for an identical number of shares of common stock and preferred stock of Egalet US, which resulted in Egalet UK becoming a wholly owned subsidiary of Egalet US. Following such exchange, we manage our operations through Egalet US, while our research and development activities continue to be conducted by Egalet UK. We refer to this transaction in this prospectus as the Share Exchange. Since Egalet UK is organized as a public limited company under the laws of England and Wales, it is not permitted to directly list its common stock (as opposed to depositary interests) on the Nasdaq Global Market. Under English law, it is not possible to change the place of incorporation of Egalet UK from one jurisdiction to another, so we effected the Share Exchange to



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migrate Egalet UK to the United States in order to enable us to list our common stock on the Nasdaq Global Market.

Our primary executive offices are located at 460 East Swedesford Road, Suite 1050, Wayne, Pennsylvania 19087 and our telephone number is (610) 833-4200. Our website address is [www.egalet.com](http://www.egalet.com). The information contained in, or that can be accessed through, our website is not part of this prospectus.

**Implications of Being an Emerging Growth Company**

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Act, or JOBS Act. As such, we are eligible to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including, but not limited to:

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;

being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations;

reduced disclosure obligations regarding executive compensation;

not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and

exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of some of the reduced reporting burdens in this prospectus and may take advantage of additional exemptions in the future. Accordingly, the information contained herein may be different than the information provided by other public companies. We do not know if some investors will find our shares less attractive as a result of our utilization of these or other exemptions. The result may be a less active trading market for our shares and our share price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will remain an "emerging growth company" until the earliest of (a) the last day of the first fiscal year in which our annual gross revenues exceed \$1.0 billion, (b) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our shares that are held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, (c) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the preceding three-year period or (d) the last day of our fiscal year containing the fifth anniversary of the date on which shares of our common stock become publicly traded in the United States.

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**THE OFFERING**

|   |   |
|---|---|
| Common stock offered by us  | 4,200,000 shares  |
| Over-allotment option to purchase additional shares                                     | We have granted the underwriters an option for a period of 30 days to purchase up to 630,000 additional shares of common stock.   |
| Common stock to be sold in the concurrent private placement to Shionogi                 | 1,250,000 shares  |
| Common stock to be outstanding after this offering and the concurrent private placement | 14,657,503 shares   |
| Use of proceeds   | We expect that the net proceeds from this offering will be approximately \$44.5 million, or approximately \$51.5 million if the underwriters exercise their over-allotment option in full, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will also receive net proceeds of approximately \$14.0 million from the sale of 1,250,000 shares of common stock in the concurrent private placement to Shionogi after deducting commissions payable by us. We expect to use the proceeds of this offering and the concurrent private placement to fund the research and development and establish commercial manufacturing capability for Egalet-001, Egalet-002 and our preclinical product candidates, and for working capital and general corporate purposes. See "Use of Proceeds" on page 54. |
| NASDAQ Global Market symbol   | EGLT  |
| Risk factors  | You should read the "Risk Factors" section of, and all of the other information set forth in, this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.  |

Unless otherwise noted, the information in this prospectus assumes:

no exercise by the underwriters of their over-allotment option to purchase up to 630,000 additional shares of common stock from us;

with respect to the financial statements and related data herein, the completion of the Share Exchange as if it had occurred as of the end of the periods for which financial information is being presented herein;

the issuance and sale of 1,250,000 shares of common stock in the concurrent private placement to Shionogi at the initial public offering price; and

the conversion of 4,441,217 shares of preferred stock of Egalet US into 5,329,451 shares of common stock of Egalet US, which will occur immediately prior to consummation of this offering.

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In addition, unless otherwise indicated, all information in this prospectus gives effect to a 1.2-for-1 forward stock split of our common stock that was effected on January 21, 2014.

The number of shares of common stock to be outstanding after this offering and the concurrent private placement is based on 1,292,307 ordinary shares of Egalet UK outstanding as of September 30, 2013 and gives effect to the Share Exchange and conversion of 4,441,217 shares of preferred stock into 5,329,451 shares of common stock of Egalet US, the 1,250,000 shares to be issued to Shionogi in the concurrent private placement and the issuance of an aggregate of 2,585,745 shares of our common stock upon the conversion of all outstanding principal and accrued interest on convertible promissory notes in the aggregate principal amount of \$15.0 million, which we issued in April 2013 and August 2013 and refer to as the convertible bridge notes, and which convert automatically upon the closing of this offering. This amount excludes, as of that date:

up to 600,000 shares of our common stock issuable upon exercise of warrants that may become exercisable immediately prior to the consummation of this offering;

an aggregate of 862,800 shares of restricted stock we expect to grant to our Chief Executive Officer, Chief Financial Officer, Chief Business Officer and Vice President of Research and Development upon the consummation of this offering;

the effect of the beneficial conversion feature charge that will be recorded upon the conversion of our convertible debt; and

817,200 additional shares of our common stock to be reserved for future issuance under our equity incentive plans following this offering.

Our existing stockholders have agreed to purchase an aggregate of 833,333 shares of our common stock in this offering at the initial public offering price.

Table of Contents**SUMMARY CONSOLIDATED FINANCIAL DATA**

The following summary consolidated historical financial information relates to Egalet US and its consolidated subsidiaries, which upon effectiveness of the Share Exchange became directly controlled by Egalet US. Prior to the Share Exchange, Egalet US had nominal assets and no operations. The summary consolidated historical statement of operations data of Egalet US and its consolidated subsidiaries for the years ended December 31, 2011 and 2012 has been derived from the audited consolidated financial statements of Egalet US appearing elsewhere in this prospectus and has been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The balance sheet data as of September 30, 2013 and the statement of operations data for the nine months ended September 30, 2012 and 2013 is derived from Egalet US's unaudited condensed consolidated financial statements appearing elsewhere in this prospectus and have been prepared in accordance with U.S. GAAP. Our historical results are not necessarily indicative of the results that may be expected in the future, and our interim period results are not necessarily indicative of the results of operations that may be expected for our full year performance or for any other interim period. The summary consolidated historical financial data of Egalet US should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and unaudited condensed consolidated financial statements of Egalet US and related notes included elsewhere in this prospectus.

|   | <b>Year Ended<br/>December 31,</b> |                | <b>Nine Months Ended<br/>September 30,</b> |                 |
|---|------------------------------------|----------------|--|-----------------|
|   | <b>2011</b>                        | <b>2012</b>    | <b>2012</b>                                | <b>2013</b>     |
| <b>Consolidated Statement of Operations Data:</b>               |                                    |                |  |                 |
| Revenues  | \$ 626,000                         | \$ 1,201,000   | \$ 1,201,000                               | \$              |
| Operating expenses:   |                                    |                |  |                 |
| Research and development  | 4,466,000                          | 4,256,000      | 2,637,000                                  | 3,220,000       |
| General and administrative                                      | 2,068,000                          | 2,241,000      | 1,931,000                                  | 3,223,000       |
| Total operating expenses  | 6,534,000                          | 6,497,000      | 4,568,000                                  | 6,443,000       |
| Loss from operations  | (5,908,000)                        | (5,296,000)    | (3,367,000)                                | (6,443,000)     |
| Interest expense  | 513,000                            | 75,000         | 75,000                                     | 4,443,000       |
| Loss on foreign currency exchange                               | 36,000                             | 27,000         | 12,000                                     | 113,000         |
|   | 549,000                            | 102,000        | 87,000                                     | 4,556,000       |
| Net loss  | \$ (6,457,000)                     | \$ (5,398,000) | \$ (3,454,000)                             | \$ (10,999,000) |
| Per share information:  |                                    |                |  |                 |
| Net loss per share of common stock, basic and diluted           | \$ (5.00)                          | \$ (4.18)      | \$ (2.67)                                  | \$ (8.51)       |
| Basic and diluted weighted average shares outstanding           | 1,292,307                          | 1,292,307      | 1,292,307                                  | 1,292,307       |
| Pro forma information(1):                                       |                                    |                |  |                 |
| Pro forma net loss per share of common stock, basic and diluted |                                    | \$ (0.88)      |  | \$ (1.50)       |
| Pro forma basic and diluted weighted average shares outstanding |                                    | 6,133,632      |  | 7,319,134       |

|   | <b>As of September 30, 2013</b> |                     |                                     |
|---|---------------------------------|---------------------|-------------------------------------|
|   | <b>Actual</b>                   | <b>Pro Forma(1)</b> | <b>Pro Forma<br/>As Adjusted(2)</b> |
| <b>Consolidated Balance Sheet Data:</b> |                                 |                     |                                     |
| Cash                                    | \$ 10,463,000                   | \$ 10,463,000       | \$ 68,879,000                       |
| Total assets                            | 14,362,000                      | 14,362,000          | 72,778,000                          |
| Total liabilities                       | 15,828,000                      | 2,234,000           | 2,234,000                           |
| Accumulated deficit                     | (24,191,000)                    | (39,375,000)        | (40,036,000)                        |
| Total stockholders' (deficit) equity    | (16,423,000)                    | 12,128,000          | 70,544,000                          |

(1)

Gives pro forma effect to the conversion of all outstanding shares of Egalet US preferred stock into 5,329,451 shares of Egalet US common stock, which will occur immediately prior to the consummation of this offering, the issuance of an aggregate of 2,530,675 shares of Egalet US common stock upon the conversion of all outstanding principal and accrued interest on the convertible bridge notes based on interest accrued through September 30,



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2013, and the effect of the beneficial conversion feature charge that will be recorded upon the conversion of the convertible bridge notes.

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(2)

Gives further effect to the sale of 4,200,000 shares of our common stock in this offering, at the initial public offering price of \$12.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, the sale and issuance of 1,250,000 shares of common stock in the concurrent private placement to Shionogi at the initial public offering price of \$12.00 per share, after deducting commissions payable by us, the issuance of 55,070 additional shares of common stock upon the conversion of all outstanding principal and accrued interest on the convertible bridge notes, representing additional interest accrued on these notes from September 30, 2013 through the expected closing date of this offering, and the issuance of an aggregate of 862,800 shares of restricted stock immediately prior to the consummation of this offering to our Chief Executive Officer, Chief Financial Officer, Chief Business Officer and Vice President of Research and Development.

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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before making your decision to invest in shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows, and our future prospects would likely be materially and adversely affected. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.*

**Risks Related to Our Financial Position and Capital Needs**

*We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.*

We are a clinical-stage pharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have not generated any revenue from product sales to date, and we continue to incur significant research, development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2010. For the year ended December 31, 2012 and the nine months ended September 30, 2013, we reported a net loss of \$5.4 million and \$11.0 million, respectively, and we had an accumulated deficit of \$24.2 million at September 30, 2013.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

*Our auditors have expressed substantial doubt as to our ability to continue as a going concern in their report.*

In its report on Egalet US's consolidated financial statements for the year ended December 31, 2012, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern. A "going concern" opinion means, in general, that our independent registered public accounting firm has substantial doubt about Egalet US's ability to continue its operations without continuing infusions of capital from external sources. This opinion could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans.

*We currently generate no revenue from the sale of products and may never become profitable.*

To date, we have not generated any revenues from Egalet-001 and Egalet-002, our clinical-stage product candidates and have generated \$2.0 million in total revenue since our inception from feasibility and collaboration agreements. We are currently party to a collaboration agreement with Shionogi, under which we received a \$10.0 million upfront payment in December 2013. Our ability to generate additional revenue and become profitable depends upon our ability to successfully commercialize products, including any of our product candidates, or other product candidates that we may in-license or acquire in the future. Even if

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we are able to successfully achieve regulatory approval for these product candidates, we do not know when any of these products will generate revenue for us, if at all. Our ability to generate revenue from our current or future product candidates also depends on a number of additional factors, including our ability to:

successfully complete development activities, including the necessary clinical trials;

complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market;

complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;

achieve the milestones contained in our collaboration agreement with Shionogi and sales sufficient to generate royalties under that agreement;

set a commercially viable price for our products;

obtain commercial quantities of our products at acceptable cost levels;

develop a commercial organization capable of sales, marketing and distribution for the products we intend to sell ourselves in the markets in which we have retained commercialization rights;

find suitable distribution partners to help us market, sell and distribute our approved products in other markets; and

obtain coverage and adequate reimbursement from third-party, including government, payors.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the process described above, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

***If we require additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to complete the development and commercialization of our product candidates.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial organization to address selected markets. We believe that the net proceeds from this offering and the concurrent private placement to Shionogi, together with existing cash and interest thereon, including our \$10.0 million upfront payment from Shionogi, will be sufficient to fund our projected operating requirements for at least the next eighteen months. However, we may require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner in order to accelerate development of our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our



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products or product candidates or one or more of our other research and development initiatives. We also could be required to:

seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

the initiation, progress, timing, costs and results of clinical trials for our product candidates, particularly Egalet-001 and Egalet-002, and any future product candidates we may in-license;

the clinical development plans we establish for these product candidates;

the ability to obtain abuse-deterrent claims in the labels for these product candidates;

our agreement with Shionogi remaining in effect and our ability to achieve milestones under this and any other license or collaboration agreement that we may enter into in the future;

the number and characteristics of product candidates that we in-license and develop;

the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the effect of competing technological and market developments;

the cost and timing of completion of commercial-scale outsourced manufacturing activities; and

the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. We do not currently have any committed external source of funds other than possible milestone payments and possible royalties under our collaboration agreement with Shionogi. To the extent that we raise

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additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in

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liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

***We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

Egalet UK was formed in July 2010. Our revenue-generating operations to date have been limited to providing services under various collaborative and research and development arrangements, organizing and staffing our company, acquiring product and technology rights, and conducting product development activities for our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

Our foreign net operating losses, or NOLs, generated by Egalet UK's operations may be carried forward indefinitely but may become subject to an annual limitation. Upon potential examination by the statutory or governing authority, it may be determined that we experienced a greater than 50% change in share capital, which would limit the availability and use of existing foreign NOLs to offset our taxable income, if any, in the future.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

**Risks Related to the Clinical Development and Regulatory Approval of Our Product Candidates**

***Development of our product candidates is not complete, and we cannot be certain that our product candidates will be commercialized.***

To date, we have only generated an aggregate of \$2.0 million in revenues from various collaborative and research and development arrangements and a \$10.0 million upfront payment under our collaboration and licensing agreement with Shionogi. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our product candidates under development. For our lead product candidates, Egalet-001 and Egalet-002, and each additional product candidate that we intend to commercialize, we or a collaborator must successfully meet a number of critical developmental milestones, including:

selecting and developing a drug delivery platform technology to deliver the proper dose of drug over the desired period of time;

determining the appropriate drug dosage;

developing drug dosages that will be tolerated, safe and effective;

demonstrating the drug formulation will be stable for commercially reasonable time periods;



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demonstrating through clinical trials that the drug is safe and effective in patients for the intended indication; and

completing the manufacturing development and scale-up to permit manufacture of our product candidates in commercial quantities and at acceptable prices.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for any of our product candidates in development. We have not yet completed development of any product. We may not be able to finalize the design or formulation of any product candidate. In addition, we may select components, solvents, excipients or other ingredients to include in our product candidates that have not been previously approved for use in pharmaceutical products, which may require us to perform additional studies and may delay clinical testing and regulatory approval of our product candidates. Even after we complete the design of a product candidate, the product candidate must still be shown to be bioequivalent to an approved drug or safe and effective in required preclinical studies and clinical trials before approval for commercialization.

We are continuing to test and develop our product candidates and may explore possible design or formulation changes to address bioequivalence, safety, efficacy, manufacturing efficiency and performance issues. We may not be able to complete development of any product candidates that will be safe and effective and that will have a commercially reasonable treatment and storage period. If we are unable to complete development of Egalet-001, Egalet-002 or any of our other product candidates, we will not be able to earn revenue from them.

***If we or our collaborator are unable to design, conduct and complete clinical trials successfully, our product candidates will not be able to receive regulatory approval.***

In order to obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA with substantial evidence that demonstrates that the product candidate is both safe and effective in humans for its intended use. This demonstration requires significant research, preclinical studies and clinical trials.

Clinical trials are time-consuming, very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. We or our collaborator could encounter problems that cause abandonment or repetition of clinical trials. If patients participating in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we or the FDA believe that participating patients are being exposed to unacceptable health risks, such clinical trials will have to be suspended or terminated. Suspensions, termination or the need to repeat a clinical trial can occur at any stage.

The clinical trial success of each of our product candidates designed to reduce potential risks of unintended use and abuse depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. There is a lack of consensus regarding standardized processes for assessing clinical outcomes based on clinician-rated scales. Accordingly, the scores from our clinical trials may not be reliable, useful or acceptable to the FDA or other regulatory agencies.

Changes in standards related to clinical trial design could affect our ability to design and conduct clinical trials as planned. For example, we have conducted or will conduct clinical trials comparing our product candidates to both placebo and other approved drugs, but regulatory authorities may not allow us to compare our product candidates to a placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct a clinical trial could increase. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the

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successful commercialization of our product candidates. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, which could limit the labeling, distribution or promotion of a drug product.

Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing and commercialization of our product candidates and significantly increase our overall costs of drug development.

***If we or our collaborator are unable to conduct and complete clinical trials on schedule, or if there is a delay in the approval process, the cost of seeking necessary regulatory approvals will be significantly increased.***

The clinical trial process also consumes a significant amount of time. The length of clinical trials will depend upon, among other factors, the number of patients required to be enrolled in such studies and the rate of trial site and patient enrollment. We or our collaborator may fail to obtain adequate levels of patient enrollment in our clinical trials. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials. In addition, even if we enroll the number of patients we expect in the time frame we expect, such clinical trials may not provide the data necessary to support regulatory approval for the product candidates for which they were conducted. Additionally, we or our collaborator may fail to effectively oversee and monitor these clinical trials, which would result in increased costs or delays of our clinical trials. Even if these clinical trials are completed, we or our collaborator may fail to complete and submit an NDA as scheduled.

Even if clinical trials are completed as planned, their results may not support expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our product candidates are safe and effective for indicated uses. Such failure may cause us to abandon a product candidate and could delay development of other product candidates, or the FDA could require additional studies, in which case we would have to expend additional time and resources which would likely delay the date of potentially receiving regulatory approval. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals would:

delay commercialization of, and product revenues from, our product candidates; and

diminish the competitive advantages that we may have otherwise enjoyed, which would have an adverse effect on our operating results and financial condition.

***Because the results of preclinical studies and early-stage clinical trials are not necessarily predictive of future results, Egalet-001, Egalet-002 or any other product candidate we or our collaborator advance into additional clinical trials may not continue to have favorable results or receive regulatory approval.***

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Many companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after reporting promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for Egalet-001 and Egalet-002, we do not know whether the clinical trials we or our collaborator may conduct will demonstrate adequate efficacy and safety or otherwise provide adequate information to result in regulatory approval to market any of our product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be compromised.

***If we or our collaborator fail to obtain the necessary regulatory approvals, or if such approvals are limited, we will not be able to commercialize our product candidates, and we will not generate product revenues.***

Even if we or our collaborator comply with all FDA pre-approval regulatory requirements, the FDA may not determine that some or all of our product candidates are safe and effective, and we may never obtain

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regulatory approval for some or all of our product candidates. If we or our collaborator fail to obtain regulatory approval for some or all of our product candidates, we will have fewer commercial products, if any, and correspondingly lower product revenues, if any. Even if our product candidates receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us or our collaborator to perform lengthy Phase 4 post-approval clinical efficacy or safety trials. These trials could be very expensive. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

In jurisdictions outside the United States, we must receive marketing authorizations from the appropriate regulatory authorities before commercializing our product candidates. Regulatory approval processes outside the United States generally include requirements and risks similar to, and in many cases in excess of, the risks associated with FDA approval.

***If the FDA does not conclude that our product candidates are sufficiently bioequivalent, or have comparable bioavailability, to approved drugs, or if the FDA does not allow us to pursue the Section 505(b)(2) approval pathway as anticipated, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not approve those product candidates.***

A key element of our strategy is to seek FDA approval for Egalet-001 and Egalet-002 through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Such reliance is typically predicated on a showing of bioequivalence or comparable bioavailability to an approved drug.

If the FDA does not allow us to pursue the Section 505(b)(2) approval pathway as anticipated, or if we cannot demonstrate bioequivalence or comparable bioavailability of our product candidates to approved products, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, our inability to pursue the Section 505(b)(2) approval pathway could result in new competitive products reaching the market more quickly than our product candidates, which could hurt our competitive position and our business prospects. Even if we are allowed to pursue the Section 505(b)(2) approval pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization on a timely basis, if at all.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to Section 505(b)(2) regulatory approvals, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

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***The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval varies among jurisdictions and may change during the course of a product candidate's clinical development. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any future product candidates we may in-license, acquire or develop will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

disagreement with or disapproval of the design or implementation of our clinical trials;

failure to demonstrate that a product candidate is safe and effective for its proposed indication;

failure to sufficiently deter abuse;

failure of clinical trials to meet the level of statistical significance required for approval;

failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

a negative interpretation of the data from our preclinical studies or clinical trials;

deficiencies in the manufacturing processes or failure of third-party manufacturing facilities with whom we contract for clinical and commercial supplies to pass inspection; or

insufficient data collected from clinical trials of our product candidates or changes in the approval policies or regulations that render our preclinical and clinical data insufficient to support the submission and filing of an NDA or to obtain regulatory approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or cause us to abandon the development program. Even if we obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, such approval may be contingent on the performance of costly post-marketing clinical trials, or we may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate. In addition, if our product candidate produces undesirable side effects or safety issues, the FDA may require the establishment of a REMS, or a comparable foreign regulatory authority may require the establishment of a similar strategy, that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us. For example, we expect that certain of our product candidates, if approved, including Egalet-001 and Egalet-002, will be subject to REMS. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In order to market and sell our products outside of the United States, we must obtain separate marketing approvals and comply with numerous and various regulatory requirements and regimes, which can involve additional testing, may take substantially longer than the FDA approval process, and still generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. FDA approval does not ensure approval by regulatory authorities in other countries or jurisdictions, approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA, and we may not obtain any regulatory approvals on a timely basis, if at all. We may not be able to file for



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marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union, China or another country, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

***Our ability to market and promote our products in the United States by describing their abuse-deterrent features will be determined by the FDA-approved labeling for them.***

The commercial success of our product candidates will depend upon our ability to obtain FDA approved labeling describing their abuse-deterrent features or benefits. Our failure to achieve FDA approval of product labeling containing such information will prevent or substantially limit our advertising and promotion of the abuse-deterrent features of our product candidates in order to differentiate them from other opioid products containing the same active ingredients. This would make our products less competitive in the market.

The FDA has publicly stated that explicit claims that a product is expected to result in a meaningful reduction of abuse must be supported by randomized, double-blind, controlled clinical studies of the abuse potential of the drug and that explicit claims that a product has demonstrated reduced abuse in the community will be required to be supported by post-marketing data, including formal post-marketing studies evaluating the effect of abuse-deterrent formulations. Although we intend to conduct such studies, there can be no assurance that our product candidates in development will receive FDA-approved labeling that describes the abuse-deterrent features of such products. If the FDA does not approve labeling containing such information, we will not be able to promote such products based on their abuse-deterrent features, may not be able to differentiate such products from other opioid products containing the same active ingredients, and may not be able to charge a premium above the price of such other products.

Because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse-deterrent characteristics of our product, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution. Any of these consequences would harm the commercial success of our products.

***Our decision to seek approval of Egalet-001 and Egalet-002 under Section 505(b)(2) may increase the risk that patent infringement suits are filed against us, which would delay the FDA's approval of such product candidates.***

In connection with any NDA that we file under Section 505(b)(2), we will also be required to notify the patent holder that we have certified to the FDA that any patents listed for the approved drug, also known as a reference listed drug, or RLD, in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If the patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and patent litigation before our product candidates may be commercialized. With regard to Egalet-002, we are aware of litigation involving the sponsor for the RLD for oxycodone and a number of generic manufacturers related to patents listed in the Orange Book that expire on various dates between 2017 and 2025. There is a risk that the sponsor for the RLD for oxycodone may bring infringement claims against us. Even if we are found not to infringe, or a plaintiff's patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming, and would delay launch of Egalet-002 and distract management from their normal responsibilities.

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***We anticipate that Egalet-001 and Egalet-002 will be subject to mandatory REMS programs, which could delay the approval of these product candidates and increase the cost, burden and liability associated with the commercialization of these product candidates.***

The FDA has indicated that some opioid drugs formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and others will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks. The FDA has approved a REMS for extended release, or ER, and long-acting, or LA, opioids as part of a federal initiative to address prescription drug abuse and misuse. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while ensuring access to needed medications for patients in pain. The ER/LA opioid REMS affects more than 20 companies that manufacture these opioid analgesics. Under the new REMS, companies are required to make education programs available to prescribers based on an FDA Blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS also requires companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

We anticipate that Egalet-001 and Egalet-002 will be subject to the REMS requirement. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of product candidates subject to the REMS requirement, which could reduce the commercial benefits to us from the sale of these product candidates.

***Our product candidates contain controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.***

Egalet-001 and Egalet-002 contain, and our future product candidates will likely contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Egalet-001 and Egalet-002 contain active ingredients that are classified as controlled substances under the Controlled Substances Act of 1970, or CSA, and regulations of the United States Drug Enforcement Administration, or DEA. A number of states also independently regulate these drugs as controlled substances. Chemical compounds are classified by the DEA as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in our lead product candidates Egalet-001 and Egalet-002, morphine and oxycodone, are listed by the DEA as Schedule II controlled substances under the CSA. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand, if our product candidates are approved for marketing.

In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates that include controlled substances. Failure to obtain and maintain required registrations or to comply with any applicable regulations could delay or

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preclude us from developing and commercializing our product candidates that contain controlled substances and subject us to enforcement action. Because of their restrictive nature, these regulations could limit commercialization of our product candidates containing controlled substances.

***Conducting clinical trials of our product candidates and any future commercial sales of a product candidate may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all.***

We currently carry clinical trial insurance with coverage up to approximately \$13 million, but we do not carry product liability insurance. Even if we successfully commercialize one or more of our product candidates, we may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. We may not be able to obtain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for any product candidates or products that we may develop;

termination of clinical trial sites or entire trial programs;

injury to our reputation and significant negative media attention;

withdrawal of clinical trial participants;

significant costs to defend the related litigation;

substantial monetary awards to trial subjects or patients;

loss of revenue;

diversion of management and scientific resources from our business operations;

the inability to commercialize any products that we may develop; and

an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of our product candidates may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise.

***Even if our product candidates receive regulatory approval, they will be subject to ongoing regulatory requirements, and we may face regulatory enforcement action if we do not comply with the requirements.***

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and other regulations. If we or a regulatory agency discover problems with a product which were previously unknown, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us,



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including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters or untitled letters;

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mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

require us to enter into a consent decree, which can include the imposition of various fines, reimbursements for inspection costs and penalties for noncompliance, and require due dates for specific actions;

seek an injunction, impose civil penalties or monetary fines or pursue criminal prosecution;

suspend or withdraw regulatory approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to applications filed by us;

suspend or impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

**Risks Related to the Commercialization of Our Product Candidates**

*We currently have no sales or marketing capabilities and, if we are unable to develop our own sales and marketing capabilities or enter into strategic alliances with collaborators, we may not be successful in commercializing our product candidates.*

Although our executive officers have experience marketing pharmaceutical products, we currently have no sales, marketing or distribution capabilities. We do not intend to begin to hire marketing personnel or establish our own sales organization in the United States unless and until we have received FDA approval of one of our product candidates. Therefore, at the time of our anticipated commercial launch of Egalet-001, assuming regulatory approval of the product candidate by the FDA, our sales and marketing team will have worked together for only a limited period of time. We cannot guarantee that we will be successful in marketing Egalet-001, Egalet-002 or any of our other product candidates in the United States. We may not be able to establish a targeted sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates in the United States include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our product candidates;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing our product candidates. Outside the

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United States, where we intend to commercialize our product candidates by entering into agreements with third-party collaborators, we may have limited or no control over the sales, marketing and distribution activities of these third parties, in which case our future revenues would depend heavily on the success of the efforts of these third parties.

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***If physicians and patients do not accept and use our product candidates, we will not achieve sufficient product revenues and our business will suffer.***

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our product candidates will depend on a number of factors including:

approved indications, warnings and precautions language that may be less desirable than anticipated;

perceptions by members of the healthcare community, including physicians, about the safety and efficacy of our product candidates, and, in particular, the efficacy of our abuse-deterrent technology in reducing potential risks of unintended use;

perceptions by physicians regarding the cost benefit of our product candidates in reducing potential risks of unintended use;

published studies demonstrating the cost-effectiveness of our product candidates relative to competing products;

availability of coverage and adequate reimbursement for our product candidates from government or healthcare payors;

our ability to implement a REMS prior to the distribution of any product candidate requiring a REMS; and

effectiveness of marketing and distribution efforts by us and other licensees and distributors.

Because we expect to rely on sales generated by our current lead product candidates, if approved, for substantially all of our revenues for the foreseeable future, the failure of any of our product candidates to find market acceptance would harm our business prospects.

***If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, it could reduce our sales of those product candidates.***

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

***Recently enacted and future legislation may increase the difficulty and cost for us or our collaborator to commercialize our product candidates and may reduce the prices we are able to obtain for our product candidates.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities or affect our

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ability to profitably sell any product candidates for which we or our collaborator obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we receive for any of our approved products. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial new provisions intended to, among other things, broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact our business. A significant number of provisions are not yet, or have only recently become, effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Other legislative changes have also been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and the American Taxpayer Relief act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could impose additional financial pressure on our customers, which could in turn diminish demand for our products or result in pricing pressure on us.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products.

In addition, state pharmacy laws may permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents, or may permit pharmacists and pharmacy benefit managers to seek prescriber authorization to substitute generics in place of our product candidates, which could significantly diminish demand for them and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

***Even if we or our collaborator are able to commercialize our product candidates, our products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.***

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some

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countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborator might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could reduce our future revenues.

***Failure to comply with ongoing governmental regulations for marketing our product candidates could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.***

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Department of Justice, the U.S. Department of Health and Human Services' Office of the Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

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In the United States, engaging in impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable.

In addition, later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing the full commercial potential of our product candidates:

failure to obtain or maintain requisite governmental approvals;

failure to obtain approvals of labeling with abuse-deterrent claims; or

FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our product candidates.

***Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioid and regulatory efforts to combat abuse, could decrease the potential market for our product candidates.***

Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies that seek to limit the availability of opioids. Such efforts may inhibit our ability to commercialize our product candidates. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs, the limitations of abuse-resistant formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, sales, marketing, distribution or storage of our drug products could harm our reputation. Such negative publicity could reduce the potential size of the market for our product candidates and decrease the revenues we are able to generate from their sale. Similarly, to the extent opioid abuse becomes less prevalent or less urgent of a public health issue, regulators and third party payers may not be willing to pay a premium for abuse-deterrent formulations of opioids.

Additionally, efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for our product candidates. For example, on September 10, 2013, the FDA announced its intention to effect labeling changes to all approved ER and long-acting opioids. In particular, the FDA intends to update the indication for ER and long-acting opioids so that ER and long-acting opioids will be indicated only for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. It is possible that such changes could reduce the number of prescriptions for opioids written by physicians and negatively impact the potential market for our product candidates.

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***We intend to market our products outside of the United States, and we will be subject to the risks of doing business outside of the United States.***

Because we intend to market products, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

failure to develop an international sales, marketing and distribution system for our products;

changes in a specific country's or region's political and cultural climate or economic condition;

unexpected changes in foreign laws and regulatory requirements;

difficulty of effective enforcement of contractual provisions in local jurisdictions;

inadequate intellectual property protection in foreign countries;

trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges;

the effects of applicable foreign tax structures and potentially adverse tax consequences; and

significant adverse changes in foreign currency exchange rates.

**Risks Related to Our Dependence on Third Parties**

***We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.***

We have relied upon and plan to continue to rely upon third-party contract research organizations, or CROs, to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations and current Good Clinical Practices, or GCP, which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, advisors and monitors, enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to



the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical

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trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future.

***We depend on our collaboration with Shionogi and may depend on collaborations with additional third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

In November 2013, we entered into our collaboration with Shionogi for the development and commercialization of hydrocodone-based product candidates. The collaboration involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified regulatory and sales-based milestones and provides us with royalty-based revenue if certain product candidates are successfully commercialized. We cannot predict the success of the collaboration.

Under the collaboration, we will have limited control over the amount and timing of resources that our collaborator dedicates to the development or commercialization of our product candidates. Our ability to generate revenues from this arrangement will depend on Shionogi's abilities to successfully perform the functions assigned to it in this arrangement.

We may also seek other third-party collaborators for the development and commercialization of our product candidates. Collaborations involving our product candidates, including our collaboration with Shionogi, pose the following risks to us:

Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, under our collaboration with Shionogi, development and commercialization plans and strategies for licensed programs will be conducted in accordance with a plan and budget approved by a joint committee comprised of equal numbers of representatives from each of us and Shionogi.

Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities. For example, it is possible for Shionogi to elect not to progress into clinical development the hydrocodone-based product candidates without triggering a termination of the collaboration arrangement.

Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing. For example, under our agreement with Shionogi, it is possible for Shionogi to terminate the agreement, upon 90 days prior written notice, with respect to any product candidate at any point in the research, development and clinical trial process, without triggering a termination of the remainder of the collaboration arrangement.

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Collaborators may conduct clinical trials inappropriately, or may obtain unfavorable results in their clinical trials, which may have an adverse effect on the development of our own programs.

Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

A collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such products.

Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, Shionogi has the first right to maintain or defend our intellectual property rights under our collaboration arrangement with respect to certain licensed programs and, although we may have the right to assume the maintenance and defense of our intellectual property rights if Shionogi does not, our ability to do so may be compromised by Shionogi's actions.

Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources.

We may lose certain valuable rights under circumstances identified in our collaborations, including, in the case of our agreement with Shionogi, if we undergo a change of control.

Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

***If we lose our relationships with CROs, our drug development efforts could be delayed.***

We rely on third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

***If third-party manufacturers of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may be higher than expected and could harm our business.***

We have no manufacturing facilities and have limited experience in drug development and commercial manufacturing. We lack the resources and expertise to formulate, manufacture or test the technical



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performance of our product candidates. We currently rely on a limited number of experienced personnel and one contract manufacturer, Halo Pharmaceutical, as well as other vendors to formulate, test, supply, store and distribute drug supplies for our clinical trials. Our reliance on a limited number of vendors and a single manufacturer exposes us to the following risks, any of which could delay our clinical trials, and, consequently, FDA approval of our product candidates and commercialization of our products, result in higher costs, or deprive us of potential product revenues:

Contract commercial manufacturers, their sub-contractors or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy clinical needs or commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations.

Our contract manufacturer could default on its agreements with us to provide clinical supplies or meet our requirements for commercialization of our products.

For certain of our product candidates, the use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products before we may use the alternative manufacturer to produce our product candidates.

It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturers and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.

The FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties, or pursuing criminal prosecution.

***Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredients of our product candidates, any production problems with our supplier could adversely affect us.***

We have relied upon supply agreements with third parties for the manufacture and supply of the bulk active pharmaceutical ingredients used in our product candidates for purposes of preclinical testing and clinical trials. We presently depend upon a single source as the sole manufacturer of our supply of APIs for our other product candidates and intend to contract with this supplier, as necessary, for commercial scale manufacturing of our products. Although we have identified alternate sources for these supplies, it would be time-consuming and costly to qualify these sources. Since we currently obtain our API from this manufacturer on a purchase-order basis, either we or our supplier may terminate our arrangement, without cause, at any time without notice. If our supplier were to terminate our arrangement or fail to meet our supply needs we might be forced to delay our development programs.

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***To the extent we elect to enter into additional licensing or collaboration agreements to further develop or commercialize our product candidates, our dependence on such relationships may reduce our revenues or could lengthen the time for us to generate cash flows from the sale of our product candidates.***

Our commercialization strategy for some of our product candidates in preclinical development may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of these product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into additional collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized.

Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators would compromise our ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to certain other programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our future collaborative arrangements may not be successful.

***We intend to rely on collaborators to market and commercialize our product candidates outside of the United States, who may fail to effectively commercialize our product candidates.***

Outside of the United States, we currently plan to utilize strategic partners or contract sales forces, where appropriate, to assist in the commercialization of our product candidates, if approved. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. By entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Our collaborators may fail to develop or effectively commercialize our product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our product candidates outside of the United States would diminish our revenues.

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**Risks Related to Our Business and Strategy**

*We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.*

We face and will continue to face competition from other companies in the pharmaceuticals, medical devices and drug delivery industries. Our product candidates, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue Pharma, Johnson & Johnson, Pfizer, Durect, Endo, Mallinckrodt, Zogenix, Elite Pharmaceuticals, Pain Therapeutics, Acura, Nektar, Collegium Pharmaceuticals, Actavis and others. Some of these companies and many others are applying significant resources and expertise to the challenges of drug delivery, and several are focusing or may focus on drug delivery to the intended site of action. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less costly than ours, and they may also be more successful than us in manufacturing and marketing their products.

Furthermore, if the FDA approves a competitor's 505(b)(2) application for a drug candidate before our application for a similar drug candidate, and grants the competitor a period of exclusivity, the FDA may take the position that it cannot approve our NDA for a similar drug candidate. For example, we believe that several competitors are developing extended-release oxycodone products, and if the FDA approves a competitor's 505(b)(2) application for an extended-release oxycodone product and grants exclusivity before our NDA for Egalet-002 is filed and approved, we could be subject to a delay that would dramatically reduce our expected market potential for Egalet-002. Additionally, even if our 505(b)(2) application for Egalet-002 is approved first, we may still be subject to competition from other oxycodone products, including approved products or other approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

In addition, competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our product candidates. Our competitors may develop products that are safer, more effective or less costly than our product candidates and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of currently available therapies with which our product candidates will compete may limit market acceptance of our product candidates even if commercialized. Oral medication, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available treatments for chronic and post-operative pain, are widely accepted in the medical community and have a long history of use. These treatments will compete with our product candidates, if approved, and the established use of these competitive products may limit the potential for our product candidates to receive widespread acceptance if commercialized.

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***The use of legal and regulatory strategies by competitors with innovator products, including the filing of citizen petitions, may delay or prevent the introduction or approval of our product candidates, increase our costs associated with the introduction or marketing of our products, or significantly reduce the profit potential of our products.***

Companies with innovator drugs often pursue strategies that may serve to prevent or delay competition from alternatives to their innovator products. These strategies include, but are not limited to:

filing "citizen petitions" with the FDA that may delay competition by causing delays of our product approvals;

seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a product's bioequivalence or "sameness" to the related innovator product;

filing suits for patent infringement that automatically delay FDA approval of Section 505(b)(2) products;

obtaining extensions of market exclusivity by conducting clinical trials of innovator drugs in pediatric populations or by other methods;

persuading the FDA to withdraw the approval of innovator drugs for which the patents are about to expire, thus allowing the innovator company to develop and launch new patented products serving as substitutes for the withdrawn products;

seeking to obtain new patents on drugs for which patent protection is about to expire; and

initiating legislative and administrative efforts in various states to limit the substitution of innovator products by pharmacies.

These strategies could delay, reduce or eliminate our entry into the market and our ability to generate revenues associated with our product candidates.

***Our future success depends on our ability to retain our key personnel.***

We are highly dependent upon the services of our key personnel, including our Chief Executive Officer, Robert Radie, and our Chief Financial Officer, Stan Musial. Although we have offer letter agreements with each of them and intend to enter into employment agreements upon consummation of this offering, these agreements are at-will and do not prevent them from terminating their employment with us at any time. We anticipate entering into new employment agreements with Messrs. Radie and Musial to be effective upon the consummation of this offering, but we expect that they will continue to be employed at will. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of either Mr. Radie or Mr. Musial could impede the achievement of our research, development and commercialization objectives.

***If we are unable to attract and retain highly qualified scientific and technical employees, we may not be able to grow effectively.***

Our future growth and success depend on our ability to recruit, retain, manage and motivate our scientific and technical employees. Because of the specialized scientific nature of our business, we rely heavily on our ability to attract and retain qualified scientific and technical personnel. The competition for qualified personnel in the pharmaceutical field is intense, and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

***We will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of September 30, 2013, we had 18 full-time employees. As our development and commercialization strategies develop, we will need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems currently in place may not be adequate to support this





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future growth. Future growth would impose significant added responsibilities on members of management, including:

managing our clinical trials effectively;

identifying, recruiting, maintaining, motivating and integrating additional employees;

managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

improving our managerial, development, operational and finance systems; and

expanding our facilities.

As our operations expand, we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

***We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders or cause us to recognize accounting charges in our financial statements.***

While we currently have no specific plans to acquire any other businesses, we may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

issue stock that would dilute our stockholders' percentage of ownership;

incur debt and assume liabilities; and

incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition candidates and we may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions could also pose numerous additional risks to our operations, including:

problems integrating the purchased business, products or technologies;

increases to our expenses;

the failure to have discovered undisclosed liabilities of the acquired asset or company;

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diversion of management's attention from their day-to-day responsibilities;

entrance into markets in which we have limited or no prior experience; and

potential loss of key employees, particularly those of the acquired entity.

We may not be able to successfully complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition.

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***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to:

comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;

provide accurate information to the FDA or comparable foreign regulatory authorities;

comply with manufacturing standards we have established;

comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;

report financial information or data accurately; or

disclose unauthorized activities to us.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We will adopt a Code of Business Conduct and Ethics, which will be effective as of the closing of this offering, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

***Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.***

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we may obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate, including:

the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;



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state and foreign anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers;

federal laws requiring drug manufacturers to report information related to payments and other transfers of value made to physicians and other healthcare providers, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, as well as other state and foreign laws regulating marketing activities; and

state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.***

In connection with our research and development activities and our manufacture of materials and product candidates, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. Although we believe that our safety

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procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

***Our business and operations would suffer in the event of computer system failures.***

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

***Fluctuations in the value of foreign currencies could negatively impact our results of operations and increase our costs.***

Some payments to our employees, suppliers and contract manufacturers are denominated in foreign currencies. Our reporting currency is the U.S. dollar. Accordingly, we are exposed to foreign exchange risk, and our reported results of operations may be negatively impacted by fluctuations in the exchange rate between the U.S. dollar and the foreign currency. A significant appreciation in the foreign currency relative to the U.S. dollar would result in higher reported expenses and would cause our net losses to increase. Likewise, to the extent that we generate any revenues denominated in foreign currencies, or become required to make payments in other foreign currencies, fluctuations in the exchange rate between the U.S. dollar and those foreign currencies could also negatively impact our reported results of operations. We have not entered into any hedging contracts to mitigate the effect of changes in foreign currency exchange rates.

**Risks Related to Our Intellectual Property**

***If we are unable to obtain or maintain intellectual property rights for our technology and product candidates, we may lose valuable assets or experience reduced market share.***

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part

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on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidates.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products identical, similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, our patent applications may not issue into patents, and any issued patents may not provide protection against competitive technologies, may be held invalid or unenforceable if challenged or may be interpreted in a manner that does not adequately protect our technology or future products. Even if our owned patent applications issue into patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The examination process may require us to narrow the claims in our patents, which may limit the scope of patent protection that may be obtained. Our competitors may design around or otherwise circumvent patents issued to us or licensed by us.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions typically are not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Recent patent reform legislation could increase the uncertainties and costs associated with the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law on September 16, 2011, made significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and litigated. Many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first to file" provisions described below, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Pursuant to the Leahy-Smith Act, the United States transitioned to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. In addition, third parties are allowed to submit prior art before the issuance of a patent by the United States Patent and Trademark Office, and may become involved in opposition, derivation, reexamination, or *inter partes* review challenging our patent



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rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties.

Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

***We may be forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets.***

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, unenforceable, or limited or narrowed in scope. Further, this can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

***Unfavorable outcomes in intellectual property litigation could result in costly litigation and potentially limit our ability to commercialize our products.***

Our commercial success depends upon our ability to develop product candidates and commercialize future products without infringing the intellectual property rights of others. Our current or future product candidates or products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. This is due in part to the considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the United States and elsewhere in the world and, to date, there is no consistency regarding the breadth of claims allowed in pharmaceutical patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products. In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights.

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications related to morphine or oxycodone drugs and formulations, including those listed in the FDA's Orange Book for oxycodone products. Since patent applications are published some time after filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Because of the

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inevitable uncertainty in intellectual property litigation, we could lose, even if the case against us was weak or flawed.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations.

In connection with any NDA that we file under Section 505(b)(2), we will also be required to notify the patent holder that we have certified to the FDA that any patents listed for the RLD in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If the patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and patent litigation before our product candidates may be commercialized. With regard to Egalet-002, we are aware of litigation involving the sponsor for the RLD for oxycodone and a number of generic manufacturers related to patents listed in the Orange Book that expire on various dates between 2017 and 2025. There is a risk that the sponsor for the RLD for oxycodone may bring infringement claims against us. Even if we are found not to infringe, or a plaintiff's patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming, and would delay launch of Egalet-002 and distract management from their normal responsibilities.

Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the United States or in countries outside the United States, or litigation against our partners may be costly and time consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could compromise the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

***We may be subject to claims by third parties of ownership of what we regard as our own intellectual property or obligations to make compensatory payments to employees.***

While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing or obtaining such an agreement with each party who, in fact, develops intellectual property that we regard as our own. In addition, they may breach the assignment agreements or such agreements may not be self-executing, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

In accordance with the provisions of the Danish Act on inventions of employees, we may be required to make a compensatory payment to an employee in return for the assignment to us of his or her rights to an

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invention made within the course of his or her employment. Any such payment would reduce the cash available to fund our operations.

***We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent rights, that is important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products candidates, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms.

***Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Any such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct the litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely impact our ability to compete in the marketplace.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and sell their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents or our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

**Risks Related to this Offering and Ownership of Our Common Stock**

***We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.***

Prior to this offering there has been no market for shares of our common stock. An active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

the success of competitive products or technologies;

regulatory actions with respect to our products or our competitors' products;

actual or anticipated changes in our growth rate relative to our competitors;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

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results of clinical trials of our product candidates or those of our competitors;

regulatory or legal developments in the United States and other countries;

developments or disputes concerning patent applications, issued patents or other proprietary rights;

the recruitment or departure of key personnel;

the level of expenses related to any of our product candidates or clinical development programs;

the results of our efforts to in-license or acquire additional product candidates or products;

actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

variations in our financial results or those of companies that are perceived to be similar to us;

fluctuations in the valuation of companies perceived by investors to be comparable to us;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

announcement or expectation of additional financing efforts;

sales of our common stock by us, our insiders or our other stockholders;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors; and

general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry

analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering and the concurrent private placement with Shionogi, we will have outstanding 14,657,503 shares of common stock based on the number of shares outstanding as of September 30, 2013. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by

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our affiliates. The remaining shares will be restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the "Shares Eligible for Future Sale" section of this prospectus. Moreover, after this offering and the concurrent private placement, holders of an aggregate of 10,457,503 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

***Future issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock, including shares of common stock sold in this offering.

Pursuant to our 2013 Stock-Based Incentive Plan, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers and other employees and service providers, including officers, employees and service providers of our subsidiaries and affiliates. The number of shares of our common stock we have initially reserved for issuance under our 2013 Stock-Based Incentive Plan is 1,680,000, and future option grants and issuances of common stock under our 2013 Stock-Based Incentive Plan may adversely affect the market price of our common stock.

In addition, some of our directors, executive officers and other employees are currently entitled to receive awards of up to an aggregate of 13.5% of the proceeds payable in connection with certain changes of control before any payments to our equityholders. If and to the extent we do not replace these rights with grants under our 2013 Stock-Based Incentive Plan, we could be required to make additional awards that would result in dilution, in addition to any dilution as a result of awards under the Stock-Based Incentive Plan, and may adversely affect the market price of our common stock.

***We have broad discretion in the use of the net proceeds from this offering and the concurrent private placement and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering and the concurrent private placement, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management may not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering and the concurrent private placement to fund clinical trials of and establish commercial manufacturing capability for Egalet-001 and Egalet-002 and for working capital and general corporate purposes. Pending their use, we may invest the net proceeds from this offering and the concurrent private placement in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering and the concurrent private placement in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause the price of our common stock to decline.

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***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

***Our principal stockholders and management own all of our stock prior to this offering and will continue to be able to exert significant control over matters subject to stockholder approval after the offering.***

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned 100% of our voting stock and, upon the closing of this offering and the concurrent private placement of common stock to Shionogi, that same group will hold approximately 65.1% of our outstanding voting stock, assuming the purchase of an aggregate of 833,333 shares of our common stock in this offering by this same group, and assuming Shionogi's purchase of 1,250,000 shares in the private placement at the initial public offering price. As a result, these stockholders will be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders will be able to determine the outcome of elections of directors, effect amendments of our organizational documents, or approve any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective in connection with the closing of this offering, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

eliminating the ability of stockholders to call a special meeting of stockholders;

establishing a staggered board of directors; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management.



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Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may also discourage, delay or prevent a third party from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$7.20 per share, based on the initial public offering price of \$12.00 per share. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. Further, investors purchasing common stock in this offering will contribute approximately 52% of the total amount invested by stockholders since our inception, but will own, as a result of such investment, only approximately 29% of the shares of common stock outstanding immediately following giving effect to this offering and the concurrent private placement to Shionogi. For a further description of the dilution that you will incur as a result of purchasing shares in this offering, see "Dilution."

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***We are an "emerging growth company" and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which could be for up to five years. See "Summary Implications of Being an Emerging Growth Company."

If investors find our common stock less attractive as a result of our reduced reporting requirements, there may be a less active trading market for our common stock and our stock price may be more volatile. We may also be unable to raise additional capital as and when we need it.

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***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with our annual report on Form 10-K for the year ending December 31, 2014, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion, which could potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the Securities and Exchange Commission, or the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected.***

In connection with the audit of Egalet US's consolidated financial statements for the year ended December 31, 2012, our management and independent registered public accounting firm identified control deficiencies in our internal control over financial reporting that constitute material weaknesses in our internal control over financial reporting. Our management and independent registered public accounting firm did not perform an evaluation of Egalet US's internal control over financial reporting as of December 31, 2012 in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed such an evaluation, additional control

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deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses.

Our management and independent registered public accounting firm identified material weaknesses in our control over financial reporting attributable to the combination of our lack of sufficient financial reporting and accounting personnel with appropriate training in generally accepted accounting principles in the United States, or U.S. GAAP, and SEC rules and regulations with respect to financial reporting and a lack of segregation of duties. As such, our controls over financial reporting were not designed or operating effectively, and as a result there were adjustments required, including with respect to revenue recognition, in connection with closing our books and records and preparing our consolidated financial statements for the year ended December 31, 2012. These control deficiencies resulted in more than a remote likelihood that a material misstatement of our annual and interim financial statements would not be prevented or detected.

In an effort to remediate our material weakness, we have recently hired a Chief Financial Officer. We intend to hire additional finance and accounting personnel with appropriate training, build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures. There can be no assurance that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weaknesses described above. There is also no assurance that we have identified all of our material weaknesses or that we will not in the future have additional material weaknesses. If we fail to remediate the material weaknesses or to meet the demands that will be placed upon us as a public company, we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. There is no assurance that we will be able to remediate the material weaknesses in a timely manner, or at all, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If our efforts to remediate the material weaknesses identified are not successful, or if other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our annual and quarterly reports under the Exchange Act, restatements of our consolidated financial statements, a decline in our stock price or suspension or delisting of our common stock from the NASDAQ Global Market.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

Upon consummation of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

We will incur increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act of 2010, as well as rules of the Securities and Exchange Commission and NASDAQ, for example, will result in significant initial

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cost to us as well as ongoing increases in our legal, audit and financial compliance costs, particularly after we are no longer an "emerging growth company." The Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and require us to incur substantial costs to maintain the same or similar coverage.

We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404 of the Sarbanes-Oxley Act of 2002 once we lose our status as an "emerging growth company." We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA**

This prospectus includes forward-looking statements. We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this prospectus and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our intellectual property position, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial functions, expectations regarding clinical trial data, our results of operations, cash needs, spending of the proceeds from this offering, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this prospectus. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this prospectus, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;

the success and timing of our preclinical studies and clinical trials;

the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain;

our plans and ability to develop and commercialize our product candidates;

our ability to achieve the milestones set forth in our collaboration agreement with Shionogi;

our failure to recruit or retain key scientific or management personnel or to retain our executive officers;

the accuracy of our estimates of the size and characteristics of the potential markets for our product candidates and our ability to serve those markets;

regulatory developments in the United States and foreign countries;

the rate and degree of market acceptance of any of our product candidates;

our use of the proceeds from this offering and the concurrent private placement;

our ability to obtain additional financing;

obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;

our ability to operate our business without infringing the intellectual property rights of others;

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the successful development of our commercialization capabilities, including sales and marketing capabilities;

recently enacted and future legislation regarding the healthcare system;

the success of competing products that are or become available; and

the performance of third parties, including contract research organizations and manufacturers.

Any forward-looking statements that we make in this prospectus speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the "Risk Factors" section of this prospectus and elsewhere to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Any information in this prospectus provided by IMS Health Incorporated, or IMS, is an estimate derived from the use of information under license from the following IMS Health information service: IMS National Sales Perspectives and NPA Audits, in each case, for the period 2007-2012. IMS expressly reserves all rights, including rights of copying, distribution and republication.

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**USE OF PROCEEDS**

We expect that our net proceeds from the sale of the shares of common stock in this offering will be approximately \$44.5 million, and after deducting underwriting discounts and commissions and estimated offering costs payable by us. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds from this offering will be approximately \$51.5 million. We will also receive net proceeds of approximately \$14.0 million from the sale of 1,250,000 shares of common stock in the concurrent private placement to Shionogi at the initial public offering price of \$12.00 per share after deducting commissions payable by us. The closing of this offering is not contingent upon the closing of the concurrent private placement with Shionogi.

We intend to use the aggregate net proceeds of this offering and the concurrent private placement for the following purposes:

approximately \$8.0 million to fund pivotal bioequivalence trials and abuse deterrence studies for Egalet-001;

approximately \$19.0 million to fund Phase 3 efficacy and safety trials, as well as alcohol interaction studies and abuse deterrence studies for Egalet-002;

approximately \$9.0 million to establish commercial manufacturing capability for Egalet-001 and Egalet-002;

approximately \$10.0 million to fund our other research and development operations; and

the remainder for working capital and general corporate purposes.

Pending the application of the net proceeds as described above, we intend to invest the net proceeds of the offering and the concurrent private placement in short-term, investment-grade, interest-bearing securities.

Our management will have broad discretion to allocate the net proceeds to us from this offering and the concurrent private placement and investors will be relying on the judgment of our management regarding the application of the proceeds from this offering and the concurrent private placement. We reserve the right to change the use of these proceeds as a result of certain contingencies such as competitive developments, the results of our commercialization efforts, acquisition and investment opportunities and other factors.

We believe that the net proceeds from this offering and the concurrent private placement and our existing cash, together with interest thereon, will be sufficient to fund our operations for a period of eighteen months after the consummation of this offering.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.



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**CAPITALIZATION**

The following table sets forth cash and capitalization as of September 30, 2013:

on an actual historical basis for Egalet US;

on a pro forma basis to give effect to:

the Share Exchange, which was effected in November 2013;

the conversion of all outstanding shares of Egalet US preferred stock into 5,329,451 shares of our common stock, which will occur immediately prior to the consummation of this offering;

the issuance of an aggregate of 2,530,675 shares of our common stock upon the conversion of all outstanding principal and accrued interest on the convertible bridge notes, based on interest accrued through September 30, 2013; and

the effect of the beneficial conversion feature charge that will be recorded upon the conversion of our convertible debt; and

on a pro forma as adjusted basis for Egalet US to give effect to the sale of 4,200,000 shares of our common stock in this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, the issuance of 55,070 additional shares of common stock upon the conversion of all outstanding principal and accrued interest on the convertible bridge notes, representing additional interest accrued on these notes from September 30, 2013 through the expected closing date of this offering and our issuance and sale of 1,250,000 shares of common stock in the concurrent private placement to Shionogi at the initial public offering price of \$12.00 per share, after deducting commissions payable by us.

You should read the information in this table together with Egalet US's consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

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|  | As of September 30, 2013 |                        |                          |
|--|--------------------------|------------------------|--------------------------|
|  | Egalet US<br>Actual      | Egalet US<br>Pro Forma | Pro Forma<br>as Adjusted |
| Cash   | \$ 10,463,000            | \$ 10,463,000          | \$ 68,879,000            |
| Related party convertible debt, net of discount  | \$ 13,594,000            | \$                     | \$                       |
| Preferred stock, \$0.01 par value per share:   |                          |                        |                          |
| Series A-1 convertible preferred stock; 1,406,894 shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted  | 1,443,000                |                        |                          |
| Series A-2 convertible preferred stock; 593,106 shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted  | 770,000                  |                        |                          |
| Series B convertible preferred stock, 2,327,301 shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted  | 12,628,000               |                        |                          |
| Series B-1 convertible preferred stock, 113,916 shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted  | 116,000                  |                        |                          |
| Total preferred stock  | 14,957,000               |                        |                          |
| Stockholders' (deficit) equity:  |                          |                        |                          |
| Common stock, \$0.01 par value; 12,000,000 shares authorized, 1,292,307 issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted   | 13,000                   |                        |                          |
| Preferred stock, \$0.001 par value per share; no shares authorized, issued and outstanding, actual; 5,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted   |                          |                        |                          |
| Common stock, \$0.001 par value per share; no shares authorized, issued and outstanding, actual; 75,000,000 shares authorized, 9,152,433 shares issued and outstanding, pro forma; 14,657,503 shares issued and outstanding, pro forma as adjusted |                          | 9,000                  | 15,000                   |
| Additional paid-in capital   | 7,431,000                | 51,170,000             | 110,241,000              |
| Accumulated other comprehensive income   | 324,000                  | 324,000                | 324,000                  |
| Accumulated deficit  | (24,191,000)             | (39,375,000)           | (40,036,000)             |
| Total stockholders' (deficit) equity   | (16,423,000)             | 12,128,000             | 70,544,000               |
| Total capitalization   | \$ 12,128,000            | \$ 12,128,000          | \$ 70,544,000            |

The number of shares of common stock outstanding in the table above as of September 30, 2013 excludes:

up to 600,000 shares of our common stock issuable upon exercise of warrants that may become exercisable immediately prior to the consummation of this offering;

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an aggregate of 862,800 shares of restricted stock we expect to grant to our Chief Executive Officer, Chief Financial Officer, Chief Business Officer and Vice President of Research and Development upon the consummation of this offering;

the effect of the beneficial conversion feature charge that will be recorded upon the conversion of our convertible debt; and

817,200 additional shares of our common stock to be reserved for future issuance under our equity incentive plans following this offering.

Table of Contents**DILUTION**

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock upon consummation of this offering. Dilution results from the fact that the initial public offering price is substantially in excess of the book value per share attributable to the existing stockholders for the presently outstanding stock after giving effect to Share Exchange.

The historical net tangible book value (deficit) of Egalet US's common stock as of September 30, 2013 was approximately \$(16.6) million, or approximately \$(12.87) per share of common stock. Historical net tangible book value (deficit) per share is determined by dividing the number of Egalet US's outstanding common stock into its total tangible assets (total assets less intangible assets) less total liabilities and preferred shares.

On a pro forma basis after giving effect to the sale by us of 1,250,000 shares of common stock in the concurrent private placement to Shionogi after deducting commissions payable by us, the conversion of the outstanding shares of preferred stock after the Share Exchange, the conversion of outstanding principal and accrued interest on the convertible bridge notes through the expected closing date of this offering, and the effect of the beneficial conversion feature charge that will be recorded upon the conversion of our convertible debt, our net tangible book value at September 30, 2013 would have been approximately \$25.9 million, or approximately \$2.47 per share of common stock.

Investors purchasing in this offering will incur immediate and substantial dilution. After giving effect to the sale of common stock offered in this offering at the initial public offering price of \$12.00 per share, and after deducting underwriting discounts and commissions and estimated offering costs payable by us, our pro forma as adjusted net tangible book value as of September 30, 2013 would have been approximately \$70.3 million, or approximately \$4.80 per share. This represents an immediate increase in pro forma net tangible book value of \$2.33 per share to existing stockholders, and an immediate dilution in the pro forma net tangible book value of \$7.20 per share to investors purchasing shares of our common stock in this offering. The following table illustrates this per share dilution:

|  |            |
|--|------------|
| Initial public offering price per share  | \$ 12.00   |
| Historical net tangible book value (deficit) per common share as of September 30, 2013   | \$ (12.87) |
| Increase in net tangible book value per share attributable to the concurrent private placement with Shionogi, the conversion of all outstanding shares of Egalet US preferred stock into 5,329,451 shares of Egalet US common stock, the issuance of shares of common stock upon conversion of bridge notes and the effect of the beneficial conversion feature charge that will be recorded upon the conversion of the convertible bridge notes | 15.34      |
| Pro forma net tangible book value per share before this offering   | 2.47       |
| Increase in pro forma net tangible book value per share attributable to investors purchasing in this offering  | 2.33       |
| Pro forma as adjusted net tangible book value per share after this offering  | 4.80       |
| Dilution per share to investors purchasing in this offering  | \$ 7.20    |

The discussion and table above assume no exercise of the underwriters' over-allotment option. If the underwriters fully exercise their option to purchase 630,000 additional shares of common stock in the offering, our pro forma as adjusted net tangible book value after this offering, calculated in the manner set forth above, would be approximately \$77.4 million, our pro forma as adjusted net tangible book value per share after this offering would be \$5.06 per share, the increase in our pro forma as adjusted net tangible

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book value per share attributable to investors participating in this offering would be \$2.59 per share and the pro forma as adjusted dilution per share to new investors in this offering would be \$6.94 per share.

The following table summarizes, on the pro forma as adjusted basis described above as of September 30, 2013, the differences between the number of shares of common stock purchased from us, the total consideration paid, and the weighted average price per share paid by existing stockholders (including the shares of common stock purchased by Shionogi in the concurrent private placement) and by investors purchasing shares of our common stock in this offering at an the initial public offering price, before deducting underwriting discounts and commissions and estimated offering costs payable by us.

|  | Shares Purchased  |             | Total Consideration |             | Weighted Average Price Per Share |
|--|-------------------|-------------|---------------------|-------------|----------------------------------|
|  | Number            | Percent     | Amount              | Percent     |                                  |
| Existing stockholders before this offering | 10,457,503        | 71%         | \$ 46,200,000       | 48%         | \$ 4.42                          |
| Investors purchasing in this offering      | 4,200,000         | 29          | 50,400,000          | 52          | 12.00                            |
| <b>Total</b>                               | <b>14,657,503</b> | <b>100%</b> | <b>96,600,000</b>   | <b>100%</b> |                                  |

If the underwriters exercise their option to purchase additional shares in full, the common stock held by existing stockholders will be reduced to 68% of the total number of shares of common stock outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be increased to 4,830,000 shares, or 32% of the total number of shares of common stock outstanding after this offering.

The table above excludes:

up to 600,000 shares of common stock issuable upon exercise of warrants that may become exercisable immediately prior to the consummation of this offering; and

an aggregate of 862,800 shares of restricted stock we expect to grant to our Chief Executive Officer, Chief Financial Officer, Chief Business Officer and Vice President of Research and Development upon the consummation of this offering;

the effect of the beneficial conversion feature charge that will be recorded upon the conversion of our convertible debt; and

817,200 additional shares of our common stock to be reserved for future issuance under our equity incentive plans following this offering.

To the extent that warrants are exercised after the offering, stock options are issued under our equity compensation plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we issue additional shares of common stock or other equity securities in the future, there will be further dilution to investors purchasing in this offering.

Our existing stockholders have agreed to purchase an aggregate of 833,333 shares of our common stock in this offering at the initial public offering price. The foregoing discussion and tables do not reflect any potential purchases by the stockholders.

Table of Contents**SELECTED CONSOLIDATED FINANCIAL DATA**

Prior to the share exchange, Egalet US had nominal assets and no operations. The selected consolidated historical statement of operations data of Egalet US and its consolidated subsidiaries for the years ended December 31, 2011 and 2012 and balance sheet data as of December 31, 2012 have been derived from the audited consolidated financial statements of Egalet US appearing elsewhere in this prospectus and have been prepared in accordance with U.S. GAAP. The balance sheet data as of September 30, 2013 and the statement of operations data for the nine months ended September 30, 2012 and 2013 is derived from Egalet US's unaudited condensed consolidated financial statements appearing elsewhere in this prospectus and have been prepared in accordance with U.S. GAAP. Our historical results are not necessarily indicative of the results that may be expected in the future, and our interim period results are not necessarily indicative of the results of operations that may be expected for our full year performance or for any other interim period. The selected consolidated historical financial data of Egalet US should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and unaudited condensed consolidated financial statements of Egalet US and related notes included elsewhere in this prospectus.

|   | <b>Year Ended<br/>December 31,</b> |                | <b>Nine Months Ended<br/>September 30,</b> |                 |
|---|------------------------------------|----------------|--|-----------------|
|   | <b>2011</b>                        | <b>2012</b>    | <b>2012</b>                                | <b>2013</b>     |
| <b>Consolidated Statement of Operations Data:</b>               |                                    |                |  |                 |
| Revenues  | \$ 626,000                         | \$ 1,201,000   | \$ 1,201,000                               | \$              |
| Operating expenses:   |                                    |                |  |                 |
| Research and development  | 4,466,000                          | 4,256,000      | 2,637,000                                  | 3,220,000       |
| General and administrative                                      | 2,068,000                          | 2,241,000      | 1,931,000                                  | 3,223,000       |
| Total operating expenses  | 6,534,000                          | 6,497,000      | 4,568,000                                  | 6,443,000       |
| Loss from operations  | (5,908,000)                        | (5,296,000)    | (3,367,000)                                | (6,443,000)     |
| Interest expense  | 513,000                            | 75,000         | 75,000                                     | 4,443,000       |
| Loss on foreign currency exchange                               | 36,000                             | 27,000         | 12,000                                     | 113,000         |
|   | 549,000                            | 102,000        | 87,000                                     | 4,556,000       |
| Net loss  | \$ (6,457,000)                     | \$ (5,398,000) | \$ (3,454,000)                             | \$ (10,999,000) |
| Per share information:  |                                    |                |  |                 |
| Net loss per share of common stock, basic and diluted           | \$ (5.00)                          | \$ (4.18)      | \$ (2.67)                                  | \$ (8.51)       |
| Basic and diluted weighted average shares outstanding           | 1,292,307                          | 1,292,307      | 1,292,307                                  | 1,292,307       |
| Pro forma information:  |                                    |                |  |                 |
| Pro forma net loss per share of common stock, basic and diluted |                                    | \$ (0.88)      |  | \$ (1.50)       |
| Pro forma basic and diluted weighted average shares outstanding |                                    | 6,133,632      |  | 7,319,134       |

|   | <b>As of<br/>December 31, 2012</b> | <b>As of<br/>September 30, 2013</b> |
|---|------------------------------------|-------------------------------------|
| <b>Consolidated Balance Sheet Data:</b> |                                    |                                     |
| Cash                                    | \$ 3,404,000                       | \$ 10,463,000                       |
| Total assets                            | 5,593,000                          | 14,362,000                          |
| Total liabilities                       | 1,934,000                          | 15,828,000                          |
| Accumulated deficit                     | (13,192,000)                       | (24,191,000)                        |
| Total stockholders' deficit             | (11,298,000)                       | (16,423,000)                        |

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations together with the historical consolidated financial statements of Egalet US and the related notes thereto appearing in this prospectus. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**Overview**

Egalet US is a Delaware corporation formed in August 2013 and prior to this offering had no operations. On November 26, 2013, Egalet US acquired all of the outstanding shares of Egalet UK. As a result, Egalet UK became a wholly owned subsidiary of Egalet US, and the former shareholders of Egalet UK now hold shares of Egalet US. The historical discussion below relates to Egalet UK prior to the Share Exchange, except that any share and per share information has been restated on a pro forma basis to give effect to such exchange.

We are a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent oral products for the treatment of pain and in other indications. Using our proprietary technology platform, we have developed a pipeline of clinical-stage, opioid-based product candidates in tablet form that are specifically designed to deter abuse by physical and chemical manipulation while also providing the ability to tailor the release of the API.

Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation in development for the treatment of moderate to severe pain. There are currently no commercially available abuse-deterrent formulations of morphine, and we believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. We have completed our Phase 1 clinical trials of Egalet-001 and we expect to initiate pivotal trials to establish bioequivalence of Egalet-001 to MS-Contin, a currently approved oral morphine formulation, in the first quarter of 2014 and to submit an NDA, to the FDA in the fourth quarter of 2014.

Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release, oral oxycodone formulation in development for the treatment of moderate to severe pain. We believe that Egalet-002, if approved, will have advantages over other currently commercially available, long-acting, abuse-deterrent oxycodone products due to its differentiated abuse-deterrent properties and a PK profile that exhibits low peak-to-trough concentration variability in drug exposure. We have conducted Phase 1 trials of Egalet-002 and have completed initial abuse deterrence studies in compliance with the FDA draft guidance. We expect to initiate the first of two Phase 3 safety and efficacy trials for Egalet-002 in the fourth quarter of 2014 and to submit an NDA to the FDA in the first half of 2016.

In November 2013, we entered into a collaboration and license agreement with Shionogi Limited, or Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. Shionogi will be responsible for all expenses associated with the development of these product candidates and is responsible for the completion of all clinical trials necessary to support NDA filings for the product candidates. Under the terms of the agreement, Shionogi made an upfront payment to us of \$10.0 million. We are eligible to receive additional payments upon the achievement of specified regulatory and sales-based milestones. These milestone payments may exceed \$300 million in the aggregate if multiple product candidates are approved. If any products are approved for marketing, we are also eligible to receive royalties at percentage rates ranging from the mid-single digits to the low-teens on net sales of licensed products.

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We plan to seek U.S. regulatory approval of Egalet-001 and Egalet-002 pursuant to Section 505(b)(2), which permits companies to rely upon the FDA's previous findings of safety and effectiveness for an approved product, such as morphine and oxycodone. If either of our clinical-stage product candidates achieve regulatory approval, we intend to establish our own specialty sales force to market such product in the United States by targeting physicians specializing in pain management. To supplement our internal U.S. sales force, we intend to contract with third parties to access sales representatives who target primary care and internal medicine physicians in the United States.

Egalet UK commenced operations in July 2010. Since commencing operations we have dedicated a significant portion of our resources to our development efforts for our clinical-stage product candidates. We have funded our operations primarily through the sale of preferred stock for net proceeds of \$10.2 million, as well as \$21.0 million in proceeds from the issuance of convertible debt, of which \$6.0 million was later converted into shares of our preferred stock. We have also received an aggregate of \$2.0 million in revenues from several research and development agreements, and in December 2013, we received an upfront payment of \$10.0 million from Shionogi under a collaboration agreement. We had \$3.4 million and \$10.5 million in cash as of December 31, 2012 and September 30, 2013, respectively. We have no products currently available for sale.

Our net losses were \$6.5 million and \$5.4 million for the years ended December 31, 2011 and 2012, respectively, and \$3.5 million and \$11.0 million for the nine months ended September 30, 2012 and 2013, respectively. We recognized revenues of \$626,000 and \$1.2 million for the years ended December 31, 2011 and 2012, respectively, and \$1.2 million for the nine months ended September 30, 2012. We did not recognize any revenues for the nine months ended September 30, 2013. As of September 30, 2013, we had an accumulated deficit of \$24.2 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, as well as scale-up manufacturing capabilities, protect and expand our intellectual property portfolio and hire additional personnel. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses in establishing a sales, marketing and distribution infrastructure to sell our products in the United States.

We will seek to license the development and commercial rights to our products outside the United States to a third-party organization that has an established track record of success in commercializing pain products outside the United States. We expect that this organization would be responsible for any further development and commercialization of the products in those regions.

Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company, hiring additional personnel and expanding our facilities. We expect that these costs will include significant legal, accounting, investor relations and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules adopted by the SEC and the NASDAQ Stock Market, requires public companies to implement specified corporate governance practices that are currently inapplicable to us as a private company. These additional rules and regulations applicable to public companies will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We currently estimate that we will incur incremental annual costs, including costs for additional personnel, of approximately \$2.0 million to \$3.0 million associated with operating as a public company, although it is possible that our actual incremental costs will be higher than we currently estimate. The increased costs will increase our net loss. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

We will seek to fund our operations primarily through public or private equity or debt financings or other sources. Other additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed could have a material adverse effect on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.



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**Internal Control Over Financial Reporting**

In preparing our consolidated financial statements as of and for the year ended December 31, 2012, we and our independent registered public accounting firm identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified was that we did not have sufficient financial reporting and accounting staff with appropriate training in U.S. GAAP and SEC rules and regulations with respect to financial reporting and a lack of segregation of duties. As such, our controls over financial reporting were not designed or operating effectively, and as a result there were adjustments, including with respect to revenue recognition, required in connection with closing our books and records and preparing our 2011 and 2012 consolidated financial statements.

In response to these material weaknesses, we intend to hire additional finance and accounting personnel with appropriate training, build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures. However, we cannot assure you that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weaknesses described above. We also cannot assure you that we have identified all of our existing material weaknesses, or that we will not in the future have additional material weaknesses.

We have not yet remediated the material weaknesses described above, and the remediation measures that we have implemented and intend to implement may be insufficient to address our existing material weakness or to identify or prevent additional material weaknesses. See "Risk Factors Risks Relating to this Offering and Ownership of Our Common Stock If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected."

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. In light of the control deficiencies and the resulting material weaknesses that were identified as a result of the limited procedures performed, we believe that it is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

**Financial Operations Overview**

***Revenue***

To date, we have derived revenue principally from activities pursuant to our collaboration arrangements and research and development agreements. We have not generated any revenue from commercial product sales and do not expect to generate any such sales in the near future. If any of our product candidates currently under development are approved for commercial sale in the United States and Europe, we may generate revenue from product sales, or alternatively, we may choose to select a collaborator to commercialize our product candidates in these markets.

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### Research and Development Expenses

Research and development expenses consist primarily of costs associated with the development and clinical testing of Egalet-001, Egalet-002 and our preclinical product candidates. Our research and development expenses consist of:

employee-related expenses, including salaries, benefits, and travel expense;

expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials and preclinical studies;

the cost of acquiring, developing and manufacturing clinical trial materials;

facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and

costs associated with preclinical activities and regulatory operations.

We expense research and development costs to operations as incurred. We account for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We plan to increase our research and development expenses for the foreseeable future.

We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we record expenses by functional department. Accordingly, we do not allocate expenses to individual projects or product candidates, although we do allocate some portion of our research and development expenses to our two clinical-stage product candidates, as shown in the table below.

The following table summarizes our research and development expenses for the years ended December 31, 2011 and 2012, for the nine months ended September 30, 2012 and 2013 and for the period from July 31, 2010 (inception) through September 30, 2013:

|  | Year Ended December 31, |              | Nine Months Ended September 30, |              | From July 31, 2010 (inception) through September 30, 2013 |
|--|-------------------------|--------------|---------------------------------|--------------|---|
|  | 2011                    | 2012         | 2012                            | 2013         | 2013  |
| Egalet-001                                 | \$ 148,000              | \$ 265,000   | \$ 53,000                       | \$ 867,000   | \$ 1,283,000  |
| Egalet-002                                 | 1,409,000               | 1,250,000    | 679,000                         | 323,000      | 2,982,000   |
| Other clinical and preclinical development | 1,493,000               | 1,158,000    | 961,000                         | 937,000      | 4,046,000   |
| Personnel related                          | 1,416,000               | 1,583,000    | 944,000                         | 1,093,000    | 4,226,000   |
|  | \$ 4,466,000            | \$ 4,256,000 | \$ 2,637,000                    | \$ 3,220,000 | \$ 12,537,000   |

We incurred research and development expenses of \$4.5 million and \$4.3 million during the years ended December 31, 2011 and 2012, respectively, and \$2.6 million and \$3.2 million during the nine months ended September 30, 2012 and 2013, respectively. Since our inception on July 31, 2010, we have incurred \$12.5 million in research and development expenses. We anticipate that a significant portion of our operating expenses will continue to be related to research and development as we continue to advance our preclinical programs and our clinical-stage product candidates.

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product

candidates that obtain

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regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of Egalet-001, Egalet-002, or any other product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if regulatory authorities were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of our clinical pipeline or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

The successful development of our product candidates is highly uncertain due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

the scope, rate of progress and expense of our research and development activities;

clinical trial results;

the terms and timing of regulatory approvals; and

the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

As a result of these uncertainties, we are unable to determine with certainty the duration and completion costs of our development projects or when and to what extent we will receive revenue from the commercialization and sale of our product candidates.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related costs for personnel in our executive and finance areas. Other general and administrative expenses include facility costs and professional fees for legal, patent, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in the future with the continued research and development and potential commercialization of our product candidates and as we operate as a public company. These increases will likely include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, investor relations, lawyers and accountants, among other expenses. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

***Loss on Foreign Currency Exchange***

The functional currency of our non-U.S. subsidiaries is the local currency. Transaction gains and losses are recorded within our consolidated statements of operations.

***Critical Accounting Policies and Significant Judgments and Estimates***

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, useful lives of assets, allowance for doubtful accounts, debt, equity, income taxes and accrued expenses, as described in greater detail below. We base our estimates on our limited historical

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experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this prospectus. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

***Revenue Recognition***

We generate revenue primarily from collaborative research and development agreements with pharmaceutical companies to perform feasibility studies. Our feasibility studies are typically completed within one year. Under these collaborative agreements, the research and development services have more than one phase. Each of the phases is critical in the continuation of the study and builds on one another. We provide a feasibility report upon completion of a feasibility study and determine whether the final feasibility report represents a significant performance obligation to us. We defer revenue recognition until all substantive performance obligations are completed. Therefore, due to the significant performance obligations we have to perform at the end of the contract period, our contracts are of relatively short duration, and due to the fact that we did not keep adequate records to show costs by each project in accordance with U.S. GAAP we recognize revenues for our collaborative research and development agreements under a completed contract method whereby revenue is recognized upon delivery of the feasibility report. We may receive non-refundable upfront payments for funding of research and development services. Upfront payments are recorded as deferred revenue in the consolidated balance sheet and are recognized as revenue upon the completion of all services and no future performance obligations are present. Direct costs incurred in fulfilling the research and development services are expensed as incurred.

Under our collaborative research and development agreements, we recognized revenue of \$626,000, \$1.2 million and \$1.2 million during the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2012, respectively. We did not recognize any revenue during the nine months ended September 30, 2013.

***Valuation of Long-Lived Assets***

Long-lived assets, including property and equipment assets, are assessed for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Recoverability of long-lived assets that will continue to be used in our operations is measured by comparing the carrying amount of the asset to the forecasted undiscounted future cash flows related to that asset. In the event the carrying value of the asset exceeds the undiscounted future cash flows, and the carrying value is not considered recoverable, an impairment loss is measured as the excess of the asset's carrying value over its fair value, generally based on a discounted future cash flow method.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant under-performance of the asset in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in our use of the assets. We have not recorded any impairment charges for the nine months ended September 30, 2012 and 2013 or the years ended December 31, 2011 and 2012.

***Indefinite-Lived Intangible Asset***

The intangible asset related to our acquired in-process research and development, or IPR&D, asset for our technology platform is considered an indefinite-lived intangible asset and is assessed for impairment

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annually, or more frequently if impairment indicators exist. We use an income approach using a discounted cash flow model to estimate the fair value of our indefinite-lived assets. Our discounted cash flow models are highly reliant on various assumptions, including estimates of future cash flow, probability of commercial feasibility of our product candidates, discount rates and expectations about variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows.

No impairment charges related to our indefinite-lived asset were recorded for the nine months ended September 30, 2012 and 2013 or the years ended December 31, 2011 and 2012.

***Acquisition of In-Process Research and Development***

Since January 1, 2009, acquired businesses are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. In connection with the acquisition of Egalet A/S, amounts allocated to IPR&D related to our technology platform were recorded at the date of the acquisition based on its estimated fair value.

We use the "income method" to determine the fair value of our IPR&D, beginning with our forecast of expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income method include the amount and timing of projected future cash flows, the amount and timing of projected costs to develop the IPR&D into commercially viable products and the discount rate selected to measure the risks inherent in the future cash flows.

***Accrued Research and Development Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, including clinical trial expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to fees paid to vendors in connection with research and development activities for which we have not yet been invoiced. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows in accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not anticipate the future settlement of existing accruals to differ materially from our estimates.

***Income Taxes***

Our income tax expense, deferred tax assets and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in Denmark, the United Kingdom and the United States. Significant judgments and estimates are required in determining the consolidated income tax expense, including a determination of whether and how much of a tax benefit taken by us in our tax filings or positions is more likely to be realized than not.

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We believe that it is more likely than not that the benefit from some of our U.S. federal, U.S. state, U.K. and Denmark net operating loss carryforwards will not be realized. At December 31, 2012, in recognition of this risk, we have provided a valuation allowance of approximately \$2.9 million on the deferred tax assets relating to these net operating loss carryforwards and other deferred tax assets. If our assumptions change and we determine we will be able to realize these net operating losses, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets at December 31, 2012 will be accounted for as a reduction of income tax expense.

Changes in tax laws and rates could also affect recorded deferred tax assets and liabilities in the future. Management is not aware of any such changes that would be expected to have a material effect on our results of operations, cash flows or financial position.

We recognize tax liabilities in accordance with Accounting Standard Codification Topic 740 and we adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which they are determined.

## Basic and Diluted Net Loss Per Share

We compute basic net loss per share by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of preferred shares. We compute diluted net loss per share by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of preferred shares outstanding during the period calculated in accordance with the treasury stock method, but such items are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between our basic and diluted net loss per share for the years ended December 31, 2011 and 2012 and for the nine months ended September 30, 2012 and 2013.

## Results of Operations

### Comparison of Nine Months Ended September 30, 2012 and 2013

|                                   | Nine Months Ended<br>September 30, |                 |                |
|-----------------------------------|------------------------------------|-----------------|----------------|
|                                   | 2012                               | 2013            | Change         |
| Revenues                          | \$ 1,201,000                       | \$              | \$ (1,201,000) |
| Operating expenses:               |                                    |                 |                |
| Research and development          | 2,637,000                          | 3,220,000       | 583,000        |
| General and administrative        | 1,931,000                          | 3,223,000       | 1,292,000      |
| Total operating expenses          | 4,568,000                          | 6,443,000       | 1,875,000      |
| Loss from operations              | (3,367,000)                        | (6,443,000)     | (3,076,000)    |
| Interest expense                  | 75,000                             | 4,443,000       | 4,368,000      |
| Loss on foreign currency exchange | 12,000                             | 113,000         | 101,000        |
|                                   | 87,000                             | 4,556,000       | 4,469,000      |
| Net loss                          | \$ (3,454,000)                     | \$ (10,999,000) | \$ (7,545,000) |

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*Revenues*

Revenues decreased from \$1.2 million for the nine months ended September 30, 2012 to zero for the nine months ended September 30, 2013, as a result of the completion of all research and development services under our collaborative agreements during 2012.

*Research and development expenses*

Research and development expenses increased by \$583,000, or 22.1%, from \$2.6 million for the nine months ended September 30, 2012 to \$3.2 million for the nine months ended September 30, 2013. This increase was driven primarily by increases in our development costs for Egalet-001 and compensation expenses of \$814,000 and \$149,000, respectively, as we began our contract manufacturing efforts to develop a process to supply our product candidates. These increases were offset by decreases in clinical trial expenses for Egalet-002 and other clinical and preclinical development expenses of \$356,000 and \$24,000 as we completed a PK trial with Egalet-002 in 2012 and shifted our resources to the contract manufacturing efforts for Egalet-001 in 2013.

*General and administrative expenses*

General and administrative expenses increased by \$1.3 million, or 66.9%, from \$1.9 million for the nine months ended September 30, 2012 to \$3.3 million for the nine months ended September 30, 2013. The increase was attributable to increases in compensation, travel costs and facility-related expenses of \$613,000, \$109,000 and \$229,000, respectively, and related to the establishment of our U.S. office and hiring of personnel, including our Chief Executive Officer and Chief Financial Officer. We also had increases in professional fees and communication expenses of \$317,000, and \$87,000, respectively, related to our increased efforts in business development, the pursuit of licensing arrangements, and the costs associated with preparing for this offering.

*Interest expense*

Interest expense increased from \$75,000 for the nine months ended September 30, 2012 to \$4.4 million for the nine months ended September 30, 2013. This change was primarily attributable to the \$3.3 million in additional interest expense we are recognizing in 2013 related to the accretion of the beneficial conversion feature that was recorded in connection with our April 2013 convertible debt issuance and the accretion of our premium that was recorded in connection with our August convertible debt issuance. The remaining increase was due to the increase in principal borrowing in 2013 due to the April and August related party convertible debt issuances.

*Loss on Foreign Currency Exchange*

We recognized a loss on foreign currency exchange of \$12,000 during the nine months ended September 30, 2012 compared to \$113,000 during the nine months ended September 30, 2013. The change was primarily attributable the change in the average rates of currency in which we transacted during 2013 when compared to 2012.



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|  | Year Ended December 31, |                |              |
|--|-------------------------|----------------|--------------|
|  | 2011                    | 2012           | Change       |
| Revenues                                 | \$ 626,000              | \$ 1,201,000   | \$ 575,000   |
| Operating expenses:                      |                         |                |              |
| Research and development                 | 4,466,000               | 4,256,000      | (210,000)    |
| General and administrative               | 2,068,000               | 2,241,000      | 173,000      |
| Total operating expenses                 | 6,534,000               | 6,497,000      | 37,000       |
| Loss from operations                     | (5,908,000)             | (5,296,000)    | 612,000      |
| Interest expense                         | 513,000                 | 75,000         | (438,000)    |
| Loss (gain) on foreign currency exchange | 36,000                  | 27,000         | (9,000)      |
|  | 549,000                 | 102,000        | (447,000)    |
| Net loss                                 | \$ (6,457,000)          | \$ (5,398,000) | \$ 1,059,000 |

*Revenues*

Revenues increased by \$575,000, from \$626,000 for the year ended December 31, 2011 to \$1.2 million for the year ended December 31, 2012, primarily as a result of the timing in which we completed feasibility studies under our collaborative research and development agreements with third parties.

*Research and development expenses*

Research and development expenses decreased by \$210,000, or 4.7%, from \$4.5 million for the year ended December 31, 2011 to \$4.3 million for the year ended December 31, 2012. The decrease was driven primarily by decreases in our clinical trial expenses for Egalet-002 and other clinical and preclinical expenses of \$159,000 and \$335,000, respectively, related to the completion of PK trials in 2011 for Egalet-002 and a substantial portion of our equipment being fully depreciated by December of 2011. These decreases were partially offset by increases in clinical trial expenses for Egalet-001 and personnel-related expenses of \$117,000 and \$167,000, respectively, related to our increased efforts to further develop Egalet-001.

*General and administrative expenses*

General and administrative expenses increased by \$173,000, or 8.4%, from \$2.1 million for the year ended December 31, 2011 to \$2.2 million for the year ended December 31, 2012. The increase was primarily attributable to increases in compensation, professional fees and communication expenses of \$237,000, \$282,000 and \$39,000, respectively, related to the hiring of our Chief Executive Officer during 2012 and an increase in our business development efforts. These increases were partially offset by decreases in facility- and supply-related expenses and a write-off of receivables with Egalet A/S of \$208,000 and \$160,000, respectively. We also had a decrease in legal fees related to patent filings of \$17,000.

*Interest expense*

Interest expense decreased by \$438,000, from \$513,000 for the year ended December 31, 2011 to \$75,000 for the year ended December 31, 2012. The decrease was primarily attributable to the amortization of deferred financing fees on our convertible debt during 2011. This convertible debt was converted into Series B and B-1 convertible preferred stock in March 2012, at which time the remaining amortization of deferred financing fees terminated.

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*Loss on Foreign Currency Exchange*

We recognized a loss on foreign currency exchange of \$36,000 for the year ended December 31, 2011 compared to \$27,000 for the year ended December 31, 2012. The change was primarily attributable to the change in the average rates of currency in which we transacted during 2012 when compared to 2011.

**Liquidity and Capital Resources**

Since our inception, we have incurred net losses and generally negative cash flows from our operations. We incurred net losses of \$6.5 million and \$5.4 million for the years ended December 31, 2011 and 2012, respectively, and \$3.5 million and \$11.0 million for the nine months ended September 30, 2012 and 2013, respectively. Our operating activities used \$3.6 million and \$7.6 million of cash flows during the nine months ended September 30, 2012 and 2013, respectively. At September 30, 2013, we had an accumulated deficit of \$24.2 million, a working capital deficit of \$3.1 million and cash of \$10.5 million. From our inception through September 30, 2013, we have received gross proceeds of \$31.2 million from the issuance of preferred stock and convertible debt. We have also financed our operations with the \$2.0 million in payments received through September 30, 2013 from our collaborative research and development agreements. In December 2013, we received an upfront payment of \$10.0 million from Shionogi under a collaboration agreement. We are potentially eligible to earn a significant amount of milestone payments and royalties under our agreement with Shionogi. Our ability to earn these payments and their timing is dependent upon the outcome of Shionogi's activities and is uncertain at this time. Except for Shionogi's obligation to make milestone payments under our agreement with them, upon the completion of this offering, we will not have any committed external source of liquidity.

*Debt Facilities*

In January and April of 2011, we issued convertible debt to several of our equity investors to fund our short-term working capital and operational needs. The convertible debt provided us with cash proceeds of \$6.0 million and bore interest at 8%.

In March 2012, we completed an equity financing and issued Series B and B-1 convertible preferred stock. Pursuant to the financing, the holders of the outstanding convertible promissory notes agreed not to demand repayment of the debt and converted their outstanding principal and unpaid interest into an aggregate of 907,467 shares of Series B convertible preferred stock and 113,916 shares of Series B-1 convertible preferred stock.

In April and August of 2013, we issued additional convertible debt to several of our equity investors. The April and August 2013 issuances provided us with aggregate cash proceeds of \$15.0 million to fund current working capital and operational needs. The loans bear interest at 6% and mature on April 26, 2014 and August 29, 2014, respectively. Upon maturity of the April and August 2013 loans, payment is due upon request from holders of 65% of the outstanding principal amount of the loan and 66% of the outstanding principal amount of the loan, respectively.

Pursuant to the April 2013 convertible debt issuances, the loans will automatically convert into (i) shares of common stock upon the closing of an initial public offering that yields a minimum of \$26.4 million in net proceeds to us, or (ii) Series B and Series B-1 convertible preferred stock upon the earlier of the affirmative vote of 65% of the outstanding loan amount or a change in control of our company. In connection with the issuance of the \$5.0 million convertible debt in April 2013, we recorded a beneficial conversion feature of \$5.0 million, which represents the intrinsic value of the conversion feature.

Pursuant to the August 2013 convertible debt issuances, the lenders are required to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an initial public offering that generates aggregate proceeds in excess of \$26.5 million (based on the exchange rate on August 29, 2013), which we refer to as the IPO Scenario. In the event of a conversion under the

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IPO Scenario, the holder will obtain a number of shares at a conversion price equal to 50% of the offering price that was initially offered to the public.

Pursuant to the August 2013 convertible debt issuances, the holders have the right to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an equity offering that generates aggregate proceeds in excess of \$5.0 million. If the offering includes a bona fide third-party investing at least \$3.0 million, the consent of the holders of at least 66% of the outstanding principal under the August 2013 loan is required, but if only the August 2013 noteholders invest in the offering, the consent of the holders of at least 51% of the outstanding principal under the August 2013 loan is required. We refer to this scenario collectively as the Equity Scenario. In the event of a conversion under the Equity Scenario, the holders will receive equity instruments equivalent to those issued in the Equity Scenario and based on the lenders' pro rata portion of outstanding principal and interest.

If we sell substantially all of our assets or merge with another company while the August 2013 convertible debt remains outstanding, immediately after which our stockholders own less than 50% of the voting shares of the surviving company, which we refer to as the Sale Scenario, then any outstanding principal and interest under the August 2013 convertible debt will be required to be redeemed for an amount equal to two times the outstanding principal amount together with any unpaid and accrued interest. In the Sale Scenario, the holders will also receive, immediately prior to the transaction, the number of shares of common stock obtained by dividing the number of fully diluted shares by 1 minus the quotient of the aggregate amount of principal and interest on the loan divided by 50% of the sale consideration, and then subtracting the number of fully diluted shares.

In connection with issuing the August 2013 convertible debt, the lenders received warrants to purchase shares of common stock that may become exercisable immediately prior to consummation of an initial public offering. Pursuant to the terms of the warrant agreement, the holder retains the right to convert into ordinary shares or shares of common stock, as applicable, at a price of \$0.01 per share (based on the exchange rate on August 29, 2013).

**Cash Flows**

The following table summarizes our cash flows for the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2012 and 2013:

|  | Year Ended<br>December 31, |                | Nine Months Ended<br>September 30, |                |
|--|----------------------------|----------------|------------------------------------|----------------|
|  | 2011                       | 2012           | 2012                               | 2013           |
| Net cash (used in) provided by:                |                            |                |                                    |                |
| Operating activities                           | \$ (4,962,000)             | \$ (5,460,000) | \$ (3,644,000)                     | \$ (7,476,000) |
| Investing activities                           | 65,000                     | (314,000)      | (223,000)                          | (727,000)      |
| Financing activities                           | 5,708,000                  | 8,218,000      | 8,218,000                          | 14,902,000     |
| Effect of foreign currency translation on cash | 163,000                    | (92,000)       | (131,000)                          | 360,000        |
| Net increase in cash                           | \$ 974,000                 | \$ 2,352,000   | \$ 4,220,000                       | \$ 7,059,000   |

*Cash Flows from Operating Activities*

Net cash used in operating activities was \$3.6 million for the nine months ended September 30, 2012 and consisted primarily of a net loss of \$3.5 million and \$492,000 in net cash outflows from changes in operating assets and liabilities. These outflows were partially offset by \$302,000 of noncash depreciation and amortization expense. Cash outflows from operating activities were primarily due to decreases in deferred revenues and accrued expenses of \$522,000 and \$56,000, respectively. Additional cash outflows were due to increases in other accounts receivable of \$40,000. These cash outflows were partially offset by

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cash inflows driven by decreases in accounts receivable and other current assets of \$98,000 and \$8,000, respectively.

Net cash used in operating activities was \$7.5 million for the nine months ended September 30, 2013 and consisted primarily of a net loss of \$11.0 million and a \$1.1 million in net cash outflows from changes in operating assets and liabilities. These outflows were partially offset by \$313,000 of noncash depreciation and amortization expense, and \$4.3 million in accretion of the beneficial conversion feature and premium. Cash outflows from changes in operating assets and liabilities were primarily due to an increase in prepaid expenses, other receivables and other current assets of \$1.1 million, \$59,000, and \$75,000, respectively. The increase in prepaid expenses and other current assets was due to the deferral of costs in connection with our IPO. The outflows were partially offset by inflows primarily due to an increase in accounts payable and accrued expenses of \$97,000 and \$41,000, respectively, as well as an increase in other current liabilities of \$90,000.

Net cash used in operating activities was \$5.0 million for the year ended December 31, 2011 and consisted primarily of a net loss of \$6.5 million offset by \$592,000 of noncash depreciation and amortization expense, \$186,000 due to the write-off of related party receivables, \$157,000 due to amortization of the beneficial conversion feature and deferred financing fees and a \$542,000 net cash inflow from changes in operating assets and liabilities. The cash inflows from changes in operating assets and liabilities included a decrease in other receivables of \$105,000. Additional cash inflows were attributable to increases in accounts payable, accrued expenses, deferred revenues and other current liabilities of \$50,000, \$153,000, \$338,000 and \$14,000, respectively. These inflows were offset by cash outflows related to increases in accounts receivable and prepaid expenses of \$90,000 and \$18,000, respectively.

Net cash used in operating activities was \$5.5 million for the year ended December 31, 2012 and consisted primarily of a net loss of \$5.4 million including \$404,000 of noncash depreciation and amortization expense and a \$466,000 net cash outflow from changes in operating assets and liabilities. The changes in operating assets and liabilities included cash inflows from increases of \$72,000 in accounts payable and \$169,000 in accrued expenses, more than offset by cash outflows from a decrease of \$508,000 in deferred revenues.

*Cash Flows from Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2012 and 2013 and for the year ended December 31, 2012 was \$223,000, \$727,000 and \$314,000, respectively. Net cash provided by investing activities was \$65,000 for the year ended December 31, 2011. In all of these periods, our cash flows from investing activities consisted of purchases and sales of property and equipment.

*Cash Flows from Financing Activities*

Net cash provided by financing activities was \$8.2 million for the nine months ended September 30, 2012 and consisted of proceeds from the issuance of convertible Series B preferred shares in March 2012. Net cash provided by financing activities was \$14.9 million for the nine months ended September 30, 2013 and consisted of proceeds from the convertible debt issuances in April and August of 2013 as well as the allocation of proceeds from the warrants issued in August 2013.

Net cash provided by financing activities was \$5.7 million for the year ended December 31, 2011 and \$8.3 million for the year ended December 31, 2012. Net cash provided by financing activities for the year ended December 31, 2011 consisted primarily of \$6.0 million in proceeds from the issuance of convertible debt that was partially offset by \$12,000 in deferred financing fee payments and \$248,000 in repayments of capital lease obligations. Net cash provided by financing activities for the year ended December 31, 2012 consisted of proceeds from the issuance of Series B convertible preferred shares in March 2012.

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**Operating and Capital Expenditure Requirements**

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs. We expect our cash expenditures to increase in the near term as we fund our clinical development of Egalet-001 and Egalet-002.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements. Upon consummation of this offering, we will not have any committed external source of liquidity. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We believe that our existing capital resources, together with the net proceeds from this offering and the concurrent private placement with Shionogi, will be sufficient to fund our operations for at least the next eighteen months. However, our future operating and capital requirements will depend on many factors, including:

whether Shionogi continues to pursue our collaboration arrangement for the development, manufacturing and commercialization of abuse-deterrent hydrocodone product candidates using our technology;

the results of our clinical trials;

the costs, timing and outcome of regulatory review;

the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs;

our ability to establish collaborations on favorable terms, if at all;

the scope, progress, results and costs of product development of our product candidates; and

the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending intellectual property-related claims.

Please see "Risk Factors" for additional risks associated with our substantial capital requirements.

Table of Contents**Contractual Obligations and Commitments**

The following table represents our contractual obligations and commitments as of September 30, 2013:

|                                |               | Payments Due By Period |             |             |                   |
|--------------------------------|---------------|------------------------|-------------|-------------|-------------------|
|                                | Total         | Less than 1 year       | 1 - 3 years | 3 - 5 years | More than 5 years |
| Related party convertible debt | \$ 15,000,000 | \$ 15,000,000          |             | \$          | \$                |
| Operating lease obligations(1) | 224,000       | 61,000                 | 163,000     |             |                   |
| Other(2)(3)                    |               |                        |             |             |                   |
| Total                          | \$ 15,224,000 | \$ 15,061,000          | \$ 163,000  | \$          | \$                |

(1) Operating lease obligations reflect our obligation to make payments in connection with the lease for our office space.

(2) In December 2012, we contracted with Halo Pharmaceutical, Inc., or Halo, in order to develop a manufacturing process to supply a drug product employing our proprietary release and formulation technology. The services to be provided by Halo under our agreement with them will include development batch manufacturing and analytical testing, design and scale-up of manufacturing, clinical trial batch manufacturing and drug product stability testing. The term of the agreement continues until Halo's completion of the requested services. As of September 30, 2013, we had paid a \$625,000 initiation fee and had committed to pay approximately \$3.0 million in contract manufacturing development costs. We expect these amounts will be paid through June 2014.

(3) We have employment agreements with our executive officers that require the funding of a specific level of payments, if specified events, such as a change in control or termination without cause, occur. However, because of the contingent nature of those payments, they are not presented in the table.

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development and manufacturing activities. We can elect to discontinue the work under these agreements at any time. We could also enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments or long-term commitments of cash.

**Purchase Commitments**

Other than described above with respect to Halo, we have no material non-cancelable purchase commitments with service providers as we have generally contracted on a cancelable purchase order basis.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission rules.

**JOBS Act**

As an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing not to delay our adoption of such new or revised accounting standards. As a result of this election, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.



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**Quantitative and Qualitative Disclosure About Market Risk**

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate and foreign currency fluctuations.

*Interest Rate Risk*

We had cash of \$3.4 million and \$10.5 million at December 31, 2012 and September 30, 2013, respectively, consisting primarily of funds in cash and money market accounts. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

*Foreign Currency Exchange Risk*

With international operations, we face exposure to adverse movements in foreign currency exchange rates. These exposures may change over time as business practices evolve. If our exposure increases, adverse movement in foreign currency exchange rates would have a material adverse impact on our financial results. As the majority of our sales contracts are denominated in Euros and Danish Krone, our primary exposures have historically been related to non-Danish Krone denominated sales in Europe. As a result, our results of operations would generally be adversely affected by a material decline in the value of foreign currencies relative to the Euro. We would not expect a 10% decline in the value of the Euro to have a material effect on our financial position or results of operations.



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**BUSINESS**

**Overview**

We are a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent oral products for the treatment of pain and in other indications. Using our proprietary technology platform, we have developed a pipeline of clinical-stage, opioid-based product candidates in tablet form that are specifically designed to deter abuse by physical and chemical manipulation while also providing the ability to tailor the release of the API. Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation in development for the treatment of moderate to severe pain. We plan to initiate pivotal bioequivalence clinical trials for Egalet-001 in the first quarter of 2014 and to submit an NDA to the FDA in the fourth quarter of 2014. Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release, oral oxycodone formulation in development for the treatment of moderate to severe pain. We plan to initiate the first of two Phase 3 safety and efficacy trials for Egalet-002 in the fourth quarter of 2014 and to submit an NDA to the FDA in the first half of 2016. In addition to our two clinical-stage product candidates, we are also developing a portfolio of preclinical, abuse-deterrent product candidates for the treatment of pain and in other indications. In November 2013, we entered into a collaboration and license agreement with Shionogi Limited, or Shionogi, to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology.

IMS estimates that total U.S. sales of analgesic narcotics, or opioids, for therapeutic purposes were \$8.3 billion for the 12 months ended September 30, 2012. Of this total opioid market, long-acting opioids accounted for approximately \$4.1 billion in total sales on 14.8 million prescriptions. Egalet-001, our abuse-deterrent oral morphine product candidate, and Egalet-002, our abuse-deterrent oral oxycodone product candidate, will target this long-acting opioid market. Long-acting morphine-based products and oxycodone-based products are the two most commonly prescribed long-acting, oral opioids, with over 13.3 million prescriptions in the aggregate resulting in sales of \$3.4 billion in the United States for the 12 months ended September 30, 2012.

Drug-related deaths, 40% of which involved the use of opioids in 2008 according to the National Center for Health Statistics, became the leading cause of accidental death in the United States in 2009, surpassing deaths caused by automobile accidents, according to a 2011 report by the U.S. Centers for Disease Control and Prevention, or the CDC. A 2011 research report prepared by SAMHSA estimated that nearly 35 million Americans have used prescription pain relievers, including opioid-containing drugs, for non-prescription purposes at least once in their lifetime, and that between 1999 and 2009 there was a 430% increase in substance abuse treatment facility admissions resulting from the use of prescription pain relievers. According to a 2011 report by the American College of Preventive Medicine, approximately 5.3 million Americans use prescription pain relievers, including opioids, each month for purposes other than those for which they were prescribed. The American Journal of Managed Care estimated in a 2013 report that the total costs of prescription drug abuse for public and private healthcare payors, largely the result of emergency room visits, rehabilitation and associated health problems, are up to \$72.5 billion annually.

Prescription medications, particularly opioids, are prone to being abused through physical and chemical manipulation for the purpose of increasing drug concentration in the bloodstream in order to accelerate and intensify their effects. Common methods of manipulating medications in pill or tablet form include crushing in order to swallow, snort or smoke, and dissolving in order to inject. Our product candidates are specifically designed to deter these common methods of abuse, as well as to prevent alcohol dose dumping, which is the acceleration of the release of the API by consuming alcohol at the same time.

In reaction to the increasing costs and other consequences of widespread prescription opioid abuse, the U.S. government and a number of state legislatures have introduced, and in some cases have enacted, legislation and regulations intended to encourage the development and adoption of abuse-deterrent forms

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of pain medications. In January 2013, the FDA issued draft guidance that for the first time outlined a regulatory pathway for the approval of drugs with abuse-deterrent claims in their product label. In addition to our planned clinical trials for Egalet-001 and Egalet-002, we are conducting abuse deterrence studies with both product candidates in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product labels.

Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation. There are currently no commercially available abuse-deterrent formulations of morphine, and we believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. We have completed our Phase 1 clinical trials of Egalet-001 and we plan to initiate pivotal trials to establish the bioequivalence of Egalet-001 to MS-Contin, a currently approved oral morphine formulation, in the first quarter of 2014. We also plan to initiate abuse deterrence studies in the first quarter of 2014 that are designed with the goal of obtaining abuse-deterrent claims in our product label. We plan to seek U.S. regulatory approval of Egalet-001 pursuant to Section 505(b)(2) using MS-Contin as our reference drug. Section 505(b)(2) permits companies to rely upon the FDA's previous findings of safety and effectiveness for an approved product, such as MS-Contin in the case of Egalet-001. Under this proposed approval pathway, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2014.

Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release oral oxycodone formulation. We believe that Egalet-002, if approved, will have advantages over commercially available, long-acting, abuse-deterrent oxycodone products, such as OxyContin OP, due to its differentiated abuse-deterrent properties and a PK profile that demonstrates low peak-to-trough concentration variability in drug exposure. We have conducted Phase 1 trials of Egalet-002 and have completed initial abuse deterrence studies in compliance with the FDA draft guidance. We plan to initiate the first of two Phase 3 safety and efficacy trials of Egalet-002 in the fourth quarter of 2014, which have been designed to demonstrate the safety and efficacy of Egalet-002 and a PK profile that exhibits low peak-to-trough concentration variability in drug exposure. Peak-to-trough concentration variability means the difference between the highest concentration of an API in the bloodstream and the lowest concentration of such API in the bloodstream. We believe the low variability we have observed in Egalet-002 will result in better, more consistent pain relief and reduced use of rescue medication to treat breakthrough pain, as compared to oxycodone-based products that exhibit higher variability. We also intend to initiate additional abuse deterrence studies in the first quarter of 2014, in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product label. We also plan to seek U.S. regulatory approval of Egalet-002 pursuant to Section 505(b)(2) using OxyContin OP as our reference drug and anticipate submitting an NDA for Egalet-002 in the first half of 2016.

If either of our clinical-stage product candidates achieves regulatory approval, we intend to establish our own specialty sales force to market such product in the United States targeting physicians specializing in pain management and access third-party sales representatives who target primary care and internal medicine physicians in the United States. We also intend to enter into collaborations with other companies to develop and commercialize our product candidates outside the United States.

In November 2013, we entered into a collaboration and license agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. Shionogi will be responsible for all expenses associated with the development of these product candidates. Under the terms of the agreement, Shionogi made an upfront payment of \$10.0 million. We are eligible to receive milestone payments upon development and approval of product candidates under the agreement, which may exceed \$300 million if multiple product candidates are approved, as well as royalties at percentage rates ranging from mid-single digit to low-teens on net sales of licensed products.

Our platform consists of two novel abuse-deterrent drug delivery systems, each of which utilizes our proprietary technology to produce tablets with physical and chemical barriers intended to deter the most

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common methods of abuse that are specific to a particular drug. Our one-component system consists of a hard matrix that erodes as it passes through the gastrointestinal tract, while our two-component system consists of a similar matrix surrounded by a biodegradable coating, or shell. Using these two systems, we have produced oral formulations of morphine and oxycodone with physical characteristics that make particle size reduction difficult and that also resist dissolution by becoming gelatinous in the presence of water or other common household solvents. Our two systems are designed to inhibit alcohol dose dumping and do not produce changes in the rate of absorption of API in the GI tract based on the presence or absence of food, also known as a food effect. In addition to its abuse-deterrent benefits, our proprietary technology enables us to tailor the release profile of the API, allowing us to formulate immediate release, or IR, extended release, or ER, and sustained release, or SR, profiles for each of our current product candidates and any that we may develop in the future.

Our technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include two APIs that can be released at the same or different rates. We have completed initial research and development efforts on 13 potential product candidates. We have developed prototypes, conducted feasibility studies and are exploring additional applications of our technology, both independently and in collaboration with major pharmaceutical companies, for the development of both single-agent and combination products for indications other than pain in which a potential for abuse exists. Our exclusively-owned product candidates and proprietary technology are protected by 55 patents and 32 patent applications, as well as unpatented know-how and trade secrets.

Members of our management team have substantial experience in product development, manufacturing, clinical development, regulatory affairs and sales and marketing and have been closely involved with the development and commercialization of several pain and central nervous system products, including Opana, Zyprexa and Prozac. We believe this experience will help us to successfully develop and commercialize our abuse-deterrent product candidates.

**Strategy**

Our goal is to be a leading specialty pharmaceutical company focused on the development, manufacture and commercialization of abuse-deterrent pharmaceutical products. Our strategy for achieving this goal is to:

*Develop and obtain FDA approval for Egalet-001 as an abuse-deterrent morphine product for the treatment of moderate to severe pain.* We are developing Egalet-001 to treat moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We intend to demonstrate bioequivalence to MS-Contin and plan to submit an NDA in the fourth quarter of 2014.

*Develop and obtain FDA approval for Egalet-002 as an abuse-deterrent oxycodone product for the treatment of moderate to severe pain.* We are developing Egalet-002 to treat moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We intend to demonstrate Egalet-002's safety and efficacy and a PK profile that exhibits low peak-to-trough concentration variability in drug exposure and plan to submit an NDA in the first half of 2016.

*Commercialize Egalet-001 and Egalet-002.* If either of our our clinical-stage product candidates achieve regulatory approval, we intend to establish our own specialty sales force to market the product in the United States by targeting physicians specializing in pain management. To supplement our internal U.S. sales force, we intend to contract with third parties to access sales representatives who target primary care and internal medicine physicians in the United States. We will seek to license the development and commercial rights to our products outside the United States to a third-party

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organization that has an established track record of success in developing and commercializing pain products outside the United States.

*Leverage our proprietary technology platform to develop additional product candidates and create out-licensing opportunities.* We plan to employ our technology to develop additional abuse-deterrent products containing APIs other than morphine and oxycodone. In addition, we will seek to out-license our proprietary technology in areas outside of our current focus, such as for abuse-deterrent combination products and in therapeutic areas beyond the treatment of pain. For example, we entered into a collaboration and license agreement with Shionogi, wherein we granted Shionogi exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology.

**Background**

***The Chronic Pain Market***

Chronic pain, typically defined as pain that lasts beyond the healing of an injury or that persists beyond three months, is a worldwide problem with serious health and economic consequences. The Institute of Medicine estimates that as of 2008, approximately 100 million Americans suffered from chronic pain, costing up to \$635 billion each year in medical treatment and lost productivity. Common types of chronic pain include lower back pain, arthritis, headache, and face and jaw pain. Moderate pain may prevent an individual from participating in his or her daily activities, and severe pain typically stops an individual from participating in those activities and induces a patient to exhibit pain avoidance behaviors.

Opioids are the most commonly prescribed drugs in the United States to address moderate to severe chronic pain. IMS estimates that for the 12 months ended September 30, 2012, long-acting opioids were prescribed 14.8 million times in the United States resulting in total sales of \$4.1 billion. The most commonly prescribed long-acting opioids include morphine, oxycodone, oxymorphone and hydromorphone.

***Prescription Opioid Abuse is an Epidemic in the United States***

Drug-related deaths, 40% of which involved the use of opioids in 2008 according to the National Center for Health Statistics, became the leading cause of accidental death in the United States in 2009 surpassing deaths caused by automobile accidents, according to a 2011 report by the CDC. According to a 2011 report by the American College of Preventive Medicine, approximately 5.3 million Americans use prescription pain relievers, including opioids, each month for purposes other than those for which they were prescribed. A 2011 SAMHSA research report estimates that nearly 35 million Americans have used prescription pain relievers, including opioid-containing drugs, for non-prescription purposes at least once in their lifetime, and that between 1999 and 2009 there was a 430% increase in substance abuse treatment facility admissions resulting from the use of prescription pain relievers. Further, according to a 2011 study by the University of Michigan, one in 12 high school seniors reported non-medical use of Vicodin, a combination of acetaminophen and hydrocodone, and one in 20 high school seniors reported non-medical use of OxyContin. Overall, the costs associated with prescription drug abuse have been estimated to be up to \$72.5 billion annually for public and private healthcare payors in the United States, according to a 2013 report by the American Journal of Managed Care.

***Legislative and Regulatory Reaction***

In reaction to the increasing costs and other consequences of widespread prescription opioid abuse, the U.S. government and a number of state legislatures have introduced, and in some cases have enacted,

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legislation and regulations intended to encourage the development and adoption of abuse-deterrent forms of pain medications. Recent activities include:

*STOPP Act:* In July 2012, a bipartisan group of Congressional leaders introduced the STOPP (Stop the Tampering of Prescription Pills) Act. Reintroduced in February 2013, this bill, if approved, would require that non-abuse-deterrent opioids be removed from the market if an abuse-deterrent formulation of that opioid has already been approved for marketing by the FDA.

*48 state and territorial attorneys general support development of abuse-deterrent opioids:* In March 2013, the National Association of Attorneys General urged the FDA to adopt standards requiring manufacturers and marketers of prescription opioids to develop abuse-deterrent versions of those products. Their letter, signed by 48 state and territorial attorneys general, commended the FDA for expeditiously proposing guidance that establishes clear standards for manufacturers who develop and market tamper- and abuse-resistant opioid products, while considering incentives for undertaking the research and development necessary to bring such products to market. It also encouraged the FDA to ensure that generic versions of such products are designed with similar tamper-resistant features.

*Abuse-deterrent language in OxyContin OP label:* In April 2013, the FDA approved the enhancement of Purdue Pharma L.P.'s OxyContin OP product label by approving the inclusion of language supporting the product's ability to deter abuse and suggested that the completion of abuse-deterrent studies by Purdue demonstrated the product's abuse-deterrent features. This decision by the FDA is consistent with its public statement that the development of abuse-deterrent opioid analgesics is a public health priority for the FDA.

*FDA's authority to support abuse deterrence:* In an April 2013 letter to the U.S. House of Representatives' Committee on Energy and Commerce, the FDA outlined its authority to address the issue of prescription opioid abuse in the United States, stating that it believes it has the authority to refrain from approving non-abuse-deterrent formulations of a drug and to initiate procedures to withdraw non-abuse-deterrent versions already on the market.

*FDA release:* On September 10, 2013, the FDA announced its intention to effect labeling changes to all approved ER and long-acting opioids. In particular, the FDA intends to update the indication for ER and long-acting opioids so that such opioids will be indicated only for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA will also require post-market studies for any such opioids.

*FDA draft guidance:* In January 2013, the FDA introduced draft guidance that for the first time provided direction as to the necessary study design and data recommendations for obtaining abuse-deterrent claims in a product label. The FDA's draft guidance has undergone a public comment period and may remain in its draft form, may be revised and finalized, or may be withdrawn at the FDA's discretion. The guidance describes four tiers of label claims that a product with abuse-deterrent properties may obtain based on studies completed either prior to NDA submission or after NDA approval:

Tier 1 the product is formulated with physical or chemical barriers to abuse.

Tier 2 the product is expected to reduce or block effects of the opioid when the product is manipulated.

Tier 3 the product is expected to result in a meaningful reduction in abuse.

Tier 4 the product has demonstrated reduced abuse in the community.

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Depending on the tier of abuse deterrence claimed, the required studies include laboratory-based *in vitro* manipulation and extraction studies, pharmacokinetic studies, clinical abuse-potential studies and studies analyzing post-marketing data to assess the impact of an abuse-deterrent formulation on actual abuse. If a product is approved by the FDA to include these claims in its label, the applicant may seek to use that information in its marketing efforts, and its sales representatives will be able to provide detail to physicians as to the abuse-deterrent features of the product.

We believe that these actions by regulators and legislators indicate a commitment to address the issue of prescription opioid abuse in the United States and highlight their desire to encourage the development of abuse-deterrent opioid products. We also believe these actions create an opportunity for us to develop and commercialize product candidates with abuse-deterrent claims on the product label.

**Our Abuse Deterrence Solution: The Egalet Technology Platform**

***Overview of Our Drug Delivery Systems***

We have created two distinct systems, each with novel abuse-deterrent features and the ability to control an API's release profile. Our one-component system is used to produce tablets, such as Egalet-001, that consist of a matrix that controls the release of the API. The matrix, which contains the API as well as inactive agents known as excipients, erodes over time in the GI tract, releasing the API. Our two-component system is used to produce tablets, such as Egalet-002, that consist of a matrix similar to the matrix that is a part of our one-component system, but that is surrounded by a water-impermeable, non-eroding, hard shell made of PLA that creates a cylinder, with the API-containing matrix exposed at both ends. The shell is a polymer blend that includes PLA as an inactive substance. The shell serves to limit the portion of the matrix's surface area that is exposed to the GI tract, which allows us to tailor the release rate of the API and makes it even more difficult to crush or grind the tablet, thereby enhancing its abuse-deterrent properties. The unchanged, excreted shell degrades over several months into lactic acid, which is a natural chemical entity found in the body and is also used as a food additive. Other than the APIs and, in the case of Egalet-002, the PLA contained in the shell, our tablets consist of substances included in the FDA's Inactive Ingredient Database. As a result, we believe that the use of these substances in our product candidates will not require extensive review by the FDA.

The following diagram illustrates our two-component system, with the matrix eroding as it passes through the GI tract. The shell, which remains unchanged, is shown in dark gray and the matrix containing the API is shown in light gray.

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One-component tablets, such as Egalet-001, are made to resist crushing in order to swallow, snort or smoke, and dissolving in order to inject. With its gelling effect, the one-component system was designed in particular to further deter abuse by injection, which is the most common method of abuse of morphine-based products, according to a 2011 article in the Harm Reduction Journal.

Both the shell and the matrix of our two component tablets, such as Egalet-002, have abuse-deterrent characteristics as a result of their physical hardness and the gelling effect of the matrix. Our two-component system was specifically designed to address abuse by crushing and snorting, which is the most common method of manipulating oxycodone-based products for abuse, according to a 2011 article in the Harm Reduction Journal.

Our technology employs a proven, reproducible, scalable and cost-efficient manufacturing process. While other pharmaceutical companies typically manufacture their abuse-deterrent products using conventional compression methods, injection molding involves the simultaneous use of both pressure and heat to form tablets using a customized mold. We use an injection molding technology that is also used in the manufacture of medical devices, including implants and diagnostics, to create our matrix and shell. We believe that we are the first company to combine standard pharmaceutical production with plastic injection molding to produce orally delivered pharmaceutical products.

***Abuse-deterrent Features***

Abusers often seek to accelerate the absorption of opioids into the bloodstream by crushing in order to swallow, snort or smoke, or dissolving in order to inject, the drug. Tablets produced using our systems have physical and chemical barriers that are intended to minimize the potential for these forms of abuse. We believe that tablets made using our proprietary technology deter the most common methods of manipulating opioids for abuse because of their features described in the table below.

**Abuse-deterrent Features of Egalet Technology**

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





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Our one-component tablets, including Egalet-001, are made to resist crushing, in order to swallow, snort or smoke, and dissolving in order to inject, and are designed to further deter abuse by injection in particular, which is the most common method of abuse of morphine-based products. Embeda®, a controlled-release morphine formulation that was voluntarily removed from the market by Pfizer in 2011 due to stability and manufacturing issues, has abuse-deterrent properties but does not inhibit these common methods of abuse. Rather, Embeda contains naltrexone, an antagonist intended to nullify the effect of the API if the tablet is manipulated. Unlike Embeda, our one-component tablets do not contain a second API that could have adverse side effects.

Our two-component tablets, including Egalet-002, are designed to deter crushing and snorting in particular, which is the most common method of manipulating oxycodone-based products for abuse. While OxyContin OP also has been shown to be resistant to crushing and snorting, we believe our product candidates have superior abuse-deterrent properties, based on preclinical testing we performed.

There are other drugs on the market with abuse-deterrent features, such as Opana® ER, a long-acting oxycodone formulation. While Opana ER has shown some resistance to crushing and snorting, we believe our product candidates have superior abuse-deterrent properties, based on preclinical testing we performed.

***Ability to Tailor Release***

In addition to its abuse-deterrent features, our proprietary technology enables us to tailor the release profiles for many classes of oral pharmaceutical products. In our tablets, the API is integrated into the matrix, which makes it difficult for abusers to quickly extract; however, when the tablet is exposed to GI fluids, the matrix erodes, thereby releasing the API. Using our technology, we can change the amount and composition of the polymer used to create the matrix formulation and can vary the surface area of the tablet. A larger surface area results in faster release of the API, while a smaller surface area results in slower release. By changing the matrix composition and surface area, we can control the rate of erosion of the matrix and the rate of release of the API in the GI tract, which allows us to develop products with IR, ER or SR profiles. Once correlation has been established between the rate of release of an API in laboratory testing and the rate of its release inside the body, the targeted release profile can be achieved with high predictability using our technology.

***Additional Applications of our Technology***

Our technology can also be used to develop other abuse-deterrent products with other APIs, as well as combination products containing two APIs regardless of the desired release rate for each API. We have developed prototypes and conducted feasibility studies of these combination products both independently and in collaboration with major pharmaceutical companies. We apply three distinct approaches for making combination products. In the first approach, two APIs are mixed with excipients to produce a tablet that releases both APIs at the same rate. In the second approach, two APIs are mixed with two separate blends and molded into a shell, allowing different rates of release of the two APIs. The third approach is used when one API needs to be released instantly and the other requires a controlled release. The immediate-release API is added to a separate coat, which surrounds a tablet containing the controlled-release API. We are continuing to evaluate potential combination product candidates using these three approaches.

Table of Contents**Our Product Candidates**

| <b>Product Candidate</b> | <b>Indication</b>   | <b>Delivery System</b> | <b>Projected Near-Term Milestones</b>   |
|--------------------------|---|------------------------|---|
| Egalet-001               | Oral morphine for the treatment of moderate to severe chronic pain  | One-Component          | Q1 2014 Initiate tier 1 abuse deterrence studies<br>Q1 2014 Initiate bioequivalence trials<br>Q2 2014 Initiate tier 2 and tier 3 abuse deterrence studies<br>Q4 2014 Submit NDA to FDA  |
| Egalet-002               | Oral oxycodone for the treatment of moderate to severe chronic pain | Two-Component          | Q1 2014 Complete tier 1 abuse deterrence studies<br>Q2 2014 Initiate tier 2 and tier 3 abuse deterrence studies<br>Q2 2014 Initiate alcohol interaction trial<br>Q4 2014 Initiate Phase 3 safety trial<br>Q1 2015 Initiate Phase 3 efficacy and safety trial<br>H1 2016 Submit NDA to FDA |
| Egalet-003               | Oral opioid for the treatment of moderate to severe chronic pain    | Two-Component          | 2014 Initiate Phase 1 trial   |

Each of our product candidates is being developed to seek FDA approval in accordance with Section 505(b)(2).

***Egalet-001: Morphine for the Treatment of Moderate to Severe Chronic Pain******Overview***

Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation for the treatment of moderate to severe chronic pain in patients requiring chronic opioid therapy. Egalet-001 consists of a well-characterized drug substance, morphine sulfate, approved by the FDA and by regulators around the world in a number of IR and ER drug products, together with inactive ingredients deemed safe for chronic oral use. Morphine-based products including MS-Contin have been available in the U.S. market for many years and have a well-established safety profile. We are developing Egalet-001 for two to three times a day dosing.

We developed Egalet-001 using our proprietary, abuse-deterrent, one-component delivery system to address common methods of abuse, such as crushing in order to swallow, snort or smoke, or dissolving in order to inject, with an emphasis on the most common method of abuse of morphine-based products, which is abuse by injection. In a series of in-house studies we performed, Egalet-001 has significantly resisted manipulation into an injectable form due to the gelling effect that occurred when attempting to dissolve it in water and other common household solvents.

We are seeking to establish bioequivalence of Egalet-001 to MS-Contin in a series of pivotal bioequivalence trials under fasted and fed conditions. In parallel, we will conduct studies consistent with the FDA draft guidance to establish its abuse-deterrent properties, with the goal of obtaining abuse-deterrent claims in our product label. With no additional efficacy trials required, and with all excipients used in the formulation not expected to require extensive review since they are included in the FDA's

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Inactive Ingredient Database, we believe Egalet-001 should have an accelerated path to approval if we can establish bioequivalence in our Section 505(b)(2) filing.

*Market Opportunity*

Egalet-001 will target the long-acting opioid market. IMS estimates that for the 12 months ended September 30, 2012, long-acting opioids were prescribed 14.8 million times in the United States, resulting in total sales of approximately \$4.1 billion. Long-acting morphine is the most commonly prescribed opioid in this market, representing approximately \$560 million in total sales on 7.1 million prescriptions in the United States for the 12 months ended September 30, 2012, up from 4.2 million prescriptions in the United States over the same period in 2007. There are currently three branded long-acting, oral morphine products on the market, MS-Contin, Kadian® and Avinza®, as well as several generic forms. These three branded products comprised 66.4% of the sales of morphine products for the 12 months ended September 30, 2011, while representing only 11.1% of the total number of prescriptions. We believe Egalet-001, if approved, will be able to capture a share of the branded component of this market.

In one third-party market research study that we commissioned, representatives from 15 healthcare payors covering a total of 168 million individuals were asked how they would expect Egalet-001 to be priced as compared to other commercially available brands of morphine products. In this study, ten of the payors surveyed indicated that they would be likely to reimburse for Egalet-001 on a basis comparable to that of other branded morphine products, while another four of the payors suggested that they would be likely to reimburse for Egalet-001 at a premium ranging from 5% to 20% more than that of the other branded morphine products. In another third-party market research study that we commissioned, 16 medical professionals were asked how often they would prescribe Egalet-001 and other currently available medications for the treatment of their next 20 patients with chronic, moderate to severe pain. Based on the responses to this hypothetical, Egalet-001 would have been the most frequently prescribed drug.

In addition to these studies, we believe that the sales results of Embeda illustrate the potential market for an abuse-deterrent formulation of morphine. Embeda was launched in September 2009 as an oral morphine formulation. Even though its manufacturer was not able to include the product's abuse-deterrent feature on its label, Embeda was designed with an abuse-deterrent feature that distinguished it from other commercially available morphine-based products. Unlike Egalet-001, Embeda uses an abuse-deterrent approach that involves the introduction of naltrexone as a second API to nullify the effect of the morphine if the tablet was manipulated. Abuse-deterrent approaches that include opioid-receptor antagonists, such as naltrexone, add additional pharmaceutical agents that may have potential adverse effects. Additionally, Embeda was removed from the market four times, most recently in early 2011, and it is not currently available due to stability and formulation issues relating to the degradation of naltrexone in the product. Prior to its removal from the market, IMS estimated that Embeda garnered 9.2% of the total sales in the long-acting morphine market within its first year. For the 12 months ended February 28, 2011, Embeda achieved approximately \$71.4 million in sales, which represented 19.2% growth compared to the 12 months ended September 30, 2010.

With no currently available abuse-deterrent morphine product on the market and the growing abuse of oral morphine, we believe Egalet-001 has the potential to be an important therapeutic alternative to existing morphine products, as we believe there is a significant need for an abuse-deterrent oral morphine formulation.

*Product Features of Egalet-001*

We believe that Egalet-001, if approved, would provide patients and physicians with the following benefits when compared to existing morphine-based products:

*Abuse-deterrent features:* Egalet-001 is designed to resist the most common methods of abuse, including crushing in order to swallow, snort or smoke, and dissolving in order to inject. Egalet-001

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uses our one-component system, which is designed to enhance the deterrence of abuse by injection in particular, the most common method of abuse of morphine-based products.

*No alcohol dose dumping:* Egalet-001 slows the release of the API in the presence of alcohol, contrary to the effects seen with some other morphine-based products, in which the release of the API is accelerated in the presence of alcohol.

*No food effect:* The PK profile of Egalet-001 is similar to that of other long-acting morphine formulations with or without the presence of food. This feature provides more consistent pain relief, as well as improved patient convenience.

*Morphine only:* Egalet-001 has the potential to be the first abuse-deterrent, ER morphine product that does not contain opioid-receptor antagonists.

*Convenient dosing:* Egalet-001 offers patients the option of a convenient two-to-three times daily dosing regimen, thereby increasing the likelihood of patient adherence. We plan to make Egalet-001 in 15, 30, 60 and 100mg doses, which are consistent with currently available morphine formulations.

*Consistent relief:* Two to three times daily dosing can offer around-the-clock pain relief. Egalet-001, with its ER profile, is designed to provide consistent relief of moderate to severe chronic pain over an eight- or 12-hour period per dose.

*Clinical Development*

We plan to seek approval of Egalet-001 under the FDA's Section 505(b)(2) approval pathway, and as a result we believe that Egalet-001 should have an accelerated path to approval if we are able to establish bioequivalence. We have completed our Phase clinical 1 trials of Egalet-001 and have completed initial abuse deterrence studies in compliance with the FDA draft guidance. On August 21, 2013, we submitted an investigational new drug application, or IND, for Egalet-001 to the FDA. Prior to submission of the IND, all of our trials were conducted in Canada. We plan to initiate pivotal clinical trials of Egalet-001 in the first quarter of 2014 to establish its bioequivalence to MS-Contin. We also plan to conduct additional abuse deterrence studies in the first quarter of 2014 designed with the goal of obtaining abuse-deterrent claims in our product label. We intend to rely on the FDA's previous conclusions of safety and effectiveness for MS-Contin, and we do not expect that any additional preclinical studies or clinical trials will be required for our formulation, as all the substances included in Egalet-001 tablets, other than the API, are included in the FDA's Inactive Ingredient Database and we do not expect them to require extensive review. We have consulted with the FDA and obtained feedback that this approach is acceptable to the FDA. Based on the expected timing of our studies and trials, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2014.

*Completed Clinical Studies*

In a Phase 1 trial with a primary endpoint of similarity to the PK profile of MS-Contin, based on standard bioequivalence parameters, including the total concentration, expressed as area under the curve, or AUC, and peak concentration, or  $C_{max}$ , Egalet-001 demonstrated a similar PK profile to MS-Contin, which we intend to use as its reference drug. Based on the results of this trial, we believed that we would be able to achieve bioequivalence to MS-Contin with our formulation. The graph below shows the PK profiles of Egalet-001 and MS-Contin in the Phase 1 trial, with the concentration of API in the bloodstream for 48 hours after administration of Egalet-001 to five healthy patients and MS-Contin to five different healthy

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patients. These results demonstrate the similarity of the PK profiles of Egalet-001 and MS-Contin based on AUC and  $C_{\max}$ .

We recently completed a second Phase 1 PK trial with Egalet-001, which was designed to evaluate its bioequivalence to MS-Contin. The trial involved 30 healthy volunteers and was conducted using a standard crossover design in which we examined the concentration of Egalet-001 and MS-Contin in the bloodstreams of the volunteers 48 hours after administration. The primary endpoints for the study were AUC and  $C_{\max}$ . The data from the trial are shown in the table below.

In order to demonstrate bioequivalence, under FDA guidance we must establish that the AUC and  $C_{\max}$  of Egalet-001 are within a 80-125% range of the same measures for MS-Contin, in each case with a 90% confidence interval. A 90% confidence interval means that the true value of these measures is between 80% and 125% of the respective measure for MS-Contin, with a probability of 90%. In this trial, the 90% confidence intervals indicated that Egalet-001 had an AUC of between 91% and 98% of that of MS-Contin and a  $C_{\max}$  of between 82% and 99% of that of MS-Contin. These results demonstrate that under the FDA guidance Egalet-001 and MS-Contin were bioequivalent in this trial.



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The trial also measured the time to maximum plasma concentration, or  $T_{\max}$ , for each of Egalet-001 and MS-Contin. The  $T_{\max}$  for Egalet-001 was slightly longer than that for MS-Contin. However, we believe the observed  $T_{\max}$  for Egalet-001 is consistent with that of other chronic morphine treatments currently on the market.

In addition to the bioequivalence measures, in the trial we evaluated the *in vitro* dissolution profile of Egalet-001, as compared to the blood concentrations of the volunteers in the trial, in order to determine whether the release profile of Egalet-001 was consistent with the results we observed in our preclinical studies. We tested Egalet-001 as well as three other morphine formulations, labeled faster, slightly faster, and slower, based on the speed of their release profile as compared to Egalet-001. The percentage of each formulation released *in vitro* over time is shown in the graph below.

We observed that the blood concentration data in the trial volunteers, after exposure to each of the four formulations, followed a similar pattern to that shown by the *in vitro* dissolution profiles. The  $C_{\max}$  for the faster, slightly faster, Egalet-001 and slower formulations were 38, 30, 25 and 22 ng/mL, respectively. We believe these results suggest that concentration levels from exposure to Egalet-001 in humans may be predicted based on its *in vitro* dissolution profile. This supports our belief that our technology will be predictable in future clinical trials.

*Completed Preclinical Abuse Deterrence Studies*

We developed Egalet-001 to address the most common method of abuse of morphine-based products, which is abuse by injection. In preclinical studies we performed, Egalet-001 prevented manipulation into an injectable form due to the gelling effect that occurred when the product was dissolved in water and other common household solvents. Egalet-001 also created barriers to other common methods of abuse, including crushing in order to swallow, snort, or smoke. For example, in one in-house study, testers attempted to grind Egalet-001, OxyContin OP and Opana ER tablets into smaller particles using a nutmeg grater, a household tool commonly used for manipulation. For each of the three products, both the intact tablet and the corresponding ground tablet particles were placed in water. In each case, we compared the amount of time it took for 80% of the API to be released from the ground product in water to the time it took for 80% of the API to be released from the intact product in water. As shown in the figure below, the manipulated OxyContin OP and Opana ER tablets exhibited significantly accelerated release profiles as compared to their respective intact forms (approximately 20 times and 35 times faster, respectively), while the manipulated Egalet-001 was only released at approximately five times the rate of release of its intact form. These results indicate that it was more difficult to accelerate the release of the API in Egalet-001 through particle size reduction than it was for OxyContin OP or Opana ER. These in-house studies were performed solely for the purpose of supporting our *in vitro* evaluations of abuse deterrence, which we will

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seek to confirm in third-party abuse deterrence studies we intend to be conducted in support of the inclusion of abuse-deterrent claims on our product label. These in-house studies are not relevant to the determination of bioequivalence and, as such, we do not believe they will be pertinent to the FDA's decision to approve or reject our NDA for Egalet-001.

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

In another in-house study, we evaluated the resistance of Egalet-001 to abuse by injection. In this study, Egalet-001, MS-Contin, OxyContin OP and Opana ER tablets were placed in a microwave and heated for up to 16 minutes in a process known as crisping. The resulting substance was then mixed with 3 mL of water, the maximum volume a typical abuser would want to inject, and then attempted to be drawn into a syringe in order to measure its viscosity. The results of this study are shown in the table below. Egalet-001 remained highly viscous after crisping for each of the time periods shown and was not injectable, as demonstrated by the 2400 cP limit in the table, which represents the limit of what can be measured and a form that is too viscous to inject. Centipoise, or cP, is a common unit of measurement of viscosity, with water at room temperature having a viscosity of approximately 1 cP. The other products had much lower levels of viscosity and were readily injectable.

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



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*Planned Clinical Trials and Abuse Deterrence Studies*

We intend to perform the following bioequivalence trials in which we will need to establish that the  $C_{max}$  and AUC of Egalet-001 fall within the 80-125% range of the  $C_{max}$  and AUC of MS-Contin:

A PK trial comparing single-dose 15 mg MS-Contin with single-dose 15 mg Egalet-001 tablets under fasting conditions in 24 to 30 patients, which we intend to initiate in the first quarter of 2014 and from which we expect to receive final data in the fourth quarter of 2014.

*In vitro* dose proportionality trials for 30 and 60 mg doses, which we intend to initiate in the first quarter of 2014 and from which we expect to receive final data in the fourth quarter of 2014.

A PK trial comparing single-dose and steady-state 100 mg MS-Contin with 100 mg Egalet-001 tablets under fasting conditions in 24 to 30 patients, which we intend to initiate in the first quarter of 2014 and from which we expect to receive final data in the fourth quarter of 2014.

A PK trial comparing 100 mg MS-Contin with 100 mg Egalet-001 tablets under fed conditions in 24 to 30 patients, which we intend to initiate in the first quarter of 2014 and from which we expect to receive final data in the fourth quarter of 2014.

We also intend to perform the following abuse deterrence studies for Egalet-001 consistent with the FDA draft guidance:

Tier 1 *in vitro* studies to test Egalet-001's ability to resist a broad range of the common methods of anticipated manipulation for the purpose of abuse, such as particle size reduction or extraction through crushing or dissolving, and common modes of intake, such as swallowing, snorting, and injecting. We intend to initiate these studies in the first quarter of 2014.

A tier 2 abuse deterrence study comparing PK characteristics of manipulated Egalet-001 and manipulated MS-Contin in 15 patients, which we intend to initiate in the second quarter of 2014.

A tier 3 randomized, double-blind, placebo-controlled and comparator-controlled crossover study to compare the likeability of Egalet-001 and MS-Contin in 30 experienced abusers, which we intend to initiate in second quarter of 2014. The purpose of a likeability study is to assess how probable it is that the formulation will be attractive to abusers of the drug.

***Egalet-002: Oxycodone for the Treatment of Moderate to Severe Chronic Pain***

*Overview*

Egalet-002 is an abuse-deterrent, extended-release, oral oxycodone formulation entering Phase 3 development for the treatment of moderate to severe chronic pain. Egalet-002 consists of an approved and well-characterized drug substance, oxycodone hydrochloride, approved by the FDA and by regulators around the world in a number of IR and ER drug products, together with inactive ingredients deemed safe for chronic oral use. Oxycodone-based products, including OxyContin, have been available in the United States for many years and have a well-established safety profile. PLA, the primary component making up the outer shell, has been used extensively in the medical devices industry, including in the manufacture of implants and diagnostics.

We developed Egalet-002 using our proprietary, abuse-deterrent, two-component delivery system to address common methods of abuse, including crushing in order to swallow, snort or smoke, or dissolving in order to inject, with an emphasis on abuse by crushing and snorting, which is the most common method of manipulating oxycodone-based products for the purpose of abuse. In Phase 1 PK trials we performed, Egalet-002 resulted in less peak-to-trough concentration variability in drug exposure than OxyContin OP. We believe this lower variability will result in fewer side effects from use of Egalet-002 as compared to OxyContin, as well as better, more consistent pain relief and reduced use of rescue medication to treat breakthrough pain. We have also completed initial tier 1 *in vitro* studies, and the results of these studies



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confirmed the abuse-deterrent features of Egalet-002. We plan to seek approval of Egalet-002 through the FDA's Section 505(b)(2) approval pathway using OxyContin OP as our reference drug. In parallel, we will conduct additional abuse deterrence studies in accordance with the draft FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product label.

*Market Opportunity*

Egalet-002 will target the long-acting opioid market. IMS estimates that for the 12 months ended September 30, 2012, long-acting opioids were prescribed 14.8 million times in the United States, resulting in total sales of \$4.1 billion. Oxycodone-based products are the market leader in sales among long-acting opioids in the United States with U.S. sales of long-acting oxycodone totaling approximately \$2.8 billion for the 12 months ended September 30, 2012 on approximately 6.2 million prescriptions, up from \$1.0 billion in sales in 2007.

Until recently, no company with an oxycodone-based product had been permitted to make label claims describing the abuse-deterrent characteristics of its product. Purdue Pharma L.P. conducted a number of abuse deterrence studies on its OxyContin OP product, which was launched in 2012. In April 2013, the FDA determined that Purdue had been successful in demonstrating OxyContin OP's abuse-deterrent characteristics and permitted Purdue to amend its label to include these claims. The FDA also concluded that the benefits of non-abuse-deterrent OxyContin no longer outweighed its risks and removed it from the list of drugs eligible to serve as a reference product for future generic or Section 505(b)(2) approvals. As a result, we expect that all long-acting oxycodone products will now be required to have abuse-deterrent claims as part of the FDA approval process. We believe this change in FDA policy creates a significant opportunity for Egalet-002, if approved, to capture a portion of the long-acting oxycodone market.

*Product Features of Egalet-002*

We believe that Egalet-002, if approved, would provide patients and physicians with the following benefits when compared to existing oxycodone-based products:

*Abuse-deterrent features:* Egalet-002 was developed to address the most common methods of abuse, including crushing in order to swallow, snort or smoke, and dissolving in order to inject. Egalet-002 uses our two-component system, which is designed to enhance the deterrence of abuse by crushing and snorting in particular, which is the most common method of manipulating oxycodone-based products for abuse.

*PK profile:* We believe that Egalet-002 provides less peak-to-trough concentration variability in drug exposure when compared to OxyContin OP, which should result in Egalet-002 having fewer side effects and providing better and more consistent pain relief, resulting in reduced use of rescue medication to treat breakthrough pain.

*No alcohol dose dumping:* Egalet-002 slows the API's release in the presence of alcohol, contrary to the effects seen with other oxycodone products.

*No formulation-related food effect:* The PK profile of Egalet-002 is similar to that of other long-acting oxycodone formulations in the presence of food.

*Consistent relief and convenient dosing:* Egalet-002, with its ER profile, is designed to provide consistent relief of moderate to severe chronic pain for a 12-hour period per dose. Egalet-002 permits twice-daily dosing, consistent with currently available oxycodone formulations, to provide around-the-clock pain relief. We intend to make Egalet-002 in 10, 20, 40 and 80 mg doses, which are consistent with currently available oxycodone formulations.

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*Clinical Development*

We plan to seek approval of Egalet-002 under the FDA's Section 505(b)(2) approval pathway using OxyContin OP as our reference drug. We plan to conduct Phase 3 safety and efficacy trials consistent with written feedback we have received from the FDA over the course of the development of Egalet-002. We have conducted Phase 1 trials of Egalet-002 and have completed initial abuse deterrence studies in compliance with the FDA draft guidance. On July 17, 2013, we submitted an IND for Egalet-002 to the FDA. Prior to submission of the IND, all of our trials were conducted in Canada. We plan to initiate the first of two Phase 3 safety and efficacy trials of Egalet-002 in the fourth quarter of 2014, as well as an alcohol interaction trial in the second quarter of 2014, designed to demonstrate the safety and efficacy of Egalet-002 and a PK profile that exhibits low peak-to-trough concentration variability in drug exposure. In addition to the safety and efficacy trials, we intend to initiate additional abuse deterrence studies in the first quarter of 2014, in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product label. Based on the expected timing of our trials and studies, we anticipate submitting an NDA for Egalet-002 in the first half of 2016.

*Completed Clinical Trials*

We have performed three Phase 1 clinical trials of Egalet-002. The first Phase 1 PK trial, a single-dose, crossover study, examined three different sizes of a 40 mg Egalet-002 tablet (6 mm, 7.5 mm and 9 mm) and an OxyContin OP tablet to determine their relative *in vivo* release profiles in 16 patients with a primary endpoint of similarity to the PK profile of OxyContin OP, based on  $C_{max}$  and AUC. The graph below shows the concentration of the API in the bloodstream over a period of 24 hours after administration of a single dose of each product. Each formulation of Egalet-002 offered slightly different release profiles from each other, and in all cases showed lower peak-to-trough variability than OxyContin OP.

We then conducted a second Phase 1 trial, which was a multiple-dose, crossover study involving 22 subjects over a dosing period of five days with a primary endpoint of similarity to the PK profile of OxyContin OP, based on  $C_{max}$  and AUC. The results from the multiple-dose study were consistent with the single-dose study. Based on the results of these two Phase 1 trials, we selected the 6 mm formulation of

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Egalet-002 because it was consistent with the twice-daily dosing schedule of OxyContin OP, with a slightly higher plasma concentration at the 12-hour point.

In these two Phase 1 trials, Egalet-002 exhibited superior PK characteristics relative to OxyContin OP. In particular, the concentration of API in the bloodstream after administration of Egalet-002 had a narrower peak-to-trough range than OxyContin OP, while maintaining a similar range of total concentration. These results are shown in the table below by the peak, expressed as  $C_{\max}$ ; the trough, expressed as  $C_{\min}$ ; and the total concentration, expressed as AUC. These results suggest that the PK profile of Egalet-002 may be more advantageous than that of OxyContin OP, which could provide more consistent pain relief and reduce side effects associated with a higher peak concentration level.

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

We completed a third Phase 1 trial, with dose proportionality and food effect as the primary endpoints, by examining 10, 20, 40 and 80 mg doses of Egalet-002 combined with a food-effect arm for the 80 mg dose. In this trial, Egalet-002 showed linear dose proportionality across the full dose range. We observed a food effect in this trial, but it was minimal and was consistent with the food effect observed in previous OxyContin studies. Based on these observations, we believe that the food effect was most likely attributable to the intrinsic characteristics of the API, oxycodone, rather than to our formulation.

*Completed Preclinical Toxicity Studies*

Based on feedback we received from the FDA, we commissioned a series of third-party preclinical animal studies to evaluate the safety of oral doses of PLA and the potential for PLA to degrade within the GI tract of dogs. In a preclinical study, the PLA had no observable effect on the GI tract. We did not observe any clinical toxicity or gross or microscopic changes attributed to oral dosing with PLA in the GI lymphoid tissue or in any organ. In another preclinical study, there was no degraded PLA following incubation of PLA granules in artificial intestinal fluid, simulating both the fasted and fed states, and only very minor breakdown products (less than 0.0125% of the original volume) following incubation of the PLA in artificial gastric fluid. Based on these preclinical studies, and the fact that PLA is currently used in approved and cleared medical devices, including in implants and diagnostics, we believe that oral use of PLA as an excipient in Egalet-002 is safe, a position that is consistent with feedback we have received from the FDA.

We plan to supplement our preclinical data by relying on the FDA's previous conclusions of safety and effectiveness with respect to OxyContin OP.

*Completed Abuse Deterrence Studies*

In compliance with the FDA draft guidance, we commissioned a third party to conduct initial tier 1 *in vitro* testing of Egalet-002 to compare the ease of achieving particle size reduction of Egalet-002 and OxyContin OP through the use of conventional mechanical and electrical tools, as well as the relative ease of manipulating the tablets into an injectable form. In one study, five Egalet-002 tablets and five OxyContin OP tablets were milled in a coffee grinder, a household tool commonly used for manipulation, for 20 seconds and then placed on a sieve stack with progressively less permeable sieves, beginning with a 1 micrometer, or  $\mu\text{m}$ , opening and continuing to a 0.053  $\mu\text{m}$  opening. After milling, the particles were shaken for one minute and allowed to settle. As shown in the graph below, approximately 60% of the Egalet-002 tablet, as measured by weight, was captured in the first, most permeable sieve with a 1  $\mu\text{m}$  opening, meaning that approximately 40% passed through the opening to be captured by one of the sieves

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with a smaller opening size. On the other hand, approximately 24% of the milled OxyContin OP was captured by the first sieve, meaning that approximately 76% of that tablet's weight was small enough to pass through to the next sieve. This result indicates that the Egalet-002 tablet was not able to be manipulated as easily through particle size reduction as compared to OxyContin OP.

*Planned Clinical Trials and Abuse Deterrence Studies*

Based on feedback we received from the FDA, we intend to conduct a clinical development program for Egalet-002 that we expect to consist of the following clinical trials:

A Phase 3 randomized, multi-center, double-blind, placebo-controlled efficacy and safety trial for the analgesic management of 300 patients with moderate to severe chronic lower back pain requiring around-the-clock opioid therapy, with efficacy endpoints of reduced pain scores and potentially reduced relief medication. The proposed trial will consist of three parts: a baseline period of up to two weeks prior to administration of Egalet-002 40 mg, an open-label titration period of up to four weeks and a double-blind placebo-controlled treatment period of 12 weeks. We intend to commence enrollment for this trial in the first quarter of 2015, and we expect to receive final data in the second half of 2015.

A second Phase 3 open-label, long-term safety trial in which up to 250 patients will be treated with Egalet-002 for a period of either one year, six months or three months in order to demonstrate the safety of the shell. We intend to commence enrollment for this trial in the fourth quarter of 2014.

A single-dose, alcohol-interaction PK trial in which subjects will ingest an Egalet-002 80 mg tablet followed by 240 mL of four liquid combinations: water with no alcohol and water with alcohol concentrations of 4%, 20% and 40%. We intend to commence enrollment for this trial in the second quarter of 2014.

We also intend to perform the following abuse deterrence studies for Egalet-002 consistent with the FDA draft guidance:

Tier 1 *in vitro* studies to test Egalet-002's ability to resist a broad range of the common methods of anticipated manipulation for the purpose of abuse, such as particle size reduction and extraction through crushing or dissolving, and common modes of administration, such as swallowing, snorting, and injecting. The first part of these studies has been completed, and the results confirmed our



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expectations with respect to Egalet-002's abuse-deterrent features. The second part will focus on extraction of the API from the product candidate when combined with various liquids. We intend to initiate the second part of these studies in the first quarter of 2014.

A tier 2 abuse deterrence study demonstrating the PK characteristics of manipulated Egalet-002 compared to manipulated OxyContin OP in 45 healthy subjects. We intend to commence enrollment for this study in the second quarter of 2014.

A tier 3 randomized, double-blind, placebo-controlled and comparator-controlled crossover abuse deterrence study to compare the likeability of Egalet-002 and OxyContin OP in 45 experienced abusers. We intend to commence enrollment for this study in the third quarter of 2014.

**Collaboration with Shionogi**

In November 2013, we entered into a collaboration and license agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. The collaboration allows Shionogi to develop and commercialize an abuse-deterrent single-agent hydrocodone product candidate and up to 20 different abuse-deterrent combination product candidates containing hydrocodone.

*Development and Commercialization.* Shionogi is responsible for all development and manufacturing activities related to the licensed product candidates under the agreement. If requested by Shionogi, we will perform, at Shionogi's expense, certain formulation and pre-clinical study activities for the licensed product candidates. In addition, at its own expense, Shionogi will be responsible for all regulatory filings for the licensed product candidates and for commercializing all licensed products resulting from the collaboration. The development of the licensed product candidates will be facilitated by a joint development committee comprised of equal numbers of representatives of the parties, with Shionogi having the right to make all decisions regarding the development, manufacturing and commercialization of the licensed product candidates.

Shionogi has the right to grant sublicenses in certain circumstances. In the event that Shionogi intends to grant a sublicense to commercialize the licensed product candidates, we have a right of first negotiation to obtain those commercialization rights, as long as specified terms and conditions are met.

*Additional Products.* For a period of six months after the effective date of the agreement, if requested by Shionogi, we have agreed to engage in an exclusive, good faith negotiation of a potential transaction in which Shionogi would receive an exclusive license to develop and commercialize an additional product candidate (other than a morphine- or oxycodone-based opioid) incorporating our technology. During these six months, we may not enter into or otherwise conduct negotiations with any third party for any license or other agreement with respect to any such product candidate. After this six-month period, for an additional period of 18 months, if Shionogi provides us with a proposal for any such additional product candidate, we have agreed to engage in the good faith negotiation, on a non-exclusive basis, of a potential transaction in which Shionogi would receive an exclusive license to such additional product candidate. During this eighteen-month period, we would not be prevented from negotiating a transaction for such additional product with a third party.

In addition, if we choose at any time during the term of the agreement to license to a third party a morphine- and/or oxycodone- based product candidate that incorporates our technology, such as Egalet-001 and Egalet-002, we will notify Shionogi, and Shionogi will have a one-time right to negotiate with us, for a period of 60 days, to obtain an exclusive license to such product candidate(s).

*Financial terms.* Under the terms of the agreement, we received an upfront payment of \$10.0 million. Shionogi has agreed, subject to specified conditions, to purchase \$15.0 million of our shares of common stock in a private placement concurrently with the closing of this offering, which is equal to 1,250,000



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shares. Following its investment, Shionogi will have the right to designate one non-voting observer to attend meetings of our board of directors.

We are eligible to receive regulatory milestone payments under the agreement as follows: (i) up to \$60.0 million upon successful achievement of specified regulatory milestones for the first licensed product candidate; (ii) up to \$42.5 million upon successful achievement of specified regulatory milestones for a defined combination product candidate; (iii) up to \$25.0 million upon successful achievement of specified regulatory milestones for a second product candidate (other than the defined combination product candidate); and (iv) up to \$12.5 million upon successful achievement of specified regulatory milestones for further product candidates. In addition, we are eligible to receive up to an aggregate of up to \$185.0 million based on successful achievement of specified net sales thresholds of licensed products.

If any products are approved for marketing, we are eligible to receive royalties at tiered, mid-single digit to low-teen percentage rates on net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the later of (i) expiration of all valid claims of the patent rights licensed to Shionogi that cover the manufacture, use, sale, offer for sale or importation of such licensed product in such country, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country, and (iii) the tenth anniversary of the date of first commercial sale of such licensed product in such country. These royalties may be reduced by Shionogi by certain specified percentages if a licensed product experiences generic competition, or if Shionogi determines it is required to in-license necessary third party intellectual property.

*Termination.* The agreement with Shionogi will remain in effect with respect to each licensed product and country until the expiration of the applicable royalty period for such licensed product in such country. Shionogi may terminate the agreement for convenience in its entirety or with respect to one or more licensed products upon 90 days written notice to us. Either we or Shionogi may terminate the agreement, in its entirety or with respect to one or more licensed products, if the other party is in material breach and fails to cure such breach within the specified cure period. Either we or Shionogi may terminate the agreement in the event of specified insolvency events involving the other party, and we may terminate the agreement in the event that Shionogi brings a challenge against us in relation to the licensed patents.

**Additional Product Candidates**

Our proprietary technology platform has the potential to become more broadly used with additional types of pharmaceutical products. We believe that the flexibility of our drug delivery systems can be applied to the administration of other classes of APIs, including combination products, where abuse deterrence or a specific release profile is desired.

Based on preclinical development we have performed, we intend to select a third abuse-deterrent, opioid product candidate, to be designated Egalet-003, based on a number of factors, including market opportunity and competitive dynamics. Once selected, we intend to initiate Phase 1 clinical trials in 2014 with this product candidate. We plan to also seek regulatory approval for this product candidate under the Section 505(b)(2) approval pathway.

Our technology can be used to develop combination products that include two APIs that can each be released at specific rates. We have developed prototypes, conducted feasibility studies and are exploring additional applications of our technology, both on our own and in collaboration with major pharmaceutical companies. In addition to our two lead product candidates, we believe that our technology also provides us with an opportunity to explore the development of abuse-deterrent forms of other types of pain medications, such as ER and IR hydromorphone, ER and IR hydrocodone, ER oxycodone and IR oxycodone.

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**Manufacturing**

*Overview*

Our product candidates are manufactured using our proprietary injection molding process in which the product is molded using pressure and heat. This process is reproducible, scalable and cost-efficient, and is commonly used in the manufacture of medical devices, including implants and diagnostics. We believe that we are the first company to combine standard pharmaceutical production with plastic injection molding to produce orally delivered pharmaceutical products.

To date, we have produced Egalet-001 and Egalet-002 for use in our clinical trials and preclinical studies at our facility in Vaerlose, Denmark. As we scale up production for later-stage clinical trials and potential commercialization, we have contracted with Halo Pharmaceutical, Inc., or Halo, a U.S.-based contract manufacturer, to supply the tablets necessary for the pivotal bioequivalence trials for Egalet-001 and the Phase 3 trials for Egalet-002. If Egalet-001 or Egalet-002 is approved by the FDA for marketing, we anticipate entering into a supply agreement with Halo for commercial production. We believe that Halo has an established record of manufacturing products approved in the United States, including controlled substances.

We have installed a commercial-scale injection molder, which we own, at Halo's manufacturing facility. We believe that this injection molding machine will be capable of manufacturing Egalet-001 and Egalet-002 tablets in quantities sufficient to meet what we believe will be our late-stage development and commercial needs.

*Drug Substances*

The APIs used in Egalet-001, morphine sulfate, and Egalet-002, oxycodone hydrochloride, are odorless white crystalline powders. We currently procure these APIs on a purchase order basis from a U.S.-based manufacturer, and we anticipate entering into commercial supply agreements with this manufacturer at a later date.

Both morphine sulfate and oxycodone hydrochloride are classified as narcotic controlled substances under U.S. federal law. We expect that Egalet-001 and Egalet-002 will be classified by the U.S. Drug Enforcement Administration, or DEA, as Schedule II controlled substances, meaning that these substances have the highest potential for abuse and dependence among drugs that are recognized as having an accepted medical use. Consequently, we expect that the manufacturing, shipping, dispensing and storing of our product candidates will be subject to a high degree of regulation, as described in more detail under the caption "Governmental Regulation DEA Regulation."

**Commercialization**

We intend to develop and commercialize Egalet-001, Egalet-002 and our other product candidates in the United States, while out-licensing commercialization rights for other regions. The members of our management team, who will lead the commercialization of Egalet-001 and Egalet-002, have substantial experience in sales and marketing based on their participation in the development and commercialization of pain and central nervous system drugs such as Opana, Zyprexa and Prozac.

We are continuing to develop our commercialization strategy with the input of key opinion leaders in the field of pain management, as well as healthcare practitioners and quality improvement organizations. We are conducting pre-commercialization activities for Egalet-001, such as developing positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies.

If Egalet-001 or Egalet-002 is approved for marketing in the United States, we intend to hire a dedicated field sales force, consisting of approximately 50 sales professionals, to target the approximately 5,000 board-certified pain management physicians in the United States, with core specialties focused in pain medicine, anesthesiology, physical medicine and rehabilitation. To supplement our internal sales force in

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the United States, we intend to contract with a third party to access sales representatives who target primary care and internal medicine physicians, which we believe will broaden our U.S. market coverage. We also expect to supplement our sales force with marketing programs and teams of healthcare professionals to support our formulary approval and customer education initiatives.

We will seek to license the development and commercial rights to our products outside the United States to a third-party organization that has an established track record of success in developing and commercializing pain products abroad. We expect that this organization would be responsible for any further development and commercialization of the products in those countries.

**Intellectual Property**

We regard the protection of patents, designs, trademarks and other proprietary rights that we own as critical to our success and competitive position. As of December 31, 2013, we owned five issued patents or allowed patent applications within the United States, and an additional 50 issued foreign patents covering our product candidates or technology platform. The terms of the five issued U.S. patents or allowed U.S. patent applications, extend to various dates between 2022 and 2030. Four of these issued U.S. patents or allowed U.S. patent applications provide protection related to the Egalet-002 composition of matter and the method of producing Egalet-002, and the fifth relates to a once-daily formulation of a different oxycodone-based product candidate. The term of our overall domestic and foreign patent portfolio related to our product candidates and technology platform, excluding possible patent extensions, extends to various dates between 2022 and 2033, if pending applications in each of our patent families issue as patents. As of December 31, 2013, we owned 9 pending patent applications under active prosecution in the United States, and an additional 22 pending foreign patent applications covering our product candidates and technology platform. We have one pending patent application in the United States and one pending foreign patent application relating to Egalet-001, three pending patent applications in the United States and four pending foreign patent applications relating to Egalet-002, and five pending patent applications in the United States and 17 pending foreign patent applications relating to our technology platform. The types of protection that may be afforded by any patents that may issue from these applications include, but are not limited to, composition of matter, process of manufacturing or method of use. Our patents provide protection in jurisdictions that include the United States, Canada, Europe, India, Hong Kong, Australia, New Zealand and Japan.

Our policy is to patent the technology, inventions and improvements that we consider important to the development of our business, but only in those cases in which we believe that the costs of obtaining patent protection is justified by the commercial potential of the technology, and typically only in those jurisdictions that we believe present significant commercial opportunities to us. Otherwise, we publish the invention such that it becomes prior art in order for us to secure freedom to operate and to prevent a third party from patenting the invention before us. Our technology and products are not in-licensed from any third party, and we own all of the rights to our product candidates.

We also rely on trademarks and trade designs to develop and maintain our competitive position. We have received trademark registration for Egalet® in the United States, Canada and the European Union.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and, in some cases, requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

In accordance with the provisions of Danish law related to inventions of employees, all of our employees located in Denmark are under an obligation to assign their rights to an invention to us upon request if the

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invention is made within the course of their employment by us. Pursuant to this legislation, we may be required to make a compensatory payment to the employee for the right to an invention. To date, we have not received any such claim for compensatory payment from any employee and we do not believe that any employee has any basis for such a claim.

**Competition**

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates include their degree of abuse deterrence, onset of action, bioavailability, therapeutic efficacy, and convenience of dosing and distribution, as well as their safety, cost and tolerability profiles. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Consequently, our competitors may develop abuse-deterrent products for the treatment of moderate to severe pain or for other indications we may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

Although we believe that the abuse-deterrent technology utilized in Opana ER has been tested by others with additional API classes, we are not aware of any current development programs by the manufacturers of either Opana ER or OxyContin OP for their respective abuse-deterrent technologies with respect to the administration of other classes of API for additional product candidates, including combination products.

In addition to the specific alternatives to our product candidates described below, our product candidates also face competition from commercially available generic and branded long-acting opioid drugs other than morphine or oxycodone, including fentanyl, hydromorphone, oxymorphone and methadone, as well as opioids that are currently in clinical development.

***Egalet-001***

If approved, Egalet-001 would compete against branded and generic, long-acting morphine products labeled for the treatment of moderate to severe pain. These existing products include Pfizer's Avinza, Actavis' Kadian, Purdue's MS-Contin, and generic morphine products produced by Actavis, Mallinckrodt, Rhoades Pharmaceuticals, Mylan and Endo. There are currently no commercially available abuse-deterrent morphine products. Pfizer's Embeda was the only previously approved morphine product with abuse-deterrent features, but it was withdrawn from the market in February 2011. However, it is possible that Pfizer will reintroduce Embeda to the market.

We are currently unaware of any abuse-deterrent morphine products in clinical development. However, any company that has developed an abuse-deterrent technology could initiate an abuse-deterrent morphine program at any time.

***Egalet-002***

If approved, Egalet-002 would compete directly against Purdue's OxyContin OP for the treatment of patients experiencing moderate to severe pain. Although no generic oxycodone products are currently commercially available, it is possible that a generic formulation with abuse-deterrent features could be developed to mirror OxyContin OP, in which case Egalet-002 would compete with any such generic oxycodone products.

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Additionally, we are aware of companies in late-stage development of abuse-deterrent oxycodone product candidates, including Pfizer's Remoxy® and ALO-02 and Collegium's COL-003®. If these products are successfully developed and approved for marketing, they could represent significant competition for Egalet-002. It is also possible that a company that has developed an abuse-deterrent technology could initiate an abuse-deterrent oxycodone program at any time.

**Government Regulation**

***FDA Approval Process***

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

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Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding \$2,169,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding \$104,000 per product and \$554,000 per establishment in 2014. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for standard review drug products are reviewed within 12 months; most applications for priority review drugs are reviewed in six to eight months. The FDA can extend these reviews by three months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee typically a panel that includes clinicians and other experts for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

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An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

***Post-Approval Requirements***

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. In addition, other regulatory action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, civil penalties, and criminal prosecution.

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or PDMA, imposes certain recordkeeping and reporting requirements and other limitations on the distribution of drug samples to physicians. The PDMA also requires that state licensing of distributors who distribute prescription drugs meet certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA and a growing majority of states also impose certain drug pedigree requirements on the sale and distribution of prescription drugs. The PDMA sets forth civil and criminal penalties for violations. In 2010, a statutory provision was enacted that required manufacturers and authorized distributors of record to report on an annual basis certain information about prescription drug samples they distributed. The FDA issued a draft compliance policy guide on the reporting requirement. The FDA stated that it would exercise enforcement discretion with regard to companies that have not submitted reports until the FDA finalizes the reporting requirement and/or provides notice that it is revising its exercise of enforcement discretion.

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***The Hatch-Waxman Amendments***

*Orange Book Listing*

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

*Exclusivity*

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug or any Section 505(b)(2) NDA, discussed in more detail below, that relies on the FDA's findings regarding that drug. A drug may obtain a three-year period of exclusivity for a change to the drug, such as the addition of a new indication to the labeling or a new formulation, during which FDA cannot approve an ANDA or any Section 505(b)(2) NDA, if the supplement includes reports of new clinical studies (other than bioavailability studies) essential to the approval of the supplement.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.



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*Section 505(b)(2) NDAs*

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and effectiveness in the approval of a similar product or published literature in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings of safety and effectiveness for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. As with traditional NDAs, a Section 505(b)(2) NDA may be eligible for three-year marketing exclusivity, assuming the NDA includes reports of new clinical studies (other than bioavailability studies) essential to the approval of the NDA.

**REMS**

The FDA has the authority to require a REMS to ensure the safe use of the drug. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. The requirement for a REMS can materially affect the potential market and profitability of a drug.

In February 2009, the FDA informed drug manufacturers that it will require a REMS for sustained release opioid drug products. Subsequently, the FDA initiated efforts to develop a new standardized REMS for these opioid medications to ensure their safe use. Extended-release formulations of morphine, oxycodone, and hydrocodone would be required to have a REMS.

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***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

***DEA Regulation***

Our product candidates, Egalet-001 and Egalet-002, if approved, will be regulated as "controlled substances" as defined in the CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution, importation, exportation and other requirements administered by the DEA. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Schedule II drugs are those that meet the following characteristics:

high potential for abuse;

currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and

abuse may lead to severe psychological or physical dependence.

We expect that Egalet-001, an abuse-deterrent morphine, and Egalet-002, an abuse-deterrent oxycodone, will be listed by the DEA as a Schedule II controlled substance under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of the products will be subject to a high degree of regulation. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special permits and notification requirements apply to imports and exports of narcotic drugs.

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In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Because Egalet-001 and Egalet-002 are expected to be regulated as a Schedule II controlled substance, they will be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much morphine and oxycodone may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of opioids that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including morphine sulfate and oxycodone hydrochloride for use in manufacturing Egalet-001 and Egalet-002 respectively. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our, or our contract manufacturers', quota of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay, limitation or refusal by the DEA in establishing our, or our contract manufacturers', quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances. We and our contract manufacturers will be subject to state regulation on distribution of these products.

***International Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval and, if applicable, DEA classification. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Many foreign countries are also signatories to the internal drug control treaties and have implemented regulations of controlled substances similar to those in the United States. Our products will be subject to such regulation which may impose certain regulatory and reporting requirements and restrict sales of these products in those countries.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within

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90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of other foreign regulations governing, among other things, the conduct of clinical trials, pricing and reimbursement and commercial distribution of our products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***Other Healthcare Laws and Compliance Requirements***

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of HHS, (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with fraud and abuse laws such as the federal Anti-Kickback Statute, the federal False Claims Act, as amended and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The federal Anti-Kickback Statute prohibits any person, including a prescription drug manufacturer, or a party acting on its behalf, from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on one hand, and prescribers, purchasers, and formulary managers, on the other. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. The reach of the federal Anti-Kickback Statute was broadened by the recently enacted Affordable Care Act, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs in at least some cases, and do not contain safe harbors.

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The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The "*qui tam*" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare numbers when detailing the provider of services, improper promotion of off-label uses not expressly approved by FDA in a drug's label, and allegations as to misrepresentations with respect to the services rendered. Our future activities relating to the reporting of discount and rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance. Also, HIPAA created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA and its implementing regulations established uniform standards for certain "covered entities," which are healthcare providers, health plans and healthcare clearinghouses, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Additionally, new requirements under the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations that manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to HHS information related to "payments or other transfers of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and that manufacturers and applicable group purchasing organizations report annually to the HHS ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection required beginning August 1, 2013, reporting to the Centers for Medicare & Medicaid Services, or CMS, required by March 31, 2014 (and by the 90th day of

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each subsequent calendar year), and disclosure of such information to be made on a publicly available website beginning in September 2014.

There are also an increasing number of state "sunshine" laws that require manufacturers to file reports with states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives. Such legislation also prohibits pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing and prohibits certain other sales and marketing practices. In addition, beginning in 2013, a similar federal requirement will require manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians, other healthcare professionals and teaching hospitals, as well as ownership or investment interests held by physicians and their immediate family members. The federal government will disclose the reported information on a publicly available website beginning in 2014. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private *qui tam* actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

***Third-Party Payor Coverage and Reimbursement***

The commercial success of our product candidates, if and when approved, will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

The cost of pharmaceuticals and devices continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict

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whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

***Healthcare Reform***

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. The Medicare Modernization Act imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In March 2010, the Affordable Care Act was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and biotechnology industry are the following:

an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;

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an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a licensure framework for follow-on biologic products;

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

new requirements under the federal Open Payments program for drug manufacturers to report information related to payments and other transfers of value made to physicians and other healthcare providers as well as ownership or investment interests held by physicians and their immediate family members;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and

establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse



effect on our customers and accordingly, our financial operations.

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***Other Regulatory Requirements***

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

**Legal Proceedings**

There is no litigation currently pending or threatened against us or any of our officers or directors in their capacity as such.

**Facilities**

Our corporate headquarters are located in Wayne, Pennsylvania, where we lease 3,190 square feet of office space under a lease agreement that expires in November 2016 unless earlier terminated. We also lease 255 square feet of office space in Malvern, Pennsylvania under a lease agreement that automatically renews every six months (currently through March 2014 unless earlier terminated). We maintain a research laboratory and pilot manufacturing and administrative facility in Vaerloose, Denmark, where we lease 7,610 square feet of space under a lease agreement that automatically renews every 12 months (currently through August 2014 unless earlier terminated).

We believe that our existing facilities are adequate for our current and expected future needs. We may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe that appropriate alternative space is readily available on commercially reasonable terms.

**Employees**

As of September 30, 2013, we had a total of 18 full-time employees and two part-time employees. Of these, 12 are engaged in full-time research and development activities. Substantially all of our employees are located in Denmark. According to the Danish Salaried Act, Danish employees have the right to be represented by a labor union, although none are currently represented by a union. We consider our employee relations to be good.

Table of Contents**MANAGEMENT****Executive Officers, Directors and Director Nominees**

The following table sets forth the name, age and position(s) of each of our directors, director nominees and executive officers, including their ages as of December 31, 2013:

| <b>Name</b>             | <b>Age</b> | <b>Position(s)</b>                              |
|-------------------------|------------|---|
| Robert Radie            | 50         | Director, President and Chief Executive Officer |
| Jean-François Formela   | 57         | Chairman of the Board of Directors              |
| Andreas Rutger Segerros | 53         | Director  |
| Renee Aguiar-Lucander   | 51         | Director  |
| Andrey Kozlov           | 38         | Director  |
| Gregory Weaver          | 57         | Director  |
| Stan Musial             | 52         | Chief Financial Officer                         |
| Karsten Lindhardt       | 41         | Vice President, Research and Development        |
| Mark Strobeck           | 43         | Chief Business Officer                          |

**Robert Radie.** Mr. Radie is our President and Chief Executive Officer and a member of our 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.

Our board of directors believes Mr. Radie's perspective and experience as our President and Chief Executive Officer, as well as his depth of operating and senior management experience in our industry and educational background, provide him with the qualifications and skills to serve as a director.

**Renee Aguiar-Lucander.** Ms. Aguiar-Lucander has been a member of our board of directors since our inception in July 2010 and served as chair from that time until March 2012. Since January 2009, Ms. Aguiar-Lucander has been a partner of Omega Fund Management, a venture capital fund focused on healthcare investments. From 2005 to 2009, she was a partner in the venture capital team of 3i Group plc, a private equity and venture capital firm. While with 3i Group, Ms. Aguiar-Lucander also was a member of the venture capital division's investment committee and a senior member of the European portfolio management team with a focus on healthcare assets. From 2003 to 2005, Ms. Aguiar-Lucander served as an advisor for private equity funds and from 2000 to 2003, she was a managing director in corporate finance with Lehman Brothers, focusing primarily on the technology, media and communications sectors. Prior to joining Lehman Brothers, Ms. Aguiar-Lucander worked for Deutsche Bank and Alex Brown & Sons, both in the United States and in Europe, focusing on mergers and acquisitions and private and public capital raising for growth companies. Ms. Aguiar-Lucander currently serves on the board of NsGene A/S and Spinevision S.A., two privately held Omega portfolio companies. Ms. Aguiar-Lucander has a bachelor's degree in finance from the Stockholm School of Economics and a M.B.A. from INSEAD.

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Our board of directors believes Ms. Aguiar-Lucander's perspective and experience from healthcare investing combined with her banking background provides her with the qualifications and skills to serve as a director.

**Andreas Rutger Segerros.** Mr. Segerros has served as a member of our board since February 2011. He is currently a partner in the life sciences group of Sunstone Capital, a venture capital firm focused on life sciences and technology, which he joined in January 2012 after having advised the group since April 2011 as a venture partner. Before joining Sunstone Capital, Mr. Segerros served as head of Corporate Development and Operations Planning at Ferring Pharmaceuticals S.A., a specialty pharmaceutical company, from October 2005 to March 2011. Prior to joining Ferring, Mr. Segerros held a number of executive positions in the U.S., Japan and corporate offices of Pharmacia, a pharmaceutical company, including as Vice President and Global Head of the Ophthalmology Division. Mr. Segerros holds an M.Sc. from the Royal Institute of Technology in Stockholm, and an M.B.A. from the University of Uppsala.

Our board of directors believes Mr. Segerros's perspective and experience as a global pharmaceutical executive in marketing and business development, as well as his educational background, provides him with the qualifications and experience to serve as a director.

**Jean-François Formela.** Dr. Formela has served as a member of our board of directors since September 2010 and has served as chair since March 2012. He is currently a partner in the life sciences group of Atlas Venture, an early stage venture capital firm focused on investments in biological and drug discovery technologies, and has served in such capacity since joining Atlas Venture in 1993. Dr. Formela currently serves on the board of directors of Horizon Pharma, Inc., a publicly held life sciences company. He is also the chairman of the board of directors of RaNA Therapeutics, Inc., which he co-founded, and serves on the board of directors of the following privately held companies: Annovation Biopharma, Inc., Arteaus Therapeutics, LLC and F-star Biotechnology Limited. Within the last five years, Dr. Formela has also served on the boards of directors of the following public companies: ARCA biopharma, Inc. and Achillon Pharmaceuticals, Inc. Prior to joining Atlas Venture, Dr. Formela served as a senior director of medical marketing and scientific affairs at Schering-Plough Corporation, a pharmaceutical company which merged with Merck & Co., Inc.. Dr. Formela began his career as a medical doctor and practiced emergency medicine at Necker University Hospital in Paris. Dr. Formela is a member of the Massachusetts General Hospital Research Advisory Council and a trustee of the Boston Institute of Contemporary Art. He received his M.D. from the Paris University School of Medicine and his M.B.A. from Columbia University.

Our board of directors believes Dr. Formela's perspective and experience as an investor and board member in the life sciences industry, as well as his medical practice, combined with his educational background, provides him with the qualifications and skills to serve as a director.

**Andrey Kozlov.** Mr. Kozlov has served as a member of our board of directors since April 2012. He currently is a director at Enso Ventures Ltd., a private investment and project management company specializing in high-technology and biotech companies, and has served in such capacity since March 2013. From June 2009 to February 2013, Mr. Kozlov served in a number of capacities with CLS Capital, Ltd., a private investment company, including as a director from August 2010 to February 2013. Prior to joining CLS Capital, Mr. Kozlov served as an associate in HSBC Global Banking's mergers and acquisitions advisory department from July 2008 to June 2009. Mr. Kozlov received a graduate degree in economics from St. Petersburg State University and an M.B.A. from the University of Chicago Booth School of Business.

Our board of directors believes Mr. Kozlov's perspective and experience as a director of our company and other companies, as well as his educational background, provide him with the qualifications and skills to serve as a director.

**Gregory Weaver.** Mr. Weaver has agreed to join our board of directors effective as of the date of the listing of our common stock on the NASDAQ Global Market. Since September 2013, Mr. Weaver has served as

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the Chief Financial Officer, Senior Vice President, Treasurer and Corporate Secretary of Fibrocell Science, Inc., a publicly held cell therapy company. From June 2011 to July 2013, Mr. Weaver served as Senior Vice President and Chief Financial Officer of Celsion Corporation, a publicly held biotechnology company, and was a director and chairman of the audit committee of Celsion's Board of Directors from 2005 to 2011. From February 2009 to September 2010, Mr. Weaver served as Senior Vice President and Chief Financial Officer of Poniard Pharmaceuticals, a public oncology drug development company. From February 2007 to February 2009, Mr. Weaver served as Chief Financial Officer of Talyst, Inc., a privately-held pharmacy information product company. In 2006 and 2007, he served as Senior Vice President and Chief Financial Officer of Sirna Therapeutics, a public RNA therapeutics company until it was acquired by Merck & Co., Inc. in December 2006. From 2002 to 2005, Mr. Weaver was Chief Financial Officer of Nastech Pharmaceuticals, a public drug delivery company. From 1999 to 2002, Mr. Weaver was Chief Financial Officer of Ilex Oncology Inc., a public oncology drug development company, and from 1996 to 1999, he was Chief Financial Officer of Prism Technologies, a privately-held medical device company. Prior to that, Mr. Weaver held increasingly senior positions with Fidelity Capital and Arthur Andersen LLP. Mr. Weaver currently serves on the board of directors and audit committee of Atossa Genetics, a publicly held diagnostics company, and also served as a director and chairman of the audit committee of SCOLR Pharmaceuticals, a public drug delivery company, from 2007 to 2009. Mr. Weaver is a certified public accountant and received an M.B.A. from Boston College and a B.S. in accounting from Trinity University.

Our board of directors believes Mr. Weaver's perspective and experience in senior management positions with drug development companies, as well as his educational background, provide him with the qualifications and skills necessary to serve as a director.

**Stan Musial.** Mr. Musial has served as our 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.

**Karsten Lindhardt, Ph.D.** Dr. Lindhardt has served as our Vice President, Research and Development since April 2011 and previously served as our 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 our predecessor Egalet A/S, and as a Project Manager from March 2008 to August 2008. Before joining Egalet A/S, Dr. Lindhardt served in management positions for Curalogic A/S, 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.** Dr. Strobeck is our Chief Business Officer, a position he has held since January 2014, and previously served as an adviser to Egalet from June 2012 to December 2013. From January 2012 to December 2013, Dr. Strobeck served as President and Chief Executive Officer and a director of Corridor Pharmaceuticals, Inc. From December 2010 to October 2011, Dr. Strobeck served as Chief Business Officer of Topaz Pharmaceuticals Inc., a specialty pharmaceutical company acquired by Sanofi Pasteur in the fourth quarter of 2011. From June 2010 to November 2010 and October 2011 to January 2012, Dr. Strobeck worked as a consultant. From January 2008 to May 2010, Dr. Strobeck served as Chief Business Officer of Trevena, Inc., a pharmaceutical company. Prior to joining Trevena, Dr. Strobeck held management roles at GlaxoSmithKline, SR One Limited and EuclidSR Partners, L.P. Dr. Strobeck

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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.

**Key Consultant**

***Roland Gerritsen van der Hoop, MD, Ph.D.*** Dr. Gerritsen van der Hoop currently serves as our Chief Medical Officer. As a consultant to our company, Dr. Gerritsen van der Hoop is overseen directly by Mr. Radie, our Chief Executive Officer, and does not perform a policy making-function for us. 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.

**Board Composition**

Our board of directors currently consists of six members. Gregory Weaver joined our board of directors effective as of the date of this prospectus. In accordance with our amended and restated certificate of incorporation to be in effect upon the consummation of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the consummation of this offering, our directors will be divided among the three classes as follows:

the Class A directors will be Andrey Kozlov and Andreas Rutger Segerros and their terms will expire at the annual meeting of stockholders to be held in 2014;

the Class B directors will be Jean-Francois Formela and Renee Aguiar-Lucander and their terms will expire at the annual meeting of stockholders to be held in 2015; and

the Class C directors will be Gregory Weaver and Robert Radie and their terms will expire at the annual meeting of stockholders to be held in 2016.

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company.

**Board Committees and Director Independence**

Upon the listing of our common stock on the NASDAQ Global Market, our board of directors will establish audit, compensation committees. Our audit committee will consist of Gregory Weaver, Andrey Kozlov and Renee Aguiar-Lucander with Mr. Weaver serving as chair. Our compensation committee will consist of Jean-Francois Formela and Andreas Rutger Segerros with Mr. Formela serving as chair. Our nominating and corporate governance committee will consist of Jean-Francois Formela and Renee Aguiar-Lucander with Ms. Aguiar-Lucander serving as chair.

Our board of directors has undertaken a review of the independence of our directors and has determined that all directors except Mr. Radie are independent within the meaning of Section 5605(a)(2)

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of the NASDAQ Stock Market listing rules and that Messrs. Weaver and Kozlov and Ms. Aguiar-Lucander meet the additional tests for independence for audit committee members imposed by Rule 10A-3 under the Securities Exchange Act of 1934 and Section 5605(c)(2)(A) of the NASDAQ Stock Market listing rules. Mr. Radie is not an independent director under these rules because he is our Chief Executive Officer.

**Audit Committee**

The primary purpose of our audit committee will be to assist the board of directors in the oversight of the integrity of our accounting and financial reporting process, the audits of our consolidated financial statements, and our compliance with legal and regulatory requirements. The functions of our audit committee will include, among other things:

hiring the independent registered public accounting firm to conduct the annual audit of our consolidated financial statements and monitoring its independence and performance;

reviewing and approving the planned scope of the annual audit and the results of the annual audit;

pre-approving all audit services and permissible non-audit services provided by our independent registered public accounting firm;

reviewing the significant accounting and reporting principles to understand their impact on our consolidated financial statements;

reviewing our internal financial, operating and accounting controls with management and our independent registered public accounting firm;

reviewing with management and our independent registered public accounting firm, as appropriate, our financial reports, earnings announcements and our compliance with legal and regulatory requirements;

reviewing potential conflicts of interest under and violations of our Code of Conduct;

establishing procedures for the treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and confidential submissions by our employees of concerns regarding questionable accounting or auditing matters;

reviewing and approving related-party transactions; and

reviewing and evaluating, at least annually, our audit committee's charter.

With respect to reviewing and approving related-party transactions, our audit committee will review related-party transactions for potential conflicts of interests or other improprieties. Under SEC rules, related-party transactions are those transactions to which we are or may be a party in which the amount involved exceeds \$120,000, and in which any of our directors or executive officers or any other related person had or will have a direct or indirect material interest, excluding, among other things, compensation arrangements with respect to employment and board membership. Our audit committee could approve a related-party transaction if it determines that the transaction is in our best interests. Our directors will be required to disclose to this committee or the full board of directors any potential conflict of interest or personal interest in a transaction that our board is considering. Our executive officers will be required to disclose any potential conflict of interest or personal interest in a transaction to the audit committee. We also plan to poll our directors and executive officers on an annual basis with respect to related-party transactions and their service as an officer or director of other entities. Any director involved in a related-party transaction that is being reviewed or approved must recuse himself or herself from participation in any related deliberation or decision. Whenever possible, the transaction should be approved in advance and if not approved in advance, must be submitted for ratification as promptly as practical.





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The financial literacy requirements of the SEC require that each member of our audit committee be able to read and understand fundamental financial statements. Our board of directors has determined that each member of our audit committee qualifies as an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities Act, and has financial sophistication in accordance with the NASDAQ Stock Market listing rules.

Our board of directors has adopted a charter for the audit committee that complies with NASDAQ Stock Market listing rules. The charter will be available on our website at [www.egalet.com](http://www.egalet.com).

**Compensation Committee**

The primary purpose of our compensation committee will be to assist our board of directors in exercising its responsibilities relating to compensation of our executive officers and employees and to administer our equity compensation and other benefit plans. In carrying out these responsibilities, this committee will review all components of executive officer and employee compensation for consistency with its compensation philosophy, as in effect from time to time. The functions of our compensation committee will include, among other things:

designing and implementing competitive compensation policies to attract and retain key personnel;

reviewing and formulating policy and determining the compensation of our executive officers and employees;

reviewing and recommending to our board of directors the compensation of our directors;

administering our equity incentive plans and granting equity awards to our employees and directors under these plans;

if required from time to time, reviewing with management our disclosures under the caption "Compensation Discussion and Analysis" and recommending to the full board its inclusion in our periodic reports to be filed with the SEC;

if required from time to time, preparing the report of the compensation committee to be included in our annual proxy statement;

engaging compensation consultants or other advisors it deems appropriate to assist with its duties; and

reviewing and evaluating, at least annually, our compensation committee's charter.

Our board of directors has adopted a charter for the compensation committee that complies with NASDAQ Stock Market listing rules. The charter will be available on our website at [www.egalet.com](http://www.egalet.com).

**Nominating and Corporate Governance Committee**

The primary purpose of our nominating and corporate governance committee will be to assist our board of directors in promoting the best interest of our company and our stockholders through the implementation of sound corporate governance principles and practices. The functions of our nominating and corporate governance committee will include, among other things:

identifying, reviewing and evaluating candidates to serve on our board;

determining the minimum qualifications for service on our board;

developing and recommending to our board an annual self-evaluation process for our board and overseeing the annual self-evaluation process;

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developing, as appropriate, a set of corporate governance principles, and reviewing and recommending to our board any changes to such principles; and

periodically reviewing and evaluating our nominating and corporate governance committee's charter.

Our board of directors has adopted a charter for the nominating and corporate governance committee that complies with NASDAQ Stock Market listing rules. The charter will be available on our website at [www.egalet.com](http://www.egalet.com).

**Code of Business Conduct and Ethics for Employees, Executive Officers and Directors**

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct will be available on our website at [www.egalet.com](http://www.egalet.com). The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers or directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

**Compensation Committee Interlocks and Insider Participation**

No member of our compensation committee has ever been an executive officer or employee of ours. None of our officers currently serves, or has served during the last completed year, on the compensation committee or board of directors of any other entity that has one or more officers serving as a member of our board of directors or compensation committee.

Table of Contents**EXECUTIVE AND DIRECTOR COMPENSATION****Summary Compensation Table**

The following table sets forth information for the fiscal years ended December 31, 2013 and 2012 concerning compensation of our principal executive officer and our only other executive officers who served as an executive officer at any time during the year ended December 31, 2013. We refer to these three executives as our named executive officers.

| <b>Name and Principal Position</b>                | <b>Year</b> | <b>Salary<br/>(\$)</b> | <b>Bonus<br/>(\$)</b> | <b>All Other<br/>Compensation<br/>(\$)</b> | <b>Total<br/>(\$)</b> |
|---|-------------|------------------------|-----------------------|--|-----------------------|
| Robert Radie                                      | 2013        | 325,000                | 130,000               |  | 455,000               |
| <i>President and Chief Executive Officer</i>      | 2012        | 264,845                | 100,000(1)            | 2,475                                      | 367,320               |
| Stan Musial(2)                                    | 2013        | 173,333                | 54,000                |  | 227,333               |
| <i>Chief Financial Officer</i>                    |             |                        |                       |  |                       |
| Karsten Lindhardt, Ph.D.                          | 2013        | 187,159                | 28,074(1)             | 18,036(3)                                  | 233,269               |
| <i>Vice President of Research and Development</i> | 2012        | 175,026                | 27,450(1)             | 17,376(3)                                  | 219,852               |

(1) Represents discretionary annual bonus amounts paid to each officer that were determined by Egalet UK's compensation committee.

(2) Mr. Musial joined our company and became an executive officer in April 2013.

(3) Consists of amounts contributed as part of the Danish labor market supplementary pension on behalf of Dr. Lindhardt.

**Employment Agreements**

We have entered into employment agreements with Mr. Radie, our President and Chief Executive Officer, Mr. Musial, our Chief Financial Officer, Dr. Strobeck, our Chief Business Officer, and Dr. Lindhardt, our Vice President of Research and Development, in substantially the forms attached as exhibits to the registration statement of which this prospectus forms a part.

*Employment Agreements with Messrs. Radie, Musial and Strobeck*

The term of employment for Messrs. Radie, Musial and Strobeck under their employment agreements will continue until the executive's employment with our company terminates for any reason. Each employment agreement sets forth the executive's annual base salary and target bonus opportunity as well as the executive's right to participate in our company's employee benefits plans, programs and arrangements. Mr. Radie's annual base salary will be \$410,000, Mr. Musial's annual base salary will be \$300,000 and Dr. Strobeck's annual base salary will be \$300,000, in each case subject to annual review and increase at the discretion of the board. Dr. Strobeck also received a signing bonus of \$50,000. Mr. Radie will have an annual target bonus opportunity equal to 40% of his annual base salary and Messrs. Musial and Strobeck will have annual target bonus opportunities equal to 30% of their respective annual base salaries. The executives' annual bonus opportunities will be subject to the terms and conditions of our Annual Incentive Bonus Plan, as described in greater detail below. The executives must be employed by us on the payment date in order to be paid any such bonus except as otherwise described below in the section entitled "Potential Payments Upon a Termination or Change in Control." Each employment agreement also provides for additional payments and benefits to be made in connection with the executive's termination of employment, as described below in the section entitled "Potential Payments upon a Termination or Change in Control." Each employment agreement provides that during the term of employment and for a period of 12 months thereafter (24 months if we terminate the executive's employment without cause or the executive terminates his employment for good reason, in either case, within 24 months following a change in control), the executive will not compete with our company or solicit our customers or employees. Each employment agreement also contains provisions requiring the executive

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to safeguard our company's confidential information and to assign to our company any intellectual property developed by the executive during his employment by our company.

*Employment Agreement with Dr. Lindhardt*

The term of employment under Dr. Lindhardt's employment agreement shall continue until the last day of the month in which he reaches the age of 70, unless terminated earlier as hereinafter provided. Dr. Lindhardt's employment may be terminated by us without cause with 12 months' prior written notice (24 months in the case of a notice of termination without cause delivered within 24 months following a change in control) or by Dr. Lindhardt with six months' prior written notice. We may also terminate Dr. Lindhardt's employment for cause without notice and with one month's notice if Dr. Lindhardt has been unable to work due to sickness for a total of 120 days during any 12 month period. Dr. Lindhardt's employment agreement sets forth his annual base salary, target bonus opportunity and other benefits. Dr. Lindhardt's annual base salary will be approximately \$225,000 (converted from Danish krone), subject to annual review. Dr. Lindhardt will have an annual target bonus opportunity equal to 30% of his annual base salary. Dr. Lindhardt must be employed by us on the payment date in order to be paid any such bonus, except as otherwise described below in the section entitled "Potential Payments upon a Termination or Change in Control." Dr. Lindhardt will also participate in a general pension scheme to which we will contribute an amount equal to ten percent of his annual base salary. Dr. Lindhardt's employment agreement provides that, during the term of his employment and any applicable notice period, Dr. Lindhardt will observe a duty of loyalty to us that prohibits him from, among other things, directly or indirectly competing with us. Dr. Lindhardt's employment agreement also contains provisions requiring him to safeguard our confidential information and to assign to us any intellectual property developed by him during his employment by us.

**Equity Award Agreements**

Upon the consummation of this offering, we intend to grant each of Mr. Radie, Mr. Musial, Dr. Lindhardt and Dr. Strobeck equity awards equal to 445,200, 139,200, 139,200 and 139,200 shares, respectively, of our common stock. Such equity will be granted pursuant to restricted stock award agreements in substantially the forms attached as exhibits to the registration statement of which this prospectus forms a part. Subject to the executive's continued employment with us on the applicable vesting date (except as otherwise described below in the section entitled "Potential Payments Upon a Termination or Change in Control") (i) 50% of Mr. Radie's equity grant, 25% of Mr. Musial's equity grant and 25% of Dr. Strobeck's equity grant will vest upon the date on which the post-IPO lockup period terminates, with 6.25% of Mr. Radie's, Mr. Musial's and Dr. Strobeck's equity grants vesting thereafter on the last day of each calendar quarter following the calendar quarter in which such lock-up period ends until such equity is fully vested, and (ii) 100% of Dr. Lindhardt's equity grant will vest in full upon the third anniversary of the grant date.

Each of Mr. Radie, Mr. Musial, Dr. Strobeck and Dr. Lindhardt intend to enter into Rule 10b5-1 trading plans upon the consummation of this offering, pursuant to which they will be able to sell up to 40% of the shares that vest on each particular vesting date of the restricted stock awards described above, in order to pay a portion of the income taxes incurred upon vesting of the restricted stock award.

**Potential Payments Upon a Termination or Change in Control**

Under the terms of their restricted stock award agreements, 100% of the unvested portion of each executive's restricted stock grant will vest upon the consummation of a change in control. In addition, if the employment of Mr. Radie, Mr. Musial or Dr. Strobeck is terminated by us without cause (other than due to the executive's death or disability), the portion of the restricted stock, if any, that, but for such termination, would have vested on the last day of the calendar quarter in which such termination occurs will vest on the executive's termination date, and, unless otherwise required by applicable law, if Dr. Lindhardt's employment is terminated for any reason, he will forfeit the unvested portion of his restricted stock.

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Under the terms of their employment agreements, Mr. Radie, Mr. Musial and Dr. Strobeck are also entitled to payments and benefits in connection with the termination of their employment with us under specified circumstances. Upon the termination of the executive's employment for any reason, we will pay the executive or the executive's estate, as applicable, the executive's accrued but unpaid base salary and accrued but unused vacation time. If the executive's employment is terminated due to death or disability, we will also pay the executive any bonus earned but not paid under the Annual Incentive Bonus Plan for the preceding fiscal year. In addition, if the executive's employment is terminated by us without cause, but not due to the executive's death or disability, or by the executive for good reason, then we will pay the executive any bonus earned by not paid under the Annual Incentive Bonus Plan for the preceding fiscal year and, subject to the executive's execution of a general release of claims and his continued compliance with the restrictive covenants described above, we will continue to pay the executive his annual base salary for a period of 12 months (24 months if such termination occurs within 24 months following a change in control) and we will reimburse the executive for the costs of continued health coverage for himself and his eligible dependents under COBRA or a private health insurance policy, less the amount that, absent such termination, the executive would have been required to pay for such coverage under our health plan. Such payments will continue for 12 months (24 months if such termination occurs within 24 months following a change in control) or, if earlier, until the executive becomes eligible for coverage under another medical plan. The executive will also be entitled to any stock-based compensation due to the executive pursuant to any written agreement with the company, on the terms and conditions set forth therein.

Under the terms of his employment agreement, Dr. Lindhardt is entitled to 12 months' prior written notice if his employment is terminated by us without cause (24 months' prior written notice if such termination occurs within 24 months following a change in control) and one month's prior written notice if his employment is terminated by us for sickness, as described above in greater detail. In addition, Dr. Lindhardt must provide us with six months' prior written notice to voluntarily terminate his employment. During the applicable notice period, we will continue to pay Dr. Lindhardt all amounts due under his employment agreement, and Dr. Lindhardt's restricted stock award will continue to vest.

**Outstanding Equity Awards at Fiscal Year-End**

None of our named executive officers had any equity awards outstanding as of December 31, 2013.

**Incentive Plans**

We believe that annual cash bonuses are an appropriate way to reward our named executive officers for superior performance and to align the interests of our named executive officers with our stockholders by tying a portion of their compensation to the achievement of company and individual performance goals. Therefore, after the consummation of this offering we intend to pay annual cash bonuses to our named executive officers pursuant to the terms and conditions of an Annual Incentive Bonus Plan, or the AIP, which our board of directors has adopted. The AIP will become effective upon the consummation of this offering.

**Eligibility.** All employees of our company, our subsidiaries and our affiliates are eligible to participate in the AIP.

**Administration.** The AIP will be administered by the compensation committee of our board of directors or a subcommittee thereof that will be composed of two or more non-employee directors who are "outside directors" within the meaning of Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code. The committee will have the authority to (i) select employees to participate in the AIP; (ii) establish and administer the performance goals and the incentive bonus opportunities applicable to each participant and certify whether the performance goals have been attained; (iii) construe and interpret the AIP and any agreement or instrument entered into under or in connection with the AIP; (iv) establish, amend, and waive rules and regulations for the AIP's administration; and (v) make all other determinations that may be necessary or advisable for the administration of the AIP. Any determination by the committee with

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respect to the AIP will be final, binding and conclusive on all employees and participants, as well as anyone claiming any rights under or through them.

***Incentive Cash Bonus Opportunities.*** The AIP provides for the payment of incentive cash bonuses based on the achievement of predetermined performance goals during a specified performance period. The compensation committee may structure incentive bonuses to qualify for the exemption for performance-based compensation to the limitations on the deductibility of compensation in excess of \$1,000,000 paid to certain of our executive officers under Section 162(m) of the Code, which is referred to as a qualified incentive bonus; however, the committee retains the discretion to pay incentive bonuses that are not fully deductible under Section 162(m) of the Code. The maximum aggregate amount of compensation that may be paid to a participant in any fiscal year pursuant to a qualified incentive bonus is \$2,000,000.

***Performance Goals.*** All incentive bonuses granted under the AIP will be subject to performance goals that must be met by the end of a performance period specified by the committee, but that are substantially uncertain to be met at the time such goals are established, and that must be based upon any one or more of the following measures as they relate to our company, our subsidiaries or affiliates, or any business unit or department thereof: (i) stock price, (ii) market share, (iii) sales, (iv) earnings per share, (v) diluted earnings per share, (vi) diluted net income per share, (vii) return on shareholder equity, (viii) costs, (ix) cash flow, (x) return on total assets, (xi) return on capital or invested capital, (xii) return on net assets, (xiii) operating income, (xiv) net income, (xv) earnings (or net income) before interest, taxes, depreciation and amortization, (xvi) improvements in capital structure, (xvii) gross, operating or other margins, (xviii) budget and expense management, (xix) productivity ratios, (xx) working capital targets, (xxi) enterprise value, (xxii) safety record, (xxiii) completion of acquisitions or business expansion, (xxiv) economic value added or other value added measurements, (xxv) expenses targets, (xxvi) operating efficiency, (xxvii) regulatory body approvals for commercialization of products, (xxviii) implementation or completion of critical projects or related milestones (including, without limitation, milestones such as clinical trial enrollment targets, commencement of phases of clinical trials and completion of phases of clinical trials) or (xxix) partnering or similar transactions. Performance goals with respect to incentive bonuses that are not intended to be qualified incentive bonuses may be based on one or more of the preceding measures or any other measure that the committee may determine in its sole discretion. Performance goals may be measured absolutely or relative to an index or peer group.

***Effects of Termination of Employment.*** The AIP gives the compensation committee the discretion to accelerate the payment of incentive bonuses without regard to the satisfaction of the applicable performance goals to participants who undergo a termination of employment, except in the case of qualified incentive bonuses, which, unless such termination is due to the participant's death or disability, may only be paid if the applicable performance goals are satisfied.

***Effects of a Change in Control and other Corporate Transactions.*** The AIP permits the compensation committee to accelerate the payment of incentive bonuses (including qualified incentive bonuses) upon the consummation of a change in control of our company without regard to the satisfaction of the applicable performance goals. In addition, in the event of specified corporate transactions involving our company, such as any subdivision or combination or exchange of the outstanding shares of our common stock, stock dividend, stock split, spin-off, split-off, recapitalization, capital reorganization, liquidation, reclassification of shares of common stock, merger, consolidation, extraordinary cash distribution or sale, lease or transfer of substantially all of our assets, the committee may make or provide for such adjustments in any performance goals applicable to an incentive bonus as the committee may determine to be appropriate in order to prevent dilution or enlargement of the benefits of participants under the AIP.

***2013 Stock-Based Incentive Compensation Plan***

After the consummation of this offering, we intend to grant stock-based incentive compensation to our named executive officers and other employees, directors and consultants pursuant to our 2013 Stock-Based Incentive Compensation Plan, or the Stock Plan. The Stock Plan has been approved by our board of directors and stockholders. The purpose of the Stock Plan is to assist our company, our subsidiaries and

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affiliates in attracting, retaining and motivating valued employees, consultants and non-employee directors by offering them a greater stake in our company's success and a closer identity with it, and to encourage ownership of our company's stock by such employees, consultants and non-employee directors.

**Share Reserve and Limitations.** We have reserved an aggregate of 1,680,000 shares of our common stock for issuance pursuant to the Stock Plan. The maximum number of shares of common stock available for awards that may be granted to an individual participant during a single year is 840,000.

**Eligibility.** All employees and consultants of our company, our subsidiaries and affiliates and all non-employee members of our board of directors are eligible to receive awards under the Stock Plan.

**Administration.** The Stock Plan will be administered by a committee composed of at least two non-employee directors who are "outside directors" within the meaning of Section 162(m) of the Code and "independent directors" within the meaning of the applicable NASDAQ listing rules. The committee will have the power to: (i) select the employees, consultants and non-employee directors who will receive awards pursuant to the Stock Plan; (ii) determine the type or types of awards to be granted to each participant; (iii) determine the number of shares of common stock to which an award will relate, the terms and conditions of any award granted under the Stock Plan, including, but not limited to, restrictions as to vesting, transferability or forfeiture, exercisability or settlement of an award and waivers or accelerations thereof, and waivers of or modifications to performance conditions relating to an award, based in each case on such considerations as the committee shall determine, and all other matters to be determined in connection with an award; (iv) determine whether, to what extent, and under what circumstances an award may be canceled, forfeited, or surrendered; (v) determine whether, and to certify that, the performance goals to which the settlement of an award is subject are satisfied; (vi) correct any defect or supply any omission or reconcile any inconsistency in the Stock Plan, and adopt, amend and rescind such rules and regulations as, in its opinion, may be advisable in the administration of the Stock Plan; (vii) determine the effect, if any, of a change in control of our company upon outstanding awards; and (viii) construe and interpret the Stock Plan and make all other determinations as it may deem necessary or advisable for the administration of the Stock Plan. The committee may delegate some or all of its powers to any executive officer of our company or any other person, other than its authority to grant awards to certain specified executives.

**Types of Awards.** Awards that can be granted under the Stock Plan include common stock, deferred stock, restricted stock, restricted stock units, or RSUs, stock options and stock appreciation rights, or SARs.

**Common Stock.** In a common stock award, a participant receives a grant of shares of our common stock that are not subject to any restrictions on transfer or other vesting conditions. Upon the grant date, the participant will have all of the customary rights of a stockholder with respect to such shares, including the right to vote such shares and to receive dividends with respect to such shares.

**Deferred Stock.** In a deferred stock award, we agree to deliver, subject to certain conditions, a fixed number of shares of common stock to the participant at the end of a specified deferral period or periods. During such period or periods, the participant will have no rights as a stockholder with respect to any such shares. No dividends will be paid with respect to shares of deferred stock during the applicable deferral period, and the participant will have no future right to any dividend paid during such period.

**Restricted Stock.** In a restricted stock award, a participant receives a grant of shares of common stock that are subject to certain restrictions, including forfeiture of such stock upon the happening of certain events. During the restriction period, holders of restricted stock will have the right to vote the shares of restricted stock. No dividends will be paid with respect to shares of restricted stock during the applicable restriction period, and the participant shall have no future right to any dividend paid during such period.

**Restricted Stock Units.** An RSU is a grant of the right to receive a payment in our common stock or cash, or in a combination thereof, equal to the fair market value of a share of our common stock on the expiration of the applicable restriction period or periods. During such period or periods, the participant will have no rights as a stockholder with respect to any such shares. No dividends will be paid with respect



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to shares underlying an RSU during the applicable restriction period, and the participant will have no future right to any dividend paid during such period.

**Stock Options.** Stock options granted under the Stock Plan may be either incentive stock options or non-qualified stock options. The exercise price of an option shall be determined by the committee, but must be at least 100% of the fair market value of our company's common stock on the date of the grant. If the participant owns, directly or indirectly, shares constituting more than 10% of the total combined voting power of all classes of stock of our company, the exercise price of an incentive stock option must be at least 110% of the fair market value of a share of common stock on the date the incentive stock option is granted.

**Stock Appreciation Rights.** A grant of a SAR entitles the holder to receive, upon exercise of the SAR, the excess of the fair market value of one share of our common stock on the date of exercise over the grant price of the SAR as determined by the committee. The grant price of a SAR may never be less than 100% of the fair market value of a share of common stock on the date of grant.

**Performance Goals.** In the discretion of the committee, any award may be granted subject to performance goals that must be met by the end of a period specified by the committee, but that are substantially uncertain to be met before the grant of the award, and that must be based upon one or more of the following as they relate to our company, our subsidiaries or affiliates, or any business unit or department thereof: (i) stock price, (ii) market share, (iii) sales, (iv) earnings per share, (v) diluted earnings per share, (vi) diluted net income per share, (vii) return on shareholder equity, (viii) costs, (ix) cash flow, (x) return on total assets, (xi) return on capital or invested capital, (xii) return on net assets, (xiii) operating income, (xiv) net income, (xv) earnings (or net income) before interest, taxes, depreciation and amortization, (xvi) improvements in capital structure, (xvii) gross, operating or other margins, (xviii) budget and expense management, (xix) productivity ratios, (xx) working capital targets, (xxi) enterprise value, (xxii) safety record, (xxiii) completion of acquisitions or business expansion (xxiv) economic value added or other value added measurements, (xxv) expense targets, (xxvi) operating efficiency, (xxvii) regulatory body approvals for commercialization of products, (xxviii) implementation or completion of critical projects or related milestones (including, without limitation, milestones such as clinical trial enrollment targets, commencement of phases of clinical trials and completion of phases of clinical trials) or (xxix) partnering or similar transactions. The committee may structure awards to qualify for the exemption for performance-based compensation to the limitations on the deductibility of compensation in excess of \$1,000,000 paid to certain of our executive officers under Section 162(m) of the Code; however, the committee retains the discretion to grant awards that are not fully deductible under Section 162(m) of the Code. Performance goals with respect to awards that are not intended to constitute qualified performance-based compensation under Section 162(m) of the Code may be based on one or more of the preceding measures or any other measure that the committee may determine in its sole discretion. Performance goals may be measured absolutely or relative to an index or peer group.

**Effects of a Change in Control.** Upon the occurrence of a change in control of our company, the compensation committee may, in its discretion: (i) fully vest any or all awards; (ii) determine whether all applicable performance goals have been achieved and the applicable level of performance; (iii) cancel any outstanding awards in exchange for a cash payment of an amount, but not less than zero, equal to the difference between the then fair market value of the award less the exercise or base price of the award; (iv) after having given the participant a chance to exercise any vested outstanding options or SARs, terminate any or all of the participant's unexercised options or SARs; (v) where our company is not the surviving corporation after a change in control, cause the surviving corporation to assume or replace all outstanding awards with comparable awards; or (vi) take such other action as the committee shall determine appropriate.

**Effects of Certain Corporate Transactions.** In the event of a stock dividend, recapitalization, forward or reverse stock split, reorganization, division, merger, consolidation, spin-off, combination, repurchase or share exchange, extraordinary or unusual cash distribution or other corporate transaction or event that

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affects our common stock, the committee shall make equitable adjustments in (i) the number and kind of shares of common stock which may thereafter be issued in connection with awards, (ii) the number and kind of shares of common stock issuable in respect of outstanding awards, (iii) the aggregate number and kind of shares of common stock available under the Stock Plan, and (iv) the exercise or grant price relating to any award, or if deemed appropriate, the committee may also make provision for a cash payment with respect to any outstanding award.

**Actions Requiring Stockholder Approval.** The board of directors must obtain stockholder approval in order to take any action that would (i) increase the number of shares subject to the Stock Plan, except for adjustments upon changes in capitalization; (ii) result in the repricing, replacement or repurchase of any option, SAR or other award; or (iii) be required to be submitted for stockholder approval under any federal or state law or regulation or NASDAQ listing rules.

**Clawback.** Any award granted under the Stock Plan, including a common stock award, will be subject to mandatory repayment by the participant to our company pursuant to the terms of any company "clawback" or recoupment policy that is directly applicable to the Stock Plan and set forth in an award agreement or as required by law to be applicable to the participant.

**Transfer Restrictions.** No award or other right or interest of a participant under the Stock Plan may be assigned or transferred for any reason during the participant's lifetime, other than to our company or any subsidiary or affiliate. Notwithstanding the foregoing, the committee may grant awards, other than incentive stock options, that are transferable by the participant during his or her lifetime, but only to the extent specifically provided in the agreement entered into with such participant. No incentive stock option shall be transferable other than by will or the laws of descent and distribution.

**Compensation of Directors**

During 2013, we did not pay any cash or other compensation to our non-employee directors, and therefore we have not presented a director compensation table. None of our non-employee directors held any equity awards of Egalet US as of December 31, 2013.

Our board of directors has adopted a formal non-employee director compensation policy in the form attached as an exhibit to the registration statement of which this prospectus forms a part. Each non-employee director will receive an annual cash retainer in the amount of \$25,000, payable in equal quarterly installments in arrears on the last day of the fiscal quarter in which such service occurred. Additional annual cash retainers will be paid on the same schedule to the chair of the board in the amount of \$15,000, the chair of the audit committee in the amount of \$10,000, the chair of the compensation committee in the amount of \$7,500, and the chair of the nominating and corporate governance committee in the amount of \$5,000.

In addition to the payment of annual cash retainers, the policy as hereafter described provides for grants of options to purchase shares of our common stock to non-employee directors pursuant to the terms and conditions of our Stock Plan, as described above. These options will vest with respect to  $\frac{1}{16}$  of the underlying shares on the last day of each calendar quarter following the grant date, such that the options will become fully vested on the last day of the calendar quarter following the fourth anniversary of the grant date, subject to the non-employee director's continuing service on the board. Each non-employee director will be granted an option having a fair market value on the grant date of \$25,000 on his or her initial election to the board. In addition, each non-employee director will be granted an option having a grant date fair value of \$10,000 at each annual stockholder meeting held after the consummation of this offering.

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**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

The following is a description of transactions since January 2011 to which we or Egalet UK has been a party, in which the amount involved in the transaction exceeds \$120,000, and in which any of our or Egalet UK's directors, executive officers or to our knowledge, beneficial owners of more than 5% of our or Egalet UK's capital stock had or will have a direct or indirect material interest.

After the completion of this offering, our audit committee will be responsible for the review, approval and ratification of related person transactions between us and any related person.

**Participation in this Offering**

Our stockholders have agreed to purchase 833,333 shares of our common stock in this offering at the initial public offering price.

**Amended and Restated Convertible Loan Agreement**

On January 21, 2011, Egalet UK entered into a Convertible Loan Agreement with Atlas Venture Fund VII, L.P., Sunstone Life Science Ventures Fund II K/S, Danish Biotech SPV I P/S, Index Ventures III (Jersey) L.P., Index Ventures III (Delaware) L.P., Index Ventures III Parallel Entrepreneur Fund (Jersey) L.P. and Yucca Partners LP (Jersey Branch), in its capacity as administrator of the Index Co-Investment Scheme, or collectively, the Series A Investors, which was amended and restated on April 12, 2011. Pursuant to the agreement, as amended and restated, the Series A Investors agreed to lend Egalet UK a total of €4,210,000, which accrued interest at a rate of 8% per annum and was convertible into Series A-1 preferred shares of Egalet UK at a rate of €1.00 per share. All such amounts outstanding, including accrued interest, were converted pursuant to the Series B Subscription Agreement described below. Each of the Series A Investors was the beneficial owner of more than 5% of Egalet UK's capital stock as of September 30, 2013.

**Series B Subscription Agreement**

On March 12, 2012, Egalet UK entered into a Subscription and Shareholders' Agreement, or the Series B Subscription Agreement, with the Series A Investors and a new investor, CLS Capital Holdings Limited, or CLS, referred to collectively as the Series B Investors. Each of the Series B Investors was the beneficial owner of more than 5% of Egalet UK's capital stock as of September 30, 2013.

Pursuant to the Series B Subscription Agreement, the Series B Investors purchased an aggregate of 1,419,834 Series B preferred shares of Egalet UK in exchange for an aggregate payment of \$6,293,558. In addition, the Series A Investors converted an aggregate of €4,527,385 of outstanding convertible loans into an aggregate of 907,467 Series B preferred shares of Egalet UK and 113,916 Series B-1 preferred shares of Egalet UK. The Series B and Series B-1 preferred shares of Egalet UK are identical except that the Series B preferred shares are entitled to receive their liquidation preference before the Series B-1 preferred shares. The Series B and Series B-1 preferred shares have a liquidation preference of €4.4326 per share.

The Series B Subscription Agreement contains provisions related to the election of Egalet UK's board of directors, restrictions on transfer of shares and registration rights. For a description of the registration rights, see "Description of Capital Stock Registration Rights." Certain of our current directors were elected pursuant to the terms of the Series B Subscription Agreement. The restrictions on transfer and rights to elect directors will terminate upon the consummation of this offering.

**April 2013 Bridge Financing**

On April 26, 2013, Egalet UK entered into a Convertible Loan Agreement, or the April 2013 Loan Agreement, with Atlas Venture Fund VII, L.P., Danish Biotech SPV I, P/S, Sunstone Life Science Ventures

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Fund II K/S, Index Ventures III (Jersey) L.P., Index Ventures III (Delaware) L.P., Index Ventures III Parallel Entrepreneurs Fund (Jersey) L.P., Yucca (Jersey) SLP, in its capacity as administrator of the Index Co-investment Scheme and CLS, or collectively, the 2013 Bridge Investors. Each of the 2013 Bridge Investors was the beneficial owner of more than 5% of Egalet UK's capital stock as of September 30, 2013.

Pursuant to the April 2013 Loan Agreement, the 2013 Bridge Investors agreed to provide an aggregate of \$5,000,000 in convertible loans to Egalet UK. Interest accrues at a rate of 6% per annum on all amounts outstanding and the loans mature on December 31, 2013. Amounts outstanding under the loans are convertible as follows:

In the event of a sale of all or substantially all of the assets of Egalet UK or the sale of more than 50% of the total voting rights in Egalet UK, the number of shares obtained by dividing the amount of the loan by €4.4326, which in the case of Atlas Venture Fund VII, L.P., Danish Biotech SPV I, P/S, Sunstone Life Science Ventures Fund II K/S and CLS Capital Holdings Limited, or collectively the Pro Rata Lenders, shall be Series B preferred shares and which in the case of Ventures Fund II K/S, Index Ventures III (Jersey) L.P., Index Ventures III (Delaware) L.P., Index Ventures III Parallel Entrepreneurs Fund (Jersey) L.P. and Yucca (Jersey) SLP, in its capacity as administrator of the Index Co-investment Scheme, or collectively, the Non-Pro Rata Lenders, shall be Series B-1 preferred shares;

In the event of an initial public offering of at least €20,000,000 of Egalet UK shares at a per share price that values Egalet UK at least €80,000,000, or a Qualifying IPO, the number of ordinary shares obtained by dividing the loan amount by 50% of the per share price of the shares in the initial public offering in the case of the Pro Rata Lenders, and by 90% in the case of the Non-Pro Rata Lenders;

In the event of a financing in which Egalet UK obtains at least €8,000,000 upon an issuance of ordinary shares or securities convertible into ordinary shares that are either senior or pari passu with the Series B preferred shares of Egalet UK but which is not a Qualifying IPO, the number of ordinary shares obtained by dividing the loan amount by 50% of the per share price of the securities sold in such offering in the case of the Pro Rata Lenders, and by 90% in the case of the Non-Pro Rata Lenders; and

In the event none of the above occur prior to the maturity date, the number of shares obtained by dividing the amount of the loan by €4.4326, which in the case of the Pro Rata Lenders shall be Series B preferred shares and which in the case of the Non-Pro Rata Lenders shall be Series B-1 preferred shares.

In connection with the Share Exchange, Egalet US and Egalet UK entered into a novation whereby Egalet US replaced Egalet UK as a party to the April 2013 Loan Agreement. As a result of this novation, amounts outstanding under the loans became convertible into our common stock instead of ordinary shares of Egalet UK. On December 23, 2013, we entered into an amendment to the April 2013 Loan Agreement with the 2013 Bridge Investors whereby the maturity date was extended until April 26, 2014.

**August 2013 Bridge Financing**

On August 29, 2013, Egalet UK entered into a Senior Convertible Loan Agreement, or the 2013 Senior Loan Agreement, with Atlas Venture Fund VII, L.P., Danish Biotech SPV I, P/S, Sunstone Life Science Ventures Fund II K/S, Index Ventures Life VI (Jersey) L.P., Index Ventures III (Jersey) L.P., Index Ventures III (Delaware) L.P., Index Ventures III Parallel Entrepreneurs Fund (Jersey) L.P., Yucca (Jersey) SLP, in its capacity as administrator of the Index Co-investment Scheme, Omega Fund IV L.P. and Enso Ventures 2 Limited, or collectively, the 2013 Senior Loan Investors. Each of the 2013 Senior Loan Investors, other than Omega Fund IV L.P., was the beneficial owner of more than 5% of Egalet UK's capital stock as of September 30, 2013.

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Pursuant to the 2013 Senior Loan Agreement, the 2013 Senior Loan Investors agreed to provide an aggregate of \$10,000,000 in convertible loans to Egalet UK upon closing of the 2013 Senior Loan Agreement. The 2013 Senior Loan Investors have the option to invest up to an additional \$10,000,000 upon the closing of a Qualifying IPO, but the failure of any such investor to invest a specified minimum amount upon a Qualifying IPO shall result in such investor's convertible notes and preferred securities being adjusted to convert into ordinary shares under adverse conversion rates, and such investor will not be entitled to its pro rata portion of the warrants described below. Specifically, amounts outstanding under the convertible loans would be convertible into ordinary shares at a per share price equal to 400% of the offering price per share and the preferred shares will be convertible into ordinary shares at a ratio of two preferred shares per ordinary share. Interest accrues at a rate of 6% per annum on all amounts outstanding, and the loans mature on August 29, 2014.

As part of the 2013 Senior Loan Agreement, the 2013 Senior Loan Investors received warrants to purchase up to 600,000 ordinary shares of Egalet UK at an exercise price of €0.01 per share. Each investor's warrants shall automatically be exercised immediately prior to a consummation of a Qualifying IPO if such investor purchases a specified minimum amount of ordinary shares in such an offering.

Amounts outstanding under the loans are convertible on the first to occur of the following:

In the event of a sale of all or substantially all of the assets of Egalet UK or Egalet US or the sale of more than 50% of the total voting rights in Egalet UK or Egalet US, the number of ordinary shares or shares of common stock obtained by dividing the number of fully diluted shares by the difference between 1 and the quotient of the aggregate amount of principal and interest on the loan divided by 50% of the sale consideration, and then subtracting the number of fully diluted shares from the result. In such event, the 2013 Senior Loan Investors will also be entitled to receive a sum equal to two times the outstanding principal amount of the loan;

In the event of a Qualifying IPO, the number of ordinary shares obtained by dividing the loan amount by 50% of the per share price of the shares in the initial public offering, which conversion will happen automatically; and

In the event of a financing in which Egalet UK or Egalet US obtains at least \$5,000,000 but which is not a Qualifying IPO, the number of shares of a new class to be created, as determined, in the case of an investment by the 2013 Senior Loan Investors, by holders of not less than 51% of the principal amount outstanding, which must include Index Ventures Life VI (Jersey) L.P., and, in the case of an investment by a third party of at least \$3,000,000, by holders of not less than 66% of the principal amount outstanding. In addition, in the event of an investment by a third party of at least \$3,000,000, Index Ventures Life VI (Jersey) L.P. will have the right to appoint a director to the board of directors of Egalet UK.

Additionally, the 2013 Senior Loan Agreement modified the April 2013 Loan Agreement by treating all Non-Pro Rata Lenders as Pro-Rata Lenders for purposes of conversion. The April 2013 Loan Agreement was also modified to amend the conversion mechanism in the event of a sale of all or substantially all of Egalet UK's assets such that all amounts outstanding would convert into the number of Series B preferred shares of Egalet UK obtained by dividing the amounts outstanding by €4.4326. In connection with the Share Exchange, Egalet US and Egalet UK entered into a novation whereby Egalet US replaced Egalet UK as a party to the 2013 Senior Loan Agreement, including the warrants to purchase up to 600,000 shares at an exercise price that became \$0.001 per share. As a result of this novation, amounts outstanding under the loans became convertible into our common stock instead of ordinary shares of Egalet UK.

**Consulting Arrangement with Paul Goldenheim**

Dr. Paul Goldenheim, a director of Egalet UK from March 2012 to August 2013, received consulting fees from Egalet UK pursuant to a consultancy agreement. In exchange for the provision of certain

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services no fewer than two days each week, Dr. Goldenheim was paid \$138,000 and \$115,000 for the years ended December 31, 2011 and 2012, respectively. This agreement was terminated in September 2013.

Dr. Mark Strobeck, our Chief Business Officer, received advisory fees from Egalet UK pursuant to an agreement with Egalet UK dated June 1, 2012. In exchange for Dr. Strobeck providing certain advisory services from time to time under the agreement, Dr. Strobeck was paid \$75,000 and \$150,000 for the years ended December 31, 2012 and 2013, respectively. This agreement was terminated effective January 1, 2014.

**Shareholders' Agreement**

In connection with the Share Exchange, Egalet US entered into a Shareholders' Agreement with each of the 2013 Bridge Investors, Enso Ventures 2 Limited and Egalet A/S, each of whom was the beneficial owner of 5% or more of Egalet UK's capital stock as of September 30, 2013. With the exception of the provisions regarding registration rights, each provision of the Shareholders' Agreement will terminate and be of no further force and effect upon consummation of this offering. See "Description of Capital Stock Registration Rights" for a description of the registration rights that will remain in effect after consummation of this offering.

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**PRINCIPAL STOCKHOLDERS**

The following table sets forth certain information regarding the beneficial ownership of our common stock as of December 31, 2013 by:

each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;

each of our directors;

each of our named executive officers; and

all of our directors and executive officers as a group.

The percentage ownership information shown in the table is based upon 1,292,307 shares of common stock of Egalet US outstanding as of December 31, 2013, and assumes the conversion of 4,441,217 shares of preferred stock of Egalet US into 5,329,451 shares of common stock of Egalet US prior to the consummation of this offering. The percentage of shares beneficially owned after the offering gives effect to the issuance by us of 4,200,000 shares of common stock in this offering, the issuance of an aggregate of 2,585,745 shares upon conversion of our convertible bridge notes, based on interest accrued through the expected closing date of this offering, and the sale and issuance by us of 1,250,000 shares of common stock in the concurrent private placement to Shionogi, but does not give effect to the issuance of shares of restricted stock to our executive officers upon the consummation of this offering or any other issuances of securities subsequent to December 31, 2013, and does not give effect to the warrants to purchase 600,000 shares of our common stock issued in connection with the issuance of the convertible bridge notes, which warrants will become exercisable immediately prior to the consummation of this offering. The percentage ownership information also assumes no exercise of the underwriters' over-allotment option.

Each individual or entity shown in the table has furnished information with respect to beneficial ownership. We have determined beneficial ownership in accordance with the SEC's rules. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Our existing investors have agreed to purchase 833,333 shares of our common stock in this offering at the initial public offering price. Except as described in the footnotes to the following table, the table does not reflect any potential purchases by these stockholders or their affiliated entities.

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Except as otherwise noted below, the address for each person or entity listed in the table is c/o Egalet Corporation, 460 East Swedesford Road, Suite 1050, Wayne, PA 19087.

| Name and Address of Beneficial Owner  | Number of<br>shares<br>beneficially<br>owned | Percentage of<br>shares beneficially<br>owned |                   |
|---|--|---|-------------------|
|   |  | Before<br>offering                            | After<br>offering |
| <b>5% or greater stockholders:</b>  |  |   |                   |
| Atlas Venture Fund VII, L.P.(1)<br>25 First Street, Suite 303<br>Cambridge, MA 02141                        | 2,005,578                                    | 30.3%   | 16.3%             |
| Danish Biotech SPV I P/S(2)<br>1 Royal Plaza, Royal Avenue<br>St. Peter Port, Guernsey GY1 2HL              | 1,528,020                                    | 23.1  | 14.1              |
| Sunstone Life Science Ventures Fund II K/S(3)<br>Lautrupsgade 7, 5, DK-2100<br>Copenhagen O, Denmark.       | 1,308,576                                    | 19.8  | 12.2              |
| Egalet A/S(4)<br>Lejrvej 37-41, Kr Vaerlose<br>DK-3500, Vaerlose, Denmark                                   | 1,292,307                                    | 19.5  | 8.8               |
| Index Entities(5)<br>No. 1 Seaton Place<br>St. Helier, Channel Islands Y9 JE48YJ                            | 1,131,443                                    | 17.1  | 13.5              |
| Enso Ventures 2 Limited(6)<br>Suite 1, Hirzel Court<br>St. Peter Port, Guernsey, GY1 2NH<br>Channel Islands | 410,555                                      | 6.2   | 4.0               |
| <b>Directors and Named Executive Officers:</b>  |  |   |                   |
| Robert Radie(7)   |  | *   | *                 |
| Renee Aguiar-Lucander(9)  |  | *   | 1.1               |
| Andreas Rutger Segerros(3)  | 1,308,576                                    | 19.8  | 12.2              |
| Jean-Francois Formela(1)  | 2,005,578                                    | 30.3  | 16.3              |
| Andrey Kozlov   |  | *   | *                 |
| Gregory Weaver  |  | *   | *                 |
| Stan Musial(7)  |  | *   | *                 |
| Mark Strobeck   |  | *   | *                 |
| Karsten Lindhardt(7)(8)   | 429  | *   | *                 |
| All current executive officers and directors as a group (9 persons)(10)                                     | 3,314,583                                    | 50.1%   | 29.6%             |

\*  
Represents beneficial ownership of less than one percent.

(1)  
The amount reported includes 1,696,852 shares held of record by Atlas Venture Fund VII, L.P. ("Atlas Venture Fund"). Atlas Venture Associates VII, L.P. ("Atlas Venture Associates") is the general partner of Atlas Venture Fund, and Atlas Venture Associates VII, Inc. ("Atlas Venture Inc.") is the general partner of Atlas Venture Associates. Jean-François Formela, one of our directors, is also a director of Atlas Venture Inc. The other directors of Atlas Venture Inc. are Peter Barrett, Bruce Booth, Fred Destin, and Jeff Fagnan. Therefore, each of Atlas Venture Associates, Atlas Venture Inc., Peter Barrett, Bruce Booth, Fred Destin, Jeff Fagnan and Dr. Formela may be deemed to share the right to direct the voting and dispositive control of shares held by Atlas Venture Fund. Atlas Venture Fund beneficially owns approximately 23.9% of the equity securities of Egalet A/S, and therefore the reported total also includes 308,727 of the shares beneficially owned by Egalet A/S as shown in the table. The percentage beneficially owned after the offering includes 383,704 shares of common stock issuable upon conversion of convertible bridge notes held by Atlas Venture Fund upon the closing of this offering. The percentage of shares beneficially owned after this offering would be 16.6%,



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assuming the purchase of all of the 41,666 shares that the entities affiliated with this stockholder have agreed to purchase in this offering.

- (2) The amount reported includes 1,213,288 shares held of record by Danish Biotech SPV I P/S ("Danish Biotech"). The directors of Danish Biotech, who have sole dispositive and voting power over shares held by Danish Biotech, consist of the following individuals: Kevin Brennan, Sharon Alvarez and Barry McClay. Danish Biotech beneficially owns approximately 24.4% of the equity securities of Egalet A/S, and therefore the reported total also includes 314,732 of the shares beneficially owned by Egalet A/S as shown in the table. The percentage beneficially owned after the offering includes 534,214 shares of common stock issuable upon conversion of convertible bridge notes held by Danish Biotech upon the closing of this offering. The percentage of shares beneficially owned after this offering would be 15.1%, assuming the purchase of all of the 156,250 shares that the entities affiliated with this stockholder have agreed to purchase in this offering.
- (3) The amount reported includes 1,153,638 shares held of record by Sunstone Life Science Ventures Fund II K/S (the "Fund"). Sunstone LSV General Partner II ApS (the "General Partner") has sole dispositive and voting power over shares held by the Fund. The members of the board of directors of the General Partner, Peter Benson, Soren Lemonius, Sten Verland and Merete Lundbye Moller, share voting and dispositive power over shares held by the General Partner. Mr. Segerros is authorized to act on the General Partner's behalf jointly with any member of the General Partner's board of directors with respect to matters relating to our company. The Fund beneficially owns approximately 12.0% of the equity securities Egalet A/S, and therefore the total also includes 154,938 of the shares beneficially owned by Egalet A/S as shown in the table. The percentage beneficially owned after the offering includes 476,645 shares of common stock issuable upon conversion of convertible bridge notes held by the Fund upon the closing of this offering. The percentage of shares beneficially owned after this offering would be 13.1%, assuming the purchase of all of the 133,333 shares that the entities affiliated with this stockholder have agreed to purchase in this offering.
- (4) The board of directors of Egalet A/S has sole dispositive and voting power over shares held by Egalet A/S. The directors of Egalet A/S are Peter Mollerup, Dr. Formela, Ms. Aguiar-Lucander and Francesco de Robertis.
- (5) The amount reported includes 561,748 shares held of record by Index Ventures III (Delaware) L.P. ("Index Delaware"), 276,534 shares held of record by Index Ventures III (Jersey) L.P. ("Index Jersey"), 10,007 shares held of record by Index Ventures Parallel Entrepreneur Fund (Jersey) L.P. ("Index PEF," and together with Index Delaware and Index Jersey, the "Index Funds"), and 6,840 shares held of record by Yucca (Jersey) SLP ("Yucca," and collectively with Index Ventures Life VI (Jersey) L.P. and the Index Funds, the "Index Entities"). Index Venture Associates III Limited ("Index Associates") is the general partner of the Index Funds and is an affiliate of Yucca and Index Ventures Life VI (Jersey) L.P., and therefore directs the voting and dispositive control of shares held by the Index Funds. The members of the board of directors of Index Associates, Bernard Dallé, David Hall, Nigel Greenwood, Ian Henderson and Sinéad Meehan, share voting and dispositive power over the shares held by Index Associates. Yucca is a co-investment vehicle that is contractually obligated to mirror the Index Funds' investments. Each of the Index Entities disclaims beneficial ownership of the shares of our common stock held of record by any of the other Index Entities. The Index Entities beneficially own approximately 21.4% of the equity securities of Egalet A/S in the aggregate, and therefore the total also includes 276,315 of the shares beneficially owned by Egalet A/S as shown in the table. The percentage beneficially owned after the offering includes 192,359 shares of common stock issuable upon conversion of convertible bridge notes held by Index Delaware, 94,693 shares of common stock issuable upon conversion of convertible bridge notes held by Index Jersey, 3,425 shares of common stock issuable upon conversion of convertible bridge notes held by Index PEF, 548,188 shares of common stock issuable upon conversion of convertible bridge notes held by Index Ventures Life VI (Jersey) L.P. and 10,690 shares of common stock issuable upon conversion of convertible bridge notes held by Yucca, in each case upon the closing of this offering. The percentage of shares beneficially owned after this offering would be 16.0%, assuming the purchase of all of the 370,833 shares that the entities affiliated with these stockholders have agreed to purchase in this offering.

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- (6) Interlock Director Ltd. has sole dispositive and voting power over shares held by Enso Ventures 2 Limited. Interlock Director Ltd. exercises such power through a combination of two directors of Albecq Directors Limited. The Albecq Directors Limited directors consist of the following individuals: Michael Kupenga, Marianne Domaille and Michael Underdown. The percentage beneficially owned after the offering includes 170,585 shares of common stock issuable upon conversion of convertible bridge notes held by Enso Ventures 2 Limited (formerly known as CLS Capital Holdings Limited) upon the closing of this offering. The percentage of shares beneficially owned after this offering would be 4.3%, assuming the purchase of all of the 47,916 shares that the entities affiliated with this stockholder have agreed to purchase in this offering.
- (7) Excludes any shares issuable upon a change in control pursuant to letters of employment each executive has with us.
- (8) Mr. Lindhardt beneficially owns approximately 0.03% of the equity securities of Egalet A/S, and therefore the total includes 429 of the shares beneficially owned by Egalet A/S as shown in the table.
- (9) The percentage beneficially owned after the offering includes 171,242 shares of common stock issuable upon conversion of convertible bridge notes held by Omega Fund IV L.P. ("Omega Fund IV"). Omega Fund IV GP, L.P. ("Omega GP") is the general partner of Omega, and Omega Fund IV GP Manager, Ltd. ("Omega Manager") is the general partner of Omega GP. Renee Aguiar-Lucander, one of our directors, is also a director of Omega Manager. Therefore, each of Omega GP, Omega Manager, and Ms. Aguiar-Lucander may be deemed to share the right to direct the voting and dispositive control of shares held by Omega Fund IV. The percentage of shares beneficially owned after this offering would be 1.7%, assuming the purchase of all of the 83,333 shares that the entities affiliated with Omega Manager have agreed to purchase in this offering.
- (10) The percentage of shares beneficially owned after this offering would be 31.4%, assuming the purchase of all of the 833,333 shares that our existing stockholders have agreed to purchase in this offering.

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**DESCRIPTION OF CAPITAL STOCK**

As of December 31, 2013, our capital stock was held of record by nine stockholders. Upon the closing of this offering, our authorized capital stock will consist of 80,000,000 shares, 75,000,000 of which are designated as common stock with a par value of \$0.001 per share and 5,000,000 of which are designated as preferred stock with a par value of \$0.001.

The following is a summary of our capital stock upon the consummation of this offering. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

**Common Stock**

*Voting Rights.* Each holder of common stock shall be entitled to one vote for each share on all matters submitted to a vote of the stockholders.

*Dividends.* Subject to the preferences that may be applicable to any outstanding preferred stock, holders of our common stock shall be entitled to receive ratably any dividends that may be declared by the board of directors out of funds legally available for that purpose.

*Liquidation.* In the event of our liquidation, dissolution or winding up, holders of our common stock shall be entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding preferred stock.

*No Preemptive or Similar Rights.* Our common stock shall not be entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions.

**Preferred Stock**

Immediately prior to the consummation of this offering, all outstanding shares of Egalet US preferred stock will be converted into an aggregate of 5,329,451 shares of common stock of Egalet US. Under our amended and restated certificate of incorporation that will be in effect following consummation of this offering, our board of directors has the authority, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. Our board of directors also can increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plan to issue any shares of preferred stock.

**Warrants**

As part of the 2013 Senior Loan Agreement, the 2013 Senior Loan Investors received warrants to purchase up to 600,000 ordinary shares of Egalet UK at an exercise price of €0.01 per share. Each Investor's warrants shall automatically be exercised immediately prior to consummation of a Qualifying IPO if the investor purchases a specified minimum amount of common stock in such an offering. As part of the Share Exchange, such warrants became exercisable for an identical number of shares of common stock of Egalet US at an exercise price of \$0.001 per share.

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**Registration Rights**

We have agreed that the holders of preferred stock and convertible notes of Egalet US will be entitled to specified registration rights with respect to the common stock of Egalet US into which their securities will be converted. We have also agreed to provide Shionogi equivalent rights with respect to the shares issued to them in a private placement concurrent with the consummation of this offering. Beginning six months after the consummation of this offering or, if earlier, the date that is four years after the date of issuance of the securities underlying such registration rights, such investors are entitled to two demand registrations whereby such investors may request that we register all or a portion of their shares of common stock. When we are eligible for the use of Form S-3, or any successor form, such investors may make unlimited requests that we register all or a portion of their common stock for sale under the Securities Act on Form S-3, or any successor form. In addition, if at any time we register any shares of our stock, such investors are entitled include all or a portion of their common stock in the registration. We have agreed to pay all expenses of a requested registration, including reasonable legal costs of a firm appointed to act on behalf of the investors participating in the registration.

**Delaware Anti-Takeover Law and Provisions of Our Certificate of Incorporation and Bylaws**

*Delaware Anti-Takeover Law.* We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or

at or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66<sup>2</sup>/<sub>3</sub>% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;

subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any person that is:

the owner of 15% or more of the outstanding voting stock of the corporation;

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an affiliate or associate of the corporation who was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the relevant date; or

the affiliates and associates of the above.

Under specific circumstances, Section 203 makes it more difficult for an "interested stockholder" to effect various business combinations with a corporation for a three-year period, although the stockholders may, by adopting an amendment to the corporation's certificate of incorporation or bylaws, elect not to be governed by this section, effective 12 months after adoption.

Our certificate of incorporation and bylaws do not exclude us from the restrictions of Section 203. We anticipate that the provisions of Section 203 might encourage companies interested in acquiring us to negotiate in advance with our board of directors since the stockholder approval requirement would be avoided if a majority of the directors then in office approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder.

*Certificate of Incorporation and Bylaws.* Provisions of our certificate of incorporation and bylaws to be in effect upon the consummation of this offering may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our certificate of incorporation and bylaws will:

permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;

provide that the authorized number of directors may be changed only by the board of directors;

provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide our board of directors into three classes;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

provide that special meetings of our stockholders may be called only by the board of directors.

**Listing on the NASDAQ Global Market**

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol "EGLT."

**Transfer Agent and Registrar**

## Edgar Filing: Egalet Corp - Form 424B4

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc. whose address is 44 West Lancaster Avenue, Ardmore, PA 19003.

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**SHARES ELIGIBLE FOR FUTURE SALE**

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of our common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

After the closing of this offering and the concurrent private placement to Shionogi, there will be outstanding 14,657,503 shares of common stock, assuming no exercise of the underwriters' over-allotment option. All of the shares sold in this offering will be freely tradable unless purchased by an affiliate of ours, as that term is defined in Rule 144 under the Securities Act. The remaining 10,457,503 shares of common stock outstanding after this offering will be restricted from resale as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the public market upon expiration of lock-up agreements at least 180 days after the date of this offering under Rule 144.

**Rule 144**

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

1% of the number of shares of our common stock then outstanding, which will equal approximately 146,575 shares immediately after this offering and the concurrent private placement; and

the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also requires that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, all holders of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

**Lock-up Agreements**

In connection with this offering, we, our officers and directors and all of our stockholders have agreed with the underwriters, subject to limited exceptions, not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 180 days after the date of this prospectus,



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except with the prior written consent of Stifel Nicolaus & Company, Incorporated and JMP Securities LLC. Stifel Nicolaus & Company, Incorporated and JMP Securities LLC have advised us that they have no current intent or arrangement to release any of the shares subject to the lock-up agreements prior to the expiration of the lock-up period.

Following the 180 day lock-up period, and assuming that the representatives of the underwriters do not release any parties from these agreements prior to the end of the lock-up period, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

**Rule 10b5-1 Sales Plans**

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

In order to pay a portion of the income taxes incurred upon the vesting of their restricted stock, upon consummation of this offering, Robert S. Radie, our President and Chief Executive Officer, Stan Musial, our Chief Financial Officer, Mark Strobeck, our Chief Business Officer and Karsten Lindhardt, our Vice President of Research and Development, intend to enter into 10b5-1 plans, pursuant to which they will be able to sell up to 40% of the shares that vest on each particular vesting date of the restricted stock granted to each employee pursuant to their respective employment agreements. None of these restricted stock grants will vest prior to expiration of the lock-up period.

**Registration Rights**

Upon consummation of this offering and the concurrent private placement to Shionogi, the holders of 10,457,503 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See "Description of Capital Stock Registration Rights."

**Equity Incentive Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act after the closing of this offering to register the shares of our common stock that are issuable pursuant to the Stock Plan. The registration statements are expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statements will be available for sale in the open market following their effective dates, subject to Rule 144 volume limitations applicable to affiliates and the lock-up arrangement described above, if applicable.

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**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following discussion is a general summary of the material U.S. federal income tax consequences applicable to Non-U.S. Holders of acquiring, owning and disposing of our common stock as of the date hereof.

For the purposes of this discussion, a "Non-U.S. Holder" of our common stock means a holder that, for U.S. federal income tax purposes, is not a U.S. Holder. A "U.S. Holder" means a holder of our common stock that is for U.S. federal income tax purposes:

an individual who is a citizen or resident of the United States;

a corporation (or other entity taxable as a corporation) created or organized in or under the laws of the U.S., any state thereof or the District of Columbia;

an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

a trust, if it (1) is subject to the primary supervision of a court within the United States, and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable United States Treasury regulations to be treated as a U.S. person.

This summary does not consider specific facts and circumstances that may be relevant to a particular Non-U.S. Holder's tax particular circumstances and does not consider the state, local or non-U.S. tax consequences of an investment in our common stock. It also does not consider Non-U.S. Holders subject to special tax treatment under U.S. federal income tax laws (including partnerships or other pass-through entities, banks and insurance companies, regulated investment companies, real estate investment trusts, dealers in securities, holders of our common stock held as part of a "straddle," hedge, "conversion transaction" or other risk-reduction transaction, controlled foreign corporations, passive foreign investment companies, companies that accumulate earnings to avoid U.S. federal income tax, foreign tax-exempt organizations, "expatriated entities," companies subject to the "stapled stock" rules, former U.S. citizens or residents and persons who hold or receive the shares of common stock as compensation). This summary is based on provisions of the Code, applicable Treasury regulations, administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, and judicial decisions, all as in effect on the date hereof, and all of which are subject to change, possibly on a retroactive basis, and different interpretations.

**This summary is general information only. It is not tax advice. We urge each prospective Non-U.S. Holder to consult their own tax advisor concerning the particular U.S. federal, state, local and non-U.S. income, estate and other tax consequences of the purchase, ownership and disposition of our common stock.**

**U.S. Trade or Business Income**

For purposes of this discussion, dividend income and gain on the sale or other taxable disposition of shares of our common stock will be considered to be "U.S. trade or business income" if such dividend income or gain is (1) effectively connected with the conduct by a Non-U.S. Holder of a trade or business within the United States; and (2) in the case of a Non-U.S. Holder that is eligible for the benefits of an income tax treaty with the United States, attributable to a "permanent establishment" or "fixed base" maintained by the Non-U.S. Holder in the United States. Generally, U.S. trade or business income is not subject to U.S. federal withholding tax (provided the Non-U.S. Holder complies with applicable certification and disclosure requirements); instead, U.S. trade or business income is subject to U.S. federal income tax on a net income basis at regular U.S. federal income tax rates in the same manner as if the recipient were a U.S. person. Any U.S. trade or business income received by a Non-U.S. Holder that is treated as a corporation also may be subject to a "branch profits tax" at a 30% rate, or such lower rate as provided under an applicable income tax treaty.

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**Distributions**

Distributions of cash or property (other than certain stock distributions) that we pay with respect to our common stock (or certain redemptions that are treated as distributions with respect to our shares of common stock) will be taxable as dividends for U.S. federal income tax purposes to the extent paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Subject to the discussion in "Recently-Enacted Federal Tax Legislation" below, a Non-U.S. Holder generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount of our distributions or such lower rate as may be specified by an applicable income tax treaty. In order to obtain a reduced rate of U.S. federal withholding tax under an applicable income tax treaty, a Non-U.S. Holder will be required to provide a properly executed IRS Form W-8BEN (or appropriate substitute or successor form) certifying its entitlement to benefits under the treaty. A Non-U.S. Holder of our common stock that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for refund with the IRS. A Non-U.S. Holder is encouraged to consult its own tax advisor regarding its possible entitlement to benefits under an income tax treaty. If the amount of a distribution exceeds our current and accumulated earnings and profits, such excess first will be treated as a tax-free return of capital to the extent of the Non-U.S. Holder's adjusted tax basis in our shares, and thereafter will be treated as capital gain. To the extent a distribution exceeds our current or accumulated earnings and profits, a Non-U.S. Holder of our common stock may obtain a refund or credit of any excess amounts withheld by filing an appropriate form for refund with the IRS. A Non-U.S. Holder's adjusted tax basis in our shares will generally be equal to the amount the Non-U.S. Holder paid for its shares, reduced by the amount of any distributions treated as a return of capital. See, "Sale, Exchange or Other Disposition of Common Stock" below.

The U.S. federal withholding tax does not apply to dividends that are U.S. trade or business income, as described above, of a Non-U.S. Holder who provides a properly executed IRS Form W-8ECI (or appropriate substitute or successor form), certifying that the dividends are subject to tax as income effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

**Sale, Exchange or Other Disposition of Our Common Stock**

Subject to the discussion in "Recently-Enacted Federal Tax Legislation" below, a Non-U.S. Holder generally will not be subject to U.S. federal income tax or withholding tax in respect of any gain recognized on a sale, exchange or other disposition of shares of our common stock unless:

the gain is U.S. trade or business income, as described above;

if a Non-U.S. Holder is an individual and holds shares of our common stock as a capital asset, the Non-U.S. Holder is present in the United States for 183 or more days in the taxable year of the sale or other disposition but is not treated as a resident of the United States for that year, and certain other conditions are met; or

we are or have been during a specified testing period a "United States real property holding corporation" for U.S. federal income tax purposes.

Gain described in the first bullet above will be subject to U.S. federal income tax in the manner described under "U.S. Trade or Business Income." Gain described in the second bullet above will be subject to a flat 30% tax (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

In general, a corporation is a "United States real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide (domestic and foreign) real property interests and its other assets used or held for use in a trade

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or business. For this purpose, real property interests generally include land, improvements and associated personal property. We believe that we have not been, and we are not and do not anticipate becoming, a "United States real property holding corporation" for U.S. federal income tax purposes. If we are or become a "United States real property holding corporation," a Non-U.S. Holder, nevertheless, will not be subject to U.S. federal income or withholding tax in respect of any gain on a sale or other disposition of our common stock so long as shares of our common stock are "regularly traded on an established securities market" as defined under applicable Treasury regulations and a Non-U.S. Holder owns, actually and constructively, 5% or less of our shares at all times during the shorter of the five-year period ending on the date of disposition and such Non-U.S. Holder's holding period for our shares. Prospective investors should be aware that no assurance can be given that our shares will be so regularly traded when a Non-U.S. Holder sells its shares of our common stock.

**U.S. Federal Estate Tax**

Individual Non-U.S. Holders and entities, the property of which is potentially includible in an individual's gross estate for U.S. federal income tax purposes (for example, a trust funded by an individual and with respect to which the individual has retained certain interests or powers), should note that, unless an applicable tax treaty provides otherwise, shares of our common stock will be treated as U.S. situs property subject to U.S. federal estate tax.

**Information Reporting Requirements and Backup Withholding**

We must annually report to the IRS and to each Non-U.S. Holder any dividend income that is subject to U.S. federal withholding tax, or that is exempt from such withholding tax pursuant to an income tax treaty with the United States. Copies of these information returns also may be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides. Under certain circumstances, the Code imposes a backup withholding obligation on certain reportable payments. Dividends paid to a Non-U.S. Holder of our common stock generally will be exempt from backup withholding if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN (or appropriate substitute or successor form) or otherwise establishes an exemption.

The payment of the proceeds from the disposition of our common stock to or through the U.S. office of any broker, U.S. or foreign, will be subject to information reporting and possible backup withholding unless the owner certifies (usually on IRS Form W-8BEN) as to its non-U.S. status under penalties of perjury or otherwise establishes an exemption, provided that the broker does not have actual knowledge or reason to know that the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied. The payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a non-U.S. broker will not be subject to information reporting or backup withholding unless the non-U.S. broker has certain types of relationships with the United States (which we refer to as a United States related person). In the case of the payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a broker that is either a U.S. person or a United States related person, the Treasury Regulations require information reporting (but not the backup withholding) on the payment unless the broker has documentary evidence in its files that the owner is a non-U.S. holder and the broker has no knowledge to the contrary. Non-U.S. Holders should consult their own tax advisors on the application of information reporting and backup withholding to them in their particular circumstances (including upon their disposition of our common stock).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder will be credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, with any excess withholding refunded to the Non-U.S. Holder, provided that the required information is furnished to the IRS.

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**Recently Enacted Legislation Affecting Taxation of Our Common Stock Held by or Through Non-U.S. Entities**

Withholding taxes may apply to certain types of payments made to "foreign financial institutions" (as specifically defined in the Code) and certain other non-United States entities. Specifically, a 30% withholding tax may be imposed on distributions and gross proceeds from the sale, exchange or other disposition of our common stock paid to a foreign financial institution or to a non-financial foreign entity unless (1) the foreign financial institution undertakes certain diligence and reporting, (2) the non-financial foreign entity either certifies it does not have any substantial United States owners or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (1) above, it must enter into an agreement with the IRS requiring, among other things, that it undertake to identify accounts held by certain United States persons or United States-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders.

The withholding provisions above will generally apply to payments of dividends made on or after July 1, 2014 and to payments of gross proceeds from the sale or disposition of stock on or after January 1, 2017. Non-U.S. Holders are urged to consult their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Table of Contents**UNDERWRITING**

Stifel, Nicolaus & Company, Incorporated and JMP Securities LLC are acting as joint book-running managers of the offering and as representatives of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus, each of the underwriters named below has severally agreed to purchase from us the aggregate number of shares of common stock set forth opposite their respective names below:

| <b>Underwriters</b>                      | <b>Number of Shares</b> |
|--|-------------------------|
| Stifel, Nicolaus & Company, Incorporated | 1,785,000               |
| JMP Securities LLC                       | 1,365,000               |
| Canaccord Genuity Inc                    | 735,000                 |
| Janney Montgomery Scott LLC              | 315,000                 |
| <b>Total</b>                             | <b>4,200,000</b>        |

The underwriting agreement provides that the obligations of the several underwriters to purchase the shares of common stock included in this offering are subject to various conditions, including approval of legal matters by counsel. The nature of the underwriters' obligations commits them to purchase and pay for all of the shares of common stock listed above, other than those covered by the over-allotment option described below, if any are purchased.

The underwriters expect to deliver the shares of common stock to purchasers on or about February 11, 2014.

**Over-Allotment Option**

We have granted an option, exercisable for 30 days from the date of this prospectus, to the underwriters to purchase up to a total of 630,000 additional shares of our common stock from us at the initial public offering price, less the underwriting discounts and commissions payable by us, as set forth on the cover page of this prospectus. If the underwriters exercise this option in whole or in part, then each of the underwriters will be separately committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of our common stock in proportion to their respective commitments set forth in the table above. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. Any shares of common stock issued or sold under the option will be issued and sold on the same terms and conditions as the other shares of common stock that are the subject of this offering.

**Determination of Offering Price**

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives of the underwriters. In addition to currently prevailing general conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our company, the factors considered in determining the initial public offering price included our results of operations, our current financial condition, our future prospects, our management, our markets and the economic conditions in and future prospects for the industry in which we compete. We cannot assure you that an active or orderly trading market will develop and continue for our common stock or that our common stock will trade in the public markets subsequent to this offering at or above the initial public offering price.

**Commissions and Discounts**

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus, and at this price less a concession not in excess

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of \$0.504 per share of common stock to other dealers specified in a master agreement among underwriters who are members of the Financial Industry Regulatory Authority. After this offering, the offering price, concessions, and other selling terms may be changed by the underwriters. Our common stock is offered subject to receipt and acceptance by the underwriters and to the other conditions, including the right to reject orders in whole or in part.

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us:

|                                  |           | Total                     |                        |
|----------------------------------|-----------|---------------------------|------------------------|
|                                  | Per Share | Without<br>Over-Allotment | With<br>Over-Allotment |
| Public offering price            | \$ 12.00  | \$ 50,400,000             | \$ 57,960,000          |
| Underwriting discount            | \$ 0.84   | \$ 3,528,000              | \$ 4,057,200           |
| Proceeds, before expenses, to us | \$ 11.16  | \$ 46,872,000             | \$ 53,902,800          |

We estimate that the total expenses of this offering payable by us, excluding underwriting discounts and commissions, will be approximately \$2.4 million. We have also agreed to reimburse the underwriters for certain FINRA-related expenses incurred by them in connection with the offering in an amount up to \$25,000 as set forth in the underwriting agreement.

**Indemnification of Underwriters**

We will indemnify the underwriters against some civil liabilities, including liabilities under the Securities Act and liabilities arising from breaches of our representations and warranties contained in the underwriting agreement. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.

**No Sales of Similar Securities**

The underwriters will require all of our directors and officers and substantially all of our stockholders to agree not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any shares of common stock or any securities convertible into or exchangeable for shares of common stock except for the shares of common stock offered in this offering without the prior written consent of Stifel, Nicolaus & Company, Incorporated and JMP Securities LLC for a period of 180 days after the date of this prospectus, subject to specified limited exceptions. Stifel, Nicolaus & Company, Incorporated and JMP Securities LLC in their sole discretion may release any of the securities subject to these agreements at any time, which, in the case of officers and directors, shall be with notice.

We have agreed that for a period of 180 days after the date of this prospectus, we will not, without the prior written consent of Stifel, Nicolaus & Company, Incorporated and JMP Securities LLC, offer, sell or otherwise dispose of any shares of common stock, except for the shares of common stock offered in this offering, the shares of common stock issuable upon exercise of outstanding options on the date of this prospectus and other specified limited exceptions.

**NASDAQ Global Market Listing**

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol "EGLT."

**Short Sales, Stabilizing Transactions, and Penalty Bids**

In order to facilitate this offering, persons participating in this offering may engage in transactions that stabilize, maintain, or otherwise affect the price of our common stock during and after this offering.

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Specifically, the underwriters may engage in the following activities in accordance with the rules of the Securities and Exchange Commission.

*Short sales.* Short sales involve the sales by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares from us in this offering. The underwriters may close out any covered short position by either exercising their over-allotment option to purchase shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are any short sales in excess of such over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

*Stabilizing transactions.* The underwriters may make bids for or purchases of the shares for the purpose of pegging, fixing, or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum. Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or slowing a decline in the market price of the shares of common stock. They may also cause the price of the shares of common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions.

*Penalty bids.* If the underwriters purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering. Stabilization and syndicate covering transactions may cause the price of the shares to be higher than it would be in the absence of these transactions. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

The transactions above may occur on the NASDAQ Global Market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. If these transactions are commenced, they may be discontinued without notice at any time.

**Discretionary Sales**

The underwriters have informed us that they do not expect to confirm sales of common stock offered by this prospectus to accounts over which they exercise discretionary authority without obtaining the specific approval of the account holder.

**Electronic Distribution**

A prospectus in electronic format may be made available on the internet sites or through other online services maintained by one or more of the underwriters participating in this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.



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**Conflicts of Interest**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates may in the future from time to time provide, investment banking and other financing and banking services to us, for which they may receive customary fees and reimbursement for their expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

**Notice to Prospective Investors in the European Economic Area**

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

to any legal entity that is authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity that has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives; or

in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive,

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive. For purposes of this provision, the expression an "offer of securities to the public" in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the securities as contemplated in this prospectus. Accordingly, no purchaser of the securities, other than the underwriters, is authorized to make any further offer of the securities on behalf of us or the underwriters.

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**Notice to Prospective Investors in the United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive (Qualified Investors) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

**Notice to Prospective Investors in France**

This prospectus has not been prepared in the context of a public offering of financial securities in France within the meaning of Article L.411-1 of the French Code Monétaire et Financier and Title I of Book II of the Règlement Général de l'Autorité des marchés financiers (the "AMF") and therefore has not been and will not be filed with the AMF for prior approval or submitted for clearance to the AMF. Consequently, the shares of our common stock may not be, directly or indirectly, offered or sold to the public in France and offers and sales of the shares of our common stock may only be made in France to qualified investors (investisseurs qualifiés) acting for their own, as defined in and in accordance with Articles L.411-2 and D.411-1 to D.411-4, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code Monétaire et Financier. Neither this prospectus nor any other offering material may be released, issued or distributed to the public in France or used in connection with any offer for subscription or sale of the shares of our common stock to the public in France. The subsequent direct or indirect retransfer of the shares of our common stock to the public in France may only be made in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code Monétaire et Financier.

**Notice to Prospective Investors in Germany**

Each person who is in possession of this prospectus is aware of the fact that no German securities prospectus (Wertpapierprospekt) within the meaning of the securities prospectus act (Wertpapierprospektgesetz, the "act") of the federal republic of Germany has been or will be published with respect to the shares of our common stock. In particular, each underwriter has represented that it has not engaged and has agreed that it will not engage in a public offering in the federal republic of Germany (öffentliches Angebot) within the meaning of the act with respect to any of the shares of our common stock otherwise than in accordance with the act and all other applicable legal and regulatory requirements.

**Notice to Prospective Investors in Switzerland**

The securities which are the subject of the offering contemplated by this prospectus may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. None of this prospectus or any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

None of this prospectus or any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA and the offer of securities has not been and will not be authorized

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under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the securities.

**Notice to Prospective Investors in the Netherlands**

The offering of the shares of our common stock is not a public offering in The Netherlands. The shares of our common stock may not be offered or sold to individuals or legal entities in The Netherlands unless (i) a prospectus relating to the offer is available to the public, which has been approved by the Dutch Authority for the Financial Markets (Autoriteit Financiële Markten) or by the competent supervisory authority of another state that is a member of the European Union or party to the Agreement on the European Economic Area, as amended or (ii) an exception or exemption applies to the offer pursuant to Article 5:3 of The Netherlands Financial Supervision Act (Wet op het financieel toezicht) or Article 53 paragraph 2 or 3 of the Exemption Regulation of the Financial Supervision Act, for instance due to the offer targeting exclusively "qualified investors" (gekwalficeerde beleggers) within the meaning of Article 1:1 of The Netherlands Financial Supervision Act.

**Notice to Prospective Investors in Japan**

The underwriters will not offer or sell any of the shares of our common stock directly or indirectly in Japan or to, or for the benefit of, any Japanese person or to others, for re-offering or re-sale directly or indirectly in Japan or to any Japanese person, except in each case pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law of Japan and any other applicable laws and regulations of Japan. For purposes of this paragraph, "*Japanese person*" means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

**Notice to Prospective Investors in Hong Kong**

The underwriters and each of their affiliates have not (1) offered or sold, and will not offer or sell, in Hong Kong, by means of any document, any shares of our common stock other than (a) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance; and (2) issued or had in its possession for the purposes of issue, and will not issue or have in its possession for the purposes of issue, whether in Hong Kong or elsewhere any advertisement, invitation or document relating to the shares of our common stock which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance and any rules made under that Ordinance. The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice.

**Notice to Prospective Investors in Singapore**

This document has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this document and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of our common stock may not be circulated or distributed, nor may shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the

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"Securities and Futures Act"), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the Securities and Futures Act or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the Securities and Futures Act.

Where shares of our common stock are subscribed or purchased under Section 275 by a relevant person, which is:

- (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares of our common stock under Section 275 except:

- (1) to an institutional investor or to a relevant person, or to any person pursuant to an offer that is made on terms that such rights or interest are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets;
- (2) where no consideration is given for the transfer; or
- (3) by operation of law.

**Notice to Prospective Investors in Denmark**

This Prospectus has not been prepared in the context of a public offering of securities in Denmark within the meaning of the Danish Securities Trading etc. Act c.f. Consolidating Act no. 982 of 6 August 2013 as amended from time to time, or any Executive Orders issued on the basis thereof and has not been and will not be filed with or approved by the Danish Financial Supervisory Authority or any other public authority in Denmark. The offering of shares will only be made to persons pursuant to one or more of the exemptions set out in Executive Order no. 643 of 19 June 2012 on Prospectuses for Securities Admitted to Trading on a Regulated Market and for Offers to the Public of Securities of more than EUR 5,000,000 and in Executive Order No. 644 of 19 June 2012 on Prospectuses for Offers to the Public of Certain Securities between EUR 1,000,000 and EUR 5,000,000, as applicable.

**Notice to Prospective Investors in Sweden**

This document is not a prospectus for the purposes of the Swedish Financial Instruments Trading Act (Sw. lag (1991:980) om handel med finansiella instrument) and does not constitute an offering of securities to the public in Sweden. Accordingly, this document has not been approved by the Swedish Financial Supervisory Authority and may not be published or otherwise distributed, in whole or in part, in Sweden. This document has been prepared on the basis that all offers of securities within Sweden will be made pursuant to an exemption under the Swedish Financial Instruments Trading Act from the requirement to prepare and register a prospectus for offers of securities. Accordingly, this document may not be made available, nor may the offering otherwise be marketed in Sweden, other than in circumstances which are deemed not to be an offer for which a prospectus is required to be prepared and registered pursuant to the Swedish Financial Instruments Trading Act.

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**LEGAL MATTERS**

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Dechert LLP, New York, New York. Cooley, LLP, New York, New York, is counsel for the underwriters in connection with this offering.

**EXPERTS**

The audited financial statements included in this prospectus and elsewhere in the registration statement have been so included in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in giving said report.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, you should refer to the registration statement and the exhibits filed as part of that document. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Room 1580 Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing or telephoning us at Egalet Corporation, 460 East Swedesford Road, Suite 1050, Wayne, PA 19087, (610) 833-4200.

Upon consummation of this offering, we will be subject to the information and periodic reporting requirements of the Exchange Act, and we will file periodic reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at [www.egalet.com](http://www.egalet.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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**Egalet Corporation and Subsidiaries**  
**Condensed Consolidated Balance Sheets**

|   | As of                |                       | Pro Forma             |
|---|----------------------|-----------------------|-----------------------|
|   | December 31,<br>2012 | September 30,<br>2013 | September 30,<br>2013 |
|   |                      | (unaudited)           | (unaudited)           |
| <b>Assets</b>   |                      |                       |                       |
| Current assets:   |                      |                       |                       |
| Cash  | \$ 3,404,000         | \$ 10,463,000         | \$ 10,463,000         |
| Related party receivable  | 34,000               | 32,000                | 32,000                |
| Prepaid expenses  | 680,000              | 1,822,000             | 1,822,000             |
| Other receivables   | 319,000              | 376,000               | 376,000               |
| Total current assets  | 4,437,000            | 12,693,000            | 12,693,000            |
| Property and equipment, net   | 931,000              | 1,437,000             | 1,437,000             |
| Intangible asset  | 200,000              | 205,000               | 205,000               |
| Deposits and other assets   | 25,000               | 27,000                | 27,000                |
| Total assets  | \$ 5,593,000         | \$ 14,362,000         | \$ 14,362,000         |
| <b>Liabilities, convertible preferred stock and stockholders' (deficit) equity</b>  |                      |                       |                       |
| Current liabilities:  |                      |                       |                       |
| Related party senior convertible debt, net of discount  |                      | 9,391,000             |                       |
| Related party subordinated convertible debt, net of discount  |                      | 4,203,000             |                       |
| Accounts payable  | 1,334,000            | 1,505,000             | 1,505,000             |
| Accrued expenses  | 581,000              | 622,000               | 622,000               |
| Other current liabilities   | 19,000               | 107,000               | 107,000               |
| Total current liabilities   | 1,934,000            | 15,828,000            | 2,234,000             |
| Commitments and contingencies   |                      |                       |                       |
| Convertible preferred stock:  |                      |                       |                       |
| Convertible Series A-1 preferred stock, \$0.01 par value, 1,406,984 shares issued and outstanding at December 31, 2012 and September 30, 2013, liquidation preference of \$13,297,000 at September 30, 2013 and no shares issued and outstanding at September 30, 2013, pro forma | 1,443,000            | 1,443,000             |                       |
| Convertible Series A-2 preferred stock, \$0.01 par value, 593,106 shares issued and outstanding at December 31, 2012 and September 30, 2013, liquidation preference of \$4,004,000 at September 30, 2013 and no shares issued and outstanding at September 30, 2013, pro forma    | 770,000              | 770,000               |                       |
| Convertible Series B preferred stock, \$0.01 par value, 2,327,301 shares issued and outstanding at December 31, 2012 and September 30, 2013, liquidation preference of \$41,786,000 at September 30, 2013 and no shares issued and outstanding at September 30, 2013, pro forma   | 12,628,000           | 12,628,000            |                       |
| Convertible Series B-1 preferred stock, \$0.01 par value, 113,916 shares issued and outstanding at December 31, 2012 and September 30, 2013, liquidation preference of \$682,000 at September 30, 2013 and no shares issued and outstanding at September 30, 2013, pro forma      | 116,000              | 116,000               |                       |
| Stockholders' (deficit) equity  |                      |                       |                       |
| Common stock, \$0.01 par value, 1,292,307 shares issued and outstanding at December 31, 2012 and September 30, 2013, and no shares authorized, issued or outstanding at September 30, 2013, pro forma   | 13,000               | 13,000                |                       |
| Common stock, \$0.001 par value, no shares authorized, issued or outstanding at December 31, 2012 and September 30, 2013, and 75,000,000 shares authorized, 9,152,433 shares issued and outstanding at September 30, 2013, pro forma  |                      |                       | 9,000                 |
| Additional paid in capital  | 1,610,000            | 7,431,000             | 51,170,000            |
| Other comprehensive income  | 271,000              | 324,000               | 324,000               |
| Accumulated deficit   | (13,192,000)         | (24,191,000)          | (39,372,000)          |
| Total stockholders' (deficit) equity  | (11,298,000)         | (16,423,000)          | 12,128,000            |
| Total liabilities, convertible preferred stock and stockholders' (deficit) equity   | \$ 5,593,000         | \$ 14,362,000         | \$ 14,362,000         |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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Table of Contents**Egalet Corporation and Subsidiaries****Unaudited Condensed Consolidated Statements of Operations**

|   | <b>For The Nine Months Ended<br/>September 30,</b> |                 |
|---|--|-----------------|
|   | <b>2012</b>  | <b>2013</b>     |
| Revenues  | \$ 1,201,000                                       | \$              |
| Operating expenses:   |  |                 |
| Research and development  | 2,637,000  | 3,220,000       |
| General and administrative  | 1,931,000  | 3,223,000       |
| Total operating expenses  | 4,568,000  | 6,443,000       |
| Loss from operations  | (3,367,000)  | (6,443,000)     |
| Interest expense  | 75,000   | 4,443,000       |
| Loss on foreign currency exchange   | 12,000   | 113,000         |
|   | 87,000   | 4,556,000       |
| Net loss  | \$ (3,454,000)                                     | \$ (10,999,000) |
| Per share information:  |  |                 |
| Net loss per share of common stock, basic and diluted                       | \$ (2.67)  | \$ (8.51)       |
| Basic and diluted weighted average shares outstanding                       | 1,292,307  | 1,292,307       |
| Pro forma net loss per share of common stock, basic and diluted (unaudited) |  | (1.50)          |
| Basic and diluted pro forma weighted average shares outstanding (unaudited) |  | 7,319,134       |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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**Egalet Corporation and Subsidiaries**

**Unaudited Condensed Consolidated Statements of Comprehensive Loss**

|  | <b>For The Nine Months Ended<br/>September 30,</b> |                 |
|--|--|-----------------|
|  | <b>2012</b>  | <b>2013</b>     |
| Net loss                                 | \$ (3,454,000)                                     | \$ (10,999,000) |
| Other comprehensive (loss) income:       |  |                 |
| Foreign currency translation adjustments | (312,000)  | 53,000          |
| Comprehensive loss                       | \$ (3,766,000)                                     | \$ (10,946,000) |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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Table of Contents**Egalet Corporation and Subsidiaries****Unaudited Condensed Consolidated Statements of Cash Flows**

|  | <b>Nine Months Ended September 30,</b> |                 |
|--|--|-----------------|
|  | <b>2012</b>                            | <b>2013</b>     |
| Operating activities:  |  |                 |
| Net loss   | \$ (3,454,000)                         | \$ (10,999,000) |
| Adjustment to reconcile net loss to net cash used in operating activities: |  |                 |
| Depreciation and amortization  | 302,000                                | 313,000         |
| Noncash interest   |  | 4,263,000       |
| Changes in assets and liabilities:   |  |                 |
| Related party receivable   | 2,000                                  | 2,000           |
| Accounts receivable  | 98,000                                 |                 |
| Prepaid expenses   |  | (1,147,000)     |
| Other receivables  | (40,000)                               | (59,000)        |
| Other current assets   | 8,000                                  | (75,000)        |
| Deposits and other assets  |  | (2,000)         |
| Accounts payable   | 31,000                                 | 97,000          |
| Accrued expenses   | (56,000)                               | 41,000          |
| Other current liabilities  | (13,000)                               | 90,000          |
| Deferred revenue   | (522,000)                              |                 |
| Net cash used in operating activities                                      | (3,644,000)                            | (7,476,000)     |
| Investing activities:  |  |                 |
| Payments for purchase of property and equipment                            | (223,000)                              | (727,000)       |
| Net cash used in investing activities                                      | (223,000)                              | (727,000)       |
| Financing activities:  |  |                 |
| Proceeds from the issuance of convertible debt                             |  | 15,000,000      |
| Payment of lender fees   |  | (98,000)        |
| Proceeds from the sale of Series B preferred stock                         | 8,218,000                              |                 |
| Net cash provided by financing activities                                  | 8,218,000                              | 14,902,000      |
| Effect of foreign currency translation on cash                             | (131,000)                              | 360,000         |
| Net increase in cash   | \$ 4,220,000                           | \$ 7,059,000    |
| Cash at beginning of period  | \$ 1,052,000                           | \$ 3,404,000    |
| Cash at end of period  | \$ 5,272,000                           | \$ 10,463,000   |
| Supplemental disclosures of cash flow information:                         |  |                 |
| Conversion of debt and interest into preferred stock                       | \$ 4,411,000                           | \$              |
| Recording of gain (loss) on extinguishment of debt                         | \$ 1,424,000                           | \$ (657,000)    |
| Recording of beneficial conversion features                                | \$                                     | \$ 5,000,000    |

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The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**1. Organization**

Egalet Corporation (the "Company" or "Egalet US") is a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent pharmaceutical products for the treatment of pain and in other indications. The Company was incorporated in Delaware in August 2013 and had nominal assets and no operations. Egalet Limited, incorporated in July 2010 in England and Wales, owned all of the Company's current assets and operations and acquired them in July 2010 pursuant to an agreement to purchase the business and certain assets of Egalet A/S, which was founded under the laws of Denmark. This transaction was accounted for as a business combination. In November 2013, all of the issued and outstanding ordinary shares and preferred shares of Egalet Limited were exchanged for an identical number of shares of common stock and preferred stock of Egalet US, which resulted in Egalet Limited becoming a wholly-owned subsidiary of Egalet US. As Egalet Limited and Egalet US are entities under common control, the consolidated financial statements reflect the historical carrying values of Egalet Limited's assets and liabilities and its results of operations as if they were consolidated for all periods presented. As a result of these transactions, the Company has a late-stage portfolio of product candidates that are being developed using the Company's broad-based drug delivery platform specifically designed to resist manipulation, to prevent easy extraction and to deter the abuse of medications via known routes of abuse, including chewing, snorting, and injecting. The Company's product candidates being developed using its technology offer a predictable and tailored pharmacokinetic profile, lack a significant food effect and resist the effect of alcohol dose dumping. The Company's technology platform can be used with a broad range of opioids and non-opioids. The Company has extensively filed patents to protect its inventions covering both the technology and product-specific patents.

**Liquidity**

The Company has incurred recurring operating losses since inception. For the nine months ended September 30, 2013, the Company incurred a net loss of \$11.0 million and as of September 30, 2013 the Company had generated an accumulated deficit of \$24.2 million. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical programs, strategic collaborations and the development of its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy.

The Company has successfully raised capital since its formation through the issuance of related party convertible debt and equity. During 2011, the Company raised \$6.0 million through the issuance of related party convertible debt that was subsequently converted into shares of convertible preferred series B and series B-1 stock. During 2012, the Company raised \$8.3 million through the issuance of preferred series B convertible preferred stock. In April and August of 2013, the Company raised \$5.0 million and \$10.0 million, respectively, through the issuance of related party convertible debt. The Company has raised a total of \$31.2 million since its formation in 2010.

In addition, the Company had entered into collaborative research and development agreements since 2010 with pharmaceutical and biotechnology companies that accounted for the majority of its \$2.0 million of revenues recognized from 2010 through December 31, 2012.

Management intends to fund future operations through additional equity offerings, revenue from additional research and development agreements, and, if any of the Company's product candidates receive marketing approval, future sales of its products. There can be no assurance, however, that the Company

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**1. Organization (Continued)**

will be successful in obtaining financing at the level needed to sustain operations or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its research and development programs and meet its obligations. If the Company is unable to successfully raise sufficient additional capital, through future debt or equity financings or through strategic and collaborative ventures with third parties, the Company will not have sufficient cash flows and liquidity to fund its planned business operations. In that event, the Company might be forced to limit many, if not all, of its programs and consider other means of creating value for its stockholders, such as licensing to others the development and commercialization of products that it considers valuable and would otherwise likely develop itself. If the Company is unable to raise the necessary capital, it may be forced to curtail all of its activities and, ultimately, potentially cease operations. Even if the Company is able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests.

The unaudited condensed consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company faces many risks associated with early-stage companies. It also faces risks inherent in its business and its industry generally. These risks include, among others, the following:

the Company's success is primarily dependent on the regulatory approval and commercialization of its two lead product candidates, Egalet-001 and Egalet-002;

the Company is subject to regulatory approval processes that are lengthy, time-consuming and unpredictable and may not obtain approval for any of its product candidates from the U.S. Food and Drug Administration or foreign regulatory authorities, if applicable;

the Company has no significant source of product revenue, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as it continues to develop and seek regulatory approvals for, and potentially begins to commercialize, its product candidates;

the Company may need to obtain additional funding to continue operations;

it is difficult and costly to protect the Company's intellectual property rights;

the Company may be unable to recruit or retain key employees, including its senior management team; and

the Company depends on the performance of third parties, including contract research organizations and third-party manufacturers.

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The financial statements are prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP"). The information reported within the Company's financial statements through September 30, 2013 was based on the accounts of Egalet Corporation and its wholly-owned subsidiaries, Egalet Limited and Egalet US, Inc.

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**2. Summary of Significant Accounting Policies and Basis of Accounting**

The unaudited consolidated financial statements are prepared in conformity with U.S. GAAP for interim financial information. Certain information and footnotes normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission. The accompanying consolidated financial statements include the accounts of Egalet Corporation and its wholly-owned subsidiaries, Egalet Limited and Egalet US, Inc. The Company's consolidation policy requires the consolidation of entities where a controlling financial interest is held. All intercompany balances and transactions have been eliminated in consolidation.

**Unaudited Interim Financial Information**

The accompanying condensed consolidated balance sheet as of September 30, 2013, condensed consolidated statements of operations and comprehensive loss and condensed consolidated statements of cash flows for the nine months ended September 30, 2012 and 2013 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2013 and the results of their operations, their comprehensive loss and their cash flows for the nine months ended September 30, 2012 and 2013. The results for the nine months ended September 30, 2013 are not necessarily indicative of results to be expected for the year ending December 31, 2013, any other interim periods, or any future year or period.

**Unaudited Pro Forma Information**

In September 2013, the Company's board of directors (the "Board") authorized management of the Company to pursue the filing of a registration statement with the Securities and Exchange Commission ("SEC") for the Company to sell shares of its common stock to the public in an initial public offering ("IPO"). The unaudited pro forma balance sheet information as of September 30, 2013 assumes the conversion of all outstanding shares of the Company's preferred stock as of that date into 5,329,451 shares of common stock, and the issuance of an aggregate of 2,530,675 shares of common stock upon the conversion of all outstanding principal and accrued interest on the convertible promissory notes at the initial public offering price of \$12.00 per share, which convert automatically upon the closing of the IPO. The unaudited pro forma net loss per share is computed using the weighted-average number of common shares outstanding and gives effect to the conversion of all outstanding shares of the Company's preferred stock as of that date into 5,329,451 shares of common stock, and the issuance of an aggregate of 2,530,675 shares of common stock upon the conversion of all outstanding principal and accrued interest on the convertible promissory notes which convert automatically upon the closing of the IPO, both as if they had occurred at January 1, 2013, or the date of original issuance, if later. Upon conversion of the convertible preferred stock into shares of the Company's common stock in the event of an IPO, the holders of the convertible preferred stock are not entitled to receive undeclared dividends. Accordingly, the impact of the redemption value and issuance costs has been excluded from the determination of net loss per share.



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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)**

**Fair Value Measurements**

The carrying amounts reported in the Company's consolidated financial statements for cash, accounts receivable, accounts payable, accrued liabilities, and approximate their respective fair values because of the short-term nature of these accounts.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Fair value should be based on the assumptions that market participants would use when pricing an asset or liability and is based on a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets (observable inputs) and the lowest priority to the Company's assumptions (unobservable inputs). Fair value measurements should be disclosed separately by level within the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with established fair value hierarchy.

Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates, and often are calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability.

Additionally, there may be inherent weaknesses in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values.

Additionally, from time to time, the Company may be required to record at fair value other assets on a nonrecurring basis, such as assets held for sale and certain other assets. These nonrecurring fair value adjustments typically involve application of lower-of-cost-or-market accounting or write-downs of individual assets.

The Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. These levels are:

**Level 1** Valuations for assets and liabilities traded in active exchange markets, such as the New York Stock Exchange.

**Level 2** Valuations for assets and liabilities that can be obtained from readily available pricing sources via independent providers for market transactions involving similar assets or liabilities. The Company's principal markets for these securities are the secondary institutional markets, and valuations are based on observable market data in those markets.

**Level 3** Valuations for assets and liabilities that are derived from other valuation methodologies, including option pricing models, discounted cash flow models and similar techniques, and are not based

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)**

on market exchange or dealer- or broker-traded transactions. Level 3 valuations incorporate certain assumptions and projections in determining the fair value assigned to such assets or liabilities.

Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management's best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1 or Level 2 at December 31, 2012 and September 30, 2013 and there were no material re-measurements of fair value with respect to financial assets and liabilities, during the nine months ended September 30, 2012 and 2013, other than those assets and liabilities that are measured at fair value on a recurring basis.

The fair value of the related party senior convertible debt is \$19,322,000 and the valuation methodology is described in Note 5. The related party subordinate convertible debt approximates its face amount of \$5,000,000. There were no transfers between Level 1 and Level 2 in any of the periods reported. This was based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, as well as the short-term maturity.

**Significant Accounting Policies**

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2012 included elsewhere in this prospectus. Since the date of those consolidated financial statements, there have been no changes to the Company's significant accounting policies.

**Segment and Geographical Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company globally manages its business within one reportable segment. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance. At December 31, 2012 and September 30, 2013, and for the nine months ended September 30, 2012 and 2013, all of the Company's revenues were derived from, and its long-lived assets were located in, Europe.

**Foreign Currency Translation**

The reporting currency of the Company and its U.S. subsidiary is the U.S. dollar. The Company's functional currency is the Danish Krone. Assets and liabilities of the Company are translated into U.S. dollars based on exchange rates at the end of each reporting period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive income. Gains and losses resulting from foreign currency transactions are reflected within the Company's results of operations. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Table of Contents**Egalet Corporation and Subsidiaries****Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)****Deferred Initial Public Offering Costs**

Deferred initial public offering ("IPO") costs as of September 30, 2013, consisting of legal, accounting, printing and filing fees, were capitalized. The deferred costs are included in prepaid expenses and other current assets on the consolidated balance sheets. The Company capitalized \$968,000 of IPO costs as of September 30, 2013.

**3. Intangible Asset**

In connection with the acquisition of Egalet A/S, the Company recognized an in-process research and development ("IPR&D") asset related to the drug delivery platform specifically designed to help deter physical abuse of pain medications. The IPR&D is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. As of December 31, 2012 and September 30, 2013, the carrying value of IPR&D was \$200,000 and \$205,000, respectively.

**4. Accrued Expenses**

Accrued expenses were as follows:

|                     | <b>December 31,<br/>2012</b> | <b>September 30,<br/>2013</b> |
|---------------------|------------------------------|-------------------------------|
| Payroll             | \$ 541,000                   | \$ 333,000                    |
| Consulting services | 40,000                       | 105,000                       |
| Accrued interest    |                              | 184,000                       |
|                     | <b>\$ 581,000</b>            | <b>\$ 622,000</b>             |

**5. Related Party Convertible Debt**

In January 2011, the Company entered into a \$1,111,000 convertible loan with several of its equity investors to provide the Company with funding to meet its short-term obligations. The loan bore interest at an annual rate of 8% and matured on April 1, 2011. At any time, the holders of the loan could elect to convert their loan balance into shares of the Company's convertible preferred series A-1 stock at a conversion price of \$1.31 per share (based on the exchange rate on January 12, 2011). Any outstanding principal and unpaid interest would automatically convert into shares of convertible preferred series A-1 stock upon a sale of the Company. In the event the Company completed an equity financing with a third party that provided proceeds of at least \$10,453,000 (based on the exchange rate on January 12, 2011), the outstanding principal and unpaid interest would automatically convert into shares of the same series of preferred equity series issued at a conversion price equal to 75% of the subscription price.

In connection with the issuance of the convertible debt in January 2011, the Company recorded a beneficial conversion feature of \$145,000 which represented the difference between the effective conversion price per share of \$1.45 and the fair value per share of the Company's convertible preferred series A-1 stock as of the commitment date of \$1.48. The beneficial conversion feature was recorded as a debt discount and was amortized into earnings over the term of convertible loan and is included in interest expense.

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**5. Related Party Convertible Debt (Continued)**

In April 2011, the Company and its investors entered into an amendment to the convertible loan to extend the maturity date to January 30, 2012 and the Company borrowed an additional \$4,857,000 (based on the exchange rate on April 12, 2011) from the same group of lenders. All other terms, such as interest and conversion rights, remained unchanged.

In March 2012, the Company completed an equity financing that was led by its current equity investors and issued shares of convertible preferred series B and B-1 stock at an issuance price of \$5.82 per share (based on the exchange rate on March 12, 2012). Pursuant to the financing, the Company amended the terms of the convertible loan to allow the holders, upon an election to convert any outstanding principal and interest, to receive shares of convertible preferred series B and B-1 stock at a conversion price of \$5.82 per share (based on the exchange rate on March 12, 2012). The holders of the convertible promissory notes converted their outstanding principal and unpaid interest into 907,467 shares and 113,916 shares of convertible preferred series B and B-1 stock, respectively, at a conversion price of \$5.82 per share. The Company determined the March 2012 amendment to the convertible promissory notes to be substantial, thus accounting for the amendment as a debt extinguishment. With the assistance of a third party valuation firm, management determined the fair value of shares of convertible preferred series B and B-1 stock to be \$4.86 per share and \$1.02 per share, respectively. The \$1,424,000 gain on extinguishment was equal to the excess carrying value of the convertible debt and related interest of \$5,949,000 over the aggregate fair value of the shares of convertible preferred series B and B-1 stock of \$4,525,000. Because the underlying convertible loan was between the Company and its equity investors, the Company accounted for the extinguishment as a noncash charge to additional paid in capital in accordance with ASC 470-50-40-2.

With respect to the convertible preferred series B and B-1 stock, the Company used the probability-weighted average expected return method, or PWERM, as the methodology for determining fair value. Under PWERM, the value of equity securities is estimated based upon an analysis of future values, assuming various outcomes. In this approach, the share value is based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to the Company as well as the rights of each class of stock. PWERM involves the determination of equity value under various exit scenarios and an estimation of the return to the shares of convertible preferred series B and B-1 stock under each of them.

The Company's application of PWERM can be broadly described in the following steps: (i) identify exit scenarios and related probabilities; (ii) determine the equity value under each scenario; and (iii) determine the return to shares of convertible preferred series B and B-1 stock in each scenario. The three exit scenarios identified were (1) complete an initial public offering, or IPO, (2) continue as a private company and (3) conduct a sale. For the IPO scenario, the Company calculated the estimated values of its convertible preferred series B and B-1 stock using assumptions as to pre-money or sale valuations and dates of those scenarios. For the staying private and sale scenarios, the Company used the income approach to estimate the value of its convertible preferred series B and B-1 stock. The income approach involves applying an appropriate risk-adjusted discount rate to projected cash flows based on forecasted revenue and costs. For the March 2012 valuation, the Company used a risk-adjusted discount rate of 20.6% to discount the projected cash flows to the valuation date within the income approach. The determination of the discount rate was based on an analysis of market risks and the risks associated with the Company's business to estimate an appropriate expected rate of return from an investment in the Company's equity, including factors such as the proximity to an IPO, reduced funding risk and the Company's progress made

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**5. Related Party Convertible Debt (Continued)**

on the drug development front. The Company assigned a 0% weighting to the IPO scenario, 20% weighting to the sale scenario, and 80% weighting to the remaining private scenario.

The Company incurred debt issuance costs of \$12,000 in connection with issuance of the convertible debt in 2011. Debt issuance costs were deferred and amortized into interest expense over the term of the loan.

In April 2013, the Company entered into a \$5,000,000 convertible loan with several of its equity investors to provide the Company with funding to meet its short-term obligations. The loan bears interest at an annual rate of 6% and was originally scheduled to mature on December 31, 2013. During December 2013, the maturity date was extended to April 26, 2014. The loan will automatically convert into shares of common stock or convertible preferred series B or series B-1 stock, as applicable, upon (i) the closing of an initial public offering that yields a minimum of approximately \$26.4 million (based on the exchange rate on April 26, 2013) in net proceeds to the Company at a per share price that values the Company at a minimum of \$105.4 million (based on the exchange rate on April 26, 2013), (ii) the affirmative vote of at least sixty-five percent (65%) of the outstanding loan amount, or (iii) a change in control of the Company.

In connection with the issuance of the convertible debt in April 2013, the Company recorded a beneficial conversion feature of \$5,000,000, which represents the difference between the effective conversion price per share of \$5.77 and the fair value per share of the Company's convertible preferred series B and B-1 stock as of the commitment date of \$16.60 and \$6.37, respectively. The beneficial conversion feature was recorded as a debt discount and a charge to additional paid-in-capital. The beneficial conversion feature is being amortized into earnings over the term of convertible loan and is included in interest expense. For the nine months ended September 30, 2012 and 2013, the Company recognized interest expense of \$76,000 and \$3,298,000, respectively.

In its determination of the fair value of the convertible preferred series B and B-1 stock, the Company used the PWERM as the methodology for determining fair value. For the IPO scenario, the Company calculated the estimated values of its convertible preferred series B and B-1 stock using assumptions as to pre-money or sale valuations and dates of those scenarios. For the staying private and sale scenarios, the Company used the income approach to estimate the value of its convertible preferred series B and B-1 stock. For the April 2013 valuation, the Company used a risk-adjusted discount rate of 21.0% to discount the projected cash flows to the valuation date within the income approach. The Company assigned a 10% weighting to the IPO scenario, 30% weighting to the sale scenario, and 60% weighting to the remaining private scenario.

The Company amended the April 2013 convertible loan on August 29, 2013 in connection with its issuance of the \$10,000,000 Senior Convertible Loan (the "2013 Loan Agreement"). The April 2013 convertible loan is subordinate to the 2013 Loan Agreement. In addition, the Company amended the conversion mechanisms for certain investors whereby they were permitted to receive shares of convertible preferred series B stock instead of shares of convertible preferred series B-1 stock. In addition, the same investor group is eligible to receive IPO shares at 50% of the initial public offering price upon conversion of the promissory notes. The Company determined the August 2013 amendment to the convertible promissory notes to be substantial, thus accounting for the amendment as a debt extinguishment. With the assistance of a third party valuation firm, management determined the fair value of the amended April 2013 convertible loan. The \$657,000 loss on extinguishment was equal to the excess carrying value of the convertible debt of \$253,000 over the fair value of the amended convertible debt of \$910,000. Because the

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**5. Related Party Convertible Debt (Continued)**

underlying convertible loan was between the Company and its equity investors, the Company accounted for the extinguishment as a noncash charge to additional paid in capital in accordance with ASC 470-50-40-2.

On August 29, 2013, the Company entered into the 2013 Loan Agreement with several of its equity investors. The 2013 Loan Agreement will be used to fund clinical and manufacturing development, working capital, and other general operational funding requirements. Upon entering into the 2013 Loan Agreement, the Company borrowed \$10,000,000 in debt proceeds. Borrowings under the 2013 Loan Agreement bear interest at an annual rate of 6% and mature on August 29, 2014. Subsequent to the maturity date, all outstanding principal and unpaid interest are due upon written request by lenders holding at least 66% of the principal amount outstanding which constitutes a lending super-majority. Prepayment of any borrowings, prior to maturity, is prohibited unless written approval from the lending super-majority is obtained.

The 2013 Loan Agreement requires the lenders to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an initial public offering that generates aggregate proceeds in excess of approximately \$26.5 million (based on the exchange rate on August 29, 2013) (the "IPO Scenario"). In the event of a conversion under the IPO Scenario, the holders will obtain a number of shares of common stock at a conversion price equal to 50% of the offering price that was initially offered to the public.

The 2013 Loan Agreement provides the holders the right to convert, with the consent of the lending super-majority, any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an equity offering that is not an IPO but that generates aggregate proceeds in excess of \$5,000,000 (the "Equity Scenario"). In the event of a conversion under the Equity Scenario, the holders will receive equity instruments equivalent to those issued in the Equity Scenario, based on the lenders' pro rata portion of outstanding principal and interest.

If the Company sells substantially all of its assets or merges with another Company while the 2013 Loan Agreement remains outstanding, immediately after which the Company's stockholders own less than 50% of the voting shares of the surviving Company (the "Sale Scenario"), then any outstanding principal and interest under the 2013 Loan Agreement will be required to be redeemed for an amount equal to two times the outstanding principal amount together with any unpaid and accrued interest. In the Sale Scenario, the holders will also receive, immediately prior to the transaction, the number of shares of common stock obtained by dividing the number of fully diluted shares by the difference between 1 and the quotient of the aggregate amount of principal and interest on the loan divided by 50% of the sale consideration, and then subtracting the number of fully diluted shares from the result.

In connection with the 2013 Loan Agreement, the lenders received 600,000 warrants that will automatically be exercised immediately prior to consummation of an IPO, provided that such lender purchases a specified minimum amount of common stock in the IPO. Pursuant to the terms of the warrant agreement, the holders would be able to exercise their warrants for shares of common stock at a price of \$0.0083 per share (based on the exchange rate on August 29, 2013). The Company allocated \$1,478,000 of debt proceeds to the warrants based on the warrants' relative fair value and recorded a debt discount.

Upon completion of an IPO Scenario and at the request of the Company, the lenders have the option to invest an additional \$10,000,000. In the event that a lender elects not to participate in the additional

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**5. Related Party Convertible Debt (Continued)**

investment, the Company may convert the outstanding principal and interest into shares of common stock at a price share equal to 400% of the IPO price. In addition, every share of preferred stock held by the defaulting lender shall be converted into shares of common stock of the Company immediately prior to the IPO at a conversion ratio of 0.60 shares of common stock for one share of preferred stock and the holder shall also forfeit its warrants.

The original amount of the 2013 Loan Agreement (\$10,000,000), which entitled the holders of the Senior Convertible Loan to a stock settlement at a price per share equal to 50% of the fair value of the stock that would be determined at the offering, represented stock-settled debt under the provisions of Topic 470-20, "*Debt with Conversion and Other Options*". Due to the conversion price, the Company has determined that this component did not provide an active beneficial conversion feature. The 2013 Loan Agreement is considered a stock-settled debt, since the value of any future stock issued upon conversion will be equal to two times the original principal amount issued under the 2013 Loan Agreement. Fair value of the 2013 Loan Agreement on August 29, 2013 was determined to be \$19,322,000. The Company recorded discount of \$9,322,000 related to the premium. The premium of \$9,322,000 will be amortized into earnings and recorded as interest expense over the term of the 2013 Loan Agreement. The Company recorded interest expense of \$1,145,000 for the nine months ended September 30, 2013.

In its determination of the fair value of the 2013 Convertible Loan, the Company applied the PWERM methodology. For the IPO scenario, the Company calculated the estimated values of its series B and B-1 shares using assumptions as to pre-money or sale valuations and dates of those scenarios. For the staying private and sale scenarios, the Company used the income approach to estimate the value of its 2013 Convertible Loan and applied a risk-adjusted discount rate of 21.7%. The Company assigned a 60% weighting to the IPO scenario, 20% weighting to the sale scenario, and 20% weighting to the remaining private scenario.

**6. Commitments and Contingencies**

**Operating Leases**

In August 2012, the Company entered into a lease for office, laboratory, and pilot manufacturing space in Vaerlose, Denmark. The initial lease term was for 12 months and automatically renews every 12 months until terminated.

The Company's corporate headquarters were previously located in Malvern, Pennsylvania, where the Company leases office space. In March 2012, the Company entered into a six-month lease agreement for its corporate headquarters, which term automatically renews every six months until terminated. The current term expires in March 2014.

Rent expense was \$96,000 and \$148,000 during the nine months ended September 30, 2012 and 2013, respectively.

**Employment Agreements**

Prior to the IPO, the Company did not have any employment agreements with its executives and employees; however the Company is bound by offer letters to such executives and employees. These offer letters provide for, among other things, salary, bonus and severance payments.

Table of Contents**Egalet Corporation and Subsidiaries****Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**6. Commitments and Contingencies (Continued)**

Upon consummation of an initial public offering, or prior to consummation of a change of control transaction, each of the Company's Chief Executive Officer and Chief Financial Officer is entitled to receive an equity grant up to 4.5% and 1.25%, respectively, of the aggregate number of outstanding shares of common stock (after giving effect to such issuance) immediately prior to the consummation of the offering, as long as the officer is employed by the Company at the time the offering is consummated. No compensation expense has been recognized as the events are not deemed probable.

**Legal Proceedings**

The Company is not involved in any legal proceeding.

**7. Net Loss Per Share of Common Stock**

The following table sets forth the computation of basic and diluted earnings per share of common stock for the nine months ended September 30, 2012 and 2013:

|   | <b>For The Nine Months Ended<br/>September 30,</b> |                 |
|---|--|-----------------|
|   | <b>2012</b>  | <b>2013</b>     |
| Basic and diluted net loss per share of common stock: |  |                 |
| Net loss  | \$ (3,454,000)                                     | \$ (10,999,000) |
| Weighted average shares outstanding                   | 1,292,307  | 1,292,307       |
| Net loss per share of common stock basic and diluted  | \$ (2.67)  | \$ (8.51)       |

Shares of convertible preferred stock outstanding of 4,441,217 at September 30, 2012 and 2013 and 600,000 warrants outstanding at September 30, 2013 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive. Potentially dilutive shares related to the Company's convertible debt were also excluded at September 30, 2012 and 2013 as they would be anti-dilutive.

**8. Related Party Transactions**

Dr. Paul Goldenheim was appointed a director of Egalet Limited on March 26, 2012. The Company incurred consultancy fees with Dr. Goldenheim of \$62,500 and \$38,000 during the nine months ended September 30, 2012 and 2013 respectively. As of September 2013, Dr. Goldenheim is no longer a director of Egalet Limited.

The Company has issued convertible debt with certain of its equity investors as discussed further in Note 5, Related Party Convertible Debt.

**9. Subsequent Events****Operating Lease**

In October 2013, the Company entered into a new three year non-cancelable lease in anticipation of relocating its corporate headquarters to Wayne, Pennsylvania. The lease commencement date was December 1, 2013 and contains escalating rent clauses, which require higher rent payments in future years.





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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**9. Subsequent Events (Continued)**

In addition, the Company is obligated to pay fixed and variable monthly operating expenses over the three year lease term.

**Collaboration and License Agreement**

In November 2013, the Company entered into a collaboration and license agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using the Company's technology. The collaboration allows Shionogi to develop and commercialize an abuse-deterrent single-agent hydrocodone-based product and up to 20 different abuse-deterrent combination product candidates containing hydrocodone.

Shionogi is responsible for all development and manufacturing activities related to the licensed product candidates under the agreement. If requested by Shionogi, the Company will perform, at Shionogi's expense, certain formulation and pre-clinical study activities for the licensed product candidates. In addition, Shionogi will be responsible for all regulatory filings for the licensed product candidates and will be responsible for commercializing all licensed products resulting from the collaboration. The development of the licensed product candidates will be facilitated by a joint development committee comprised of equal numbers of representatives of the parties, with Shionogi having the right to make all decisions regarding the development, manufacturing and commercialization of the licensed product candidates.

For a period of six months after the effective date of the agreement, if requested by Shionogi, the Company has agreed to engage in an exclusive, good faith negotiation of a potential transaction in which Shionogi would receive an exclusive license to develop and commercialize an additional product candidate (other than a morphine- or oxycodone-based opioid) incorporating the Company's technology. During these six months, the Company may not enter into or otherwise conduct negotiations with any third party for any license or other agreement with respect to any such product candidate. After this six-month period, for an additional period of 18 months, if Shionogi provides the Company with a proposal for any such additional product candidate, the Company has agreed to engage in the good faith negotiation, on a non-exclusive basis, of a potential transaction in which Shionogi would receive an exclusive license to such additional product candidate. During this eighteen-month period, the Company would not be prevented from negotiating or completing a transaction for such additional product with a third party.

In addition, if the Company chooses at any time during the term of the agreement to license to a third party a morphine- and/or oxycodone-based product candidate that incorporates the Company's technology, such as Egalet-001 and Egalet-002, the Company will notify Shionogi, and Shionogi will have a one-time right to negotiate with the Company, for a period of 60 days, to obtain an exclusive license to such product candidate(s).

Under the terms of the agreement, the Company received an upfront payment of \$10.0 million. The Company is eligible to receive regulatory milestone payments under the agreement as follows: (i) up to \$60.0 million upon successful achievement of specified regulatory milestones for the first licensed product candidate; (ii) up to \$42.5 million upon successful achievement of specified regulatory milestones for a defined combination product candidate; (iii) up to \$25.0 million upon successful achievement of specified regulatory milestones for a second product candidate (other than the defined combination product candidate); and (iv) up to \$12.5 million upon successful achievement of specified regulatory milestones for

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**Egalet Corporation and Subsidiaries**

**Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

**As of December 31, 2012 and September 30, 2013 and  
for the Nine Months Ended September 30, 2012 and 2013**

**9. Subsequent Events (Continued)**

further product candidates. In addition, the Company is eligible to receive up to an aggregate of \$185.0 million based on successful achievement of specified net sales thresholds of licensed products.

If any products are approved for marketing, the Company is eligible to receive royalties at tiered, mid-single digit to low-teen percentage rates on net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the later of (i) expiration of all valid claims of the patent rights licensed to Shionogi that cover the manufacture, use, sale, offer for sale or importation of such licensed product in such country, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country, and (iii) the tenth anniversary of the date of first commercial sale of such licensed product in such country. These royalties may be reduced by Shionogi by certain specified percentages if a licensed product experiences generic competition, or if Shionogi determines it is required to in-license necessary third party intellectual property.

The agreement with Shionogi will remain in effect with respect to each licensed product and country until the expiration of the applicable royalty period for such licensed product in such country. Shionogi may terminate the agreement for convenience in its entirety or with respect to one or more licensed products upon 90 days written notice to the Company. Either the Company or Shionogi may terminate the agreement, in its entirety or with respect to one or more licensed products, if the other party is in material breach and fails to cure such breach within the specified cure period. Either the Company or Shionogi may terminate the agreement in the event of specified insolvency events involving the other party, and the Company may terminate the agreement in the event that Shionogi brings a challenge against the Company in relation to the licensed patents.

**10. Forward Stock Split**

In connection with preparing for this offering, the Company's Board of Directors and stockholders approved a 1.2 to 1 forward stock split of the Company's Common Stock. The forward stock split became effective on January 21, 2014. All share and per share amounts in the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this forward stock split, including reclassifying an amount equal to the increase in par value of common stock to additional paid-in capital.

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Egalet Corporation and Subsidiaries

We have audited the accompanying consolidated balance sheets of Egalet Corporation and Subsidiaries (collectively, the "Company") as of December 31, 2011 and 2012, and the related consolidated statements of operations, comprehensive loss, changes in convertible preferred stock and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Egalet Corporation and Subsidiaries as of December 31, 2011 and 2012, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company incurred a net loss of \$5.4 million during the year ended December 31, 2012, and as of that date has a total stockholders' deficit of \$11.3 million. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

Philadelphia, Pennsylvania

December 4, 2013 (except as to Note 15, which is as of January 23, 2014)

Table of Contents**Egalet Corporation and Subsidiaries****Consolidated Balance Sheets**

|  | <b>December 31,</b> |                     |
|--|---------------------|---------------------|
|  | <b>2011</b>         | <b>2012</b>         |
| <b>Assets</b>  |                     |                     |
| Current assets:  |                     |                     |
| Cash   | \$ 1,052,000        | \$ 3,404,000        |
| Related party receivable   | 34,000              | 34,000              |
| Accounts receivable  | 97,000              |                     |
| Prepaid expenses   | 31,000              | 680,000             |
| Other receivables  | 2,000               | 319,000             |
| Other current assets   | 8,000               |                     |
| <b>Total current assets</b>  | <b>1,224,000</b>    | <b>4,437,000</b>    |
| Property and equipment, net  | 652,000             | 931,000             |
| Intangible asset   | 197,000             | 200,000             |
| Deposits and other assets  | 25,000              | 25,000              |
| <b>Total assets</b>  | <b>\$ 2,098,000</b> | <b>\$ 5,593,000</b> |
| <b>Liabilities, convertible preferred stock, and stockholders' deficit</b>   |                     |                     |
| Current liabilities:   |                     |                     |
| Related party convertible debt, net of discount  | \$ 5,810,000        | \$                  |
| Accounts payable   | 255,000             | 1,334,000           |
| Accrued expenses   | 405,000             | 581,000             |
| Deferred revenue   | 514,000             |                     |
| Other current liabilities  | 13,000              | 19,000              |
| <b>Total current liabilities</b>   | <b>6,997,000</b>    | <b>1,934,000</b>    |
| Commitments and contingencies  |                     |                     |
| Convertible preferred stock:   |                     |                     |
| Convertible Series A-1 preferred stock, \$0.01 par value, 1,406,894 shares issued and outstanding at December 31, 2012 and 2011, liquidation preference of \$12,986,000 at December 31, 2012 | 1,443,000           | 1,443,000           |
| Convertible Series A-2 preferred stock, \$0.01 par value, 593,106 shares issued and outstanding at December 31, 2012 and 2011, liquidation preference of \$3,910,000 at December 31, 2012    | 770,000             | 770,000             |
| Convertible Series B preferred stock, \$0.01 par value, 2,327,301 shares issued and outstanding at December 31, 2012, liquidation preference of \$40,808,000 at December 31, 2012            |                     | 12,628,000          |
| Convertible Series B-1 preferred stock, \$0.01 par value, 113,916 shares issued and outstanding at December 31, 2012, liquidation preference of \$666,000 at December 31, 2012               |                     | 116,000             |
| Stockholders' deficit  |                     |                     |
| Common stock, \$0.01 par value, 1,292,307 shares issued and outstanding at December 31, 2011 and 2012  | 13,000              | 13,000              |
| Additional paid in capital   | 186,000             | 1,610,000           |
| Accumulated other comprehensive income   | 483,000             | 271,000             |
| Accumulated deficit  | (7,794,000)         | (13,192,000)        |
| <b>Total stockholders' deficit</b>   | <b>(7,112,000)</b>  | <b>(11,298,000)</b> |
| <b>Total liabilities, convertible preferred stock and stockholders' deficit</b>  | <b>\$ 2,098,000</b> | <b>\$ 5,593,000</b> |

The accompanying notes are an integral part of these consolidated financial statements.



Table of Contents**Egalet Corporation and Subsidiaries****Consolidated Statements of Operations**

|   | <b>Year Ended December 31,</b> |                |
|---|--------------------------------|----------------|
|   | <b>2011</b>                    | <b>2012</b>    |
| Revenues  | \$ 626,000                     | \$ 1,201,000   |
| Operating expenses:   |                                |                |
| Research and development  | 4,466,000                      | 4,256,000      |
| General and administrative  | 2,068,000                      | 2,241,000      |
| Total operating expenses  | 6,534,000                      | 6,497,000      |
| Loss from operations  | (5,908,000)                    | (5,296,000)    |
| Interest expense  | 513,000                        | 75,000         |
| Loss on foreign currency exchange   | 36,000                         | 27,000         |
|   | 549,000                        | 102,000        |
| Net loss  | \$ (6,457,000)                 | \$ (5,398,000) |
| Per share information:  |                                |                |
| Net loss per share of common stock, basic and diluted                       | \$ (5.00)                      | \$ (4.18)      |
| Basic and diluted weighted average shares outstanding                       | 1,292,307                      | 1,292,307      |
| Pro forma net loss per share of common stock, basic and diluted (unaudited) |                                | \$ (0.88)      |
| Basic and diluted pro forma weighted average shares outstanding (unaudited) |                                | 6,133,632      |

The accompanying notes are an integral part of these consolidated financial statements.

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**Egalet Corporation and Subsidiaries**

**Consolidated Statements of Comprehensive Loss**

|  | <b>Year Ended December 31,</b> |                |
|--|--------------------------------|----------------|
|  | <b>2011</b>                    | <b>2012</b>    |
| Net loss                                 | \$ (6,457,000)                 | \$ (5,398,000) |
| Other comprehensive income (loss):       |                                |                |
| Foreign currency translation adjustments | 396,000                        | (212,000)      |
| Comprehensive loss                       | \$ (6,061,000)                 | \$ (5,610,000) |

The accompanying notes are an integral part of these consolidated financial statements.

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**Egalet Corporation and Subsidiaries**

**Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit**

|  | Convertible Preferred Stock |              |            |            |           |               |            |            | Stockholders' Deficit |           |                                  |                        |  |                 |
|--|-----------------------------|--------------|------------|------------|-----------|---------------|------------|------------|-----------------------|-----------|----------------------------------|------------------------|--|-----------------|
|  | Series A-1                  |              | Series A-2 |            | Series B  |               | Series B-1 |            | Common Stock          |           | Additional<br>Paid in<br>Capital | Accumulated<br>Deficit | Accumulated<br>Comprehensive<br>Income | Total           |
|  | Shares                      | Amount       | Shares     | Amount     | Shares    | Amount        | Shares     | Amount     | Shares                | Amount    |                                  |                        |  |                 |
| Balance at January 1, 2011   | 1,406,894                   | \$ 1,443,000 | 593,106    | \$ 770,000 |           | \$            |            | \$         | 1,292,307             | \$ 13,000 | \$ 41,000                        | \$ (1,337,000)         | \$ 87,000                              | \$ (1,196,000)  |
| Beneficial conversion feature in connection with convertible debt    |                             |              |            |            |           |               |            |            |                       |           | 145,000                          |                        |  | 145,000         |
| Foreign currency translation adjustment                              |                             |              |            |            |           |               |            |            |                       |           |                                  |                        | 396,000                                | 396,000         |
| Net loss   |                             |              |            |            |           |               |            |            |                       |           |                                  | (6,457,000)            |  | (6,457,000)     |
| Balance at December 31, 2011   | 1,406,894                   | 1,443,000    | 593,106    | 770,000    |           |               |            |            | 1,292,307             | 13,000    | 186,000                          | (7,794,000)            | 483,000                                | (7,112,000)     |
| Gain on extinguishment of convertible debt                           |                             |              |            |            |           |               |            |            |                       |           | 1,424,000                        |                        |  | 1,424,000       |
| Conversion of debt into convertible preferred Series B and C-1 stock |                             |              |            |            | 907,467   | 4,358,000     | 113,916    | 116,000    |                       |           |                                  |                        |  |                 |
| Issuance of convertible preferred Series B stock                     |                             |              |            |            | 1,419,834 | 8,270,000     |            |            |                       |           |                                  |                        |  |                 |
| Foreign currency translation adjustment                              |                             |              |            |            |           |               |            |            |                       |           |                                  |                        | (212,000)                              | (212,000)       |
| Net loss   |                             |              |            |            |           |               |            |            |                       |           |                                  | (5,398,000)            |  | (5,398,000)     |
| Balance at December 31, 2012   | 1,406,894                   | \$ 1,443,000 | 593,106    | \$ 770,000 | 2,327,301 | \$ 12,628,000 | 113,916    | \$ 116,000 | 1,292,307             | \$ 13,000 | \$ 1,610,000                     | \$ (13,192,000)        | \$ 271,000                             | \$ (11,298,000) |

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Egalet Corporation and Subsidiaries****Consolidated Statements of Cash Flows**

|  | <b>Year Ended December 31,</b> |                |
|--|--------------------------------|----------------|
|  | <b>2011</b>                    | <b>2012</b>    |
| Operating activities:  |                                |                |
| Net loss   | \$ (6,457,000)                 | \$ (5,398,000) |
| Adjustment to reconcile net loss to net cash used in operating activities: |                                |                |
| Depreciation and amortization  | 592,000                        | 404,000        |
| Loss on asset disposal   | 18,000                         |                |
| Write-off of related party receivable                                      | 186,000                        |                |
| Amortization of beneficial conversion feature and deferred financing fees  | 157,000                        |                |
| Changes in assets and liabilities:   |                                |                |
| Related party receivable   |                                | 1,000          |
| Accounts receivable  | (90,000)                       | 96,000         |
| Prepaid expenses   | (18,000)                       | (2,000)        |
| Other receivables  | 105,000                        | (310,000)      |
| Other current assets   | (9,000)                        | 8,000          |
| Deposits and other assets  | (1,000)                        |                |
| Accounts payable   | 50,000                         | 72,000         |
| Accrued expenses   | 153,000                        | 169,000        |
| Deferred revenue   | 338,000                        | (508,000)      |
| Other current liabilities  | 14,000                         | 8,000          |
| Net cash used in operating activities                                      | (4,962,000)                    | (5,460,000)    |
| Investing activities:  |                                |                |
| Payments for purchase of property and equipment                            | (78,000)                       | (314,000)      |
| Proceeds from the sale of property and equipment                           | 143,000                        |                |
| Net cash provided by (used in) investing activities                        | 65,000                         | (314,000)      |
| Financing activities:  |                                |                |
| Proceeds from the issuance of convertible debt                             | 5,968,000                      |                |
| Repayment of lease financing obligations                                   | (248,000)                      |                |
| Payment of deferred financing fees   | (12,000)                       |                |
| Proceeds from the sale of Series B preferred stock                         |                                | 8,218,000      |
| Net cash provided by financing activities                                  | 5,708,000                      | 8,218,000      |
| Effect of foreign currency translation on cash                             | 163,000                        | (92,000)       |
| Net increase in cash   | 974,000                        | 2,352,000      |
| Cash at beginning of period  | 78,000                         | 1,052,000      |
| Cash at end of period  | \$ 1,052,000                   | \$ 3,404,000   |
| Supplemental disclosures of cash flow information:                         |                                |                |
| Non-cash prepayment for manufacturing project initiation fee               |                                | \$ (631,000)   |
| Non-cash purchases of property and equipment                               | \$ (3,000)                     | \$ (348,000)   |

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### Non-cash financing activities:

|  |    |         |              |
|--|----|---------|--------------|
| Recording of beneficial conversion feature           | \$ | 145,000 | \$           |
| Gain on extinguishment of debt                       | \$ |         | \$ 1,424,000 |
| Conversion of debt and interest into preferred stock | \$ |         | \$ 5,949,000 |

The accompanying notes are an integral part of these consolidated financial statements.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements**

**For the Years Ended December 31, 2011 and 2012**

**1. Organization**

Egalet Corporation (the "Company" or "Egalet US") is a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent pharmaceutical products for the treatment of pain and in other indications. The Company was incorporated in Delaware in August 2013 and had nominal assets and no operations. Egalet Limited, incorporated in July 2010 in England and Wales, owned all of the Company's current assets and operations and acquired them in July 2010 pursuant to an agreement to purchase the business and certain assets of Egalet A/S, which was founded under the laws of Denmark. This transaction was accounted for as a business combination. In November 2013, all of the issued and outstanding ordinary shares and preferred shares of Egalet Limited were exchanged for an identical number of shares of common stock and preferred stock of Egalet US, which resulted in Egalet Limited becoming a wholly-owned subsidiary of Egalet US. As Egalet Limited and Egalet US are entities under common control, the consolidated financial statements reflect the historical carrying values of Egalet Limited's assets and liabilities and its results of operations as if they were consolidated for all periods presented. As a result of these transactions, the Company has a late-stage portfolio of product candidates that are being developed using the Company's broad-based drug delivery platform specifically designed to resist manipulation, to prevent easy extraction and to deter the abuse of medications via known routes of abuse, including chewing, snorting, and injecting. The Company's product candidates being developed using its technology offer a predictable and tailored pharmacokinetic profile, lack a significant food effect and resist the effect of alcohol dose dumping. The Company's technology platform can be used with a broad range of opioids and non-opioids. The Company has extensively filed patents to protect its inventions covering both the technology and product-specific patents.

**Liquidity**

The Company has incurred recurring operating losses since inception. For the year ended December 31, 2012, the Company incurred a net loss of \$5.4 million and as of December 31, 2012, the Company had generated an accumulated deficit of \$13.2 million. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical programs, strategic collaborations and the development of its administrative organization. The Company will require substantial additional financing to fund its operations and to continue to execute its strategy.

The Company has successfully raised capital since its formation through the issuance of convertible debt and equity. During 2011, the Company raised \$6.0 million through the issuance of related party convertible debt that was subsequently converted into shares of convertible preferred series B and B-1 stock. During 2012, the Company raised \$8.3 million through the issuance of shares of convertible preferred series B stock. In April and August of 2013, the Company raised \$5.0 million and \$10.0 million, respectively, through the issuance of related party convertible debt. The Company has raised a total of \$31.2 million since its formation in 2010, including \$15.0 million in additional capital raised in 2013.

In addition, the Company has entered into collaborative research and development agreements since 2010 with pharmaceutical and biotechnology companies, accounting for the majority of its \$2.0 million of revenues recognized through December 31, 2012.

Management intends to fund future operations through additional equity offerings, revenue from additional research and development agreements, and, if any of the Company's product candidates receive marketing approval, future sales of its products. There can be no assurance, however, that the Company

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**1. Organization (Continued)**

will be successful in obtaining financing at the level needed to sustain operations or on terms acceptable to the Company, or that the Company will obtain approvals necessary to market its products or achieve profitability or sustainable, positive cash flow.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is dependent on its ability to raise additional capital to fund its research and development programs and meet its obligations. If the Company is unable to successfully raise sufficient additional capital, through future debt or equity financings or through strategic and collaborative ventures with third parties, the Company will not have sufficient cash flows and liquidity to fund its planned business operations. In that event, the Company might be forced to limit many, if not all, of its programs and consider other means of creating value for its stockholders, such as licensing to others the development and commercialization of products that it considers valuable and would otherwise likely develop itself. If the Company is unable to raise the necessary capital, it may be forced to curtail all of its activities and, ultimately, potentially cease operations. Even if the Company is able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests.

The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company faces many risks associated with early-stage companies. It also faces risks inherent in its business and its industry generally. These risks include, among others, the following:

the Company's success is primarily dependent on the regulatory approval and commercialization of its two lead product candidates, Egalet-001 and Egalet-002;

the Company is subject to regulatory approval processes that are lengthy, time consuming and unpredictable and may not obtain approval for any of its product candidates from the U.S. Food and Drug Administration or foreign regulatory authorities, if applicable;

the Company has no significant source of product revenue, may never become profitable and may incur substantial and increasing net losses for the foreseeable future as it continues to develop and seek regulatory approvals for, and potentially begins to commercialize, its product candidates;

the Company may need to obtain additional funding to continue operations;

it is difficult and costly to protect the Company's intellectual property rights;

the Company may be unable to recruit or retain key employees, including its senior management team; and

the Company depends on the performance of third parties, including contract research organizations and third-party manufacturers.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**2. Summary of Significant Accounting Policies and Basis of Accounting**

**Basis of Accounting**

The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The information reported within the Company's consolidated financial statements through December 31, 2012 was based on the accounts of Egalet Corporation and its wholly-owned subsidiaries, Egalet Limited and Egalet US, Inc. The Company's consolidated financial statements include the accounts of Egalet Corporation and its wholly-owned subsidiaries, Egalet Limited and Egalet US, Inc. The Company's consolidation policy requires the consolidation of entities where a controlling financial interest is held. All intercompany balances and transactions have been eliminated in consolidation.

**Use of Estimates**

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period.

Significant areas that require management's estimates include intangible assets, contingent payment liabilities, allowance for doubtful accounts, revenue recognition, useful lives of assets, the outcome of litigation, convertible debt, equity, and income taxes. The Company is subject to risks and uncertainties due to changes in the healthcare environment, regulatory oversight, competition, and legislation that may cause actual results to differ from estimated results.

**Unaudited Pro Forma Information**

In September 2013, the Company's board of directors (the "Board") authorized management of the Company to pursue the filing of a registration statement with the Securities and Exchange Commission ("SEC") for the Company to sell shares of its common stock to the public in an initial public offering ("IPO"). The unaudited pro forma net loss per share is computed using the weighted-average number of common shares outstanding and gives effect to the conversion of all outstanding shares of the Company's preferred stock as of that date into 5,329,451 shares of common stock as if it had occurred at January 1, 2012, or the date of original issuance, if later. Upon conversion of the convertible preferred stock into shares of the Company's common stock in the event of an IPO, the holders of the convertible preferred stock are not entitled to receive undeclared dividends. Accordingly, the impact of the redemption value and issuance costs has been excluded from the determination of net loss per share.

**Segment and Geographic Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company globally manages the business within one reportable segment. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance. At and during the years ended December 31, 2011 and 2012, all long-lived assets and revenues based upon geographic location were derived from and located in Europe.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)**

**Concentrations of Credit Risk and Off-Balance Sheet Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash. The Company maintains its cash balances in accounts with financial institutions that management believes are creditworthy. The Company has no financial instruments with off-balance sheet risk of loss.

**Cash**

Cash balances are maintained at a Danish financial institution. Bank deposits are insured up to approximately \$132,000 (using an exchange rate of Danish Krone 5.66 to 1.00 U.S. Dollar at December 31, 2012). The Company has uninsured cash balances at December 31, 2012 of approximately \$3.3 million.

**Accounts Receivable and Allowance for Doubtful Accounts**

The majority of the Company's accounts receivable is composed of amounts due from several pharmaceutical companies under collaborative arrangements. The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a regular basis, the Company evaluates its accounts receivable and estimates an allowance for doubtful accounts, as needed, based on various factors such as its customers' current credit conditions, length of time past due, and the general economy as a whole. Receivables are written off against the allowance when they are deemed uncollectible. As of December 31, 2011 and 2012, the Company's allowance for doubtful accounts was zero.

**Fair Value Measurements**

The carrying amounts reported in the Company's consolidated financial statements for cash, accounts receivable, accounts payable, and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Fair value should be based on the assumptions that market participants would use when pricing an asset or liability and is based on a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets (observable inputs) and the lowest priority to the Company's assumptions (unobservable inputs). Fair value measurements should be disclosed separately by level within the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with established fair value hierarchy.

Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates, and often are calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)**

Additionally, from time to time, the Company may be required to record at fair value other assets on a nonrecurring basis, such as assets held for sale and certain other assets. These nonrecurring fair value adjustments typically involve application of lower-of-cost-or-market accounting or write-downs of individual assets.

The Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. These levels are:

- Level 1** Valuations for assets and liabilities traded in active exchange markets, such as the New York Stock Exchange.
- Level 2** Valuations for assets and liabilities that can be obtained from readily available pricing sources via independent providers for market transactions involving similar assets or liabilities. The Company's principal markets for these securities are the secondary institutional markets, and valuations are based on observable market data in those markets.
- Level 3** Valuations for assets and liabilities that are derived from other valuation methodologies, including option pricing models, discounted cash flow models and similar techniques, and are not based on market exchange or dealer- or broker-traded transactions. Level 3 valuations incorporate certain assumptions and projections in determining the fair value assigned to such assets or liabilities.

Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management's best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1 or Level 2 during the years ended December 31, 2011 and 2012 and there were no material re-measurements of fair value with respect to financial assets and liabilities, during those years, other than those assets and liabilities that are measured at fair value on a recurring basis.

Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, as well as the short-term maturity, the carrying value of the related party convertible debt approximates its fair value at December 31, 2011. There were no transfers between Level 1 and Level 2 in any of the periods reported.

**Property and Equipment**

Property and equipment consist primarily of laboratory equipment, furniture and fixtures, and leasehold improvements, all of which are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is



Table of Contents**Egalet Corporation and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2011 and 2012****2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)**

shorter. Maintenance and repairs are expensed as incurred. The following estimated useful lives were used to depreciate the Company's assets:

|                        | <b>Estimated Useful Life</b>                       |
|------------------------|--|
| Laboratory equipment   | 3 - 10 years                                       |
| Furniture and fixtures | 3 - 5 years  |
| Leasehold improvements | Shorter of the lease term or estimated useful life |

Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is charged to income.

**Intangible Asset**

Intangible asset consists of in-process research and development ("IPR&D") related to the Company's drug delivery platform technology acquired by the Company as part of the acquisition of Egalet A/S. IPR&D is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets would be written-off and the Company would record a non-cash impairment loss on its consolidated statement of operations. For those product candidates that reach commercialization, the IPR&D asset will be amortized over its estimated useful lives. For the years ended December 31, 2011 and 2012, the Company determined that there was no impairment of its intangible asset.

**Impairment of Long-Lived Assets**

The Company assesses the recoverability of its long-lived assets, which include property and equipment, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset and a charge to operating results. For the years ended December 31, 2011 and 2012, the Company determined that there was no impairment of its long-lived assets.

**Revenue Recognition**

The Company generates revenue primarily from collaborative research and development agreements with pharmaceutical companies to perform feasibility studies. Generally, the Company's collaborative research and development agreements are completed within one year. Under these collaborative agreements, the research and development services have more than one phase. Each of the phases is critical in the continuation of the study and builds on one another. Upon completion of such services the Company provides a feasibility report, which management has determined to be a significant performance obligation. The Company defers revenue recognition until all substantive performance obligations are completed. Therefore, due to the significant performance obligations the Company has to perform until the end of the contract period and the fact that the Company's contracts are of relatively short duration and the fact that the Company did not keep adequate records to show the cost of each project in accordance with U.S. GAAP the Company recognizes revenues for its collaborative research and development agreements under a completed contract performance method whereby revenue is recognized

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)**

upon delivery of the feasibility report. The Company may receive non-refundable upfront payments for funding of research and development services. Upfront payments are recorded as deferred revenue in the consolidated balance sheet and are recognized upon the completion of all services and no future performance obligations are present. Direct costs incurred in fulfilling the research and development services are expensed as incurred.

**Research and Development Expenses**

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, license fees related to the acquisition of in-licensed products; employee-related expenses, including salaries, benefits and travel; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies; the cost of acquiring, developing and manufacturing clinical trial materials; facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and costs associated with preclinical activities and regulatory operations.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as the case may be.

**Foreign Currency Translation**

The reporting currency of the Company is the U.S. dollar. The functional currency of the Company's non-U.S. operations is the Danish Krone. Assets and liabilities of foreign operations are translated into U.S. dollars based on exchange rates at the end of each reporting period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive loss or income. Gains and losses resulting from foreign currency transactions are reflected within the Company's results of operations. The Company has not utilized any foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

**Comprehensive Loss**

Comprehensive loss is defined as changes in stockholders' deficit exclusive of transactions with owners (such as capital contributions and distributions). Comprehensive income (loss) is comprised of net (loss) and foreign currency translation gains or losses.

**Income Taxes**

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)**

be recovered or settled. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company recognizes the benefit of an uncertain tax position that it has taken or expects to take on its income tax return if such a position is more likely than not to be sustained.

**Clinical Trial Expense Accruals**

As part of the process of preparing its consolidated financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in its consolidated financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2011 and 2012, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Table of Contents**Egalet Corporation and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2011 and 2012****2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)****Basic and Diluted Net Loss Per Share of Common Stock**

Basic net loss per share of common stock is computed by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, excluding the dilutive effects of preferred stock. Diluted net loss per share of common stock is computed by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of common shares outstanding during the period plus the potential dilutive effects of preferred stock outstanding during the period calculated in accordance with the if-converted method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of common stock for the years ended December 31, 2012 and 2011.

**Customer Concentration**

For the years ended December 31, 2011 and 2012, the Company had one and two significant customers, respectively, that accounted for consolidated total revenues as follows:

|            | <b>2011</b> | <b>2012</b> |
|------------|-------------|-------------|
| Customer A | 93.9%       | 44.8%       |
| Customer B | 0.0%        | 55.2%       |

**3. Property and Equipment**

Property and equipment and related accumulated depreciation and amortization are as follows:

|  | <b>December 31,</b> |             |
|--|---------------------|-------------|
|  | <b>2011</b>         | <b>2012</b> |
| Laboratory equipment                           | 1,448,000           | 2,151,000   |
| Less accumulated depreciation and amortization | (796,000)           | (1,220,000) |
| Property and equipment, net                    | \$ 652,000          | \$ 931,000  |

Depreciation and amortization expense was \$592,000 and \$404,000 for the years ended December 31, 2011 and 2012, respectively.

**4. Intangible Asset**

In connection with the acquisition of substantially all of the assets and liabilities of Egalet A/S, the Company recognized an IPR&D asset related to the broad-based drug delivery platform specifically designed to help deter physical abuse of pain medications. The IPR&D is considered an indefinite-lived intangible asset and is assessed for impairment annually, or more frequently if impairment indicators exist. As of December 31, 2011 and 2012, the carrying value of IPR&D was \$197,000 and \$200,000, respectively.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**5. Lease Financing Obligations**

The Company leased certain equipment under lease agreements accounted for as a capital lease financing obligation. During the year ended December 31, 2011, the Company made principal and interest payments of \$248,000 and \$11,900, respectively. There was no capital lease financing obligation at December 31, 2012 or during the year ended December 31, 2012.

**6. Related Party Convertible Debt, Net of Discount**

In January 2011, the Company entered into a \$1,111,000 convertible loan with several of its equity investors to provide the Company with funding to meet its short-term obligations. The loan bore interest at an annual rate of 8% and matured on April 1, 2011. At any time, the holders of the loan could elect to convert their loan balance into shares of the Company's convertible preferred series A-1 stock at a conversion price of \$1.31 per share (based on the exchange rate on January 12, 2011). Any outstanding principal and unpaid interest would automatically convert into shares of convertible preferred series A-1 stock upon a sale of the Company. In the event the Company completed an equity financing with a third party that provided proceeds of at least \$26,132,000, (based on the exchange rate on January 12, 2011) the outstanding principal and unpaid interest would automatically convert into shares of the same series of preferred stock issued at a conversion price equal to 75% of the subscription price.

In connection with the issuance of the convertible debt in January 2011, the Company recorded a beneficial conversion feature of \$145,000 which represented the difference between the effective conversion price per share of \$1.45 and the fair value per share of the Company's convertible preferred series A-1 stock as of the commitment date of \$1.48. The beneficial conversion feature was recorded as a debt discount and was amortized into earnings over the term of convertible loan and is included in interest expense.

In April 2011, the Company and its investors entered into an amendment to the convertible loan to extend the maturity date to January 30, 2012, or later upon demand by the investors, and the Company borrowed an additional \$4,857,000 (based on the exchange rate on April 12, 2011) from the same group of lenders. All other terms, such as interest and conversion rights, remained unchanged.

In March 2012, the Company completed an equity financing that was led by its current equity investors and issued shares of convertible preferred series B and B-1 stock at an issuance price of \$5.82 per share (based on the exchange rate on March 12, 2012). Pursuant to the financing, the Company amended the terms of the convertible loan to allow the holders, upon an election to convert any outstanding principal and interest, to receive shares of convertible preferred series B and B-1 stock at a conversion price of \$5.82 per share (based on the exchange rate on March 12, 2012). The holders of the convertible promissory notes converted their outstanding principal and unpaid interest into 907,467 shares and 113,916 shares of convertible preferred equity series B and B-1 stock, respectively, at a conversion price of \$5.82 per share. The Company determined the March 2012 amendment to the convertible promissory notes to be substantial, thus accounting for the amendment as a debt extinguishment. With the assistance of a third party valuation firm, management determined the fair value of shares of convertible preferred series B and B-1 stock to be \$4.86 per share and \$1.02 per share, respectively. The \$1,424,000 gain on extinguishment was equal to the excess carrying value of the convertible debt and related interest of \$5,949,000 over the aggregate fair value of the shares of convertible preferred series B and B-1 stock of \$4,525,000. Because the underlying convertible loan was between the Company and its equity investors, the Company

Table of Contents**Egalet Corporation and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2011 and 2012****6. Related Party Convertible Debt, Net of Discount (Continued)**

accounted for the extinguishment as a noncash charge to additional paid in capital in accordance with ASC 470-50-40-2.

With respect to the convertible preferred series B and B-1 stock, the Company used the probability-weighted average expected return method, or PWERM, as the methodology for determining fair value. Under PWERM, the value of equity securities is estimated based upon an analysis of future values, assuming various outcomes. In this approach, the share value is based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to the Company as well as the rights of each class of stock. PWERM involves the determination of equity value under various exit scenarios and an estimation of the return to the convertible preferred series B and B-1 stock under each of them.

The Company's application of PWERM can be broadly described in the following steps: (i) identify exit scenarios and related probabilities; (ii) determine the equity value under each scenario; and (iii) determine the return to shares of convertible preferred series B and B-1 stock in each scenario. The three exit scenarios identified were (1) complete an initial public offering, or IPO, (2) continue as a private company and (3) conduct a sale. For the IPO scenario, the Company calculated the estimated values of its convertible preferred series B and B-1 stock using assumptions as to pre-money or sale valuations and dates of those scenarios. For the staying private and sale scenarios, the Company used the income approach to estimate the value of its convertible preferred series B and B-1 stock. The income approach involves applying an appropriate risk-adjusted discount rate to projected cash flows based on forecasted revenue and costs. For the March 2012 valuation, the Company used a risk-adjusted discount rate of 20.6% to discount the projected cash flows to the valuation date within the income approach. The determination of the discount rate was based on an analysis of market risks and the risks associated with the Company's business to estimate an appropriate expected rate of return from an investment in the Company's equity, including factors such as the proximity to an IPO, reduced funding risk and the Company's progress made on the drug development front. The Company assigned a 0% weighting to the IPO scenario, 20% weighting to the sale scenario, and 80% weighting to the remaining private scenario.

**7. Accrued Expenses**

Accrued expenses were as follows:

|                     | <b>December 31,</b> |             |
|---------------------|---------------------|-------------|
|                     | <b>2011</b>         | <b>2012</b> |
| Payroll             | \$ 305,000          | \$ 541,000  |
| Consulting services | 100,000             | 40,000      |
|                     | \$ 405,000          | \$ 581,000  |

Table of Contents**Egalet Corporation and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2011 and 2012****8. Income Taxes**

The Company accounts for income taxes under Financial Accounting Standards Board Accounting Standard Codification ("ASC") 740. Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

|  | <b>As of December 31,</b> |                |
|--|---------------------------|----------------|
|  | <b>2011</b>               | <b>2012</b>    |
| Domestic operations                    | \$                        | \$             |
| Foreign operations                     | (6,457,000)               | (5,398,000)    |
| Loss before provision for income taxes | \$ (6,457,000)            | \$ (5,398,000) |

As of December 31, 2012, the Company had net operating loss ("NOL") carry forwards of \$11,392,000 from its operations in Denmark, which are available to reduce future foreign taxable income. The NOL carry forwards are not subject to future expiration and may be carried forward indefinitely. However, if there is a more than 50% change of stockholders by value or vote at the end of the tax year as compared to the beginning of the tax year, these existing foreign NOLs may not be available to offset certain types of future foreign income (generally, "net financial income", which includes interest income net of interest expense, dividends, and capital gains and losses). In addition, if there are domestic losses in the future, the domestic NOL carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%. This could limit the amount of NOLs that the Company can utilize annually to offset future domestic taxable income or tax liabilities, if any. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized. The Company recognized a liability of \$34,000 and \$33,000 for unrecognized income tax benefits during the years ended December 31, 2011 and 2012, respectively, which reduced the amount of the reported deferred tax asset for net operating loss carry forwards. Through December 31, 2012, the Company had \$67,000 of unrecognized tax benefits and related interest and penalties accrued. Any interest and penalties relating to unrecognized tax benefits will be recorded as a component of income tax expense. The following table indicates the changes to the Company's unrecognized tax benefits:

|                       | <b>For the Year Ended</b> |             |
|-----------------------|---------------------------|-------------|
|                       | <b>December 31,</b>       |             |
|                       | <b>2011</b>               | <b>2012</b> |
| Beginning balance     | \$ 34,000                 | \$ 34,000   |
| Current year increase | 34,000                    | 33,000      |
| Ending balance        | \$ 34,000                 | \$ 67,000   |

Of the Company's unrecognized tax benefits, none would affect the Company's effective tax rate in the period recognized due to the offsetting impact of the valuation allowance recorded against the net

Table of Contents**Egalet Corporation and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2011 and 2012****8. Income Taxes (Continued)**

operating losses. The Company does not expect its unrecognized tax benefit liability to change significantly over the next 12 months. As of December 31, 2012, there was no accrued interest and penalties.

The principal components of the Company's deferred tax assets were as follows:

|                               | <b>As of December 31,</b> |             |
|-------------------------------|---------------------------|-------------|
|                               | <b>2011</b>               | <b>2012</b> |
| Deferred tax assets:          |                           |             |
| Fixed assets                  | \$ 19,000                 | \$ 3,000    |
| Leased assets                 | 22,000                    |             |
| Net operating losses          | 1,684,000                 | 2,848,000   |
| Deferred tax assets           | 1,725,000                 | 2,851,000   |
| Less: Valuation allowance     | (1,725,000)               | (2,851,000) |
| Total net deferred tax assets | \$                        | \$          |

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2011 and 2012, respectively, because the Company's management has determined that it is more likely than not that these assets will not be fully realized. The Company experienced a net change in valuation allowance of \$1,504,000 and \$1,126,000 for the years ended December 31, 2011 and 2012, respectively.

At December 31, 2012, no provision has been made for U.S. federal and state income taxes of foreign earnings due to the history of losses. However, the Company expects the future earnings, if any, of its foreign subsidiaries will continue to be reinvested indefinitely. Upon becoming profitable, distribution of these earnings, in the form of dividends or otherwise, may result in the Company to fall subject to U.S. income taxes and foreign withholding taxes. The determination of the amount of unrecognized deferred U.S. income tax and foreign withholding tax liabilities on these future earnings, if any, is not practicable because of the complexities with the hypothetical calculations.

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

|  | <b>For the Year Ended December 31,</b> |             |
|--|--|-------------|
|  | <b>2011</b>                            | <b>2012</b> |
| Federal income tax at the statutory rate | 34.0%                                  | 34.0%       |
| Permanent items                          | 0.6                                    | (4.5)       |
| State income tax, net of federal benefit | 0.0                                    | 0.0         |
| Change in valuation allowance            | (25.0)                                 | (19.9)      |
| Change in foreign rate                   | (9.0)                                  | (9.0)       |
| Increase in tax reserves                 | (0.6)                                  | (0.6)       |
| Effective income tax rate                | 0.0%                                   | 0.0%        |



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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**9. Commitments and Contingencies**

**Operating Leases**

In August 2012, the Company entered into a lease for office, laboratory, and pilot manufacturing space in Vaerloose, Denmark. The initial lease term was for 12 months and automatically renews every 12 months thereafter until terminated.

The Company's corporate headquarters are located in Malvern, Pennsylvania, where the Company leases office space. In March 2012, the Company entered into a six-month lease agreement for its corporate headquarters, which term automatically renews every six months until terminated.

Rent expense was \$171,000 and \$162,000 for the years ended December 31, 2011 and 2012, respectively.

**Employment Agreements**

The Company does not have any employment agreements with its executives and employees; however the Company is bound by offer letters to such executives and employees. These offer letters provide for, among other things, salary, bonus and severance payments.

Upon consummation of an initial public offering, or prior to consummation of a change of control transaction, each of the Company's Chief Executive Officer and Chief Financial Officer is entitled to receive an equity grant up to 4.5% and 1.25%, respectively, of the aggregate number of outstanding shares of common stock (after giving effect to such issuance) immediately prior to the consummation of the offering, as long as the officer is employed by the Company at the time the offering is consummated. No compensation expense has been recognized as the events are not deemed probable.

**Legal Proceedings**

The Company is not involved in any legal proceeding.

**10. Convertible Preferred Stock and Stockholders' Deficit**

As of December 31, 2012, the Company is authorized to issue two (2) classes of stock to be designated, respectively, "Common Stock" and "Convertible Preferred Stock."

**Common Stock**

On July 30, 2010, the Company issued 1,292,307 shares of common stock with a par value of \$0.01 per share in connection with the acquisition of Egalet A/S. Shares of common stock carry no voting rights or rights to receive notice of a general meeting prior to an initial public offering. Upon a liquidation event or a return of capital, preferred stockholders receive unpaid dividends plus return on capital in priority to any remittances to common stockholders but have no entitlement thereafter.

**Deferred Stock**

In the event of a claim for breach of warranty under the asset purchase agreement in connection with the acquisition of Egalet A/S, the relevant number of shares of common stock necessary to satisfy the claim shall automatically and immediately convert to shares of deferred stock. There were no shares of deferred stock outstanding as of December 31, 2011 and 2012.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**10. Convertible Preferred Stock and Stockholders' Deficit (Continued)**

**Convertible Preferred Stock**

On July 30, 2010, the Company entered into a Subscription and Shareholders' Agreement, or the Series A Subscription Agreement, with Egalet A/S and Atlas Venture Fund VII, L.P., Sunstone Life Science Ventures Fund II K/S, Danish Biotech SPV I P/S, Index Ventures III (Jersey) L.P., Index Ventures III (Delaware) L.P., Index Ventures III Parallel Entrepreneur Fund (Jersey) L.P. and Yucca Partners LP (Jersey Branch), in its capacity as administrator of the Index Co-Investment Scheme (collectively, "the Series A Investors"). Pursuant to the Series A Subscription Agreement, the Series A Investors purchased an aggregate of 413,647 shares of convertible preferred series A-1 stock and 383,835 shares of convertible preferred series A-2 stock in exchange for an aggregate payment of \$1,030,000. In addition, certain of the Series A Investors converted an aggregate of \$304,000 of outstanding convertible loans into 514,548 shares of convertible preferred series A-1 stock. Certain of the Series A Investors also agreed to purchase an aggregate of 478,699 shares of convertible preferred series A-1 stock in exchange for an aggregate payment of \$611,000 upon the completion of certain conditions after the date of the Series A Subscription Agreement, which such conditions were later satisfied and such shares later issued. Certain investors were given the opportunity to subscribe to up to an aggregate of 474,271 shares of convertible preferred series A-2 stock at a price of \$1.28 per share by August 20, 2010. Subsequent to the Series A Subscription Agreement, certain investors exercised this option and purchased 209,271 shares of convertible preferred series A-2 stock in exchange for \$267,000. At December 31, 2012, the convertible preferred series A-1 and A-2 stock have a liquidation preference of \$12,986,000 and \$3,910,000, respectively.

On March 12, 2012, the Company entered into a Subscription and Shareholders' Agreement, or the Series B Subscription Agreement, with Egalet A/S and the Series A Investors and a new investor, CLS Capital Holdings Limited ("CLS," and collectively, the "Series B Investors"). Pursuant to the Series B Subscription Agreement, the Series B Investors purchased an aggregate of 1,419,834 shares of convertible preferred series B stock in exchange for an aggregate payment of \$8,270,000. In addition, the Series A Investors converted an aggregate of \$5,949,000 of outstanding convertible debt and related interest into an aggregate of 907,467 shares of series B convertible preferred stock and 113,916 shares of convertible preferred series B-1 stock. The holders of convertible preferred series B stock are entitled to receive their liquidation preference before the holders of convertible preferred series B-1 stock. At December 31, 2012, the convertible preferred series B and B-1 stock have a liquidation preference of \$40,808,000 and \$666,000, respectively.

Each share of convertible preferred stock is convertible into common stock at each holder's option, or automatically, at any time after the date of issuance until the earlier of an initial public offering which yields a minimum of at least \$26,372,000 in net proceeds to the Company, or upon the affirmative vote of holders of at least sixty percent (60%) of the shares of outstanding convertible preferred stock. The conversion ratio is stipulated in the Company's certificate of incorporation. As of December 31, 2012, the shares of series A-1 and series A-2 convertible preferred stock were convertible into common stock at \$1.10 per share and shares of the series B and series B-1 convertible preferred stock were convertible into common stock at \$4.87 per share.

In addition, upon the occurrence of an initial public offering all classes of convertible preferred stock convert into common stock at a ratio of 1.2 to one. Each share of convertible preferred stock shall have the right to one vote.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**10. Convertible Preferred Stock and Stockholders' Deficit (Continued)**

Convertible preferred stockholders shall be entitled to participate in any distribution of available profits, as defined in the Company's certificate of incorporation, which the Company may determine to distribute pari passu with any other class or classes of stock to whom such distribution is made (as if the convertible preferred stock and other relevant class or classes of stock constituted one class of stock) pro rata on an as converted basis to their respective holdings of stock.

**Liquidation Preference**

In the event of any liquidation, return of capital, or winding up of the Company, either voluntary or involuntary, the surplus assets remaining after payment of its liabilities shall be applied as follows:

- (a) first in paying to each of the series B convertible preferred stockholders, in priority to any other classes of stock, an amount equal to three times the preference amount for each issued share of series B convertible preferred stock held (provided that if there are insufficient surplus assets to pay the amounts per share equal to the relevant preference amount, the remaining surplus assets shall be distributed to the Series B convertible preferred stockholders pro rata to their respective holdings of Series B convertible preferred stock), plus declared but unpaid dividends on each share of series B convertible preferred stock;
- (b) second in paying to each of the series B-1 convertible preferred stockholders, in priority to any other classes other than the series B convertible preferred stock, an amount equal to the preference amount for each issued share of series B-1 convertible preferred stock held (provided that if there are insufficient surplus assets to pay the amounts per share equal to the relevant preference amount, the remaining surplus assets shall be distributed to the series B-1 convertible preferred stockholders pro rata to their respective holdings of shares of series B-1 convertible preferred stock), plus declared but unpaid dividends on each share of series B-1 convertible preferred stock;
- (c) third in paying to each of the series A-1 convertible preferred stockholders and series A-2 convertible preferred stockholders, in priority to the common stock, an amount equal to the preference amount for each issued share of series A-1 convertible preferred stock and share of series A-2 convertible preferred stock held (provided that if there are insufficient surplus assets to pay the amounts per share equal to the relevant preference amount, the remaining surplus assets shall be distributed to the Series A-1 convertible preferred stockholders and series A-2 convertible preferred stockholders pro rata to their respective holdings of series A-1 convertible preferred stock and series A-2 convertible preferred stock), plus declared but unpaid dividends on each share of series A-1 convertible preferred stock and each share of series A-2 convertible preferred stock;
- (d) fourth, in paying to the holders of deferred stock, if any, a total of \$1.32 for the entire class of deferred stock (which payment shall be deemed satisfied by payment to any one holder of deferred stock); and
- (e) the balance of the surplus assets (if any) shall be distributed among the holders of common stock (as if the common stock constituted one and the same class) pro rata to the number of common stock held.

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**10. Convertible Preferred Stock and Stockholders' Deficit (Continued)**

In the event of any return of capital, bonus issue of stock or other securities of the Company by way of capitalization of profits or reserves (other than a capitalization issue in substitution for or as an alternative to a cash dividend which is made available to the preferred stockholders) consolidation or sub-division or any repurchase or redemption of stock (other than preferred stock) or any variation in the subscription price or conversion rate applicable to any other outstanding shares of stock of the Company ("Bonus Issue or Reorganization"), the preference amount shall be subject to adjustment on such basis as may be agreed by the Company and the holders of at least 60% of the shares of preferred stock, which represents an investor majority, within 10 business days after any Bonus Issue or Reorganization.

**Redemption Rights**

The convertible preferred stock is subject to redemption under certain "deemed liquidation" events, as defined, and as such, the convertible preferred stock is considered contingently redeemable for accounting purposes. Accordingly, the convertible preferred stock has been recorded within temporary equity in the consolidated financial statements. The Company has not adjusted the convertible preferred stock to its redemption amount at each reporting period, as the redemption of such convertible preferred stock is not deemed probable of occurrence during the periods presented. The redemption of the convertible preferred stock is not considered probable as the redemption is contingent on the occurrence of "deemed liquidation" events, which include (i) the acquisition of the Company by another entity by means of any transaction or a series of related transactions, unless the existing stockholders of the Company continue to hold at least 50% of the voting power of the surviving or acquiring entity after such transaction; (ii) a sale of all or substantially all of the assets of the Company; and (iii) a transaction or series of transactions in which a person or group of persons acquires beneficial ownership of more than 50% of the voting power of the Company. The Company has concluded that none of these events are probable during the periods presented.

**11. Benefits Plan**

For its employees based in Denmark, the Company subscribes to a state plan for which the pension expense for the financial year is equal to the contributions called by, and thus payable to, such plan. Under Denmark's state plan, contributions paid by the Company are in full discharge of the Company's liability and are recognized as an expense for the period. For the years ended December 31, 2011 and 2012, the Company recorded \$65,000 and \$101,000, respectively, for contributions under its state plan for Denmark employees.

Table of Contents**Egalet Corporation and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****For the Years Ended December 31, 2011 and 2012****12. Net Loss Per Share of Common Stock**

The following table sets forth the computation of basic and diluted loss per share of common stock for the years ended December 31, 2011 and 2012:

|  | <b>Year Ended December 31,</b> |                |
|--|--------------------------------|----------------|
|  | <b>2011</b>                    | <b>2012</b>    |
| Basic and diluted net loss per share of common stock |                                |                |
| Net loss applicable to common stockholders           | \$ (6,457,000)                 | \$ (5,398,000) |
| Weighted average common stock outstanding            | 1,292,307                      | 1,292,307      |
| Net loss per share of common stock basic and diluted | \$ (5.00)                      | \$ (4.18)      |

Shares of convertible preferred stock outstanding of 2,000,000 and 4,441,217 at December 31, 2011 and 2012, respectively, have been excluded from the computation of diluted weighted average ordinary shares outstanding, as they would be anti-dilutive.

**13. Related Party Transactions****Related Party Receivables**

Certain bank accounts remained in the name of Egalet A/S, who is also an investor in the Company. Amounts due from Egalet A/S related to these cash accounts was \$34,000 as of December 31, 2011 and 2012.

**Related Party Expenses**

During the years ended December 31, 2011, the Company recognized \$160,000 in operational expenses that were paid on behalf of Egalet A/S and not expected to be reimbursed by Egalet A/S.

Dr. Paul Goldenheim was appointed a director of Egalet Limited on March 26, 2012. The Company incurred consultancy fees with Dr. Goldenheim of \$138,000 and \$115,000 for the years ended December 31, 2011 and 2012, respectively. As of September 2013, Dr. Goldenheim is no longer a director of Egalet Limited.

The Company has issued convertible debt with certain of its equity investors as discussed further in Note 6, Related Party Convertible Debt, Net of Discount.

**14. Subsequent Events**

The Company has evaluated subsequent events from the balance sheet date through December 4, 2013, the date of the filing, the date at which the financial statements were available to be issued.

**Convertible Loan Agreement**

In April 2013, the Company entered into a \$5,000,000 convertible loan with several of its equity investors to provide the Company with funding to meet its short-term obligations. The loan bears interest at an annual rate of 6% and was originally scheduled to mature on December 31, 2013. The loan will automatically convert into shares of common stock or shares of Series B or Series B-1 convertible preferred stock, as applicable, upon (i) the closing of an initial public offering that yields a minimum of



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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**14. Subsequent Events (Continued)**

\$26,372,000 (based on the exchange rate on April 26, 2013) in net proceeds to the Company at a per share price that values the Company at a minimum of approximately \$105.4 million (based on the exchange rate on April 26, 2013), (ii) the affirmative vote of at least sixty-five percent (65%) of the outstanding loan amount, or (iii) a change in control of the Company.

**Senior Convertible Loan Agreement**

On August 29, 2013, the Company entered into a \$10,000,000 Senior Convertible Loan Agreement (the "2013 Loan Agreement") with several of its equity investors. The 2013 Loan Agreement will be used to fund clinical and manufacturing development, working capital, and other general operational funding requirements. Upon entering into the 2013 Loan Agreement, the Company borrowed \$10,000,000 in debt proceeds. Borrowings under the 2013 Loan Agreement will bear interest at an annual rate of 6% and mature on August 29, 2014. Subsequent to the maturity date, all outstanding principal and unpaid interest are due upon written request by lenders holding at least 66% of the principal amount outstanding which constitutes a lending super-majority. Prepayment of any borrowings, prior to maturity, is prohibited unless written approval from the lending super-majority is obtained.

The 2013 Loan Agreement requires the lenders to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an initial public offering that generates aggregate proceeds in excess of approximately \$26.5 million (based on the exchange rate on August 29, 2013) (the "IPO Scenario"). In the event of a conversion under the IPO Scenario, the holders will obtain a number of shares of common stock at a conversion price equal to 50% of the offering price that was initially offered to the public.

The 2013 Loan Agreement provides the holder the right to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an equity offering that generates aggregate proceeds in excess of \$5,000,000 (the "Equity Scenario"). In the event of a conversion under the Equity Scenario, the holders will receive equity instruments equivalent to those issued in the Equity Scenario, based on the lenders' pro rata portion of outstanding principal and interest.

If the Company sells substantially all of its assets or merges with another Company while the 2013 Loan Agreement remains outstanding, immediately after which the Company's stockholders owned less than 50% of the voting stock of the surviving company (the "Sale Scenario"), then any outstanding principal and interest under the credit facility will be required to be redeemed for an amount equal to two times the outstanding principal amount together with any unpaid and accrued interest. In the Sale Scenario, the holders will also receive, immediately prior to the transaction, the number of shares of common stock obtained by dividing the number of fully diluted shares by the difference between 1 and the quotient of the aggregate amount of principal and interest on the loan divided by 50% of the sale consideration, and then subtracting the number of fully diluted shares from the result.

In connection with the 2013 Loan Agreement, the lenders received 600,000 warrants that will automatically be exercised immediately prior to consummation of an IPO, provided that such lender purchases a specified minimum amount of ordinary shares of common stock offered to such lender by the Company in the IPO. Pursuant to the terms of the warrant agreement, the warrants will automatically be exercised for ordinary shares of common stock at a price of \$0.0083 per share (based on the exchange rate on August 29, 2013).

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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**14. Subsequent Events (Continued)**

Upon completion of an IPO Scenario and at the request of the Company, the lenders have the option to invest an additional \$10,000,000. In the event that a lender elects not to participate in the additional investment, the Company may convert the outstanding principal and interest into ordinary shares of common stock at a price share equal to 400% of the IPO price. In addition, every share of preferred stock held by the defaulting lender shall be converted into ordinary shares of common stock of the Company immediately prior to the IPO at a conversion ratio of 0.60 shares of common stock for one share of preferred stock and the holder shall also forfeit its warrants.

**Operating Lease**

In October 2013, the Company entered into a new three year non-cancelable lease in anticipation of relocating its corporate headquarters to Wayne, Pennsylvania. The lease commencement date is December 1, 2013 and contains escalating rent clauses, which require higher rent payments in future years. In addition, the Company is obligated to pay fixed and variable monthly operating expenses over the three year lease term.

**Collaboration and License Agreement**

In November 2013, the Company entered into a collaboration and license agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using the Company's technology. The collaboration allows Shionogi to develop and commercialize an abuse-deterrent single-agent hydrocodone-based product and up to 20 different abuse-deterrent combination product candidates containing hydrocodone.

Shionogi is responsible for all development and manufacturing activities related to the licensed product candidates under the agreement. If requested by Shionogi, the Company will perform, at Shionogi's expense, certain formulation and pre-clinical study activities for the licensed product candidates. In addition, Shionogi will be responsible for all regulatory filings for the licensed product candidates and will be responsible for commercializing all licensed products resulting from the collaboration. The development of the licensed product candidates will be facilitated by a joint development committee comprised of equal numbers of representatives of the parties, with Shionogi having the right to make all decisions regarding the development, manufacturing and commercialization of the licensed product candidates.

For a period of six months after the effective date of the agreement, if requested by Shionogi, the Company has agreed to engage in an exclusive, good faith negotiation of a potential transaction in which Shionogi would receive an exclusive license to develop and commercialize an additional product candidate (other than a morphine- or oxycodone-based opioid) incorporating the Company's technology. During these six months, the Company may not enter into or otherwise conduct negotiations with any third party for any license or other agreement with respect to any such product candidate. After this six-month period, for an additional period of 18 months, if Shionogi provides the Company with a proposal for any such additional product candidate, the Company has agreed to engage in the good faith negotiation, on a non-exclusive basis, of a potential transaction in which Shionogi would receive an exclusive license to such additional product candidate. During this eighteen-month period, the Company would not be prevented from negotiating or completing a transaction for such additional product with a third party.



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**Egalet Corporation and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2012**

**14. Subsequent Events (Continued)**

In addition, if the Company chooses at any time during the term of the agreement to license to a third party a morphine- and/or oxycodone-based product candidate that incorporates the Company's technology, such as Egalet-001 and Egalet-002, the Company will notify Shionogi, and Shionogi will have a one-time right to negotiate with the Company, for a period of 60 days, to obtain an exclusive license to such product candidate(s).

Under the terms of the agreement, the Company received an upfront payment of \$10.0 million. The Company is eligible to receive regulatory milestone payments under the agreement as follows: (i) up to \$60.0 million upon successful achievement of specified regulatory milestones for the first licensed product candidate; (ii) up to \$42.5 million upon successful achievement of specified regulatory milestones for a defined combination product candidate; (iii) up to \$25.0 million upon successful achievement of specified regulatory milestones for a second product candidate (other than the defined combination product candidate); and (iv) up to \$12.5 million upon successful achievement of specified regulatory milestones for further product candidates. In addition, the Company is eligible to receive up to an aggregate of \$185.0 million based on successful achievement of specified net sales thresholds of licensed products.

If any products are approved for marketing, the Company is eligible to receive royalties at tiered, mid-single digit to low-teen percentage rates on net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the later of (i) expiration of all valid claims of the patent rights licensed to Shionogi that cover the manufacture, use, sale, offer for sale or importation of such licensed product in such country, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country, and (iii) the tenth anniversary of the date of first commercial sale of such licensed product in such country. These royalties may be reduced by Shionogi by certain specified percentages if a licensed product experiences generic competition, or if Shionogi determines it is required to in-license necessary third party intellectual property. The agreement with Shionogi will remain in effect with respect to each licensed product and country until the expiration of the applicable royalty period for such licensed product in such country. Shionogi may terminate the agreement for convenience in its entirety or with respect to one or more licensed products upon 90 days written notice to the Company. Either the Company or Shionogi may terminate the agreement, in its entirety or with respect to one or more licensed products, if the other party is in material breach and fails to cure such breach within the specified cure period. Either the Company or Shionogi may terminate the agreement in the event of specified insolvency events involving the other party, and the Company may terminate the agreement in the event that Shionogi brings a challenge against the Company in relation to the licensed patents.

**15. Forward Stock Split**

In connection with preparing for this offering, the Company's Board of Directors and stockholders approved a 1.2 to 1 forward stock split of the Company's Common Stock. The forward stock split became effective on January 21, 2014. All share and per share amounts in the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this forward stock split, including reclassifying an amount equal to the increase in par value of common stock to additional paid-in capital.

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**4,200,000 Shares**

**Common Stock**

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**PROSPECTUS**

**February 5, 2014**

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**Stifel**

**JMP Securities**

**Canaccord Genuity**

**Janney Montgomery Scott**

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