Egalet Corp
Form 10-K
March 16, 2015

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark one)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

Or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number 001-36295

Egalet Corporation

(Exact name of registrant as specified in its charter)

Delaware	**46-3575334**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
460 East Swedesford Road **Suite 1050** **Wayne, PA**	**19087**
(Address of principal executive offices)	(Zip Code)

(610) 833-4200
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes o No ý

As of June 30, 2014 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $132.0 million based on the last reported sale price of the registrant's common stock on June 30, 2014.

There were 17,323,663 shares of Common Stock outstanding as of March 16, 2015.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for the 2015 Annual Meeting of Stockholders, to be filed within 120 days of December 31, 2014, are incorporated by reference in Part III. Such Proxy Statement, except for the parts therein which have been specifically incorporated by reference, shall not be deemed "filed" for the purposes of this Annual Report on Form 10-K.

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EGALET CORPORATION
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On November 26, 2013, Egalet Corporation (the "Company") acquired all of the outstanding shares of Egalet Limited ("Egalet UK"). As a result, Egalet UK became a wholly-owned subsidiary of the Company, and the former shareholders of Egalet UK received shares of the Company (the "Share Exchange"). Unless the context indicates otherwise, as used in this Annual Report on Form 10-K, the terms "Egalet," "we," "us," "our," "our company" and "our business" refers to the Company for all periods subsequent to the Share Exchange, and to Egalet UK for all periods prior to the Share Exchange. The Egalet logo is our trademark and Egalet is our registered trademark. All other trade names, trademarks and service marks appearing in this Annual Report on Form 10-K 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 Annual Report on Form 10-K, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Annual Report on Form 10-K 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. Unless otherwise indicated, all statistical information provided about our business in this report is as of December 31, 2014.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K (this "Annual Report") 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 Annual Report 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 our initial public 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 Annual Report, 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 Annual Report. 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 Annual Report, 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 products and product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our products and product candidates;
- our ability to achieve the milestones set forth in our collaboration agreement with Shionogi;

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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 our initial public 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;

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.

You should also read carefully the factors described in the "Risk Factors" section of this Annual Report 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 Annual Report 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.

Any forward-looking statements that we make in this Annual Report speak only as of the date of such statement, and, except as required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report 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.

We obtained the industry, market and competitive position data in this Annual Report 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 Annual Report provided by IMS Health Incorporated ("IMS") is an estimate derived from the use of information under license from the following IMS Health information services: IMS National Sales Perspectives and NPA Audits, in each case, for the period 2007-2013. IMS expressly reserves all rights, including rights of copying, distribution and republication.

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PART I

ITEM 1. ***BUSINESS***

Overview

We are a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative medicines for patients with acute and chronic pain while helping to protect physicians, families and communities from the burden of prescription abuse. On January 8, 2015 we announced the acquisition and license of two innovative pain products, SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO (oxycodone HCI, USP) tablets for oral use only CII, both approved by the U.S. Food and Drug Administration ("FDA") to treat pain. SPRIX Nasal Spray, a non-steroidal anti-inflammatory drug ("NSAID"), is indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. OXAYDO is the first and only approved immediate-release ("IR") oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate. In addition, using our proprietary Guardian Technology, we are developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. We have initiated a pivotal bioequivalence ("BE") study for our lead product candidate based on our proprietary technology in the first quarter of 2015 and plan to start a Phase 3 program for our second product candidate in the second quarter of 2015. We plan to submit a new drug application ("NDA") for our first product candidate in the fourth quarter of 2015 and an NDA for our second product candidate in the second half of 2016. We also have a collaboration and license agreement with Shionogi Limited ("Shionogi") to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. Our Guardian Technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple active pharmaceutical ingredients with similar or different release profiles and offers us a number of long-term growth opportunities.

Pain is associated with a wide range of injuries and disease, and is sometimes the disease itself according to the American Academy of Pain Medicine. Pain that comes on quickly referred to as acute pain can be severe, but lasts a relatively short time, however in some cases leads to chronic pain. The millions suffering from acute or chronic pain every year greatly impacts our country with increasing health care costs, rehabilitation and lost worker productivity. Pain is a significant public health problem that costs society at least $560 to $635 billion annually, an amount equal to about $2,000 for every individual living in the United States according to the Institute of Medicine of the National Academies 2011 report, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research, 2011*. Severe pain typically stops an individual from participating in activities and causes individuals to change their behavior to avoid such activities. The costs of unrelieved pain can result in longer hospital stays, increased rates of re-hospitalization, increased outpatient visits and decreased ability to function fully leading to lost income and insurance coverage. The Institute of Medicine estimates that approximately 100 million Americans more than those affected by heart disease, cancer, and diabetes combined suffer from chronic pain a significant portion of the population that excludes those affected by acute pain. Opioids are powerful analgesics which are commonly used and found to be effective for many types of pain according to the American Academy of Pain Medicine. IMS prescription data from 2013 show that they are the most widely prescribed products for pain, with prescriptions exceeding 200 million in 2013.

The combination of the widespread incidence of chronic pain and the use of opioids to treat chronic pain, has led to an epidemic of prescription drug abuse. Deaths from drug overdose have been rising steadily over the past two decades and have become the leading cause of death in the United States surpassing deaths caused by automobile accidents. Opioids were involved in more than 70 percent of the prescription drug-related deaths in 2013 according to the Centers for Disease Control

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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 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 payers, largely the result of emergency room visits, rehabilitation and associated health problems, are up to $72.5 billion annually.

In reaction to the increasing costs and other consequences of widespread prescription opioid abuse, the United States 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, legislation was introduced into the U.S. Congress that suggested all opioids should be in an abuse-deterrent form and in 2015, PhRMA and BIO, the U.S. biopharmaceutical industry's two largest trade groups, called on the FDA to not approve or revoke approval for generic equivalents or non-abuse deterrent painkillers if a drug manufacturer has since made improvements to a drug to make it harder to abuse.

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.

OXAYDO is the first and only approved immediate-release oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate. OXAYDO was approved in 2011 and has data in its label from a Category 3 intranasal human abuse liability ("HAL") study. The study compared drug liking and potential to "take drug again" in a population of recreational non-dependent opioid users after snorting crushed OXAYDO and crushed IR oxycodone. The responses on both "take drug again" and drug liking were lower for OXAYDO compared to IR oxycodone.

Immediate-release oxycodone is more often abused than extended-release ("ER") oxycodone and is most often abused via the route of snorting. There has been a 40 percent increase in the abuse of IR oxycodone since the reformulation of ER oxycodone according to the National Poison Data System survey. With 52.3 million prescriptions of IR oxycodone written in 2013, there is a substantial need for an abuse-deterrent IR oxycodone like OXAYDO.

SPRIX Nasal Spray is the first and only approved nasal spray formulation of NSAID, in this case ketorolac, used for short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. This product targets the significant short-acting analgesic market, of which there are approximately 97 million prescriptions written annually for short-acting pain treatments (for less than five days) according to IMS data. SPRIX provides analgesia at the opioid level without the side effects or issues of misuse or abuse common to opioids. Our initial commercial focus will be to introduce the product and its unique profile to pain care specialists who routinely see patients that require short-term analgesics requiring opioid level analgesia. We have begun our promotional efforts on this product in the first quarter of 2015.

To commercialize SPRIX and OXAYDO and ultimately our pipeline products candidates, we are building a 50 to 60 person specialty sales force targeting the approximately 5,700 physicians in the

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high-decile of prescribing pain medicines in the United States. We intend to consider partnerships to access third-party sales representatives who target primary care and internal medicine physicians in the United States and collaborations with other companies to develop and commercialize our product candidates outside the United States.

Formulated using our proprietary Guardian Technology, we are developing two late-stage product candidates specifically designed to deter abuse by physical and chemical manipulation. The lead program, Egalet-001, an abuse-deterrent, extended-release, oral morphine formulation, and our second product candidate Egalet-002, an abuse-deterrent, extended-release, oral oxycodone formulation, are in late-stage clinical development for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments are inadequate. We initiated a bioequivalence study for our lead product candidate based on our proprietary technology in the first quarter of 2015 and plan to start a Phase 3 program for our second product candidate in the second quarter of 2015. We plan to submit an NDA for our first product candidate in the fourth quarter of 2015 and an NDA for our second product candidate in the second half of 2016.

Using our proprietary Guardian Technology, 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 Guardian Technology allows us to create physical and chemical barriers intended to deter the most common methods of abuse that are specific to a particular drug. For instance with Egalet-001, an abuse-deterrent, extended-release morphine, it was designed to deter all forms of abuse but primarily abuse via the route of injection the most common method of morphine abuse. The Egalet-001 system consists of a hard matrix that erodes as it passes through the gastrointestinal tract. This polymer matrix construct makes extracting the API into a solution which could be drawn into a syringe very challenging making this product very difficult to be abused via the route of injection.

We believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. We have completed a Phase 1 study and four BE studies of Egalet-001. The fourth BE study was recently completed with positive results announced in March 2015. Based on this study which showed bioequivalence of Egalet-001 30 mg to MS Contin 30 mg as well of two Egalet-001 15 mg tablets to one MS Contin 30 mg tablet and supportive feedback from the FDA, we are seeking to establish bioequivalence of Egalet-001 to MS Contin. In parallel, we are conducting 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. In January of 2015 we announced positive top-line data from a Category 3 abuse-deterrent oral HAL study. This was the first clinical demonstration in which Egalet-001 showed lower abuse potential compared to MS Contin when taken orally. We are currently conducting a Category 3 intranasal HAL study as well. We have initiated a pivotal bioequivalence study to evaluate BE of Egalet-001 60 mg to MS Contin 60 mg and to assess the food effect on Egalet-001 60 mg in healthy subjects with results expected in the fourth quarter of 2015. We plan to seek U.S. regulatory approval of Egalet-001 pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. Under this proposed approval pathway, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2015.

Also using our Guardian Technology for Egalet-002, we designed a tablet with a similar matrix construct and have added a hard impermeable coating, or shell, around the outside. The shell, which passes safely through the gastrointestinal ("GI") tract intact, adds a layer of rigidity to the tablet which makes particle size reduction even more difficult. This is important because oxycodone is abused most often via particle size reduction and insufflation or snorting. In addition, the Guardian system used to formulate Egalet-002 was designed to inhibit alcohol dose dumping and intended to not produce changes in the rate of absorption of the API in the GI tract based on the presence or absence of food.

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We believe Egalet-002, if approved, will have advantages over commercially available, long-acting, abuse-deterrent oxycodone products, such as OxyContin®, due to its differentiated abuse-deterrent properties and a pharmacokinetic ("PK") profile that demonstrates low peak-to-trough concentration variability in drug exposure. We have conducted Phase 1 trials of Egalet-002 and completed initial abuse-deterrent studies in compliance with the FDA draft guidance. We plan to initiate a Phase 3 safety and efficacy program for Egalet- 002 in the second quarter of 2015. Peak-to-trough concentration variability means the difference between the highest concentration of an active pharmaceutical ingredient ("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 could 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 are also conducting additional abuse-deterrent studies in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product label. We plan to seek U.S. regulatory approval of Egalet-002 pursuant to Section 505(b)(2) and anticipate submitting an NDA for Egalet-002 in the second half of 2016.

Egalet-001, our abuse-deterrent oral morphine product candidate, and Egalet-002, our abuse-deterrent oral oxycodone product candidate, will target the 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 more than $3.0 billion in the United States in 2013.

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 is 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. Shionogi also invested $15 million in a private placement concurrently with our initial public offering. 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 Guardian 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 Guardian Technology are protected by 66 issued and pending patent applications worldwide as well as unpatented know-how and trade secrets.

Members of our management team have substantial experience in formulation and 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®, Lidoderm®, Fentora®, Maxalt®, Zyprexa® and Prozac®. We believe this experience will help us to successfully develop and commercialize SPRIX®, OXAYDO and our abuse-deterrent product candidates.

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Strategy

Our goal is to be a leading specialty pharmaceutical company focused on developing and commercializing innovative pain treatments. Key elements of our strategy include:

Executing our sales and marketing strategy for SPRIX and OXAYDO. SPRIX Nasal Spray, an NSAID, is indicated for the short-term (up to 5 days in adults) management of moderate to moderately severe pain that requires analgesia at the opioid level. SPRIX is currently available to patients and has remained available following our acquisition of the product from Luitpold Pharmaceuticals, Inc. ("Luitpold") on January 8, 2015. We announced an increase in the wholesale acquisition cost to $942 per prescription on January 12, 2015. We began promotional efforts in the first quarter of 2015. OXAYDO, which we licensed from Acura Pharmaceuticals, Inc. ("Acura") also on January 8, 2015, is approved for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. We plan to launch OXAYDO in the third quarter of 2015. To support these commercial activities, we are building our commercial infrastructure by adding resources to our sales, marketing, medical affairs, managed markets and distribution functions. We are building a 50 to 60 person specialty sales force targeting the approximately 5,700 high-decile prescribing pain medicines physicians in the United States to build awareness and increase adoption of both SPRIX and OXAYDO.

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 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. In March 2015 we announced positive study results that showed bioequivalence of Egalet-001 30 mg to MS Contin 30 mg as well as two Egalet-001 15 mg tablets to one MS Contin 30 mg tablet. In addition, we received supportive feedback from the FDA in the first quarter of 2015 to pursue approval by establishing Egalet-001 bioequivalence to MS Contin. Also in January 2015 we announced positive top-line data from a Category 3 abuse-deterrent oral HAL study which demonstrated lower abuse potential of Egalet-001 compared to MS Contin. We have initiated a pivotal bioequivalence study to evaluate BE of Egalet-001 60 mg to MS Contin 60 mg and to assess the food effect on Egalet-001 60 mg in healthy subjects with results expected in the fourth quarter of 2015. We plan to seek U.S. regulatory approval of Egalet-001 pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. The FDA has granted us Fast Track status with respect to Egalet-001. Under this proposed approval pathway, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2015.

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 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. We plan to initiate a pivotal Phase 3 safety and efficacy program in the second quarter of 2015 along with a long-term, open-label safety trial. We have conducted Phase 1 PK trials of Egalet-002, an extensive battery of Category 1 abuse-deterrent studies compared to OxyContin, are in the clinic with a Category 3 oral HAL study, and will field a head-to-head intranasal HAL study compared to OxyContin later this year. The FDA has granted us Fast Track status with respect to Egalet-002. Based on this, and the expected timing of our clinical trials, we anticipate submitting an NDA for Egalet-002 in the second half of 2016.

Commercialize Egalet-001 and Egalet-002. If either of our clinical-stage product candidates achieve regulatory approval, we intend to employ our established commercial organization to market our products in the United States by targeting the approximately 5,700 physicians in the high-decile of prescribing pain medicines in the United States. To supplement our internal U.S.

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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 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 Guardian 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 may 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. We have already 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. We also will look to develop new and innovative applications of our Guardian Technology to create safer medicines.

Approved Products

SPRIX Nasal Spray for short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level

Overview

SPRIX® (ketorolac tromethamine) Nasal Spray is an NSAID indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. Roxro Pharma, Inc. received FDA approval for SPRIX Nasal Spray on May 14, 2010 and Regency Therapeutics, a division of Luitpold, Inc., and its co-promotion partner Daiichi Sankyo, Inc., announced the launch of SPRIX on May 17, 2011. On January 8, 2015, we entered into an agreement with Luitpold to purchase SPRIX Nasal Spray. Under the terms of the agreement with Luitpold, we acquired all intellectual property and certain other assets required to commercialize SPRIX. We agreed to pay Luitpold $7 million. We have begun promotional activities to build awareness and increase adoption of SPRIX.

Formulated as an easy-to-use spray, SPRIX is rapidly absorbed through the nasal mucosa, achieving peak blood levels as fast as an intramuscular injection of ketorolac. SPRIX has been studied in patients with moderate to moderately severe pain. The NDA package for SPRIX included data from more than 1,000 subjects and 14 clinical trials. SPRIX has been tested in four controlled efficacy studies, and met the primary efficacy endpoints in each trial. Phase 3 studies of adults who underwent elective abdominal or orthopedic surgery (n=300 and n=321) indicated that SPRIX provided a statistically significant reduction in the summed pain intensity difference, a commonly accepted measure of pain, over 48 hours as compared to those using placebo. SPRIX has also demonstrated a 26 to 34 percent reduction in morphine use by patients over a 48-hour period in a post-operative setting as compared with placebo.

Market Opportunity

There are approximately 97 million prescriptions written for acute pain treatments for less than five days. Historically a range of physicians, from podiatrists to orthopedic surgeons have prescribed SPRIX, with limited prescriptions coming from pain care specialists. While pain care specialists are generally familiar with other forms of ketorolac, there is limited familiarity with SPRIX Nasal Spray. There were 1.5 million ketorolac prescriptions and 29,000 SPRIX prescriptions in 2013. We plan to maintain the base business through a customer service center and proactively market to high-decile prescribing physicians in the United States with a commercial sales force.

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Commercialization Strategy

To commercialize SPRIX, OXAYDO and ultimately our pipeline products, we are building a 50 to 60 person specialty sales force to market our products in the United States targeting the approximately 5,700 physicians in the high-decile of prescribing pain medicines in the United States. We will consider partnerships to access third-party sales representatives who target physicians outside the pain space in the United States and collaborations with other companies to develop and commercialize our product candidates outside the United States.

OXAYDO for the management of acute and chronic moderate to severe pain

Overview

OXAYDO is a Schedule II narcotic indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. OXAYDO utilizes Acura's Aversion Technology. Pfizer received FDA approval for its 505(b)(2) NDA for OXAYDO on June 17, 2011 and introduced the product into the market in February 2012. Acura re-acquired the product on April 10, 2014.

The development program for OXAYDO 5 mg and 7.5 mg tablets was designed around demonstrating bioequivalence to Roxicodone, a commercially available immediate-release oxycodone product, which served as the reference label drug ("RLD") in the 505(b)(2) submission for OXAYDO that supported its FDA approval. The label for OXAYDO describes elements unique to Acura's Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for OXAYDO includes the results from a Category 3 abuse-deterrent study that evaluated drug liking after snorting crushed OXAYDO compared to crushed Roxicodone. The clinical study evaluated 40 non-dependent recreational opioid users, who self-administered via nasal insufflation the equivalent of 15 mg of oxycodone. Because of a sequence effect that was observed in the study, results from the first period only demonstrated:

30% of subjects exposed to OXAYDO responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;

subjects taking OXAYDO reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;

a decreased ability to completely insufflate two crushed OXAYDO tablets within a fixed time period (21 of 40 subjects), while all subjects were able to completely insufflate the entire dose of immediate-release oxycodone; and

small numeric differences in the median and mean drug liking scores, which were lower in response to OXAYDO than immediate-release oxycodone.

Although we believe these abuse deterrent characteristics differentiate OXAYDO from immediate-release oxycodone products currently on the market, the clinical significance of the difference in drug liking and difference in response to taking the drug again in this study has not been established. There is no evidence that OXAYDO has a reduced likeability compared to immediate release oxycodone. As part of our licensing agreement with Acura, we are responsible for a post-approval commitment with the FDA to perform a Category 4 abuse-deterrent epidemiologic study to assess the actual impact on abuse of OXAYDO tablets out in the community.

Further, OXAYDO's product label guides patients not to crush and dissolve the tablets or pre-soak, lick or otherwise wet the tablets prior to administration. Similarly, caregivers are advised not to crush and dissolve the tablets or otherwise use OXAYDO for administration via nasogastric, gastric or other feeding tubes as it may cause an obstruction.

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Collaboration and License Agreement with Acura

On January 7, 2015, we entered into a Collaboration and License Agreement, (the "License Agreement") with Acura to commercialize OXAYDO. In accordance with the License Agreement, we are responsible for all manufacturing and commercialization activities in the territory for OXAYDO. Subject to certain exceptions, we will have final decision making authority with respect to all development and commercialization activities for OXAYDO. We may develop OXAYDO for other countries and in additional strengths in its discretion.

We paid Acura an upfront payment of $5 million dollars and will pay a $2.5 million milestone on the earlier to occur of (A) the launch of OXAYDO and (B) January 1, 2016, but in no event earlier than June 30, 2015. In addition, Acura will be entitled to a one-time $12.5 million milestone payment when OXAYDO net sales reach a specified level of $150 million in a calendar year.

In addition, Acura will receive from us a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on OXAYDO net sales during such year. In any calendar year in which net sales exceed a specified threshold, Acura will receive a double digit royalty on all OXAYDO net sales in that year. Our royalty payment obligations commence on the first commercial sale of OXAYDO and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering OXAYDO in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by us to acquire intellectual property rights to commercialize OXAYDO, with an aggregate minimum floor.

Product Candidates

Current Environment Supports Development of Abuse-Deterrent Opioids

In reaction to the increasing costs and other consequences of widespread prescription opioid abuse, the United States 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. Recent activities include:

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.

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.

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STOPP Act: February 2013 the STOPP (Stop the Tampering of Prescription Pills) Act that was created by a bipartisan group of Congressional leaders was reintroduced. If approved this bill 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.

Language in OxyContin label: In April 2013, the FDA approved the enhancement of Purdue Pharma L.P.'s OxyContin 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.

Approved abuse-deterrent products: As of February 27, 2015 there are five products approved with abuse-deterrent language in the product label: our product OXAYDO, Purdue Pharmaceutical's products Targiniq ER , OxyContin and Hysingla ER and Pfizer's product Embeda®.

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 Solution: The Guardian Technology

Overview

Our proprietary Guardian Technology allows us to create oral tablets with physical and chemical properties intended to deter the most common and rigorous methods of abuse that are specific to a particular drug, while also offering a tailored release of the API. Employing our Guardian Technology, we designed our first product candidate in development, Egalet-001, which is a specialized matrix created through our proprietary manufacturing process, and 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 second product candidate, Egalet-002, employs a similar matrix system,

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however this tablet is surrounded by a water-impermeable, non-eroding, hard shell containing polylactic acid ("PLA") that creates a cylinder, with the API-containing matrix exposed at both ends.

Egalet-001 was developed with the Guardian Technology to resist crushing in order to swallow, snort or smoke, and dissolving in order to inject. This tablet was specifically designed with its gelling effect, 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.

Egalet-002, which was developed using our Guardian technology, adds a shell that surrounds the matrix, and each component of the tablet has abuse-deterrent characteristics as a result of their physical hardness and the gelling effect of the matrix. This 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.

The following diagram illustrates how the Guardian Technology system used with Egalet-002 delivers its payload containing the API in the GI tract. The shell, which remains unchanged, is shown in dark gray and the matrix containing the API is shown in light gray.

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. Our Egalet-002 tablets consist only of excipients included in the FDA's Inactive Ingredient Database.

Our Guardian 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

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Guardian Technology have physical and chemical properties that are intended to minimize the potential for these forms of abuse. We believe that tablets made using our Guardian 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

Egalet Abuse-Deterrent Feature	Type of Abuse Deterred	Advantages
Extremely Hard	Chewing Snorting Injecting 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. 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.
Matrix Composition	Alcohol Dose-Dumping	Our formulations exhibit resistance to extraction of the API from the matrix in water and other common household solvents. 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 solvents, such as alcohol, as compared to more polar solvents, such as water.

Ability to Tailor Release

In addition to its abuse-deterrent features, our proprietary Guardian 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, DR or SR profiles. Once a 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 Guardian 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

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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.

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 are recognized as effective analgesic agents. We are developing Egalet-001 for twice a day dosing.

We developed Egalet-001 using our proprietary, abuse-deterrent, Guardian Technology 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 pivotal 60 mg bioequivalence study that began in the first quarter of 2015. In parallel, we are conducting 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. We plan to seek U.S. regulatory approval of Egalet-001 pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. With our receipt of Fast Track designation from the FDA and with all excipients used in the formulation not expected to require extensive review since they are included in the FDA's Inactive Ingredient Database, we anticipate an NDA submission in the fourth quarter of 2015.

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 uses our Guardian Technology, which is designed to deter 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.

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

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

Consistent relief: Twice 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.

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Clinical Development

On August 21, 2013, we submitted an investigational new drug application ("IND"), for Egalet-001 to the FDA. We plan to seek approval of Egalet-001 under the FDA's Section 505(b)(2) approval pathway, with MS CONTIN® (morphine sulfate controlled-release) tablets serving as the RLD. Following recently announced positive results from a bioequivalence study and positive feedback from the FDA, we are pursuing a BE pathway for filing the NDA for Egalet-001. We will complete the full package of abuse-deterrent studies in 2015 with the goal of obtaining abuse-deterrent claims in our product label. The FDA has granted us Fast Track status with respect to Egalet-001. Based on the expected timing of our studies and trials, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2015.

Completed Clinical Studies

We have completed Phase 1 clinical PK trials of Egalet-001, Category 1 abuse-deterrent studies, a Category 3 oral HAL study, and are in the clinic conducting a Category 3 intranasal HAL study, consistent with the FDA draft guidance on abuse-deterrent opioid development. The clinical development program for Egalet-001 was designed to demonstrate bioequivalence to MS CONTIN®. After the identification of an optimal formulation, which demonstrated bioequivalence to MS CONTIN, Egalet conducted a relative bioavailability study and two BE trials with the goal of demonstrating BE across the dosage range from 15 mg to 100 mg. The results from these three PK studies that compared different dosage strengths of Egalet-001 to the comparable dosage strength of MS CONTIN showed that, while Egalet-001 met the criteria for BE to MS CONTIN in all three studies with respect to the area under the curve ("AUC"), the maximum plasma concentration ("Cmax") was within the range of BE in one of the three studies (60 mg), but fell just outside the 90% confidence interval range to demonstrate BE (which is 80% - 125%) in the other two studies (78.99% in the 15 mg study and 127.3% in the 100 mg study). The findings from these studies are shown in the table below:

In the first quarter of 2015 we announced positive results demonstrating Egalet-001 bioequivalence to MS Contin at 30 mg. We have initiated a pivotal 60 mg bioequivalence study of Egalet-001 compared to MS Contin with results expected in the fourth quarter.

Based on these findings, Egalet engaged in discussions with the FDA regarding the viability of these data being supportive of a BE regulatory path going forward. In March 2015, we shared that the outcome of our interactions with the FDA was that they felt that our revised investigational plan that

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we proposed was acceptable for us to pursue a BE path for approval of Egalet-001. Subsequent to that discussion, we announced the results of an additional PK study which evaluated the BE of Egalet-001 30 mg compared to MS Contin 30 mg and two Egalet 15 mg tablets compared to one MS Contin 30 mg tablet. The findings from this study are shown in the table below:

Consistent with our proposed revised IND plan and the comments from the FDA, we have initiated a pivotal 60 mg BE study and expect results in the fourth quarter.

Completed Abuse-Deterrent Studies

We developed Egalet-001 to address the most common method of abuse of morphine-based products, which is abuse by injection. In a Category 1 abuse-deterrent study, 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.

A comprehensive series of Category 1 *in vitro* laboratory studies for assessment of physical and chemical manipulations of Egalet-001 were conducted in accordance with the Food and Drug Administration Draft Guidance (January, 2013; Guidance for Industry: Abuse-Deterrent Opioids Evaluation and Labeling). Category 1 experiments were designed based on knowledge of "real-world" tampering practices that are known or could plausibly be carried out by patients, recreational users, and drug abusers in attempts to provide faster release and potentially faster absorption. With this input, physical and chemical tests were designed to be conducted in a laboratory setting with rigorous, scientific design intended to produce data predictive of the product's strengths and weaknesses to physical and chemical challenges.

Overall, the Category 1 studies of Egalet-001 demonstrated that the formulation will likely be resistant to most common forms of tampering (crushing, grinding, and extraction). The physico-chemical properties of morphine sulfate, together with the properties of the formulation (low tablet porosity, high hardness, controlled-release properties, and gelling properties in aqueous solvents), are expected to reduce abuse of the product by many routes of administration.

Comprehensive assessments were conducted with a variety of household tools and instruments that might be used for particle size reduction. A range of mechanical and electrical methods of manipulation were attempted, including spoons, mortar and pestle, pill crusher, hammer, food grater,

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foot file (PedEgg), razor blade, knife, spice grinder, coffee grinder, pill splitter, and industrial mill. These assessments included possible effects of temperature pre-treatment (freezing and heating) prior to attempts at particle size reduction. The outcome of these procedures was documented by photographic records, particle size analyses, determination of morphine content in different particle size fractions, and percent weight recovery. Testing of various dosage strengths (15-100 mg) was initially performed showing no significant difference in the properties and therefore the 100 mg dose was selected as the model strength, as it provided the highest amount of morphine concentration.

Due to the unique properties (e.g., hardness) of the Egalet-001 tablets, the only means of producing powders, although not very effectively, was by use of the spice grinder, whereas MS CONTIN was easily ground by numerous methods, including using a mortar and pestle. Following use of a spice grinder, less than 5% of ground Egalet-001 tablets had particle sizes <500 microns (appropriate for insufflation). In contrast, following use of a mortar and pestle, 68.5% of ground MS CONTIN had particle sizes <500 microns. A summary chart of the particle size distribution for Egalet-001 ground with a spice grinder and MS CONTIN ground with a mortar and pestle is shown below.

Mean (n=6, SD) Particle Size Distribution

Category 1 studies of Egalet-001 demonstrated that the formulation will likely be very resistant to most common forms of tampering (crushing, grinding, and extraction) and will also require a great deal of effort to attempt to defeat the tablet. The physico-chemical properties of morphine sulphate, together with the unique properties of Egalet's formulation (low tablet porosity, high hardness, controlled-release properties, and gelling properties in aqueous solvents), and manufacturing technology, are expected to reduce the abuse liability of Egalet-001 by most routes of administration.

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With regard to Category 3 abuse-deterrent studies, Egalet completed an oral HAL study which compared Egalet-001 to MS Contin on the primary outcome of maximum drug liking ("Emax"). This Category 3 study was conducted in accordance with the FDA draft guidance on Abuse-Deterrent Opioids: Evaluation and Labeling (January 2013). It was a single-center, randomized, double-blind, double-dummy, four-way crossover study which assessed the abuse potential of Egalet-001 versus MS Contin in 38 nondependent, recreational opioid users when taken orally. The primary objective was to compare the relative abuse potential of intact and manipulated formulations of Egalet-001 versus manipulated MS Contin. Since Egalet-001 is extremely hard and difficult to chew, the manipulation of the product involved a series of maneuvers using different household tools to try and reduce the particle size to maximally defeat the tablet. This procedure was based on the outcome of the first phase, physical tampering, of the Category 1 abuse-deterrent studies for Egalet-001. Top line results from the study included the following:

On the primary endpoint of drug liking as measured by Emax, the score for manipulated Egalet-001 was significantly lower than the Emax for manipulated MS Contin ($p < 0.007$);

There was no statistical difference on drug liking scores (Emax) between intact and manipulated Egalet-001, indicating that even after significant manipulation, Egalet-001 retains its abuse-deterrent characteristics;

The corresponding PK data from this study demonstrated a higher Cmax and shorter time to maximum plasma concentration ("Tmax') for manipulated MS Contin compared to manipulated Egalet-001; and,

The 'Abuse Quotient,' which is defined as the Cmax/Tmax, for each of the treatment arms, was as follows:

5.7 for intact Egalet-001

16.4 for manipulated Egalet-001 and

45.9 for manipulated MS Contin

Ongoing/Planned Clinical Trials and Abuse-Deterrent Studies

A randomized, double-blind, double-dummy, active and placebo-controlled, crossover study comparing the abuse potential of manipulated Egalet-001 versus manipulated MS CONTIN following intranasal administration in nondependent recreational opioid users; this is an ongoing study with data expected in the second quarter of 2015

BE trial description

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 other Regulatory Authorities around the world in a number of IR and ER formulations. Oxycodone-based products, including OxyContin, have been available in the United States for many years and have a well-established safety profile. Egalet-002 tablets are designed with an inner matrix, composed of the API and polyethylene oxide (PEO), which is surrounded by an outer inert shell composed of 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.

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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. The design was optimized 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 that Egalet conducted, Egalet-002 resulted in less peak-to-trough concentration variability in drug exposure than OxyContin. The tablet was designed to minimize this PK variability, with the goal of improving upon the efficacy, safety, and tolerability profile of Egalet-002 as compared to OxyContin. We have also completed initial Category 1 abuse-deterrent studies, and the results of these studies confirmed robust abuse-deterrent features of Egalet-002 as compared to OxyContin. We plan to seek approval of Egalet-002 through the FDA's Section 505(b)(2) approval pathway, using OxyContin as the RLD. In parallel, we are conducting a full set of abuse-deterrent studies in accordance with the FDA draft guidance, with the goal of obtaining Tier 1 and Tier 3 abuse-deterrent claims in our product label.

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: Egalet-002 produces less peak-to-trough concentration variability in drug exposure when compared to OxyContin, which could result in Egalet-002 having fewer side effects and providing better and more consistent pain relief than OxyContin.

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. Since this interaction with food is seen with other extended-release oxycodone products, it has been postulated that this is more of a physiologic interaction rather than a formulation-related food effect. This is supported by *in vitro* dissolution data for Egalet-002 that indicated the formulation is resistant to physical impact, pH and food type media.

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 will be labeled for twice-daily dosing, consistent with currently available oxycodone formulations, to provide around-the-clock pain relief. We intend to manufacture Egalet-002 in 10, 20, 40 and 80 mg doses, which are consistent with currently available oxycodone formulations.

Clinical Development

On July 17, 2013, we submitted an IND for Egalet-002 to the FDA. We plan to seek approval of Egalet-002 under the FDA's Section 505(b)(2) approval pathway using OxyContin as the RLD. We are preparing to conduct a pivotal Phase 3 safety and efficacy trial, as well as an open label, long term safety study, consistent with written feedback we have received from the FDA over the course of the development of Egalet-002. We have conducted Phase 1 PK trials of Egalet-002, an extensive battery of Category 1 abuse-deterrent studies compared to OxyContin, are in the clinic with a Category 3 oral HAL study. We intend to conduct a, head-to-head intranasal HAL study compared to OxyContin later

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this year. Egalet will also complete a clinical alcohol interaction study for Egalet-002 in the second quarter. The FDA has granted us Fast Track status with respect to Egalet-002. Based on this, and the expected timing of our clinical trials, we anticipate submitting an NDA for Egalet-002 in the second 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, two-period, crossover study, examined three different sizes of a 40 mg Egalet-002 tablet (6 mm, 7.5 mm and 9 mm) compared to OxyContin 40 mg tablets to determine their relative bioavailability in 16 subjects. The primary endpoint was a comparison of PK profiles based on C_{max} and AUC. The PK graph below shows the concentration time curves of oxycodone for each of the formulations over a period of 24 hours after administration of a single dose of each product. Each formulation of Egalet-002 exhibited a slightly different release profile the and, in all cases, showed lower peak-to-trough variability than OxyContin.

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. The primary endpoint was the assessment of the PK profiles of OxyContin and Egalet-002, 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 Egalet-002, because it was consistent with the twice-daily dosing schedule of OxyContin, with a slightly higher plasma concentration at the 12-hour time point.

In these two Phase 1 trials, Egalet-002 exhibited improved PK characteristics relative to OxyContin. In particular, the concentration of oxycodone in the bloodstream after administration of Egalet-002 had a narrower peak-to-trough range than OxyContin, while maintaining a similar range of total concentration, as measured by AUC. These results are represented in the table below as follows: C_{max} or peak plasma concentration; C_{min} or trough plasma concentration; and, the total exposure measured as AUC. These results demonstrate that the PK profile of Egalet-002 shows less fluctuation

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in plasma oxycodone concentration which could result in an improved efficacy, safety, and tolerability profile as compared to OxyContin.

Steady State	Egalet-002	OxyContin	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 which evaluated the dose proportionality of Egalet-002 10, 20, 40 and 80 mg. In addition, this study included a fed arm with the highest dose, 80 mg, to assess the food effect of Egalet-002. In this trial, Egalet-002 showed linear dose proportionality across the full dosage range. A food effect was observed, which was consistent with the magnitude of food effect observed in previous OxyContin studies.

Completed Preclinical Toxicity Studies

Based on feedback we received from the FDA regarding the PLA shell, we commissioned a series of third-party preclinical animal studies to evaluate the safety of oral doses of PLA and the potential for it 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 the dog study. 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) were generated following incubation of the PLA in artificial gastric fluid. Based on these preclinical studies, and the fact that PLA is currently used in approved medical devices, including 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. The FDA requested an open label long term safety study to assess the shell component of the Egalet-002 tablet in humans, which Egalet will be conducting this year.

Completed Abuse-Deterrent Studies

In accordance with the FDA draft guidance on abuse-deterrent opioids, we commissioned a third party to conduct Category 1 abuse-deterrent studies of Egalet-002 to evaluate the physical and chemical properties of Egalet-002 compared to the abuse-deterrent formulation of OxyContin. These experiments included the full battery of Phase 1 physical manipulations and Phase 2 chemical manipulations as referenced in the FDA draft guidance to fully interrogate the abuse-deterrent properties of Egalet-002 compared to OxyContin. In one study, five Egalet-002 tablets and five OxyContin tablets were milled in a coffee grinder, a household tool commonly used to defeat these tablets for recreational use and abuse, for successive rounds of 20 seconds and then placed on a sieve stack with progressively smaller filters to measure the particle size of the ground up tablets. For Egalet-002, this can either be done with the outer shell intact or work must be done to try and remove

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the shell. The picture below shows part of a shell on the left and the inner core on the right after hammering an Egalet-002 tablet.

After this step, an intact OxyContin tablet (below left) and an Egalet-002 tablet after hammering (below right) was put into a coffee grinder and milled down.

The result of this Category 1 study with regard to particle size reduction showed that, for Egalet-002, 12.5% of particles were less than 500 microns (suitable for snorting) compared to 74.2% or particles for OxyContin ($p < 0.0001$). These results are displayed graphically below.

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Krups Coffee Grinder

Ongoing/Planned Clinical Trials and Abuse-Deterrent Studies

Clinical alcohol interaction study of Egalet-002 80 mg with varying concentrations of alcohol to assess the PK profile for evidence of dose dumping in the presence of alcohol; this study is currently ongoing

A randomized, double-blind, quadruple-dummy, active and placebo-controlled, five-way crossover study comparing the abuse potential of manipulated and intact Egalet-002 tablets versus manipulated immediate-release oxycodone and manipulated OxyContin following oral administration in nondependent recreational opioid users; this study is currently ongoing

A randomized, double-blind, double-dummy, active and placebo-controlled, crossover study comparing the abuse potential of manipulated Egalet-002 versus manipulated OxyContin following intranasal administration in nondependent recreational opioid users; this study will be initiated in the second half of 2015

A Phase 3, multi-center, placebo-controlled, randomized withdrawal trial to assess the analgesic efficacy, safety, and tolerability of Egalet-002 in both opioid-experienced and opioid- naïve patients with chronic moderate to severe low back pain; this trial will initiate in second quarter of 2015

An open label, long term safety trial of Egalet-002 in patients with chronic moderate to severe pain to assess the long term exposure of Egalet-002 in patients up to 1 year; this trial will initiate in the second quarter of 2015

Collaboration with Shionogi

Development and Commercialization. Through our Shionogi collaboration 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

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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. Until May 2015, 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. Also pursuant to the agreement, Shionogi purchased 1,250,000 shares of our common stock in a private placement concurrently with the closing of our initial public offering. Shionogi has 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.

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Additional Product Candidates

Our proprietary Guardian 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.

Our Guardian 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 CNS medications. Egalet intends to select a third product candidate, to be designated Egalet-003, based on a number of factors, including market opportunity and competitive dynamics in 2015.

Commercialization

We intend to commercialize SPRIX, OXAYDO, Egalet-001, Egalet-002 and our other product candidates in the United States, while out-licensing commercialization rights for other regions. With the acquisition and license of SPRIX and OXAYDO respectively, we have begun the build out of our commercial infrastructure. The members of our management team 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®, Lidoderm®, Fentora®, Maxalt®, Zyprexa® and Prozac®. In addition we have been building our commercial infrastructure by adding resources to our sales, marketing, medical affairs, managed markets and distribution functions.

We are developing our commercialization strategy for SPRIX and OXAYDO to focus on promotion to pain care specialists. We are developing positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies for both of our approved products. We are hiring a dedicated field sales force, consisting of approximately 50 to 60 sales professionals, to target the 5,700 physicians in the high-decile of prescribing pain medicines in the United States. To supplement our internal sales force in the United States, we may contract with a third party to access sales representatives who target primary care and other specialists, which could broaden our U.S. market coverage.

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.

Manufacturing

Overview

Our marketed products will be manufactured at contract manufacturing facilities in the United States. We are working on finalizing our contracts with contract manufacturers for both SPRIX Nasal Spray and OXAYDO.

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.

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To date, we have produced Egalet-001 and Egalet-002 for use in our clinical trials and preclinical studies at our U.S. based manufacturer Halo Pharmaceuticals, Inc. ("Halo") and our facility in Vaerlose, Denmark. 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.

Drug Substances

The API used in SPRIX is ketorolac tomethamine, in OXAYDO is oxycodone hydrochloride, in Egalet-001 is morphine sulfate, and in Egalet-002 is oxycodone hydrochloride. We currently procure these APIs on a purchase order basis. Ketorolac is acquired from a European based manufacturer, while the opioid APIs are secured 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. OXAYDO is classified as a Schedule II controlled substance. We expect that Egalet-001 and Egalet-002 will be classified by the U.S. Drug Enforcement Administration ("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."

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, 2014, we owned twelve issued patents or allowed patent applications within the United States, and an additional 54 issued foreign patents or allowed foreign patent applications covering our product candidates or technology platform. The terms of the twelve issued U.S. patents or allowed U.S. patent applications, extend to various dates between 2018 and 2033. Recently, we acquired three U.S. patents and four pending U.S. applications directed to processes of manufacture, devices, and compositions related to SPRIX. One of these U.S. patents is listed in the Orange Book and expires in 2018. The term of our overall domestic and foreign patent portfolio related to Egalet-001 and Egalet-002 product candidates and our Guardian 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.

We have also licensed five Orange Book listed patents that cover OXAYDO and Acura Pharmaceuticals Aversion Technology and these patents expire between 2023 and 2025.

As of December 31, 2014, we owned 13 pending patent applications under active prosecution in the United States, and an additional 32 pending foreign patent applications covering our product candidates and technology platform. We have two pending patent applications in the United States and eleven pending foreign patent applications relating to Egalet-001. 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, Brazil, Mexico, Europe, Eurasian, India, Hong Kong, Australia, New Zealand, Republic of Korea, China 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 Guardian Technology and products

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related thereto 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 trademarks for Egalet Guardian Technology, ARYMO, our brand name for Egalet-001, in the United States, Canada and the European Union, and SPRIX in United States, Brazil and Mexico.

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 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.

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.

OXAYDO

OXAYDO competes against other marketed branded and generic pain therapeutics. Opioid therapeutics generally fall into two classes: codeines, which include oxycodones and hydrocodones and morphines. OXAYDO is an oxycodone, and competes with therapeutics within both the codeine and morphine classes. These therapeutics include both Schedule II and Schedule III controlled substance

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products being marketed by companies such as Endo Pharmaceuticals Holdings Inc., Mallinckrodt Inc., Pfizer, Purdue Pharma L.P., Teva Pharmaceutical Industries Limited and Actavis, Inc.

OXAYDO also will compete with a significant number of opioid product candidates under development, including abuse deterrent and tamper resistant formulations of currently available opioids, novel opioids and alternative delivery forms of various opioids under development at other pharmaceutical companies, including single-entity extended-release *hydrocodone* product candidates, which include abuse deterrent and tamper resistant formulations, being developed by Pfizer, Purdue Pharma L.P. and Teva Pharmaceutical Industries Limited. OXAYDO may also face competition from non-opioid product candidates including new chemical entities, as well as alternative delivery forms of NSAIDs. These new opioid and non-opioid product candidates are being developed by companies such as Acura Pharmaceuticals, Inc., Collegium Pharmaceutical, Inc., Eli Lilly and Company, Elite Pharmaceuticals, Inc., Hospira, Inc., Inspirion Delivery Technologies, LLC, Intellipharmaceutics International Inc., Nektar Therapeutics, Pfizer and QRxPharma Ltd.

SPRIX

SPRIX competes in the short-term analgesic market which is defined as patients needing therapy for five days or less. There is a high degree of generic competition, however, branded drugs continue to play an important role for patients. There are numerous categories of products in this space and various delivery methods of these analgesics including pills, gels, sprays and injections. Product categories include NSAIDS such as ibuprofen, diclofenac, celecoxib and ketorolac and immediate release opioids such as oxycodone, hydrocodone and tapentadol.

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. Pfizer's Embeda was approved in October of 2014 and is expected to be made commercially available in early 2015.

We believe there are abuse-deterrent morphine products in clinical development by Purdue, Inspirion and Elite. In addition, 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 for the treatment of patients experiencing moderate to severe pain. Targiniq was approved but Purdue has withdrawn it from the market. 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, in which case Egalet-002 would compete with any such generic oxycodone products.

Additionally, we are aware of companies in late-stage development of abuse-deterrent oxycodone product candidates, including Pain Therapeutic's Remoxy® and ALO-02 and Collegium's XTAMPZA ER. 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.

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Government Regulations

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act ("FFDCA") 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 Good Clinical Practices ("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 ("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.

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

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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 $2,335,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding $110,000 per product and $569,000 per establishment in 2015. 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 current good manufacturing practices ("cGMP") is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the 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 Risk Evaluation and Mitigation Strategy ("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 ("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 abbreviated new drug application ("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 ("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 ("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

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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.

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 OXAYDO is and our product candidates, Egalet-001 and Egalet-002, if approved, each will be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970 ("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.

OXAYDO, an oxycodone product formulated to deter abuse via snorting, is listed by the DEA as a Schedule II controlled substance under the CSA and we expect that Egalet-001, an abuse-deterrent morphine, and Egalet- 002, an abuse-deterrent oxycodone, will be as well. Consequently, the manufacturing, shipping, storing, selling and using of the products is 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. 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 and will have the same high degree of regulation.

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.

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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.

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. Any of our products regulated as a Schedule II controlled substances 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 license partners and 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 and OXAYDO 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 license partners 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 are 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

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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 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 the U.S. Department of Health and Human Services ("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

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Anti-Kickback Statute liability in all cases. The reach of the federal Anti-Kickback Statute was broadened by the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "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.

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 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, the federal Health Insurance Portability and Accountability Act of 1996 ("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

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Health Information Technology for Economic and Clinical Health Act ("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 require 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 ("CMS"), required by March 31, 2014 (and by the 90th day of each subsequent calendar year), and disclosure of such information is made on a publicly available website.

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 has required 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. 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. With respect to any of our products 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.

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Third-Party Payor Coverage and Reimbursement

The commercial success of our products and product candidates, if and when approved, depends and 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 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

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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;

- 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, 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

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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.

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 and other environmental and safety regulations. 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.

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 terminated earlier. In January 2015, we entered into a sub-lease where we occupy an additional 3,409 square feet in the same building as our existing headquarters (6,599 square feet in the aggregate). Under the terms of the sub-lease agreement, the sublease expires in December 2017 unless terminated earlier. In addition, we are leasing approximately 200 square feet of office space in Roseland, New Jersey in close proximity to our contract manufacturer, Halo. We also maintain a research laboratory, pilot manufacturing and administrative facility in Vaerlose, Denmark, where we lease 12,895 square feet of space under a lease agreement that automatically renews every 12 months (currently through August 2015 unless terminated earlier).

We believe that our existing facilities are adequate for our current needs. We plan to seek to negotiate new leases or evaluate additional or alternate space as we plan for the growth of our commercial operations in the United States. We believe that appropriate alternative space is readily available on commercially reasonable terms.

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Employees

As of February 28, 2015, we had 44 employees, of which 19 were employed in the United States and 25 were 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.

Available Information

We file electronically with the SEC annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. The public may read and copy any materials we have filed with or furnished to the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, ownership reports for insiders and any amendments to these reports filed with or furnished to the SEC are available free of charge through our internet website (www.egalet.com) as soon as reasonably practicable after filing with the SEC. We use the Investor Relations section of our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the Investor Relations section of our website, in addition to following press releases, SEC filings and public conference calls and webcasts.

Additionally, we make available free of charge on our internet website:

our Code of Conduct;

the charter of our Nominating and Corporate Governance Committee;

the charter of our Compensation Committee; and

the charter of our Audit Committee.

ITEM 1A. *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 Annual Report, including our financial statements and the related notes appearing at the end of this Annual Report, before making a 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 have a history of net losses and negative cash flow from operations.

We are a pharmaceutical company at an early stage of commercialization. As a result, we have a limited operating and commercialization history and there is little historical basis upon which to assess how we will respond to competitive or economic challenges or other challenges to our business. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies in the early stages of commercialization.

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We have generated substantial net losses and negative cash flow from operations since our inception, and we continue to incur significant research, development and other expenses related to our ongoing operations for other product candidates. For the years ended December 31, 2014 and 2013, we reported a net loss of $43.2 million and $20.2 million, respectively.

We expect to incur losses and negative cash flow for the foreseeable future. Our ability to generate sufficient revenues from SPRIX and OXAYDO, or our marketed products, and Egalet-001 and Egalet-002 and any of our other product candidates, if approved, will depend on numerous factors described in the following risk factors. We expect that our gross margin may fluctuate from period to period as a result of changes in product mix sold, potentially by the introduction of new products by us or our competitors, manufacturing efficiencies related to our products and a variety of other factors. 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 have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently generate limited 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 only limited revenues from our marketed products, and have generated $3.9 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 general additional revenue and become profitable depends upon our ability to expand the marketing of our marketed products and commercialize our product candidates, or other product candidates that we may in license or acquire in the future. Even if we are able to successfully achieve regulatory approval for our 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 products 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;
- further penetrate the market for existing products and ultimately increase sales for our products relative to our competition;
- 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

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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 meaningful 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 Egalet-001 and Egalet-002, and the development of our other 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 to commercialize our marketed products, as well as any product candidates for which we receive regulatory approval, including building our own commercial organization to address selected markets. We believe that our existing cash will be sufficient to fund our projected operating requirements through September 30, 2015 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 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;

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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;

the timing and amount of revenue from sales of our marketed products and any subsequently approved product candidates that are commercialized;

the size and cost of our commercial infrastructure; and

costs and timing of completion of any outsourced commercial manufacturing supply arrangements that we may establish.

Current and future debt obligations expose us to risks that could adversely affect our business, operating results and financial condition and may result in further dilution to our shareholders.

We have entered into a loan and security agreement with Hercules Technology Growth Capital, Inc., or Hercules, pursuant to which we have borrowed $15,000,000 from Hercules at an initial interest rate equal to the greater of either (i) 9.40% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (ii) 9.40%. We must repay the indebtedness on or before July 1, 2018. We must make interest only payments on the amounts borrowed until January 2016, after which we must make 30 equal monthly payments of principal plus interest. To the extent we desire to prepay the indebtedness prior to maturity, we will be obligated to pay a prepayment penalty to Hercules ranging from 1.0% to 3.0% of the amounts being prepaid, depending on when such prepayment occurs. In addition, at the time that the loan is either due or prepaid, we must pay Hercules a fee equal to 3.85% of the total amounts funded at such time. Our ability to make payments on this indebtedness depends on our ability to generate cash in the future. We expect to experience negative cash flow for the foreseeable future as we fund our operations and capital expenditures. There can be no assurance that we will be in a position to repay this indebtedness when due or obtain extensions of the maturity date. We anticipate that we will need to secure additional funding in order for us to be able to satisfy our obligations when due. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If that additional funding involves the sale of equity securities or convertible securities, it would result in the issuance of additional shares of our capital stock, which would result in dilution to our stockholders. The indebtedness is secured by substantially all of our assets other than intellectual property on which we have given Hercules a negative pledge. In addition, under the loan agreement, we are subject to certain customary covenants that limit or restrict our ability to, among other things, incur additional indebtedness, grant any security interests, pay cash dividends, repurchase our common stock, make loans, or enter into certain transactions without the prior consent of Hercules.

This level of debt could have important consequences to you as an investor in our securities. For example, it could:

limit our flexibility in planning for the development, clinical testing, approval and marketing of our products;

place us at a competitive disadvantage compared to any of our competitors that are less leveraged than we are;

increase our vulnerability to both general and industry-specific adverse economic conditions; and

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limit our ability to obtain additional funds.

In addition, as part of this financing with Hercules, we issued a warrant to Hercules to purchase 113,421 shares of our common stock at an exercise price of $5.29 per share. Such warrant will be exercisable for five years following the consummation of this offering. The exercise of such warrant may result in dilution of your ownership interest. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources" for a more detailed discussion of the transaction with Hercules.

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 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 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.

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

Our foreign net operating losses ("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.

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

In its report on our consolidated financial statements for the year ended December 31, 2014, our independent registered public accounting firm included an explanatory paragraph expressing substantial

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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 our 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 have only limited sources of revenue and our ability to continue as a going concern is dependent on our ability to raise capital to fund our future business plans. Additionally, volatility in the capital markets and general economic conditions in the United States may be a significant obstacle to raising the required funds. These factors raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern. If the going concern basis were not appropriate for these financial statements, adjustments would be necessary in the carrying value of assets and liabilities, the reported expenses and the balance sheet classifications used.

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

In addition to the level of commercial success of our marketed products, our future growth is also dependent on our ability to successfully develop a pipeline of product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval or that any approved products will be successfully commercialized.

Our long-term growth will be limited unless we can successfully develop a pipeline of additional product candidates. To date, we have only generated an aggregate of $3.9 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;

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.

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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 and 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.

We may be unable to establish bioequivalence for our product candidates at a statistically significant level, which would require us to design and complete additional clinical trials to establish the safety and efficacy of our product candidates. For instance, if we are unable to agree with the FDA on an accelerated development plan for Egalet-001 given our existing bioequivalence data, we will forced to design and complete a Phase 3 trial to examine its efficacy in safety. We have already commenced planning for such trial.

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 successful commercialization of our product candidates. Approval may be contingent on a 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.

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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, any 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. 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 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, and correspondingly lower product revenues. 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

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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 our product candidates through the Section 505(b)(2) regulatory pathway. 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. 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 similar to Egalet-001, we cannot demonstrate bioequivalence or comparable bioavailability of our other product candidates to approved products at a statistically significant level, 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.

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

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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, including Egalet-001 and Egalet-002, if approved, 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 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.

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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 our product candidates 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, 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 may bring an 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 product candidates 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 ER and long-acting ("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.

One of our marketed products and 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.

One of our marketed products and 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. OXAYDO, Egalet-001 and Egalet-002 contain active ingredients that are classified as controlled substances under the CSA and regulations of the 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 OXAYDO and our lead product candidates Egalet-001 and Egalet-002 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.

The commercial use of our products and clinical use of our product candidates expose us to the risk of product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with our marketed products, or an applicable foreign regulatory authority.

We currently carry clinical trial and product liability insurance with coverage up to approximately $10 million. 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 consumers, pharmaceutical companies, 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;

product recall or withdrawal from the market;

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.

Our marketed products are, and our product candidates, if approved, 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 cGMP and other

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

- issue warning letters or untitled letters;
- 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;
- deny or reduce quota allotments for the raw material for commercial production of our controlled substance products;
- 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 and our collaborators' abilities to commercialize our products and generate revenue.

Additionally, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We are also subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and with GCPs and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries. In addition, our product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

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Risks Related to the Commercialization of Our Products and Product Candidates

Our future prospects are dependent on the success of our current products, and we may not be able to successfully commercialize these products. Failure to do so would adversely impact our financial condition and prospects.

A substantial portion of our resources are focused on the commercialization of our current products, OXAYDO and SPRIX. Our ability to generate significant product revenues and to achieve commercial success in the near-term will initially depend almost entirely on our ability to successfully commercialize these products in the United States. Before we can market and sell these products in a particular jurisdiction, we need to obtain necessary regulatory approvals (from the FDA in the United States and from similar foreign regulatory agencies in other jurisdictions) and in some jurisdictions, reimbursement authorization. There are no guarantees that we or our commercialization partners will obtain any additional regulatory approvals for our products. Even if we or our commercialization partners obtain all of the necessary regulatory approvals, we may never generate significant revenues from any commercial sales of our products. If we fail to successfully commercialize our current and future products, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected.

Our limited history of commercial operations makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our shares.

Following our acquisition and license in January 2015 of SPRIX and OXAYDO, respectively, we have two products approved in the United States. However, we have a limited history of marketing these markets. We plan to begin the commercial sale of OXYADO in the United States in the third quarter of 2015 and SPRIX has remained commercially available in the United States following our acquisition of the product on January 8, 2015. We face considerable risks and difficulties as a company with limited commercial operating history. If we do not successfully address these risks, our business, prospects, operating results and financial condition will be materially and adversely harmed. Our limited commercial operating history, including our limited history commercializing SPRIX and OXAYDO, makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected.

We currently have limited sales or marketing capabilities and, if we are unable to further 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 limited sales, marketing or distribution capabilities. We cannot guarantee that we will be successful in marketing our marketed products, or if approved, 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

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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 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.

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

If our marketed products, or any of our product candidates for which we receive regulatory approval, do not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate from those products will be limited. Coverage and reimbursement of our approved products by third-party payors is also necessary for commercial success. Acceptance and use of our marketed products and 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 marketed products and 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 marketed products and product candidates in reducing potential risks of unintended use;

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

availability of coverage and adequate reimbursement for our marketed products and 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 Egalet-001 and Egalet-002 to achieve profitability in the future, the failure of either product candidate to find market acceptance would harm our business prospects.

We face intense competition, including from generic products. If our competitors market or develop alternative treatments that are approved more quickly or marketed more effectively than our product candidates or are demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

Our marketed products compete, and if approved, Egalet-001 and Egalet-002 will compete, against numerous branded and generic products already being marketed and potentially those which are or will be in development. Many of these competitive products are offered in the United States by large, well-capitalized companies.

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,

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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 ANDA. The FFDCA, 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.

Our competitors may also develop products that are more effective, better tolerated, subject to fewer or less severe side effects, more useful, more widely-prescribed or accepted, or less costly than ours. For each product we commercialize, sales and marketing efficiency are likely to be significant competitive factors. We are building a commercial organization to market our marketed products in the United States, and expect to expand and utilize this commercial organization in the United States for any additional proprietary product candidates that we develop, and there can be no assurance that we can maintain and augment these capabilities in a manner that will be cost efficient and competitive with the sales and marketing efforts of our competitors, especially since some or all of those competitors could expend greater economic resources than we do and/or employ third-party sales and marketing channels.

If Shionogi Inc. is successful in its claim against our chief commercial officer, our commercialization efforts could be delayed.

As previously disclosed, Shionogi Inc., our collaborator, recently initiated legal action against Deanne F. Melloy, our chief commercial officer, seeking to prevent her from working at Egalet. A temporary restraining order was issued on February 11, 2015 precluding Ms. Melloy from working at Egalet pending a hearing on Shionogi Inc.'s motion for a preliminary injunction. If Shionogi Inc. is successful in obtaining a preliminary injunction to prevent Ms. Melloy from working at Egalet, there can be no assurance that our commercialization efforts with respect to our marketed products will not be delayed, or that our efforts to build our commercial organization in anticipation of the launch of our product candidates will not be adversely affected.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the commercial sales of our products and the clinical testing of our product candidates. For example, we may be sued if any of our products or product candidates allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a

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successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates; and
- a decline in our share price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies and commercial product sales in the amount of approximately $10 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Recently enacted and future legislation may increase the difficulty and cost for us or our collaborator to commercialize our product candidates, may reduce the prices we are able to obtain for our marketed products and our product candidates and hinder or prevent the commercial success.

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 ability to profitably sell our marketed products or 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 ("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. If our marketed products or any of our product candidates that are approved by the FDA are not widely included on the formularies of these plans, our ability to market our products to the Medicare population could suffer. 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.

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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.

Our marketed products, and if approved, our product candidates, 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 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 our marketed products and, if approved, our product candidates, successfully will also depend in part on the extent to which coverage and adequate reimbursement for

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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 our marketed products, or any product that we commercialize. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Coverage and reimbursement may impact the demand for, or the price of, any product 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 our marketed products or 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 HHS 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.

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

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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 OXAYDO and 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 OXAYDO and 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 OXAYDO and decrease the revenues and royalties 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 and OXAYDO.

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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 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.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize our products in the United States will be harmed.

As we did not acquire OXAYDO or SPRIX until January 2015, the members of our sales force have limited experience promoting the products. As a result, we are required to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense our products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff. We have also experienced, and may continue to experience, turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of our products and their proper administration and label indication, our efforts to successfully commercialize our products could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

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 ("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 ("GLP") and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations and current 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

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FDA, the Competent Authorities of the Member States of the European Economic Area ("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 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 our product candidates and the marketing of Egalet-001 and Egalet-002. 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.

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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.

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

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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 Shionogi seeks to terminate our collaboration agreement with them for cause, our rights with respect to our hydrocodone-based products would be adversely affected.

In connection with Shionogi Inc.'s legal action against our chief commercial officer, Shionogi, an affiliate of Shionogi Inc. sent us a notice of breach letter alleging a breach of the collaboration and license agreement with Shionogi by hiring Ms. Melloy and demanding that we terminate Ms. Melloy to remedy the alleged breach. If the dispute is not resolved, Shionogi may seek to terminate such agreement for cause. If Shionogi takes such action and succeeds, our rights to pursue the development and commercialization of our hydrocodone-based product candidates would be adversely affected. In particular, the royalty-bearing license we granted Shionogi with respect to such candidates would become perpetual and irrevocable and Shionogi would have the right to make any decisions and take any actions that were previously the responsibility of the joint development committee we formed with them. Further, Shionogi's agreement to not compete with the hydrocodone-based product candidates we licensed to them would terminate.

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, we may be unable to continue to commercialize Egalet-001 and Egalet-002, 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 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. We expect to rely solely on Halo Pharmaceutical for the commercial supply of Egalet-001 and Egalet-002. With respect to our marketed products, we plan to rely on contract manufacturers to manufacture SPRIX and OXAYDO. Our reliance on a limited number of vendors and manufacturers 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

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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 manufacturers could default on their 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.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on our business, results of operations, financial condition and prospects.

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredients of our product candidates, and sole suppliers for each of our marketed products 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 product candidates and intend to contract with this supplier, as necessary, for commercial scale manufacturing of our products. We also rely on sole suppliers for each of our marketed 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 our manufacturers on a purchase-order basis, either we or our suppliers may terminate our arrangements, without cause, at any time without notice. If our suppliers were to terminate our arrangements or fail to meet our supply needs we might be forced to delay our development programs or we could face disruptions in the distribution and sale of our marketed products.

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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 marketed products and our product candidates outside of the United States, who may fail to effectively market our marketed products and 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 marketing of our marketed products and 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.

Our business operations may subject us to numerous commercial disputes, claims and/or lawsuits.

Operating in the pharmaceutical industry, particularly the commercialization of pharmaceutical products, involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of

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disputes, claims and lawsuits. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. Any commercial dispute, claim or lawsuit may divert our management's attention away from our business, we may incur significant expenses in addressing or defending any commercial dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.

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 or in development by Purdue Pharma, Johnson & Johnson, Pfizer, Durect, Endo, Mallinckrodt, Zogenix, Elite Pharmaceuticals, Pain Therapeutics, Nektar, Collegium Pharmaceuticals, Inspirion, Teva, 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

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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.

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, our chief medical officer, Jeffrey Dayno, MD, our chief business officer and head of strategic planning, Mark Strobeck, our chief commercial officer, Deanne Melloy, our chief financial officer, Stan Musial, and our senior vice president of research and development, Karsten Lindhardt. Although we have entered into employment agreements with each of them, these agreements are at-will and do not prevent them from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of either Mr. Radie, Mr. Musial, Dr. Strobeck, Miss. Melloy, Dr. Dayno and Dr. Lindhardt could impede the achievement of our research, development, clinical, business and commercialization objectives.

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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.

Our management and personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. With the acquisition of our marketed products, we have increased our number of full-time employees from 19 on December 31, 2013 to 44 as of February 28, 2015, primarily because we established a commercial organization and our commercial infrastructure over that period, and the complexity of our business operations has substantially increased. As our development and commercialization strategies develop, we will need additional managerial, operational, sales, marketing, financial and other resources. 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;

manage our commercialization activities for our marketed products and Egalet-001 and Egalet-002 effectively and in a cost-effective manner;

complying with increased regulatory requirements;

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.

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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;
- 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.

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 have adopted a Code of Business Conduct and Ethics, 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.

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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 commercial products. 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;

- 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;

- 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,

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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 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

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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, 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 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 from pending patent applications 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 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 patent applications, 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.

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Further, 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 ("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 rights or the patent rights of others. An adverse determination in any such submission, proceeding or opposition 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.

We may be forced to litigate to enforce or defend our intellectual property, and/or the intellectual property rights of our licensors, 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. In so doing, we may place our intellectual property at risk of being invalidated, unenforceable, or limited or narrowed in scope. Further, an adverse result in any litigation or defense proceedings may place pending applications at risk of non-issuance. In addition, if any licensor fails to enforce or defend their intellectual property rights, this may adversely affect our ability to develop and commercialize our product candidates and prevent competitors from making, using, and selling competing products. Any such litigation, even if resolved in our favor, could cause us to incur significant expenses, and distract our technical or management personnel from their normal responsibilities. 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. 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

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and financial results. Further, 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.

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. 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.

If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject to claims by our licensors.

We license rights to OXAYDO from Acura, and we may enter into additional licenses in the future for products and technology that may be important to our business. Under our agreement with Acura we are subject to, and under future license agreements we may be subject to, a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations. Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim, particularly relating to our agreement with respect to OXAYDO, could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of products and result in time-consuming and expensive litigation or arbitration. In addition, on termination we may be required to license to the licensor any related intellectual property that we developed.

If third parties claim that intellectual property used by us infringes upon their intellectual property, this could result in costly litigation and potentially limit our ability to commercialize our products.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights, or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us or any third-party proprietary technologies we have licensed. 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

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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 after a certain period of 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 inevitable uncertainty in intellectual property litigation, any litigation could result in an adverse decision, even if the case against us was weak or flawed.

If we are found to infringe a third party's intellectual property rights, or if a third party that we were licensing technologies from was found to infringe upon a patent or other intellectual property rights of another third party, 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. 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 technology or product candidates, or reengineer or rebrand our product candidates, if feasible, 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. There is always a risk that someone may bring an infringement claim 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

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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 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, which 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.

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

We rely on trade secrets, to protect our proprietary know-how, technology and other proprietary information, where we do not believe patent protection is appropriate or obtainable, to maintain our competitive position. However, trade secrets are difficult to protect. We rely, 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.

We rely upon a combination of patents, trade secret protection (i.e., know how), and confidentiality agreements to protect the intellectual property of our product candidates. The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. Where appropriate, we seek patent protection for certain aspects of our products and technology. 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.

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.

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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.

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 Ownership of Our Common Stock

The trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for a stock quoted on the NASDAQ Global Market. We do not know whether an active, liquid and orderly trading market for our common stock will develop or continue to exist or what the market price of our common stock will be in the future, and as a result it may be difficult for you to sell your shares of our common stock.

Prior to our initial public offering there was no market for shares of our common stock. Since our initial listing on the NASDAQ Global Market on February 6, 2014, the trading market in our common stock has been limited and substantially less liquid than the average trading market for companies quoted on the NASDAQ Global Market. The quotation of our common stock on the NASDAQ Global Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more active market for our common stock will develop in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of February 27, 2015, approximately 87.5% of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5% or more of our capital stock and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

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Our share price may be volatile, which could subject us to securities class action litigation and result in substantial losses to our stockholders.

The trading price of our common stock is 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 Annual Report, 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;
- 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.

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

The market price of our common stock has been and may continue to 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

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litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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.

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 reserved for issuance under our 2013 Stock-Based Incentive Plan is 3,680,000, 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.

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

On February 11, 2014, we completed our initial public offering of 4,200,000 shares of Common Stock, at a price of $12.00 per share, and we issued an additional 630,000 shares of Common Stock at the initial public offering price of $12.00 per share upon the exercise in full by the underwriters of their over-allotment option on March 7, 2014. We received net proceeds of $51,549,600 from the sale, net of underwriting discounts and commissions and other estimated offering expenses. The offer and sale of all of the shares in the offering were registered under the Securities Act in accordance with the Company's final prospectus filed on February 7, 2013 with the SEC pursuant to Rule 424(b)(4) of the Securities Act.

Our management has broad discretion in the application of the net proceeds from our initial public offering and the concurrent private placement. We expect to use the net proceeds from our initial public offering and the concurrent private placement to fund clinical trials of product candidates and establish commercial manufacturing capability for Egalet-001 and Egalet-002 and for working capital and general corporate purposes. Pending their use, we will invest the net proceeds from our initial public 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 our initial public 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.

Our principal stockholders and management exert significant control over matters subject to stockholder approval.

As of February 27, 2015, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 87.5% of our outstanding voting stock. 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

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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 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, 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.

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.

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.

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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.

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 this annual report on Form 10-K, 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

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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, 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 ("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.

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

We are 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 once we are no longer an "emerging growth company."

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 ongoing increases in our legal, audit and financial compliance costs 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.

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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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 is influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

None.

ITEM 2. ***PROPERTIES***

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 terminated earlier. In January 2015, we entered into a sub-lease where we occupy an additional 3,409 square feet in the same building as our existing headquarters. Under the terms of the sub-lease agreement, the sublease expires in December 2017 unless terminated earlier. In addition, we are leasing approximately 180 square feet of office space in Roseland, New Jersey in close proximity to our contract manufacturer Halo. We also maintain a research laboratory, pilot manufacturing and administrative facility in Vaerlose, Denmark, where we lease 12,895 square feet of space under a lease agreement that automatically renews every 12 months (currently through August 2015 unless terminated earlier).

We believe that our existing facilities are adequate for our current needs. We plan to seek to negotiate new leases or evaluate additional or alternate space as we plan for the growth of our commercial operations in the United States. We believe that appropriate alternative space is readily available on commercially reasonable terms.

ITEM 3. ***LEGAL PROCEEDINGS***

Shionogi Inc. commenced an action against our chief commercial officer, Deanne F. Melloy on February 5, 2015. Based on Shionogi Inc.'s allegations that Ms. Melloy's confidentiality and separation agreements with Shionogi Inc. prevent her from working for us, the Court issued a temporary restraining order on February 11, 2015, precluding Ms. Melloy from working for us pending a hearing on Shionogi Inc.'s motion for a preliminary injunction. A hearing on that motion is expected to be held in mid-April. In addition, Shionogi (an affiliate of Shionogi Inc.) sent us a notice of breach letter dated February 3, 2015, asserting that we breached the collaboration and license agreement with Shionogi by hiring Ms. Melloy. We believe that any action would be without merit and would defend any such claim vigorously, but there can be no guarantee that Shionogi Inc. will not commence an action or as to the timing or outcome of any potential action. The collaboration and license agreement we have with Shionogi provides for a 30-day period of good faith negotiations before an action can be commenced. The agreement also provides a 90-day cure period for a material breach. We are working with Shionogi to resolve this matter and do not anticipate a material impact or delay as we continue to move forward with our commercial plans for both OXAYDO and SPRIX, however, there can be no assurance that this matter will be resolved amicably.

On August 10, 2012, Luitpold, the prior exclusive licensee of U.S. Patent No. 6,333,044 ("the '044 patent"), filed a complaint for infringement of the '044 patent against Amneal Pharmaceuticals, LLC et al. in response to Amneal's certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that the '044 Patent covering Sprix is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Luitpold's generic ketorolac tromethamine nasal spray, filed under ANDA No. 23-382 with the FDA. On November 19, 2013, Luitpold and Amneal entered into a settlement and license agreement permitting Amneal to launch its generic product on or after March 25, 2018 subject to royalty payments.

On January 26, 2015, Egalet was substituted for Luitpold as plaintiff in a patent litigation against Apotex Corp. and Apotex, Inc. (collectively, "Apotex"), involving the SPRIX Nasal Spray. Apotex submitted an ANDA to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of generic ketorolac tromethamine

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nasal spray 15.75 mg/spray ("ANDA Product"). In so doing, Apotex made a certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that the '044 Patent covering Sprix is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product. On July 11, 2014, Luitpold filed a complaint for infringement of the '044 patent against Apotex, prompting a 30-month stay on the approval of Apotex's ANDA application by the FDA. This litigation is currently ongoing. We are aggressively defending our legal positions to preserve the exclusivity of SRIX in the market. As is the case with patent litigation, there is a risk that the '044 patent may be invalidated, held unenforceable, or not infringed or limited or narrowed in scope. Even if resolved in our favor, this litigation may result in significant expense, and may distract our technical or management personnel from their normal responsibilities. The '044 Patent expires on December 25, 2018.

There have been a number of generic challengers to OXAYDO (formerly Oxecta) during 2012 and 2013, including Watson Laboratories, Inc., Par Pharmaceuticals, Inc., Impax Laboratories, Inc., Sandoz, Inc., and Ranbaxy Laboratories, Ltd. Along with their ANDA submissions, each generic challenger made a certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that U.S. Patent Nos. 7,201,920; 7,510,726; 7,981,439; 8,409,616; and/or 8,637,540 are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of their generic oxycodone HCl product. In response, Acura filed a complaint for infringement of U.S. Patent No. 7,510,726 (the "'726 Patent") against each generic challenger. As of November 2013, Acura resolved all claims at issue in each of the litigations: Watson amended its ANDA to a Paragraph III certification (i.e., launch at expiry of the patents) and the lawsuit was dismissed; Acura entered into a settlement agreement and consent judgment with Ranbaxy that its generic oxycodone HCl product does not infringe Acura's patents; and Acura entered into settlement and license agreements with the remaining generic challengers allowing entry of a generic oxycodone HCl product on or after January 1, 2022, subject to the occurrence of certain events which may permit for an earlier entry date. There is currently no litigation involving Oxaydo.

ITEM 4. *MINE SAFETY DISCLOSURES*

Not applicable.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Market Information

Our common stock began trading on the NASDAQ Global Market on February 6, 2014 under the symbol "EGLT." Prior to that time, there was no public market for our common stock. Shares sold in our initial public offering on February 5, 2014 were priced at $12.00 per share. The following table sets forth the high and low sales price of our common stock, as reported by the Nasdaq Global Market for the periods indicated:

	High	Low
Year Ended December 31, 2014		
Fourth Quarter	$ 7.53	$ 3.81
Third Quarter	14.26	5.42
Second Quarter	15.50	9.54
First Quarter (beginning February 5, 2014)	19.85	11.82

Stockholders

As of March 3, 2015, there were 848 beneficial holders for shares of our common stock.

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Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding securities authorized for issuance under our equity compensation plans is contained in Part III, Item 12 of this Annual Report.

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.

Performance Graph

The performance graph below compares the cumulative total stockholder return on our common stock beginning on February 6, 2014, the date our stock began trading on the NASDAQ Global Market, and for each subsequent quarter period end through and including December 31, 2014, with the cumulative return of the NASDAQ Composite Index and NASDAQ Biotechnology Index.

The performance graph comparison assumes $100 was invested in our common stock and in each of the other indices described above on February 6, 2014. The stock performance shown on the graph below is not necessarily indicative of future price performance.

Cumulative Total Return
Assumes $100 Initial Investment
December 31, 2014

The performance graph above is being furnished solely to accompany this Annual Report on Form 10-K pursuant to Item 201(e) of Regulation S-K, is not being filed for purposes of Section 18 of the Exchange Act, shall not be deemed to be "soliciting material" or subject to Rule 14A of the Exchange Act and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except to the extent that we specifically incorporate this information by reference.

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Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Use of Proceeds from Registered Securities

On February 5, 2014, our registration statement on Form S-1 (File No. 333-191759) was declared effective by the SEC for our initial public offering pursuant to which we sold an aggregate of 4,830,000 shares of our common stock at a price to the public of $12.00 per share. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on February 5, 2014 pursuant to Rule 424(b)(4) of the Securities Act.

ITEM 6. *SELECTED FINANCIAL DATA*

The selected financial data set forth below is derived from our audited consolidated financial statements and may not be indicative of future operating results. The following selected consolidated financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the notes thereto included elsewhere in this report. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

Prior to the Share Exchange, we had nominal assets and no operations. We have derived the following consolidated historical statement of operations data for the years ended December 31, 2012, 2013 and 2014 and balance sheet data as of December 31, 2013 and 2014 from our audited financial statements included elsewhere in this report. Our historical results are not necessarily indicative of the results that may be expected in the future for any full year or any other interim period.

	Year Ended December 31,		
	2012	**2013**	**2014**
Consolidated Statement of Operations Data:			
Revenues	$ 1,201,000	$	$ 1,920,000
Operating expenses:			
Research and development	4,256,000	6,280,000	22,395,000
General and administrative	2,241,000	5,095,000	16,661,000
Total operating expenses	6,497,000	11,375,000	39,056,000
Loss from operations	(5,296,000)	(11,375,000)	(37,136,000)
Other income		(222,000)	(1,045,000)
Interest expense	75,000	8,842,000	7,079,000
Loss (gain) on foreign currency exchange	27,000	190,000	(3,000)
	102,000	8,810,000	6,031,000
Loss before provision for income taxes	(5,398,000)	(20,185,000)	(43,167,000)
Provision for income taxes		22,000	47,000
Net loss	$ (5,398,000)	$ (20,207,000)	$ (43,214,000)
Per share information:			
Net loss per share of common stock, basic and diluted	$ (4.18)	$ (15.64)	$ (2.97)
Basic and diluted weighted average shares outstanding	1,292,307	1,292,307	14,556,927

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	As of December 31, 2013	As of December 31, 2014
Consolidated Balance Sheet Data:		
Cash	$ 15,700,000	$ 52,738,000
Total assets	20,363,000	60,570,000
Total liabilities	30,236,000	16,309,000
Accumulated deficit	(33,399,000)	(76,613,000)
Total stockholders' (deficit) equity	(24,830,000)	44,261,000

ITEM 7. *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 our historical consolidated financial statements and the related notes thereto appearing in this Annual Report. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, 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 Annual Report, 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

We are a Delaware corporation formed in August 2013. On November 26, 2013, we acquired all of the outstanding shares of Egalet UK in the Share Exchange. As a result, Egalet UK became our wholly-owned subsidiary, and the former shareholders of Egalet UK received shares of the Company. 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 fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative medicines for patients with acute and chronic pain while helping to protect physicians, families and communities from the burden of prescription abuse. On January 8, 2015 we announced the acquisition and license of two innovative pain products, SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO (oxycodone HCl, USP) tablets for oral use only CII, both approved by the U.S. Food and Drug Administration ("FDA") to treat pain. SPRIX Nasal Spray, a non-steroidal anti-inflammatory drug ("NSAID"), is indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. OXAYDO is the first and only approved immediate-release ("IR") oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate. In addition, using our proprietary Guardian Technology, we are developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. We plan to initiate a bioequivalence ("BE") study for our lead product candidate based on our proprietary technology in the first quarter of 2015 and start a Phase 3 program for our second product candidate in the second quarter of 2015 and plan to submit a new drug application ("NDA") for our first product candidate in the fourth quarter of 2015 and an NDA for our second product candidate in the second half of 2016. We also have a collaboration and license agreement with Shionogi Limited ("Shionogi") to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. Our Guardian Technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple active pharmaceutical ingredients with similar or different release profiles.

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OXAYDO is the first and only approved immediate-release oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate. OXAYDO was approved in 2011 and has data in its label from a Category 3 intranasal human abuse liability ("HAL") study. The study compared drug liking and potential to "take drug again" in a population of recreational non-dependent opioid users after snorting crushed OXAYDO and crushed IR oxycodone. The responses on both "take drug again" and drug liking were lower for OXAYDO compared to IR oxycodone.

Immediate-release oxycodone is more often abused than extended-release ("ER") oxycodone and is most often abused via the route of snorting. There has been a 40 percent increase in the abuse of IR oxycodone since the reformulation of ER oxycodone according to the National Poison Data System survey. With 52.3 million prescriptions of IR oxycodone written in 2013, there is a substantial need for an abuse-deterrent IR oxycodone like OXAYDO.

SPRIX Nasal Spray is the first and only approved nasal spray formulation of NSAID, in this case ketorolac, used for short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. This product targets the significant short-acting analgesic market, of which there are approximately 97 million prescriptions written annually. As an NSAID, SPRIX provides analgesia at the opioid level without the side effects or issues of misuse or abuse common to opioids. Our initial commercial focus will be to introduce the product and its unique profile to pain care specialists who routinely see patients that require short-term analgesics requiring opioid level analgesia. We intend to begin our promotional efforts on this product in the first quarter of 2015.

To commercialize SPRIX and OXAYDO and ultimately our pipeline product candidates, we are building a 50 to 60 person specialty sales force targeting the approximately 5,700 physicians in the high-decile of prescribing pain medicines in the United States. We intend to consider partnerships to access third-party sales representatives who target primary care and internal medicine physicians in the United States and collaborations with other companies to develop and commercialize our product candidates outside the United States.

Formulated using our proprietary Guardian Technology, we are developing two late-stage product candidates specifically designed to deter abuse by physical and chemical manipulation. The lead program, Egalet-001, an abuse-deterrent, extended-release, oral morphine formulation, and our second product candidate Egalet-002, an abuse-deterrent, extended-release, oral oxycodone formulation, are in late-stage clinical development for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments are inadequate. We plan to initiate a bioequivalence study for our lead product candidate based on our proprietary technology in the first quarter of 2015 and start a Phase 3 program for our second product candidate in the second quarter of 2015 and plan to submit an NDA for our first product candidate in the fourth quarter of 2015 and an NDA for our second product candidate in the second half of 2016.

Using our proprietary Guardian Technology, 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 Guardian Technology allows us to create physical and chemical barriers intended to deter the most common methods of abuse that are specific to a particular drug. For instance with Egalet-001, an abuse-deterrent, extended-release morphine, it was designed to deter all forms of abuse but primarily abuse via the route of injection the most common method of abuse of morphine. The Egalet-001 system consists of a hard matrix that erodes as it passes through the gastrointestinal tract. This polymer matrix construct makes extracting the API into a solution which could be drawn into a syringe very difficult making this product very difficult to be abused via the route of injection.

We believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. Clinically, we have successfully completed a Phase 1 study and three bioequivalence studies of

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Egalet-001. Also, we have completed Category 1 abuse-deterrent studies demonstrating physical and chemical properties of the product. We announced in January of 2015 positive top-line data from a Category 3 abuse-deterrent oral HAL study. This was the first clinical demonstration in which Egalet-001 showed lower abuse potential compared to MS Contin when taken orally. We are currently conducting a Category 3 intranasal HAL study as well. We intend to initiate in the first quarter of 2015, a pivotal 60 mg bioequivalence study to establish the bioequivalence of Eglalet-001 to MS Contin with results expected in the fourth quarter of 2015. We plan to seek U.S. regulatory approval of Egalet-001 pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. Under this proposed approval pathway, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2015.

Also using our Guardian Technology, for Egalet-002, we designed a tablet with a similar matrix construct but have added a hard impermeable shell, around the outside. The shell, which passes safely through the gastrointestinal ("GI") tract intact, adds a layer of rigidity to the tablet which makes particle size reduction even more difficult. This is important because oxycodone is abused most often via particle size reduction and insufflation or snorting through the nose. In addition Egalet-002 was designed to inhibit alcohol dose dumping and does not produce changes in the rate of absorption of the API in the GI tract based on the presence or absence of food, also known as a food effect.

We believe our second product candidate, Egalet-002, if approved, will have advantages over commercially available, long-acting, abuse-deterrent oxycodone products, such as OxyContin®, due to its differentiated abuse-deterrent properties and a pharmacokinetic ("PK") profile that demonstrates low peak-to-trough concentration variability in drug exposure. We have conducted Phase 1 trials of Egalet-002 and completed initial abuse-deterrent studies in compliance with the FDA draft guidance. We plan to initiate a Phase 3 safety and efficacy program for Egalet- 002 in the second quarter of 2015. Peak-to-trough concentration variability means the difference between the highest concentration of an active pharmaceutical ingredient ("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 are also conducting additional abuse-deterrent studies ongoing in accordance with the FDA draft guidance, with the goal of obtaining abuse-deterrent claims in our product label. We plan to seek U.S. regulatory approval of Egalet-002 pursuant to Section 505(b)(2) and anticipate submitting an NDA for Egalet-002 in the second half of 2016.

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 is 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. Shionogi invested $15 million in a private placement concurrently with our initial public offering. 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 net losses were $43.2 million, $20.2 million and $5.4 million for the years ended December 31, 2014, 2013 and 2012 respectively. We recognized revenues of $1.9 million for the year ended December 31, 2014 and $1.2 million for the year ended December 31, 2012. We did not recognize any revenues for the year ended December 31, 2013. As of December 31, 2014, we had an accumulated deficit of $76.6 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. Additionally, we expect to incur significant commercialization expenses in establishing a sales, marketing and distribution infrastructure to sell our products in the United States, including launching our recently licensed product, OXAYDO, and our recently acquired product SPRIX.

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We will seek to register and license the 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.

As a result of our initial public offering, we have incurred additional costs associated with operating as a public company, including hiring additional personnel and expanding our facilities. These costs include 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 have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We currently estimate that these annual costs, including costs for additional personnel, are approximately $2.0 million to $3.0 million associated with operating as a public company. 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.

Internal Control Over Financial Reporting

In preparing our consolidated financial statements as of and for the year ended December 31, 2013, 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, during the years ended December 31, 2013 and 2012. 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 were 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 2012 and 2013 consolidated financial statements.

In response to these material weaknesses, we have hired a team of experienced accounting and finance personnel in the US. In addition we have implemented and improved a number of internal controls over financial reporting. In management's opinion, the material weaknesses identified above have been remediated as of December 31, 2014. However, we 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 maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide

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reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of its inherent limitations, disclosure controls and procedures may not prevent all misstatements.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2014 at the reasonable assurance level.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control Integrated Framework (1992) during any period in accordance with the provisions of the Sarbanes-Oxley Act. 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 generated no revenues from Egalet-001 and Egalet-002, our clinical stage product candidates, and only limited revenues from our marketed products, and have generated $3.9 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 expand the marketing of our marketed products and commercialize our product candidates, or other product candidates that we may in license or acquire in the future.

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.

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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, 2012, 2013 and 2014 and for the period from July 31, 2010 (inception of Egalet UK) through December 31, 2014:

	Year Ended December 31, 2012	Year Ended December 31, 2013	Year Ended December 31, 2014
Egalet-001	$ 265,000	$ 2,552,000	$ 10,547,000
Egalet-002	1,250,000	382,000	3,397,000
Other clinical and preclinical development	1,158,000	1,767,000	2,634,000
Personnel related	1,583,000	1,579,000	5,817,000
	$ 4,256,000	$ 6,280,000	$ 22,395,000

We incurred research and development expenses of $4.3 million, $6.3 million and $22.4 million during the years ended December 31, 2012, 2013 and 2014, respectively. 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 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

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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, with our recent acquisition of Sprix and license of Oxaydo, 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. subsidiary 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 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

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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.

Our collaborative research and license agreements contain multiple deliverables which may include (i) licenses, (ii) research and development activities, and (iii) royalty and related commissions. Revenue is recognized when we have satisfied our service obligations under a written contract with our customer (or collaboration partner) where the price for the services have been agreed upon and when we have reasonable assurance that the resulting receivable will be collected within contractually agreed upon terms. We have adopted the provisions of Accounting Standards Update ("ASU") 2009-13, "Multiple-Deliverable Revenue Arrangements," which amends ASC 605-25, and also adopted ASU 2010-17, "Revenue Recognition Milestone Method." In accordance with ASU 2009-13, we consider whether the deliverables under the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have stand-alone value.

Under our collaborative research and development agreements, we recognized revenue of $1.2 and $1.9 million during the years ended December 31, 2012 and 2014 respectively. We did not recognize any revenue during the year ended December 31, 2013.

Stock-Based Compensation

We account for all share-based compensation payments issued to employees, directors and non-employees using an option pricing model for estimating fair value. Accordingly, share-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative accounting guidance, we re-measure the fair value of non-employee share-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

The stock-based compensation expense for restricted stock awards is determined based on the closing market price of our common stock on the grant date of the awards applied to the total number of awards that are anticipated to vest.

We recognize the grant date fair value of each option and restricted share over its vesting period. Options and restricted shares generally vest over a four year period and generally have a term of ten years. We estimate the fair value of each stock option award on the grant date using the Black-Scholes option-pricing model, wherein expected volatility is based on historical volatility of comparable guideline public companies because of our brief history as a public company. We base the expected term calculation on the "simplified" method described in Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) No. 107, Share-Based Payment and SAB No. 110, Share-Based Payment, because we have limited experience as a public company. We base the risk-free interest rate on the U.S. Treasury yield in effect at the time of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield is zero as we have never paid cash dividends on our common stock, and have no present intention to pay cash dividends.

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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 years ended December 31, 2013 and 2014.

Indefinite-Lived Intangible Asset

The intangible asset related to our acquired in-process research and development ("IPR&D") asset for our technology platform is considered an indefinite-lived intangible asset and is assessed for impairment 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 years ended December 31, 2012, 2013 and 2014.

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 by Egalet UK, 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

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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.

Related Party Convertible Debt

We accounted for our related party convertible debt issued in April 2013 in accordance with ASC 470-20, "Debt with Conversion and Other Options" ("ASC 470-20"). Under the guidelines of ASC 470-20, we measure an embedded beneficial conversion feature on the date of issuance, by allocating a portion of the proceeds equal to the intrinsic value of the feature to additional paid in capital. The intrinsic value of the feature is calculated on the date of issuance using the effective conversion price which resulted from the difference between the effective conversion price and the fair value of the Company's convertible preferred series A-1 stock as of the commitment date. The intrinsic value is limited to the portion of the proceeds allocated to the convertible debt. We recognize an embedded beneficial conversion feature related to our related party convertible debt. The beneficial conversion feature is amortized to our consolidated statements of comprehensive loss over the term of the liability.

We also accounted for our related party convertible debt issued in August 2013 as stock-settled debt, since the value of future stock issued upon conversion was equal to two times the original principal amount issued under the 2013 Loan Agreement. The premium is amortized into earnings and recorded as interest expense over the term of the loan.

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.

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, 2014, in recognition of this risk, we have provided a valuation allowance of approximately $14.0 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, 2014 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.

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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, 2012, 2013 or 2014.

Results of Operations

Comparison of Years Ended December 31, 2013 and 2014

	Year Ended December 31,		
	2013	**2014**	**Change**
Revenues	$	$ 1,920,000	$ 1,920,000
Operating expenses:			
Research and development	6,280,000	22,395,000	16,115,000
General and administrative	5,095,000	16,661,000	11,566,000
Total operating expenses	11,375,000	39,056,000	27,681,000
Loss from operations	(11,375,000)	(37,136,000)	(25,761,000)
Other income	(222,000)	(1,045,000)	(823,000)
Interest expense	8,842,000	7,079,000	(1,763,000)
Loss (gain) on foreign currency exchange	190,000	(3,000)	(193,000)
	8,810,000	6,031,000	(2,779,000)
Loss from operations before income taxes	(20,185,000)	(43,167,000)	(22,982,000)
Provision for income taxes	22,000	47,000	25,000
Net loss	$ (20,207,000)	$ (43,214,000)	$ (23,007,000)

Revenues

Revenues increased from $0 for the year ended December 31, 2013 to $1.9 million for the year ended December 31, 2014, as a result of the amortization of deferred revenue and certain research and development services performed under our collaboration and license agreement with Shionogi.

Research and development expenses

Research and development expenses increased by $16.1 million, or 256.6%, from $6.3 million for the year ended December 31, 2013 to $22.4 million for the year ended December 31, 2014. This change was driven primarily by increases in our development costs for Egalet-001 and Egalet-002 of

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$8.0 million and $3.0 million, respectively, due to increased clinical study costs including the manufacturing of product. In addition, we implemented a stock compensation plan in 2014 which resulted in $3.4 million of stock compensation expense.

General and administrative expenses

General and administrative expenses increased by $11.6 million, or 227.0%, from $5.1 million for the year ended December 31, 2013 to $16.7 million for the year ended December 31, 2014. The increase was driven primarily by the implementation of our stock compensation plan resulting in $5.1 million of stock compensation expense in 2014, as well as an increase of $2.3 million in salary and related expenses due to the growth of our operations the United States. In addition, professional fees increased $2.9 million in 2014 as a result of growing our U.S. operations and becoming a publicly traded company.

Other income

Other income was $1.0 million and $222,000 for the years ended December 31, 2014 and 2013, respectively, and consisted entirely of a Danish research and development tax credit.

Interest expense

Interest expense decreased from $8.8 million for the year ended December 31, 2013 to $7.1 million for the year ended December 31, 2014. Interest expense for the year ended December 31, 2013 consisted primarily of $8.4 million in additional interest expense related to the accretion of the beneficial conversion feature recorded in connection with our April 2013 convertible debt issuance and the accretion of our premium recorded in connection with our August 2012 convertible debt issuance. Interest expense for the year ended December 31, 2014 was primarily attributable to the recognition of the unamortized premium upon conversion of our related party senior convertible debt in connection with our IPO in February 2014.

Loss (gain) on Foreign Currency Exchange

We recognized a loss on foreign currency exchange of $190,000 during the year ended December 31, 2013 compared to a gain of $3,000 during the year ended December 31, 2014. The difference during the year ended December 31, 2014 was primarily attributable a change in the average rates of currency in which we transacted during 2013 when compared to 2014.

Provision for Income Taxes

We had a provision for income taxes of $47,000 and $22,000 during the years ended December 31, 2014 and 2013, respectively, primarily due to state income taxes for the year ended December 31, 2014 and to deferred tax expense for the year ended December 31, 2013 related to the tax amortization of the in-process research and development intangible asset which results in an indefinite-lived deferred tax liability.

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Comparison of Years Ended December 31, 2012 and 2013

	Year Ended December 31,		
	2012	2013	Change
Revenues	$ 1,201,000	$	$ (1,201,000)
Operating expenses:			
Research and development	4,256,000	6,280,000	2,024,000
General and administrative	2,241,000	5,095,000	2,854,000
Total operating expenses	6,497,000	11,375,000	4,878,000
Loss from operations	(5,296,000)	(11,375,000)	(6,079,000)
Other income		(222,000)	(222,000)
Interest expense	75,000	8,842,000	8,767,000
Loss on foreign currency exchange	27,000	190,000	163,000
	102,000	8,810,000	8,708,000
Loss from operations before income taxes	(5,398,000)	(20,185,000)	(14,787,000)
Provision for income taxes		22,000	22,000
Net loss	$ (5,398,000)	$ (20,207,000)	$ (14,809,000)

Revenues

Revenues decreased from $1.2 million for the year ended December 31, 2012 to zero for the year ended December 31, 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 $2.0 million, or 47.6%, from $4.3 million for the year ended December 31, 2012 to $6.3 million for the year ended December 31, 2013. This increase was driven primarily by an increases in our development costs for Egalet-001 and other clinical and pre-clinical development costs of $2.3 million and $609,000, 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 employee compensation expenses of $868,000 and $4,000, respectively. 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 $2.9 million, or 127.4%, from $2.2 million for the year ended December 31, 2012 to $5.1 million for the year ended December 31, 2013. The increase was attributable to increases in compensation, travel costs and facility-related expenses of $1.1 million, $144,000 and $392,000, 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 $902,000 and $81,000, respectively, related to our increased efforts in business development, the pursuit of licensing arrangements, and the costs associated with preparing for our initial public offering.

Other Income

Other income was $222,000 in 2013 and consisted entirely of a Danish research and development tax credit.

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Interest expense

Interest expense increased from $75,000 for the year ended December 31, 2012 to $8.8 million for the year ended December 31, 2013. This change was primarily attributable to the $8.4 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 $27,000 during the year ended December 31, 2012 compared to $190,000 during 2013. The difference during the year ended December 31, 2013 primarily attributable the change in the average rates of currency in which we transacted during 2012 when compared to 2013 and the increase in intercompany payables and receivables between our UK and U.S. wholly-owned subsidiaries.

Provision for Income Taxes

We had a provision for income taxes of $22,000 during the year ended December 31, 2013 primarily due to deferred tax expense related to the tax amortization of the in-process research and development intangible asset, which results in a indefinite-lived deferred tax liability for reporting purposes. For the year ended December 31, 2012, no provision had been made for U.S. federal and state income taxes of foreign earnings due to the history of losses.

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 $20.2 million and $43.2 million for the years ended December 31, 2013 and 2014, respectively. Our operating activities used $433,000 and $25.1 million of cash flows during the years ended December 31, 2013 and 2014, respectively. At December 31, 2014, we had an accumulated deficit of $76.6 million, a working capital surplus of $47.7 million and cash of $52.7 million.

From our inception through December 31, 2014, 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 $2.7 million in payments received through December 31, 2014 from our collaborative research and development agreements along with 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 our and Shionogi's activities and is uncertain at this time.

On February 11, 2014, 4,200,000 shares of our common stock were sold at an initial public offering price of $12.00 per share, for aggregate gross proceeds of $50.4 million. On March 7, 2014, in connection with the exercise by the underwriters of the IPO of a portion of the over-allotment option granted to them in connection with the IPO, 630,000 additional shares of our common stock were sold at the IPO price of $12.00 per share, for aggregate gross proceeds of approximately $7.6 million. In addition, as part of the IPO, we converted all of our convertible preferred stock and related party senior convertible debt into 5,329,451 and 2,585,745 shares of common stock, respectively. Also, Shionogi, our collaboration partner, purchased 1,250,000 shares of our common stock in a separate private placement which closed concurrently with the completion of the IPO at a price per share equal to $12.00 per share, for aggregate gross proceeds of $15.0 million. In addition, upon the closing of the IPO, the 2013 related party senior convertible debt holders automatically exercised 600,000 warrants for shares of common stock at an exercise price of $0.0083 per share.

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The Company may never achieve profitability, and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through the sale of equity, debt financings or other sources, including potential additional collaborations. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

Debt Facilities

In March 2012, we completed an equity financing and issued Series B and B-1 convertible preferred stock. Pursuant to the financing, holders of our then outstanding convertible promissory notes agreed not to demand repayment of the notes 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. The shares of Series B and Series B-1 convertible preferred stock converted into shares of our common stock on a 1-for-1 basis upon the closing of the IPO in February 2014.

In April 2013, we entered into a $5.0 million convertible loan with several of its equity investors to provide the Company with funding to meet its short-term obligations. The loan had an interest 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 had provisions whereby it would 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 IPO that yielded a minimum of approximately $20 million in net proceeds to the Company at a per share price that values the Company at a minimum of $105.4 million (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 Company's IPO, the outstanding principal and interest of $5.0 million and $240,000, respectively, was converted into shares of the Company's common stock.

On August 29, 2013, we entered into a loan agreement (the "2013 Loan Agreement") with several of our equity investors. The 2013 Loan Agreement was used to fund clinical and manufacturing development, working capital, and other general operational funding requirements. Upon entering into the 2013 Loan Agreement, we borrowed $10.0 million in debt proceeds. Borrowings under the 2013 Loan Agreement had an annual interest rate of 6% and were initially scheduled to mature on August 29, 2014. Subsequent to the maturity date, all outstanding principal and unpaid interest were to be 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, was prohibited unless written approval from the lending super-majority is obtained.

The 2013 Loan Agreement had provisions requiring the lenders to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an IPO 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 would 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.

In connection with the 2013 Loan Agreement, the lenders received 600,000 warrants that would automatically exercise 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 were 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) in connection with our IPO.

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Immediately prior to completing its IPO on February 6, 2014, the Company accelerated the recognition of the premium immediately prior to converting into equity. The outstanding principal, premium and interest of $10.0 million, $10.0 million, and $275,000, respectively, were converted into shares of the Company's common stock. The unamortized debt discount balance of $802,000 was also converted. For the three and nine months ended September 30, 2014 the Company recognized interest expense of $0 and $7.1 million, respectively, of which $0 and $7.0 million, respectively, was related to the accretion of premiums and the amortization of debt discounts, respectively.

In addition, the 2013 related party senior convertible debt holders automatically exercised warrants for 600,000 shares of common stock at an exercise price of $0.0083 per share in connection with the conversion of the senior convertible debt into shares of common stock.

In January 2015, the Company entered into a Loan and Security Agreement, ("the Loan Agreement"), with Hercules Technology Growth Capital, Inc., ("Hercules"), pursuant to which the Company borrowed $15,000,000 pursuant to a term loan, all of which was funded in January 2015. The term loan bears an interest rate per annum equal to the greater of either (i) 9.40% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (ii) 9.40%. Pursuant to the terms of the Loan Agreement, the Company will make interest-only payments for 12 months, and then repay the principal balance of the loan in 30 equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2018. In connection with the Loan Agreement, the Company granted a security interest in substantially all of its assets, excluding intellectual property and certain new drug applications and related approvals, as collateral for the obligations under the Loan Agreement.

The Loan Agreement also contains representations and warranties, and indemnification in favor of Hercules and the other lenders. The Company is required to comply with various customary covenants, including, among others, restrictions on indebtedness, investments, distributions, transfers of assets and acquisitions. The Loan Agreement contains several events of default, including, among others, payment defaults, breaches of covenants or representations, material impairment in the perfection of Hercules' security interest or in the collateral and events related to bankruptcy or insolvency. Upon an event of default, Hercules may declare all outstanding obligations immediately due and payable, and Hercules may take such further actions as set forth in the Loan Agreement, including collecting or taking such other action with respect to the collateral pledged in connection with the Loan Agreement.

In connection with the Loan Agreement, the Company issued Hercules a warrant (the "Warrant") to purchase $600,000 in shares of the Company's common stock at an exercise price of $5.29 per share (or, approximately 113,421 shares of Common Stock). The Warrant is exercisable for a period of five years beginning on the date of issuance and has an expected fair value of $328,610 as of January 7, 2015 that will be included in equity in future reporting periods.

Collaboration and License Agreement with Acura

On January 7, 2015, the Company entered into a Collaboration and License Agreement, (the "License Agreement") with Acura Pharmaceuticals, Inc. ("Acura") to commercialize Oxaydo (oxycodone hydrochloride) tablets containing Acura's Aversion® Technology. Under the terms of the License Agreement, Acura transferred the approved NDA for Oxaydo to the Company and the Company was granted an exclusive license under Acura's intellectual property rights for development and commercialization of Oxaydo worldwide in all strengths.

The Company will pay a significant portion of the expenses relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States and will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States.

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The Company was also required to pay Acura an upfront payment of $5 million dollars within 10 days after signing of the License Agreement and will be required to make a $2.5 million milestone on the earlier to occur of (A) the launch of Oxaydo and (B) January 1, 2016, but in no event earlier than June 30, 2015. In addition, Acura will be entitled to a one-time $12.5 million milestone payment when Oxaydo net sales reach a specified level of $150 million in a calendar year.

In addition, Acura will receive from the Company a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxyado net sales during such year. In any calendar year in which net sales exceed a specified threshold, Acura will receive a double digit royalty on all Oxaydo net sales in that year. The Company's royalty payment obligations commence on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by the Company to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Agreement expires upon the expiration of the Company's royalty payment obligations in all countries, and may be terminated by each party under certain circumstances, including a material breach of the License Agreement by the other party.

Asset Purchase Agreement with Luitpold

On January 8, 2015, the Company entered into and consummated the transactions contemplated by an Asset Purchase Agreement (the "Purchase Agreement") with Egalet US and Luitpold Pharmaceuiticals, Inc. ("Luitpold"). Pursuant to the Purchase Agreement, Egalet US acquired specified assets and liabilities associated with Sprix® (ketorolac tromethamine) Nasal Spray for a purchase price of $7,000,000, $315,000 of which was deposited into an escrow account to secure Luitpold's indemnification obligations under the Purchase Agreement. The purchase price is subject to adjustment based on a final inventory count of the finished goods being purchased by Egalet US. Egalet US concurrently purchased an additional $1,128,000 of glassware, equipment and active pharmaceutical agreement from Luitpold, and agreed to purchase an additional $339,823 of active pharmaceutical ingredient after closing within two business days of the release of such active pharmaceutical ingredient from Luitpold's supplier.

As part of the Purchase Agreement, Luitpold and Egalet US entered into a Transition Services Agreement, pursuant to which, Luitpold has agreed to provide Egalet US certain transition services for specified periods of time in exchange for the payment of agreed-upon amounts for such services.

Cash Flows

Comparison of Years Ended December 31, 2013 and 2014

The following table summarizes our cash flows for the years ended December 31, 2013 and 2014:

	Year Ended December 31,	
	2013	**2014**
Net cash (used in) provided by:		
Operating activities	$ (433,000)	$ (25,074,000)
Investing activities	(1,791,000)	(3,743,000)
Financing activities	13,557,000	66,982,000
Effect of foreign currency translation on cash	963,000	(1,127,000)
Net increase in cash	$ 12,296,000	$ 37,038,000

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Cash Flows from Operating Activities

Net cash used in operating activities was $25.1 million for the year ended December 31, 2014 and consisted primarily of a net loss of $43.2 million. These outflows were partially offset by $641,000 of noncash depreciation and amortization expense, $8.5 million in stock based compensation, $7.0 million in accretion of the debt premium to interest expense, and $2.0 in net cash inflows from changes in operating assets and liabilities. Cash inflows from changes in operating assets and liabilities were primarily due to an increase in accounts payable of $3.3 million and $1.4 million in accrued expenses due to an increase in our expense base and the timing in which we pay our consultants. We also had a decrease in our prepaid expenses of $540,000.

Net cash used in operating activities was $433,000 for the year ended December 31, 2013 and consisted primarily of a net loss of $20.2 million. These outflows were partially offset by $483,000 of noncash depreciation and amortization expense, $8.4 million in accretion of beneficial conversion features and premiums, a change in our deferred income taxes of $22,000 and $10.8 million in net cash inflows from changes in operating assets and liabilities. Cash inflows from changes in operating assets and liabilities were primarily due to an increase in deferred revenue of $10.0 million related to our collaboration agreement with Shionogi and $706,000 in accrued expenses due to the interest for our related convertible debt and the timing of payments to our consultants. We also had a decrease in our prepaid expenses of $350,000. These inflows were offset by outflows primarily due to the $378,000 decrease in our accounts payable.

Cash Flows from Investing Activities

Net cash used in investing activities for the years ended December 31, 2013 and 2014 was $1.8 million and $3.7 million, respectively. In both periods, these cash flows consisted primarily of purchases of property and equipment as well as deposits on future related purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities was $67.0 million for the year ended December 31, 2014 and consisted primarily of $53.0 million in proceeds from the completion of our IPO in February of 2014. There were additional proceeds of $14.0 million from the issuance of common stock in connection with our concurrent private placement with Shionogi.

Net cash provided by financing activities was $13.6 million for the year ended December 31, 2013 and consisted primarily 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. These proceeds in 2013 were offset by $1.4 million in payments of deferred financing fees primarily due to the deferred costs in connection with our IPO.

Comparison of Years Ended December 31, 2012 and 2013

The following table summarizes our cash flows for the years ended December 31, 2012 and 2013:

	Year Ended December 31,	
	2012	**2013**
Net cash (used in) provided by:		
Operating activities	$ (5,460,000)	$ (433,000)
Investing activities	(314,000)	(1,791,000)
Financing activities	8,218,000	13,557,000
Effect of foreign currency translation on cash	(92,000)	963,000
Net increase in cash	$ 2,352,000	$ 12,296,000

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Cash Flows from Operating Activities

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.

Net cash used in operating activities was $433,000 for the year ended December 31, 2013 and consisted primarily of a net loss of $20.2 million. These outflows were partially offset by $483,000 of noncash depreciation and amortization expense, and $8.4 million in accretion of the beneficial conversion feature and premium, the change in our deferred income taxes of $22,000 along with $10.8 in net cash inflows from changes in operating assets and liabilities. Cash inflows from changes in operating assets and liabilities were primarily due to an increase in deferred revenue of $10.0 million related to our collaboration agreement with Shionogi and $706,000 in accrued expenses due to the interest for our related convertible debt and the timing in which we pay our consultants. We also had a decrease in our prepaid expenses of $350,000. These inflows were offset by outflows primarily due to the $378,000 decrease in our accounts payable.

Cash Flows from Investing Activities

Net cash used in investing activities for the years ended December 31, 2012 and 2013 was $314,000 and $1.8 million, respectively. In both periods, our cash flows from investing activities consisted of purchases and sales of property and equipment. During 2013, we began our manufacturing efforts under our agreement with Halo.

Cash Flows from Financing Activities

Net cash provided by financing activities was $8.2 million for the year ended December 31, 2012 and consisted of proceeds from the issuance of convertible Series B preferred shares in March 2012. Net cash provided by financing activities was $13.6 million for the year ended December 31, 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. These proceeds in 2013 were offset by $1.4 million in payments of deferred financing fees primarily due to the deferred costs in connection with our initial public offering.

Operating and Capital Expenditure Requirements

We have generated substantial net losses and negative cash flow from operations since our inception, and we continue to incur significant research, development and other expenses related to our ongoing operations for our product candidates. For the years ended December 31, 2014 and 2013, we reported a net loss of $43.2 million and $20.2 million, respectively.

We expect to incur losses and negative cash flow for the foreseeable future. Our ability to generate sufficient revenues from SPRIX and OXAYDO, our marketed products, or Egalet-001 and Egalet-002 and any of our other product candidates, if approved, will depend on numerous factors described under the heading "Risk Factors" and elsewhere in this Annual Report. We expect that our gross margin may fluctuate from period to period as a result of changes in product mix sold, potentially by the introduction of new products by us or our competitors, manufacturing efficiencies related to our products and a variety of other factors. 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 have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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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. 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.

The Company reasonably expects that the net proceeds from the Company's IPO, its pre-existing cash and cash equivalents, together with expected revenues to be generated by the assets licensed and purchased subsequent to December 31, 2014, will enable it to fund its operating expenses and capital expenditure requirements through September 30, 2015.

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 of our marketed products, 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.

Contractual Obligations and Commitments

The following table represents our contractual obligations and commitments as of December 31, 2014. See " Liquidity and Capital Resources Debt Facilities" above for a discussion of our Loan

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Agreement with Hercules which we entered into in January 2015 and is not reflected in the table below.

	Payments Due By Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations(1)	$ 411,476	$ 227,118	$ 184,359	$	$
Other(2)(3)	1,401,575	1,390,811	10,764		
Total	$ 1,813,052	$ 1,617,929	$ 195,123	$	$

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

(2) In 2014, we contracted with a third party to purchase raw materials to be used in the manufacturing of our clinical trial drug supply. The materials are scheduled to be delivered in first half of 2015. We expect the remaining balance of $1,194,000 will be paid through June 2015.

(3) We have employment agreements with our executive officers that require the funding of a specific level of payments if specified events occur, such as a change in control or termination without cause. 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 the purchase of raw materials, 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.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES 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.

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Interest Rate Risk

We had cash of $15.7 million and $52.7 million at December 31, 2013 and December 31, 2014, 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. As a result of this exposure, adverse movement in foreign currency exchange rates may have a material adverse impact on our financial results. We are party to contracts which are primarily denominated in US Dollars and Danish Krone.

All assets and liabilities of our international subsidiary, which maintains its financial statements in the local currency, are translated to U.S. dollars at period-end exchange rates. Translation adjustments arising from the use of differing exchange rates are included in accumulated other comprehensive income in stockholders' equity. Gains and losses on foreign currency transactions and short term inter-company receivables from foreign subsidiaries are included in Loss (gain) on foreign currency exchange. The reported results of our foreign operations will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar.

A 10% increase in foreign currency exchange rates would have increased our 2014 net loss from $43.2 million to $45.5 million, an increase of $2.3 million.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

The financial statements and supplementary data required by this item are listed in Item 15 "Exhibits and Financial Statement Schedules" of this Annual Report.

ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

None.

ITEM 9A. ***CONTROLS AND PROCEDURES***

In preparing our consolidated financial statements as of and for the year ended December 31, 2013, 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, during the years ended December 31, 2013 and 2012. 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 were 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,

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required in connection with closing our books and records and preparing our 2012 and 2013 consolidated financial statements.

In response to these material weaknesses, we have hired a team of experienced accounting and finance personnel in the US. In addition we have implemented and improved a number of internal controls over financial reporting. In management's opinion, the material weaknesses identified above have been remediated as of December 31, 2014. However, we 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.

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

In management's opinion, the material weaknesses identified above have been remediated as of December 31, 2014. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of its inherent limitations, disclosure controls and procedures may not prevent all misstatements.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2014 at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control

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over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(e) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "*Internal Control Integrated Framework (1992)"* published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2014, the end of our most recent fiscal year.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. 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.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) that occurred during the fourth quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting, except during 2014 the Company remediated the material weaknesses identified by our auditors in prior year. We enhanced our accounting staff by adding personnel with accounting and reporting experience in U.S. GAAP and SEC Reporting. This additional staff provided us with appropriate segregation of duties.

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

ITEM 10. ***DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

Information with respect to this item is set forth in the Proxy Statement for the 2015 Annual Meeting of Stockholders ("Proxy Statement") under the headings "Election of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," "Code of Ethics" and "Corporate Governance" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

ITEM 11. ***EXECUTIVE COMPENSATION***

Information with respect to this item is set forth in the Proxy Statement under the headings "Executive Compensation" and "Director Compensation," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

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ITEM 12. ***SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

Information with respect to this item is set forth in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

Information with respect to this item is set forth in the Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

ITEM 14. ***PRINCIPAL ACCOUNTING FEES AND SERVICES***

Information with respect to this item is set forth in the Proxy Statement under the heading "Ratification of the Selection of Independent Registered Public Accounting Firm," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***

(a) (1) Financial Statements: See Index to Consolidated Financial Statements on page F-1.
(3) Exhibits: See Exhibits Index on page 113.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 16, 2015

Egalet Corporation

By: /s/ ROBERT RADIE

Robert Radie

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ ROBERT RADIE Robert Radie	Director, President and Chief Executive Officer (Principal Executive Officer)	March 16, 2015
/s/ STAN MUSIAL Stan Musial	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2015
/s/ JEAN-FRANÇOIS FORMELA Jean-François Formela	Chairman, Board of Directors	March 16, 2015
/s/ RENEE AGUIAR-LUCANDER Renee Aguiar-Lucander	Director	March 16, 2015
/s/ TIMOTHY P. WALBERT Timothy P. Walbert	Director	March 16, 2015
/s/ GREGORY WEAVER Gregory Weaver	Director	March 16, 2015

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Exhibits Index

Exhibit Number	Exhibit Description
2.1^	Asset Purchase Agreement, dated as of January 8, 2015, by and between Egalet US, Inc. and Luitpold Pharmaceuticals, Inc.
3.1	Third Amended and Restated Certificate of Incorporation of Egalet Corporation (incorporated by reference to Exhibit 3.1 to Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on February 11, 2014).
3.2	Amended and Restated Bylaws of Egalet Corporation (incorporated by reference to Exhibit 3.2 to Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on February 11, 2014).
4.1	Form of Certificate of Common Stock (incorporated by reference to Exhibit 4.1 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
4.2	Warrant Issued to Hercules Technology Growth Capital, Inc. dated January 7, 2015.
10.1	Loan and Security Agreement, dated January 7, 2015, by and among Egalet Corporation, Egalet US, Inc., Hercules Technology Growth Capital, Inc. and the several other banks, financial institutions and entities from time to time party thereto.
10.2	Amendment No. 1, dated January 28, 2015, to the Loan and Security Agreement by and among Egalet Corporation, Egalet US, Inc., Hercules Technology Growth Capital, Inc. and the several other banks, financial institutions and entities from time to time party thereto.
10.3	Amendment No. 2, dated February 20, 2015, to the Loan and Security Agreement by and among Egalet Corporation, Egalet US, Inc., Hercules Technology Growth Capital, Inc. and the several other banks, financial institutions and entities from time to time party thereto.
10.4*	Collaboration and License Agreement, dated as of January 7, 2015, by and among Egalet Corporation, Egalet US, Inc., Egalet Ltd. and Acura Pharmaceuticals, Inc.
10.5*	Collaboration and License Agreement, dated as of November 26, 2013, by and among Egalet Limited, Shionogi Limited and Egalet Corporation (incorporated by reference to Exhibit 10.11 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.6	Common Stock Purchase Agreement, dated as of November 26, 2013, by and between Egalet Corporation and Shionogi Limited (incorporated by reference to Exhibit 10.12 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.7*	Agreement, dated as of December 4, 2012, by and between Egalet Limited and Halo Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.4 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.8+	Employment Agreement by and between Egalet Corporation and Robert S. Radie (incorporated by reference to Exhibit 10.1 to Egalet Corporation's current report on Form 8-K filed on February 11, 2014).

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Exhibit Number	Exhibit Description
10.9+	Employment Agreement by and between Egalet Corporation and Stan Musial (incorporated by reference to Exhibit 10.2 to Egalet Corporation's current report on Form 8-K filed on February 11, 2014).
10.10+	Employment Agreement by and between Egalet Corporation and Karsten Lindhardt (incorporated by reference to Exhibit 10.3 to Egalet Corporation's current report on Form 8-K filed on February 11, 2014).
10.11+	Employment Agreement by and between Egalet Corporation and Mark Strobeck (incorporated by reference to Exhibit 10.4 to Egalet Corporation's current report on Form 8-K filed on February 11, 2014).
10.12+	Employment Agreement by and between Egalet Corporation and Jeffrey M. Dayno, M.D. (incorporated by reference to Egalet Corporation's current report on Form 8-K filed on July 28, 2014).
10.13+	Employment Agreement by and between Egalet Corporation and Deanne F. Melloy (incorporated by reference to Exhibit 10.1 to Egalet Corporation's current report on Form 8-K filed on January 12, 2015).
10.14+	Egalet Corporation 2013 Annual Incentive Bonus Plan (incorporated by reference to Exhibit 10.2 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.15+	Egalet Corporation 2013 Stock-Based Incentive Plan, as amended, and forms of agreement thereunder (incorporated by reference to Exhibit 10.3 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.16+	Amendment No. 1 to the Egalet Corporation 2013 Stock-Based Incentive Plan, as amended, and forms of agreement thereunder (incorporated by reference to Exhibit 10.1 to Egalet Corporation's current report on Form 8-K filed on June 10, 2014).
10.17+	Egalet Corporation Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.18+	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.6 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.19+	Form of Egalet Corporation Restricted Stock Award (incorporated by reference to Exhibit 10.1 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
10.20+	Form of Egalet Corporation Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.2.

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Exhibit Number	Exhibit Description
10.21	Lease Agreement, dated as of October 25, 2013, by and between Liberty Property Limited Partnership and Egalet Limited (incorporated by reference to Exhibit 10.10 to Egalet Corporation's registration statement on Form S-1 (File No. 333-191759)).
21.1	List of Significant Subsidiaries.
23.1	Consent of Grant Thornton LLP.
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

^ All exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish the omitted exhibits and schedules to the SEC upon request by the SEC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Egalet Corporation

We have audited the accompanying consolidated balance sheets of Egalet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2013 and 2014, and the related consolidated statements of operations, comprehensive loss, changes in convertible preferred stock and stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2014. 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. We were not engaged to perform an audit of the Company's 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, 2013 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 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 consolidated financial statements, the Company continues to incur losses from operations and has negative cash flow from operations that raise substantial doubt about its 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, PA
March 16, 2015

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Egalet Corporation and Subsidiaries

Consolidated Balance Sheets

	December 31,	
	2013	**2014**
Assets		
Current assets:		
Cash	$ 15,700,000	$ 52,738,000
Related party receivable		679,000
Prepaid expenses	1,812,000	698,000
Other receivables	231,000	1,011,000
Total current assets	17,743,000	55,126,000
Property and equipment, net	2,378,000	4,417,000
Intangible asset	209,000	184,000
Deposits and other assets	33,000	843,000
Total assets	$ 20,363,000	$ 60,570,000
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Related party senior convertible debt, net of discount	$ 17,209,000	$
Accounts payable	1,046,000	4,209,000
Accrued expenses	1,755,000	2,554,000
Deferred revenue	557,000	588,000
Other current liabilities	55,000	78,000
Total current liabilities	20,622,000	7,429,000
Deferred revenue non-current portion	9,592,000	8,855,000
Deferred income tax liabilities	22,000	25,000
Total liabilities	30,236,000	16,309,000
Convertible preferred stock:		
Convertible Series A-1 preferred stock, $0.01 par value, 1,406,894 shares issued and outstanding at December 31, 2013 and 0 shares issued and outstanding at December 31, 2014, liquidation preference of $13,559,000 at December 31, 2013	1,443,000	
Convertible Series A-2 preferred stock, $0.01 par value, 593,106 shares issued and outstanding at December 31, 2013 and 0 shares issued and outstanding at December 31, 2014, liquidation preference of $4,083,000 at December 31, 2013	770,000	
Convertible Series B preferred stock, $0.01 par value, 2,327,301 shares issued and outstanding at December 31, 2013 and 0 shares issued and outstanding at 2014, liquidation preference of $42,610,000 at December 31, 2013	12,628,000	
Convertible Series B-1 preferred stock, $0.01 par value, 113,916 shares issued and outstanding at December 31, 2013 and 0 shares issued and outstanding at December 31, 2014, liquidation preference of $695,000 at December 31, 2013	116,000	
Stockholders' deficit		
Common stock, $0.01 par value and $0.001 par value at December 31, 2013 and December 31, 2014 respectively; 75,000,000 shares authorized at December 31, 2014; 1,292,307 and 17,283,663 shares issued and outstanding at December 31, 2013 and 2014, respectively	13,000	17,000
Additional paid in capital	7,431,000	121,028,000

Accumulated other comprehensive income	1,125,000	(171,000)
Accumulated deficit	(33,399,000)	(76,613,000)
Total stockholders' equity (deficit)	(24,830,000)	44,261,000
Total liabilities, convertible preferred stock and stockholders' deficit	$ 20,363,000	$ 60,570,000

The accompanying notes are an integral part of these consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Operations

	Year Ended December 31,		
	2012	**2013**	**2014**
Revenues	$ 1,201,000	$	$ 1,920,000
Operating expenses:			
Research and development	4,256,000	6,280,000	22,395,000
General and administrative	2,241,000	5,095,000	16,661,000
Total operating expenses	6,497,000	11,375,000	39,056,000
Loss from operations	(5,296,000)	(11,375,000)	(37,136,000)
Other income		(222,000)	(1,045,000)
Interest expense	75,000	8,842,000	7,079,000
Loss (gain) on foreign currency exchange	27,000	190,000	(3,000)
	102,000	8,810,000	6,031,000
Loss before provision for income taxes	(5,398,000)	(20,185,000)	(43,167,000)
Provision for income taxes		22,000	47,000
Net loss	$ (5,398,000)	$ (20,207,000)	$ (43,214,000)
Per share information:			
Net loss per share of common stock, basic and diluted	$ (4.18)	$ (15.64)	$ (2.97)
Basic and diluted weighted average shares outstanding	1,292,307	1,292,307	14,556,927

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

	Year Ended December 31,		
	2012	**2013**	**2014**
Net loss	$ (5,398,000)	$ (20,207,000)	$ (43,214,000)
Other comprehensive income (loss):			
Foreign currency translation adjustments	(212,000)	854,000	(1,296,000)
Comprehensive loss	$ (5,610,000)	$ (19,353,000)	$ (44,510,000)

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

Redeemable Convertible Preferred Stock									Stockholders' (Deficit) Equity				
Series A-1		Series A-2		Series B		Series B-1			Common Stock				
umber Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Total	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumu Compreh Incor
,406,894	1,443,000	593,106	770,000					2,213,000	1,292,307	13,000	186,000	(7,794,000)	483
											1,424,000		
				907,467	4,358,000	113,916	116,000	4,474,000					
				1,419,834	8,270,000			8,270,000					
													(212
												(5,398,000)	
,406,894	1,443,000	593,106	770,000	2,327,301	12,628,000	113,916	116,000	14,957,000	1,292,307	13,000	1,610,000	(13,192,000)	271
											5,000,000		
											1,478,000		
											(657,000)		
													854
												(20,207,000)	
,406,894	1,443,000	593,106	770,000	2,327,301	12,628,000	113,916	116,000	14,957,000	1,292,307	13,000	7,431,000	(33,399,000)	$ 1,125

									2,585,745	3,000	24,710,000				
									600,000	1,000	(1,000)				
									4,830,000	5,000	51,458,000				
,406,894)	(1,443,000)	(593,106)	(770,000)	(2,327,301)	(12,628,000)	(113,916)	(116,000)	(14,957,000)	5,329,451	(7,000)	14,964,000				
									1,250,000	1,000	13,949,000				
									1,396,160	1,000	(1,000)				
									.		8,518,000				
															(1,296
												(43,214,000)			
$	$	$	$	$	$	$	$	$	17,283,663	$ 17,000	$ 121,028,000	$ (76,613,000)	$		(171

The accompanying notes are an integral part of these consolidated financial statements

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Egalet Corporation and Subsidiaries

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2012	**2013**	**2014**
Operating activities:			
Net loss	$ (5,398,000)	$ (20,207,000)	$ (43,214,000)
Adjustment to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	404,000	483,000	641,000
Stock-based compensation			8,518,000
Noncash interest		8,431,000	6,987,000
Deferred income taxes		22,000	6,000
Changes in assets and liabilities:			
Related party receivable	1,000	34,000	(744,000)
Accounts receivable	96,000		
Prepaid expenses	(2,000)	350,000	(540,000)
Other receivables	(310,000)	99,000	(883,000)
Deposits and other assets		(7,000)	
Accounts payable	72,000	(378,000)	3,268,000
Accrued expenses	169,000	706,000	1,412,000
Deferred revenue	(508,000)	10,000,000	(557,000)
Other current liabilities	16,000	34,000	32,000
Net cash used in operating activities	(5,460,000)	(433,000)	(25,074,000)
Investing activities:			
Deposits for purchases of property and equipment			(854,000)
Payments for purchase of property and equipment	(314,000)	(1,791,000)	(2,889,000)
Net cash used in investing activities	(314,000)	(1,791,000)	(3,743,000)
Financing activities:			
Proceeds from IPO, net of costs			53,032,000
Proceeds from issuance of commons stock, net of costs			13,950,000
Proceeds from the issuance of convertible debt		15,000,000	
Payment of deferred financing fees		(1,443,000)	
Proceeds from the sale of Series B preferred stock	8,218,000		
Net cash provided by financing activities	8,218,000	13,557,000	66,982,000
Effect of foreign currency translation on cash	(92,000)	963,000	(1,127,000)
Net increase in cash	2,352,000	12,296,000	37,038,000
Cash at beginning of period	1,052,000	3,404,000	15,700,000
Cash at end of period	$ 3,404,000	$ 15,700,000	$ 52,738,000
Supplemental disclosures of cash flow information:			
Non-cash prepayment for manufacturing project initiation fee	$ (631,000)	$	$

Non-cash purchases of property and equipment	$ (348,000)	$ (62,000)	$
Non-cash financing activities:			
Conversion of debt and interest into preferred stock	$ 5,949,000	$	$
Gain (loss) on extinguishment of debt	$ 1,424,000	$ (657,000)	$
Beneficial conversion features	$	$ 5,000,000	$
Conversion of convertible preferred stock	$	$	$ 14,957,000
Conversion of related party convertible debt	$	$	$ 24,713,000

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

December 31, 2012, 2013 and 2014

1. Organization and Description of the Business

Egalet Corporation (the "Company") is a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative medicines for patients with acute and chronic pain while helping to protect physicians, families and communities from the burden of prescription abuse. The Company was incorporated in Delaware in August 2013 and until its initial public offering ("IPO") in February 2014, had nominal assets and no operations. Egalet Limited ("Egalet UK"), 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 UK were exchanged for an identical number of shares of common stock and preferred stock of the Company, which resulted in Egalet UK becoming a wholly-owned subsidiary of the Company. As Egalet UK and Egalet US Inc. are entities under common control, the consolidated financial statements reflect the historical carrying values of Egalet UK'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. On January 8, 2015, the Company announced the acquisition and license of two innovative pain products, SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO (oxycodone HCI, USP) tablets for oral use only CII, both approved by the U.S. Food and Drug Administration ("FDA") to treat pain (See Note 17). SPRIX Nasal Spray, a non-steroidal anti-inflammatory drug (NSAID), is indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. OXAYDO is the first and only approved immediate-release ("IR") oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate. In addition, using our proprietary Guardian Technology, the Company is developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. The Company's technology platform can be used with a broad range of opioids and non-opioids. The Company has filed patents to protect its inventions covering both the technology and product-specific patents.

Initial Public Offering

On February 11, 2014, 4,200,000 shares of common stock were sold on the Company's behalf at an initial public offering ("IPO") price of $12.00 per share, for aggregate gross proceeds of $50.4 million. On March 7, 2014, in connection with the exercise by the underwriters of a portion of the over-allotment option granted to them as a part of the Company's IPO, 630,000 additional shares of common stock were sold by the Company at the IPO price of $12.00 per share, for aggregate gross proceeds of approximately $7.6 million. In addition, as part of the IPO, the Company converted all of its convertible preferred stock and related party senior convertible debt into 5,329,451 and 2,585,745 shares of common stock, respectively. Also, Shionogi Limited ("Shionogi"), the Company's collaboration partner, purchased 1,250,000 shares of the Company's common stock in a separate private placement concurrent with the completion of the IPO at a price per share equal to $12.00 per share,

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

1. Organization and Description of the Business (Continued)

for aggregate gross proceeds of $15.0 million. The sale of such shares has not and will not be registered under the Securities Act of 1933, as amended. In addition, the 2013 related party senior convertible debt holders automatically exercised 600,000 warrants for shares of common stock at an exercise price of $0.0083 per share.

The Company paid to the underwriters discounts and commissions of approximately $5.1 million in connection with the offering, including discounts and commissions from the exercise of the over-allotment option. In addition, the Company incurred legal, accounting, and other offering-related expenses of approximately $2.4 million in connection with the offering, which when added to the underwriting discounts and commissions paid by the Company, amounts to total expenses of approximately $7.5 million. Thus, the net proceeds to the Company from the IPO, after deducting underwriting discounts and commissions and offering expenses, were approximately $51.5 million. Additionally, after deducting the expenses related to the private placement with Shionogi, the net proceeds to the Company from the private placement were approximately $14.0 million.

Liquidity

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

The Company has incurred recurring operating losses since inception. As of December 31, 2014, the Company had an accumulated deficit of $76.6 million and will require substantial additional capital to fund its research and development. The Company reasonably expects that the net proceeds from the Company's IPO, its pre-existing cash and cash equivalents, together with expected revenues to be generated by the assets licensed and purchased subsequent to December 31, 2014, will enable it to fund its operating expenses and capital expenditure requirements through September 30, 2015. 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, and the development of its administrative organization. As the Company continues to incur losses, a transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and the achievement of a level of revenue adequate to support the Company's cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through the sale of equity, debt financings or other sources, including potential additional collaborations. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

These factors, amongst others, raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments related to the recovery of assets and classification of liabilities that might be necessary should the Company be unable to continue in existence.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

1. Organization and Description of the Business (Continued)

Forward Stock Split

In connection with preparing for the IPO, 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.

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, 2014 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.

Reclassification

Certain amounts in prior year's presentations have been reclassified to conform to the current presentation. These reclassifications had no effect on previously reported net income.

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.

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

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)

performance. As of December 31, 2013 and 2014, long-lived assets based upon geographic location were located in both the United States and Europe. As of the years ended December 31, 2012 and 2014 revenues based upon geographic location were derived substantially from Europe. There were no revenues recognized for the year ended December 31, 2013.

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 of $4.3 million and $48.4 million are maintained at financial institutions in the United States (U.S.) and Denmark, respectively, at December 31, 2014. Bank deposits are insured up to approximately $250,000 and $122,000 for U.S. and Danish financial institutions, respectively. The Company has uninsured cash balances at December 31, 2014 of approximately $52.1 million.

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)

December 31, 2012, 2013 and 2014

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, 2013 and 2014 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, 2013. There were no transfers between Level 1 and Level 2 in any of the periods reported.

Stock-Based Compensation

We account for all share-based compensation payments issued to employees, directors and non-employees using an option pricing model for estimating fair value. Accordingly, share-based compensation expense is measured based on the estimated fair value of the awards on the date of

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)

grant, net of forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative accounting guidance, we re-measure the fair value of non-employee share-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

The stock-based compensation expense for restricted stock awards is determined based on the closing market price of our common stock on the grant date of the awards applied to the total number of awards that are anticipated to vest.

Property and Equipment

Property and equipment consist primarily of laboratory and manufacturing equipment, furniture, fixtures, and other property, all of which are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Maintenance and repairs are expensed as incurred. The following estimated useful lives were used to depreciate the Company's assets:

	Estimated Useful Life
Laboratory and manufacturing equipment	3 - 10 years
Furniture, fixtures and other property	3 - 7 years

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, 2013 and 2014, 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

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)

to operating results. For the years ended December 31, 2013 and 2014, the Company determined that there was no impairment of its long-lived assets.

Revenue Recognition

During 2013, we entered into a collaborative research and license agreement with Shionogi. The terms of this agreement contains multiple deliverables which may include (i) licenses, (ii) research and development activities, and (iii) royalty and related commissions. Revenue is recognized when we have satisfied our service obligations under a written contract with our customer (or collaboration partner) where the price for the services have been agreed upon and when we have reasonable assurance that the resulting receivable will be collected within contractually agreed upon terms. We have adopted the provisions of Accounting Standards Update ("ASU") 2009-13, "Multiple-Deliverable Revenue Arrangements," which amends ASC 605-25, and also adopted ASU 2010-17, "Revenue Recognition Milestone Method." In accordance with ASU 2009-13, we consider whether the deliverables under the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have stand-alone value.

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.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)

Intercompany payables and receivables are considered to be long-term in nature and any change in balance due to foreign currency fluctuation is included as a component of the Company's consolidated statements of comprehensive loss and accumulated other comprehensive income within the Company's consolidated balance sheets.

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. Current tax liabilities or receivables are recognized for the amount of taxes we estimate are payable or refundable for the current year. 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 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. Then, the tax benefit recognized is the largest amount of benefit, determined on a cumulative probability basis, which is more likely than not to be realized upon ultimate settlement. The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the accompanying consolidated statement of operations and comprehensive loss. Accrued interest and penalties are included within the related tax liability line in the consolidated balance sheet. The Company did not have any accrued interest or penalties associated with any unrecognized tax positions at December 31, 2013 and 2014, and there were no such interest or penalties recognized during the year ended December 31, 2013 and 2014.

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

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)

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, 2013 and 2014, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Other income

Other income was $1.0 million and $222,000 for the years ended December 31, 2014 and 2013, respectively and consisted entirely of a Danish research and development tax credit.

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, 2013 and 2014.

Customer Concentration

For the year ended December 31, 2014, the Company had one significant customer that accounted for consolidated total revenues as follows:

Customer A	100.0%

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09 "*Revenue from Contracts with Customers*". ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. ASU 2014-09 may be applied using either a full retrospective or a modified retrospective approach and is effective for the Company's fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. The Company is currently evaluating the impact of this amendment to its financial position and results of operations.

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Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

2. Summary of Significant Accounting Policies and Basis of Accounting (Continued)

In June 2014, the FASB issued ASU No. 2014-12, "*Compensation Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period*," ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The Company does not anticipate that the adoption of this standard will have a material impact on its financial statements.

In August 2014, FASB issued ASU 2014-15, *Presentation of Financial Statements Going Concern*. The amendments in this update require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period, including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this update are effective for the Company as of January 1, 2017. Early application is permitted. The Company is currently assessing the impact of this update on its future discussion of its liquidity position in Management's Discussion and Analysis.

3. Property and Equipment

Property and equipment and related accumulated depreciation and amortization are as follows:

	December 31,	
	2013	2014
Laboratory and manufacturing equipment	4,613,000	6,879,000
Furniture, fixtures and other property	835,000	827,000
Less accumulated depreciation	(3,070,000)	(3,289,000)
Property and equipment, net	$ 2,378,000	$ 4,417,000

Depreciation expense was $483,000 and $641,000 for the years ended December 31, 2013 and 2014, respectively.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

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, 2013 and 2014, the carrying value of IPR&D was $209,000 and $184,000, respectively. The change in the carrying value is solely due to the weakening of the Danish Kroner compared to the US Dollar.

5. Related Party Senior Convertible Debt, Net of Discount

In April 2013, the Company entered into a $5.0 million convertible loan with several of its equity investors to provide the Company with funding to meet its short-term obligations. The loan had an interest 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 had provisions whereby it would 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 IPO that yields a minimum of approximately $20 million in net proceeds to the Company at a per share price that values the Company at a minimum of $105.4 million (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 Company's IPO on February 6, 2014 (see Note 1), the outstanding principal and interest of $5.0 million and $240,000, respectively, was converted into shares of the Company's common stock. For the years ended December 31, 2013 and 2014 the Company recognized interest expense of $0 and $35,000, respectively.

On August 29, 2013, the Company entered into the 2013 Loan Agreement with several of its equity investors. The 2013 Loan Agreement was 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 $10.0 million in debt proceeds. Borrowings under the 2013 Loan Agreement had an annual interest rate of 6% and were initially scheduled to 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 had provisions requiring the lenders to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an IPO 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 would 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.

In connection with the 2013 Loan Agreement, the lenders received 600,000 warrants that automatically exercised immediately prior to consummation of the IPO, provided that such lender purchases a specified minimum amount of common stock in the IPO. Pursuant to the terms of the

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

5. Related Party Senior Convertible Debt, Net of Discount (Continued)

warrant agreement, the holders were 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).

Immediately prior to completing its IPO on February 6, 2014 (See Note 1), the Company accelerated the recognition of the premium immediately prior to converting into equity. The outstanding principal, premium and interest of $10.0 million, $10.0 million, and $275,000, respectively, were converted into shares of the Company's common stock. The unamortized debt discount balance of $802,000 was also converted. For the year ended September 30, 2014 the Company recognized interest expense of $7.1 million, of which $7.0 million was related to the accretion of premiums and the amortization of debt discounts, respectively.

In addition, the 2013 related party senior convertible debt holders automatically exercised warrants for 600,000 shares of common stock at an exercise price of $0.0083 per share in connection with the conversion of the senior convertible debt into shares of common stock.

6. Accrued Expenses

Accrued expenses were as follows:

	December 31,	
	2013	2014
Payroll	$ 371,000	$ 1,078,000
Clinical research		970,000
Consulting services	866,000	304,000
Interest	411,000	
Other	107,000	202,000
	$ 1,755,000	$ 2,554,000

7. Stock-based Compensation

2013 Stock-Based Incentive Plan

In November 2013, the Company adopted its 2013 Stock-Based Incentive Plan (the "Plan"). Pursuant to the Plan, the Company's compensation committee is authorized to grant equity-based incentive awards to its directors, executive officers and other employees and service providers, including officers, employees and service providers of its subsidiaries and affiliates. The number of shares of common stock initially reserved for issuance under the Plan was 1,680,000, in the form of restricted stock and stock options. A 2,000,000 share increase to shares reserved for issuance under the plan was authorized by the Company's stockholders in June 2014. The amount, terms of grants and exercisability provisions are determined by the board of directors. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors. All options vest over time as stipulated in the individual award agreements.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

7. Stock-based Compensation (Continued)

Shares Reserved for Future Issuance

As of December 31, 2014, the Company has reserved the following shares of common stock for issuance:

Shares initially reserved under the Plan	1,680,000
Authorized increase to the Plan	2,000,000
Common stock options outstanding	(638,548)
Restricted stock awards outstanding	(1,396,160)
Option Expirations	(5,135)
Remaining shares available for future issuance	1,640,127

The estimated grant-date fair value of the Company's share-based awards is amortized ratably over the awards' service periods. Stock-based compensation expense recognized was as follows:

	Twelve Months Ended December 31,	
	2013	2014
Research and development	$	$ 3,348,000
General and administrative		5,170,000
Total stock-based compensation expense	$	$ 8,518,000

Stock Options Granted under the 2013 Stock-Based Incentive Plan

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted-average Remaining Contractual Term (in years)
Balance, December 31, 2013			
Granted	643,683	$ 7.51	
Exercised			
Forfeited			
Expired	(5,135)	13.04	
Balance, December 31, 2014	638,548	$ 7.47	9.68
Vested or expected to vest at December 31, 2014	638,548	$ 7.47	9.68

Exercisable at December 31, 2014	3,623	$	9.62	9.59

The intrinsic value of the Company's 634,926 unvested options as of December 31, 2014 was $148,000 based on a per share price of $5.69, the Company's closing stock price on that date, and a weighted-average exercise price of $7.37 per share.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

7. Stock-based Compensation (Continued)

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company's common stock, assumptions related to the expected price volatility of the Company's stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

The per-share weighted-average grant date fair value of the options granted to employees during the twelve months ended December 31, 2014 was estimated at $4.93 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.81%
Expected term of options (in years)	6.24
Expected volatility	74.88%
Dividend yield	

The weighted-average valuation assumptions were determined as follows:

Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

Expected term of options: The Company estimated the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data.

Expected stock price volatility: The Company estimated the expected volatility based on actual historical volatility of the stock price of similar companies with publicly-traded equity securities. The Company calculated the historical volatility of the selected companies by using daily closing prices over a period of the expected term of the associated award. The companies were selected based on their enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would have decreased the fair value of the underlying instrument.

Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0.0%.

As of December 31, 2014, there was $2.9 million of total unrecognized compensation expense, related to unvested options granted under the Plan, which will be recognized over the weighted-average remaining period of 2.19 years.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

7. Stock-based Compensation (Continued)

Restricted stock

Upon consummation of the IPO, the Company granted an aggregate of 862,800 shares of restricted stock to its chief executive officer, chief financial officer, chief business officer and senior vice president of research and development. On March 3, 2014, the Company granted an aggregate of 250,560 shares of restricted stock to three individuals who were providing research and development consulting services to the Company. On May 1, 2014, the Company granted an aggregate of 257,800 shares of restricted stock to certain employees at a grant date fair value of $11.15 per share. On August 5, 2014, the Company granted 25,000 shares of restricted stock to its chief medical officer.

A summary of the status of the Company's restricted stock awards at September 30, 2014 and of changes in restricted stock awards outstanding under the Plan for the nine months ended September 30, 2014 is as follows:

	Shares	Weighted-average Grant Date Fair Value per Share
Outstanding balance at December 31, 2013		$
Granted	1,396,160	$ 12.02
Vested restricted stock awards	(563,625)	$ 12.42
Outstanding balance at December 31, 2014	832,535	$ 11.75

For stock awards that vest subject to the satisfaction of service requirements, compensation expense is measured based on the fair value of the award on the date of grant and is recognized as expense on a straight-line basis (net of estimated forfeitures) over the requisite service period. All restricted stock awards issued above vest over time as stipulated in the individual award agreements. In the event of a change in control, the unvested awards will be accelerated and fully vested immediately prior to the change in control. There are no performance based features or market conditions.

As of December 31, 2014, there was $8.2 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.68 years.

8. Income Taxes

Income taxes have been recorded on the following income (loss) before income tax expense:

	As of December 31,	
	2013	2014
Domestic operations	$ (4,087,000)	$ (21,829,000)
Foreign operations	(16,098,000)	(21,338,000)
Loss before provision for income taxes	$ (20,185,000)	$ (43,167,000)

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

8. Income Taxes (Continued)

The provision for income taxes consists of the following for 2013 and 2014:

	As of December 31,	
	2013	2014
Current:		
U.S. Federal	$	$
State and local		44,000
Foreign		
Total Current		44,000
Deferred:		
U.S. federal	$	$
State and local		
Foreign	22,000	3,000
Total deferred	22,000	3,000
Total expense (benefit)	$ 22,000	$ 47,000

The Company recognized a reduction of $(21,000) and an increase of $13,000 for unrecognized income tax benefits during the years ended December 31, 2013 and 2014, respectively, which reduced the amount of the reported deferred tax asset for net operating loss carry forwards. Through December 31, 2014, the Company had no interest or penalties accrued related to unrecognized tax benefits. 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:

	For the Year Ended December 31,	
	2013	2014
Beginning balance	$ 67,000	$ 46,000
Increase/(Decrease) related to prior tax years	(21,000)	13,000
Increase related to current year	0	0
Ending balance	$ 46,000	$ 59,000

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 operating losses. The Company does not expect its unrecognized tax benefit liability to change significantly over the next 12 months.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

8. Income Taxes (Continued)

The principal components of the Company's deferred tax assets and liabilities were as follows:

	As of December 31,	
	2013	2014
Deferred tax assets:		
Fixed assets	$	$
Accrued expenses	77,000	218,000
Fx gain/loss	75,000	
Deferred revenue		2,078,000
Stock compensation		351,000
Net operating losses	5,148,000	11,401,000
Deferred tax assets	5,300,000	14,048,000
Deferred tax liabilities:		
Fixed assets	$ (77,000)	$ (26,000)
Indefinite-lived intangibles	(22,000)	(25,000)
Deferred tax liabilities	(99,000)	(51,000)
Less: Valuation allowance	(5,223,000)	(14,023,000)
Total net deferred tax liabilities	$ (22,000)	$ (25,000)

As of December 31, 2014, the Company had foreign net operating loss ("NOL") carry forwards of $27,802,000 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). The Company files income tax returns in the U.K., because Egalet UK was incorporated in that jurisdiction; however, Egalet UK has no business operations in the U.K. and the Company has no plans to commence operations in that jurisdiction in the foreseeable future. As such, the Company has determined that it will not record U.K. NOL's as a component of their deferred tax inventory, since there is currently no expectation that they will ever be realized. As of December 31, 2014, the Company had U.S. federal and state NOL's of $12,910,000 and $13,576,000, respectively. These 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. These federal and state NOL's will begin to expire in 2033 and through 2034.

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

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

8. Income Taxes (Continued)

Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2013 and 2014, respectively, because the Company's management has determined that is it more likely than not that these assets will not be fully realized. The Company experienced a net change in valuation allowance of $2,372,000 and $8,799,000 for the years ended December 31, 2013 and 2014, respectively.

At December 31, 2014, no provision has been made for U.S. federal and state income taxes of foreign earnings due to the history of foreign losses. However, the Company expects that the future earnings, if any, of its foreign subsidiaries will be reinvested indefinitely. Upon becoming profitable, if ever, distribution of these earnings, in the form of dividends or otherwise, may result in the Company falling 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.

The Company files income tax returns in Denmark, the U.K., the United States, and in the state of Pennsylvania. The foreign tax returns are subject to tax examinations for the tax years ended July 31, 2011 through December 31, 2014. The domestic tax returns are subject to tax examinations for the tax years ended December 31, 2012 through December 31, 2014. However, to the extent the Company utilizes in the future any tax attribute NOL carry forwards from a tax period that may otherwise be closed to examination, the Internal Revenue Service, state tax authorities, or other governing parties may still adjust the NOL upon their examination of the future period in which the attribute was utilized.

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:

	For the Year Ended December 31,	
	2013	2014
Federal income tax at the statutory rate	34.0%	34.0%
Permanent items	(4.2)	(3.9)
Convertible note interest expense	(7.6)	(5.6)
State income tax, net of federal benefit	0.7	1.7
Change in valuation allowance	(13.5)	(20.4)
Change in foreign rate	(9.5)	(5.9)
Indefinite-lived intangible	(0.1)	
Increase in tax reserves	0.1	
Effective income tax rate	(0.1)%	(0.1)%

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

9. Employee Benefit Plans

The Company's 401(k) Employee Savings Plan (the "401(k) Plan") is available to all employees meeting certain eligibility criteria. As the Company has elected a Safe-Harbor provision for the 401(k) Plan, participants are always fully vested in their employer contributions. The Company matches 100% of the first 3% of participating employee contributions and 50% of the next 2% of participating employee contributions. The Company contributed approximately $51,000 to the 401(k) Plan in the year ended December 31, 2014. The Company's contributions are made in cash. The Company's common stock is not an investment option available to participants in the 401(k) 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, 2013 and 2014, the Company recorded $176,000, and $225,000, respectively, for contributions under its state plan for Denmark employees.

10. 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 thereafter until terminated.

During 2012 and 2013, the Company's corporate headquarters were located in Malvern, Pennsylvania, where the Company leased office space. In November 2013, the Company moved its corporate headquarters to Wayne, Pennsylvania upon entering into a three-year lease that expires in November 2016. In January 2015, the Company entered into a sub-lease in the same building as our existing headquarters. Under the terms of the sub-lease agreement, the sublease expires in December 2017 unless terminated earlier. In addition, the Company is leasing office space in Roseland, New Jersey in close proximity to the Company's contract manufacturer, Halo. The Company will incur fixed annual rent and operating expenses of $1.6 million, and $118,000 in 2015, and 2016, respectively.

Rent expense was $223,000 and $325,000 for the years ended December 31, 2013 and 2014, respectively.

Employment Agreements

The Company has entered into employment agreements with its president and chief executive officer, chief financial officer, chief business officer, chief medical officer, chief commercial officer and senior vice president of research and development, that provide for, among other things, salary, bonus and severance payments.

Legal Proceedings

Shionogi Inc. commenced an action against our chief commercial officer, Deanne F. Melloy on February 5, 2015. Based on Shionogi Inc.'s allegations that Ms. Melloy's confidentiality and separation agreements with Shionogi Inc. prevent her from working for us, the Court issued a temporary restraining order on February 11, 2015, precluding Ms. Melloy from working for us pending a hearing on Shionogi's motion for a preliminary injunction. A hearing on that motion is expected to be held in

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

10. Commitments and Contingencies (Continued)

mid-April. In addition, Shionogi, an affiliate of Shionogi Inc., sent us a notice of breach letter dated February 3, 2015, asserting that we breached the collaboration and license agreement with Shionogi by hiring Ms. Melloy and demanding that we terminate Ms. Melloy to remedy the alleged breach. The collaboration and license agreement we have with Shionogi provides for a 30-day period of good faith negotiations before an action can be commenced. The agreement also provides a 90-day cure period for a material breach. Egalet does not anticipate a material impact or delay as it continues to move forward with its commercial plans for both OXAYDO and SPRIX however, there can be no guarantee that this matter will be resolved amicably.

On August 10, 2012, Luitpold, the prior exclusive licensee of U.S. Patent No. 6,333,044 ("the '044 patent"), filed a complaint for infringement of the '044 patent against Amneal Pharmaceuticals, LLC et al. in response to Amneal's certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that the '044 Patent covering Sprix is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Luitpold's generic ketorolac tromethamine nasal spray, filed under ANDA No. 23-382 with the FDA. On November 19, 2013, Luitpold and Amneal entered into a settlement and license agreement permitting Amneal to launch its generic product on or after March 25, 2018 subject to royalty payments.

On January 26, 2015, Egalet was substituted for Luitpold as plaintiff in a patent litigation against Apotex Corp. and Apotex, Inc. (collectively, "Apotex"), involving the SRPIX Nasal Spray. Apotex submitted an ANDA to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of generic ketorolac tromethamine nasal spray 15.75 mg/spray ("ANDA Product"). In so doing, Apotex made a certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that the '044 Patent covering Sprix is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product. On July 11, 2014, Luitpold filed a complaint for infringement of the '044 patent against Apotex, prompting a 30-month stay on the approval of Apotex's ANDA application by the FDA. This litigation is currently ongoing. We are aggressively defending our legal positions to preserve the exclusivity of SRIX in the market. As is the case with patent litigation, there is a risk that the '044 patent may be invalidated, unenforceable, not infringed or limited or narrowed in scope. Even if resolved in our favor, this litigation may result in significant expense, and may distract our technical or management personnel from their normal responsibilities. The '044 Patent expires on December 25, 2018.

There have been a number of generic challengers to OXAYDO (formerly Oxecta) during 2012 and 2013, including Watson Laboratories, Inc., Par Pharmaceuticals, Inc., Impax Laboratories, Inc., Sandoz, Inc., and Ranbaxy Laboratories, Ltd. Along with their ANDA submissions, each generic challenger made a certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that U.S. Patent Nos. 7,201,920; 7,510,726; 7,981,439; 8,409,616; and/or 8,637,540 are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of their generic oxycodone HCl product. In response, Acura filed a complaint for infringement of U.S. Patent No. 7,510,726 (the "'726 Patent") against each generic challenger. As of November 2013, Acura resolved all claims at issue in each of the litigations: Watson amended its ANDA to a Paragraph III certification (i.e., launch at expiry of the patents) and the lawsuit was dismissed; Acura entered into a settlement agreement and consent judgment with Ranbaxy that its generic oxycodone HCl product does not infringe Acura's patents; and Acura entered into settlement and license agreements with the remaining generic challengers allowing entry of a generic oxycodone HCl product on or after January 1, 2022. There is currently no litigation involving Oxaydo.

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

11. Convertible Preferred Stock and Stockholders' Deficit

As of December 31, 2014, 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, 2013 and 2014.

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, 2014, the convertible preferred series A-1 and A-2 stock have a liquidation preference of $13,559,000 and $4,083,000, 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,

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11. Convertible Preferred Stock and Stockholders' Deficit (Continued)

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, 2014, the convertible preferred series B and B-1 stock have a liquidation preference of $42,610,000 and $695,000, 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.

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.

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

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

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11. Convertible Preferred Stock and Stockholders' Deficit (Continued)

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.

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.

Upon consummation of the Company's initial public offering that occurred on February 5, 2014, the Company converted all of its convertible preferred stock into 5,329,451 shares of common stock.

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December 31, 2012, 2013 and 2014

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, 2013 and 2014:

	Year Ended December 31,	
	2013	2014
Basic and diluted net loss per share of common stock		
Net loss applicable to common stockholders	$ (20,207,000)	$ (43,214,000)
Weighted average common stock outstanding	1,292,307	14,556,927
Net loss per share of common stock basic and diluted	$ (15.64)	$ (2.97)

The following outstanding securities for the year ended December 31, 2013 and 2014 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Year Ended December 31,	
	2013	2014
Redeemable convertible preferred stock	5,329,451	
Options outstanding		638,458
Unvested restricted stock awards		832,535
Total	5,329,451	1,470,993

13. License and Collaboration Agreement

In November 2013, the Company entered into a license and collaboration agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using certain of the Company's core technologies. 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.

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.

The Company determined that the deliverables under the Shionogi agreement were the exclusive, royalty-bearing, worldwide license to its abuse-deterrent hydrocodone-based product candidates using certain of the Company's core technologies, the research and development services to be completed by the Company and the Company's obligation to serve on a joint committee. The license did not have standalone value to Shionogi and was not separable from the research and development services,

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Egalet Corporation and Subsidiaries

Notes to the Consolidated Financial Statements (Continued)

December 31, 2012, 2013 and 2014

13. License and Collaboration Agreement (Continued)

because of the uncertainty of Shionogi's ability to develop the product candidates without the research and development services of the Company during the transfer period and over the term of the agreement.

Due to the lack of standalone value for the license and research and development services, the upfront payment is being recognized ratably using the straight line method through November 2030, the expected term of the agreement. The Company recorded the $10.0 million upfront payment as deferred revenue within its consolidated balance sheet as of December 31, 2013. For the year ended December 31, 2014, the Company recognized revenue of $557,000, related to the $10.0 million upfront payment the Company received.

Additionally, during the year ended December 31, 2014, the Company recognized revenue of $1.4 million related to certain development costs incurred under the Company's collaborative research and license agreement. In accordance with the accounting guidance, the Company recorded revenue on a gross basis for the reimbursement of development costs.

14. Related Party Transactions

Related Party Receivables

The Company has derived all of its revenue for the twelve months ended December 31, 2014 under its license and collaboration agreement with Shionogi who is also an investor in the Company. As of December 31, 2014, related party receivables with Shionogi were $679,000.

15. Quarterly Financial Information (unaudited)

This table summarizes the unaudited consolidated financial results of operations for the quarters ended:

	March 31,	June 30,	September 30,	December 31,
2014 Quarter Ended				
Revenues	$ 256,000	$ 490,000	$ 346,000	$ 826,000
Operating expenses	6,049,000	12,089,000	10,540,000	10,365,000
Other income (expense)	(7,088,000)	(43,000)	51,000	1,035,000
Net loss	12,916,000	11,658,000	10,178,000	8,467,000
Net loss per share of commons stock, basic and diluted(1)	(1.34)	(0.73)	(0.63)	(0.52)
2013 Quarter Ended				
Revenues	$	$	$	$
Operating expenses	1,818,000	2,316,000	2,309,000	4,710,000
Other income (expense)	22,000	(1,378,000)	(3,200,000)	(4,476,000)
Net loss	1,796,000	3,694,000	5,509,000	9,208,000
Net loss per share of commons stock, basic and diluted(1)	(1.39)	(2.86)	(4.26)	(7.13)

(1) Net income per share amounts may not agree to the per share amounts for the full year due to the use of weighted average shares for each period.

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Egalet Corporation and Subsidiaries

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December 31, 2012, 2013 and 2014

16. Subsequent Events

Collaboration and License Agreement with Acura

In January 2015, the Company entered into a Collaboration and License Agreement, (the "License Agreement") with Acura Pharmaceuticals, Inc., a New York corporation ("Acura") to commercialize OXAYDO (oxycodone hydrochloride) tablets containing Acura's Aversion® Technology. OXAYDO (formerly known as Oxecta®) is currently approved by the FDA for marketing in the United States in 5 and 7.5 mg strengths. Under the terms of the License Agreement, Acura transferred the approved NDA for OXAYDO to the Company and the Company was granted an exclusive license under Acura's intellectual property rights for development and commercialization of OXAYDO worldwide (the "Territory") in all strengths.

In accordance with the License Agreement, Acura and the Company will form a joint steering committee to coordinate commercialization strategies and the development of product line extensions. The Company will pay a significant portion of the expenses relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for OXAYDO and (iii) expenses of clinical studies for product line extensions (additional strengths) of OXAYDO for the United States and will bear all of the expenses of development and regulatory approval of OXAYDO for sale outside the United States.

The Company is responsible for all manufacturing and commercialization activities in the Territory for OXAYDO. Subject to certain exceptions, the Company will have final decision making authority with respect to all development and commercialization activities for OXAYDO. The Company may develop OXAYDO for other countries and in additional strengths in its discretion.

The Company paid Acura an upfront payment of $5.0 million dollars in January 2015 and will pay a $2.5 million milestone on the earlier to occur of first commercial sale of OXAYDO or January 1, 2016, but in no event earlier than June 30, 2015. In addition, Acura will be entitled to a one-time $12.5 million milestone payment when OXAYDO net sales reach a specified level of $150 million in a calendar year.

In addition, Acura will receive from the Company a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on OXAYDO net sales during such year. In any calendar year in which net sales exceed a specified threshold, Acura will receive a double digit royalty on all OXAYDO net sales in that year. The royalty payment obligations commence on the first commercial sale of OXAYDO and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering OXAYDO in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by the Company to acquire intellectual property rights to commercialize OXAYDO, with an aggregate minimum floor. The term for the License Agreement, unless earlier terminated for cause, convenience or other triggering events, is tied to the timing of the expiration of patents in the United States and other countries where such patents have been issued. The United States patent expires in 2022.

Asset Purchase Agreement with Luitpold

In January 2015, the Company entered into and consummated the transactions contemplated by an Asset Purchase Agreement (the "Purchase Agreement") with Luitpold Pharmaceuticals, Inc.

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16. Subsequent Events (Continued)

("Luitpold"). Pursuant to the Purchase Agreement, the Company acquired specified assets and liabilities associated with SPRIX® (ketorolac tromethamine) Nasal Spray for a purchase price of $7,000,000, $315,000 of which was deposited into an escrow account to secure Luitpold's indemnification obligations under the Purchase Agreement. The purchase price is subject to adjustment based on a final inventory count of the finished goods being purchased by the Company. The Company concurrently purchased an additional $1,128,000 of glassware, equipment and active pharmaceutical ingredient from Luitpold, and agreed to purchase an additional $339,823 of active pharmaceutical ingredient after closing within two business days of the release of such active pharmaceutical ingredient from Luitpold's supplier. Sprix is a non-steroidal anti-inflammatory drug (NSAID) indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

The Company accounted for the acquisition as a business combination and the purchase price has been preliminarily allocated to the acquisition date fair values as follows:

Inventory	$	3,160,000
Property, plant & equipment		100,000
Finite lived intangible-intellectual property		2,080,000
Goodwill		2,788,000
Net assets acquired	$	8,128,000

The above estimated fair values of assets acquired are provisional and are based on the information that was available as of the acquisition date to estimate the fair value of assets acquired. The Company believes that information provides a reasonable basis for estimating the fair values but the Company is waiting for additional information and analyses necessary to finalize all of the amounts listed above. Thus, the provisional measurements of fair value reflected above are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one year from the acquisition date.

The fair value of the intellectual property was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the SPRIX. Thus, the Company derived the hypothetical royalty income from the projected revenues. Cash flows were assumed to extend through the remaining economic useful life of the intellectual property, which is 5 years.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $2,788,000 was recorded as goodwill, [which is not expected to be deductible for tax purposes] and represents the future economic benefits arising from the acquisition that could not be individually identified and separately recognized and the other benefits that the Company believes will result from the acquisition of SPRIX.

The Company recognized $235,000 of SPRIX acquisition-related costs that were expensed in the year ended December 31, 2014.

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16. Subsequent Events (Continued)

Hercules Loan and Security Agreement

In January 2015, the Company entered into a Loan and Security Agreement, ("the Loan Agreement"), with Hercules Technology Growth Capital, Inc., ("Hercules"), pursuant to which the Company may borrow up to $15,000,000, all of which was funded in January 2015. The term loan bears an interest rate per annum equal to the greater of either (i) 9.40% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (ii) 9.40%. Pursuant to the terms of the Loan Agreement, the Company will make interest-only payments for 12 months, and then repay the principal balance of the loan in 30 equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2018. In connection with the Loan Agreement, the Company granted a security interest in substantially all of its assets, excluding intellectual property and certain new drug applications and related approvals, as collateral for the obligations under the Loan Agreement.

The Loan Agreement also contains representations and warranties, and indemnification in favor of Hercules. The Company is required to comply with various customary covenants, including, among others, restrictions on indebtedness, investments, distributions, transfers of assets and acquisitions. The Loan Agreement contains several events of default, including, among others, payment defaults, breaches of covenants or representations, material impairment in the perfection of Hercules' security interest or in the collateral and events related to bankruptcy or insolvency. Upon an event of default, Hercules may declare all outstanding obligations immediately due and payable, and Hercules may take such further actions as set forth in the Loan Agreement, including collecting or taking such other action with respect to the collateral pledged in connection with the Loan Agreement.

In connection with the Loan Agreement, the Company issued Hercules a warrant (the "Warrant") to purchase $600,000 in shares of the Company's common stock ("Common Stock") at an exercise price of $5.29 per share (or, approximately 113,421 shares of Common Stock). The Warrant is exercisable for a period of five years beginning on the date of issuance and has an expected fair value of $328,610 that will be included in equity.