Egalet Corp
Form 10-K
March 11, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10 K

(Mark one)

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

For the fiscal year ended December 31, 2015

Or

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.)
600 East Lee Road Suite 100 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 No

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 No

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 No

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 No

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.

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	Accelerated filer	Non accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

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

As of June 30, 2015 (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 $189.1 million based on the last reported sale price of the registrant's common stock on June 30, 2015.

There were 25,085,554 shares of Common Stock outstanding as of March 11, 2016.

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, 2015, 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 Com 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, 2015.

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," "shoul "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, the commercial success of our products and, if approved, our product candidates, our ability to execute on our sales and marketing strategy, 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 products and product candidates, our intellectual property position, the degree of clinical utility of our products, particularly in specific patient populations, current and future government regulations, expectations regarding clinical trial data, our business development plans, our results of operations, cash needs and ability to obtain additional funding, financial condition, liquidity, prospects, growth and strategies, foreign exchange rates, 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;
- our current and future indebtedness;
- our ability to obtain additional financing;
- the level of commercial success of our products and, if approved, our product candidates;
- the continued development of our commercialization capabilities, including sales and marketing capabilities;

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- our ability to execute on our sales and marketing strategy, including developing relationships with customers, physicians, payors and other constituencies;
- the difficulties in obtaining and maintaining regulatory approval of our products and product candidates, and any related restrictions, limitations and/or warnings in the product label under any approval we may obtain;
- the success and timing of our preclinical studies and clinical trials;
- 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;
- the rate and degree of market acceptance of any of our product candidates;
- the performance of third parties, including contract research organizations, manufacturers and collaborators;
- our failure to recruit or retain key scientific or management personnel, including our executive officers;
- regulatory developments in the United States and foreign countries;
- obtaining and maintaining intellectual property protection for our products and product candidates and our proprietary technology;
- our ability to operate our business without infringing the intellectual property rights of others
- recently enacted and future legislation regarding the healthcare system;
- the success of competing products that are or become available; and
- our ability to integrate and grow any businesses or products that we may acquire.

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 2015. 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 treatments for pain and other conditions. Egalet was founded around our proprietary Guardian™ Technology that can be applied broadly across different classes of pharmaceutical products. Using this technology, we have two late-stage product candidates in development; ARYMO ER™, formerly known as Egalet-001, an abuse-deterrent ("AD"), extended-release ("ER"), oral morphine formulation, which, if approved by the U.S. Food and Drug Administration ("FDA"), could be on the market in 2016, and Egalet-002, an AD, ER, oral oxycodone formulation, which is in a Phase 3 program (our "lead product candidates"). Both lead product candidates are in development 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 January 2015, we acquired and in-licensed two FDA-approved products—SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO® (oxycodone HCI, USP) tablets for oral use only—CII (our "approved products")—that complement our pain portfolio. With the addition of these products, we built our commercial organization ahead of the anticipated launch of our lead product candidates and market our approved products to the same target high decile pain medicine prescribers to whom we expect to market ARYMO ER and Egalet-002, if approved. In addition, we have Egalet-003, an AD stimulant, for which we plan to file an investigational new drug ("IND") application in the fourth quarter of 2016 and Egalet-004, an AD hydrocodone based product candidate, that has completed a Phase 1 study—both of which were formulated using our proprietary technology. Our Guardian Technology also can be used to develop combination products that include multiple active pharmaceutical ingredients ("APIs") with similar or different release profiles and offers us a number of long term growth opportunities. We plan to continue to grow Egalet through business development and organic development leveraging our proprietary Guardian Technology.

With the approximately 100 million Americans suffering from chronic pain according to the Institute of Medicine—more than those affected by heart disease, cancer, and diabetes combined—there is a substantial need for effective pain treatments. The millions suffering from acute or chronic pain every year greatly impact our country with increasing health care costs, rehabilitation and lost worker productivity. Pain is a significant public health problem that costs society between $560 and $635 billion annually according to the Institute of Medicine. 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 2015 shows that opioids are the most widely prescribed products for pain, with prescriptions exceeding 200 million in 2015.

The combination of the pervasive issue of chronic pain and the use of opioids to treat chronic pain has led to an epidemic of prescription drug misuse and abuse. According to the American Society of Addiction Medicine, between 26 and 36 million people abuse opioids worldwide. According to the Centers for Disease Control and Prevention ("CDC"), opioids cause 75 percent of prescription drug overdoses. Importantly, 70 percent of Americans misusing painkillers obtained them from a friend or relative according to a 2013 National Survey on Drug Use and Health. This issue of prescription misuse and abuse is a costly one with 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—up to $72.5 billion annually according to the American Journal of Managed Care.

Prescription medications, particularly opioids (both ER and immediate-release ("IR") forms), are prone to being misused or abused through physical and chemical manipulation for the purpose of increasing the speed of the drug release into the bloodstream in order to accelerate and intensify their effects. A study of prescription opioid abusers in a drug rehabilitation program published in the Journal of Pain & Palliative Care Pharmacotherapy found that 80 percent

tampered with opioid tablets to accelerate drug release by chewing or administering the drug intranasally or intravenously. 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.

In reaction to this widespread prescription opioid misuse and abuse, the U.S. government and the FDA have established this issue as a top priority. In February of 2016, President Obama proposed $1.1 billion in new funding to

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address the prescription opioid misuse and abuse and heroin use epidemic. In addition, just days later the FDA announced an action plan to combat the growing problem of prescription abuse, importantly highlighting the development of AD formulations as a part of the solution.

According to RADARS System's 3rd Quarter 2015 Technical Report, 91 percent of prescription opioid abusers have abused IR opioids. In the case of IR oxycodone, data from the Addiction Severity Index-Multimedia Version shows the preferred route of abuse is snorting (61 percent of the respondents). With the large issue of intranasal abuse, we believe OXAYDO, an IR oral formulation of oxycodone indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate, represents an important treatment option. OXAYDO is the first and only approved IR oxycodone product designed to discourage abuse via the route of snorting. OXAYDO, which was approved in 2011, has data in its label from a Category 3 intranasal human abuse liability ("HAL") study. In that study, after snorting crushed OXAYDO and crushed Roxicodone, an IR oxycodone product manufactured by Mallinckrodt Pharmaceuticals ("Mallinckrodt"), a population of recreational non dependent opioid users responded that both "take drug again" and drug liking were lower for OXAYDO compared to Roxicodone.

SPRIX Nasal Spray is the first and only approved nasal spray formulation of a nonsteroidal anti-inflammatory drug ("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. While providing analgesia at the opioid level, SPRIX Nasal Spray does not have the side effects or issues of misuse or abuse common to opioids.

To commercialize SPRIX and OXAYDO and ultimately our pipeline products candidates, we are using a 71-person specialty sales force targeting approximately 11,500 physicians in the high decile of pain medicine prescribers in the United States. We also 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. To expand the commercial reach of SPRIX, we have signed agreements with two third parties. Teva Pharmaceutical Industries Ltd. ("Teva") has exclusive marketing and commercialization rights to SPRIX Nasal Spray in Israel, Gaza and the West Bank and Septodont has the rights to promote SPRIX Nasal Spray exclusively to dentists in the United States using its focused specialty sales force.

A critical part of our commercial strategy is to ensure patient access to our products by using our IMPACT-Rx (IMproving Patients ACcess To Medicines) initiative which we launched in conjunction with the launch of OXAYDO in the third quarter of 2015. The IMPACT-Rx initiative is applied to each of our commercial products to ensure that virtually no barrier exists to patients gaining access to these critical medicines they need. This national initiative employs three key features: 1) reimbursement support, 2) easier access to fill a prescription and 3) patient education. As part of this initiative, we established the My OXAYDO Patient Savings Program. All eligible patients receive ongoing savings through this program and will pay no more than $15 for a prescription of OXAYDO at all pharmacies. Similarly all eligible SPRIX patients will have a $0 co-pay for SPRIX.

Formulated using our proprietary Guardian Technology, we have two product candidates specifically designed to deter misuse and abuse by physical and chemical manipulation in late-stage of development. Having concluded our bioequivalence and AD studies, we submitted a new drug application ("NDA") for our lead program ARYMO ER in December of 2015 which the FDA accepted in February 2016 and we have initiated a Phase 3 program for our second product candidate Egalet 002. We will conduct AD studies on Egalet-002 as well which will be submitted in combination with the Phase 3 data to support an anticipated NDA filing in mid-2017.

ARYMO ER and Egalet 002 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 12.4 million prescriptions in the aggregate resulting in sales of more than $3.5 billion in the United States in 2015.

Developed using our Guardian Technology, we have Egalet-003, an AD stimulant product candidate, and Egalet-004, an AD hydrocodone product candidate. In addition, we have completed initial research and development efforts on 13 potential other product candidates. We have developed prototypes, conducted feasibility studies and are exploring additional applications of our technology, both independently and in collaboration with other pharmaceutical companies, for the development of both tailored precision oral drug delivery of single agent products and combination

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products for indications other than pain in which a potential for abuse exists. Our exclusively owned product candidates and Guardian Technology are protected by 84 issued and 44 pending patent applications worldwide as well as unpatented know how and trade secrets.

Strategy

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

- Execute our sales and marketing strategy for SPRIX and OXAYDO. SPRIX Nasal Spray 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 began promotional efforts for SPRIX in the second quarter of 2015. We launched OXAYDO, which we licensed from Acura Pharmaceuticals, Inc. ("Acura") on January 7, 2015, in the third quarter of 2015. To support these commercial activities, we have built commercial infrastructure by adding sales, marketing, medical affairs, managed markets and distribution functions. As of the beginning of 2016, we have a 71-person specialty sales force targeting the approximately 11,500 physicians in the high decile of pain medicine prescribers in the United States to build awareness and increase adoption of both SPRIX and OXAYDO.
- Obtain FDA approval for ARYMO ER as an AD, ER morphine product 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 December of 2015, we submitted an NDA for ARYMO ER tablets based on the pivotal pharmacokinetic ("PK") studies that demonstrated bioequivalence of ARYMO ER 15 mg, 30 mg and 60 mg to equivalent doses of Purdue Pharmaceutical's ("Purdue") MS Contin (morphine sulfate controlled-release). In addition, the submission included a battery of AD studies (Categories 1, 2 and 3) which were conducted to support AD label claims for intravenous injection, snorting and oral abuse. We are seeking FDA approval of ARYMO ER pursuant to Section 505(b)(2) ("Section 505(b)(2)") of the Federal Food, Drug and Cosmetic Act ("FFDCA"). The FDA has granted us Fast Track status with respect to ARYMO ER. In February 2016, the FDA accepted the submission and with the Prescription Drug User Fee Act ("PDUFA") goal date for a decision of October 14, 2016, we believe ARYMO ER could be on the market, if approved, before the end of 2016.
- Develop Egalet 002 as an AD, ER oxycodone product 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 and obtain FDA approval. We initiated a pivotal Phase 3 clinical development program for Egalet-002 in 2015 that is ongoing. We have conducted Phase 1 PK trials of Egalet 002, a battery of Category 1 AD studies compared to OxyContin, and plan to conduct a Category 3 intranasal human abuse potential ("HAP") study in 2016 with OxyContin as one of the comparators. We also plan to field a head to head oral HAP study comparing Egalet-002 to OxyContin in 2017. 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 mid-2017.
- Commercialize ARYMO ER and Egalet 002. If either or both of our clinical stage product candidates achieve regulatory approval, we intend to employ our established commercial organization to market our products by targeting approximately 11,500 physicians in the high decile of pain medicine prescribers in the United States. To supplement our sales force, we plan to explore contracting 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 Guardian Technology to fuel pipeline growth. Given the broad application of our Guardian Technology, we will look to drive pipeline growth through research and development. Using our proprietary technology, we will look to discover new innovative products concepts.

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· Conduct business development to leverage our assets and build on our product portfolio. Our business development activities will be concentrated in three areas: 1) augment our product portfolio through potential in-licenses, product acquisitions or other strategic transactions; 2) collaborate to develop and commercialize our products outside of the United States; and 3) partner to access physicians and patients outside our commercial focus.

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 agreement we paid Luitpold $7 million to acquire all intellectual property and certain other assets required to commercialize SPRIX and began marketing SPRIX in the second quarter of 2015.

Formulated as an easy to use spray, SPRIX Nasal Spray is rapidly absorbed through the nasal mucosa, achieving peak blood levels as fast as an intramuscular injection of ketorolac. SPRIX Nasal Spray has been studied in patients with moderate to moderately severe pain. The NDA submission 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 Nasal Spray 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.

Commercialization Strategy

Following the acquisition of SPRIX, we set up SPRIX Direct which provides the patient with direct product shipping from a specialty pharmacy, education and claims adjudication. We conducted non-personal promotion in the first quarter and began promotional activities with the sales force to build awareness and increase adoption of SPRIX in the second quarter of 2015. With our sales force we are targeting the approximately 11,500 physicians in the high decile of pain medicine prescribers in the United States. 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. We are working to educate our target physicians on the benefits of SPRIX Nasal Spray for the treatment of moderate to severe short-term pain.

Partnerships

While our primary commercial focus is educating the 11,500 physicians in the high decile of pain medicine prescribers in the United States, we are broadening our commercial reach through partnerships. We have signed agreements with two companies to bring SPRIX to regions and physician specialties outside of our focus areas. In December 2015, we granted Teva exclusive marketing and commercialization rights to SPRIX Nasal Spray in Israel, Gaza and the West Bank. In February 2016, we established an agreement with Septodont to promote SPRIX Nasal Spray exclusively to dentists in the United States using its focused specialty sales force. We will continue to evaluate other partnership

opportunities to bring SPRIX to other potential specialties that treat patients with short-term pain.

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OXAYDO for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate

Overview

On January 7, 2015, we entered into an agreement with Acura to in-license and commercialize OXAYDO, the first and only approved IR oxycodone product designed to discourage abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate. We paid Acura an upfront fee of $5 million and in October of 2015 paid a $2.5 million milestone payment on the commercial launch of OXAYDO. In addition, Acura will be entitled to a one time $12.5 million milestone payment if OXAYDO net sales reach $150 million in a calendar year.

Designed to discourage abuse via snorting

The label for OXAYDO includes the results from a Category 3 AD 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 percent of subjects exposed to OXAYDO responded that they would not take the drug again compared to 5 percent of subjects exposed to Roxicodone;
- subjects taking OXAYDO reported a higher incidence of nasopharyngeal and facial adverse events compared to Roxicodone;
- a decreased ability to completely insufflate two crushed OXAYDO tablets within a fixed time period among 21 of 40 subjects, while all subjects were able to completely insufflate the entire dose of Roxicodone; and
- small numeric differences in the median and mean drug liking scores, which were lower in response to OXAYDO than Roxicodone.

Although we believe these characteristics differentiate OXAYDO from IR 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. We are conducting a Category 4 AD epidemiologic study to assess the actual impact on abuse of OXAYDO tablets out in the community as part of our post approval commitment with the FDA.

Further, OXAYDO's product label guides patients not to crush and dissolve, 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.

We are performing additional in vitro and clinical work to evaluate the OXAYDO AD properties in line with the April 2015 U.S. FDA Guidance for Industry, Abuse-Deterrent Opioids – Evaluation and Labeling ("FDA AD Guidance"). In addition, we are conducting additional formulation work with the goal of developing a new dosage strength, including a 15 mg dose, to be available to market by the second half of 2017.

Commercial Strategy

Given the increasing number of IR opioid prescriptions and the high incidence of abuse, OXAYDO has the potential to be an important treatment option. According to a report commissioned by the Division of Epidemiology II for the Division of Anesthesia, Analgesia, and Addiction Products ("DAAAP") of the FDA, prescriptions of IR opioids increased from 2010 to 2014. In addition, 98.7 percent of prescription opioid abusers have abused IR opioids. With approximately 56 million prescriptions of IR oxycodone written in 2015, there is a substantial need for an IR

oxycodone

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product like OXAYDO that is designed to discourage abuse. We are focused on educating with our sales force approximately 11,500 physicians in the high decile of pain medicine prescribers in the United States on the attributes of OXAYDO.

Product Candidates

Current Environment Supports Development of Abuse Deterrent Opioids

In reaction to the widespread prescription opioid abuse issue in the United States, the U.S. government and the FDA have taken action, introduced regulations and, in some cases, enacted legislation intended to encourage the development and adoption of AD forms of pain medications. Recent activities include:

· FDA Action Plan: In February 2016, the FDA Opioids Action Plan was introduced to reduce the impact of prescription abuse on American families and communities. The Action Plan features a number of action items including:
- The FDA convening advisory committees to review the NDA of any form of opioid that does not have AD properties;
- Developing changes to IR opioid labeling, including additional warnings and safety information that incorporate elements similar to the ER/long-acting opioids labeling that is currently required;
- Supporting expanded access to AD formulations (“ADFs”); and
- Issuing draft guidance on generic ADFs soon.
· $1.1 billion in new funding proposed: In February 2016, President Obama proposed $1.1 billion in new funding to address the prescription opioid abuse and heroin use epidemic.
· FDA AD guidance: In April 2015, the FDA issued guidance providing direction as to the necessary study design and data recommendations for obtaining AD claims in a product label. The guidance describes four types of label claims that a product with AD properties may obtain based on studies completed either prior to NDA submission or after NDA approval:
- Based on Category 1 in vitro studies, the following label claim may be attained—the product is formulated with physical or chemical barriers to abuse.
- Based on Category 2 pharmacokinetic studies, the following claim may be obtained —the product is expected to reduce or block effects of the opioid when the product is manipulated.
- Based on Category 3 clinical human abuse potential studies showing a significant reduction in maximal drug liking, the following label claim may be attained—the product is expected to result in a meaningful reduction in abuse.
- Based on Category 4 post-marketing studies, which are required for all products approved with AD labeling, the following claim may be attained —the product has demonstrated reduced abuse in the community.

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- STOPP Act: In February 2013, a bipartisan group of Congressional leaders introduced the Stop the Tampering of Prescription Pills Act. In 2015 it was reintroduced and if approved this bill will require that non AD opioids be removed from the market if an AD formulation of that opioid has already been approved for marketing by the FDA.
- 48 state and territorial attorneys general support development of AD 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 AD 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.
- Approved AD products: As of February 27, 2015, there are five products approved with AD language in the product label: Purdue Pharmaceutical's products OxyContin, Hysingla™ ER and Targiniq ER™, Pfizer's product Embeda® and Inspirion's product MorphaBond™. In addition, our product OXAYDO has data from an intranasal human abuse potential study in its label, performed prior to when the FDA AD Guidance was issued, that demonstrates how OXAYDO was designed to discourage abuse via snorting—the most common route of abuse of oxycodone-based products.

We believe that these actions by regulators and legislators indicate a commitment to addressing 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 AD claims on the product label.

Our Solution: The Guardian Technology

Overview

Our proprietary Guardian Technology is a polymer matrix tablet technology that utilizes a novel manufacturing process, injection molding, which results in tablets with controlled-release properties as well as physical and chemical features that have been demonstrated to resist both common and rigorous methods of manipulation. Our Guardian Technology can be used to create tablets that are extremely hard, very difficult to chew, resistant to particle size reduction, and inhibit/block attempts at chemical extraction of the active pharmaceutical ingredient. In addition, the technology results in a viscous hydrogel on contact with liquid, making injection with a syringe very difficult. These features are important to address the risk of accidental misuse (e.g., chewing) in patients with chronic pain, as well as intentional abuse using more rigorous methods of manipulation.

While our Guardian Technology creates a pill that is extremely hard and has AD features, the construct of the pill allows for controlled release of the active pharmaceutical ingredient ("API") in the gastrointestinal ("GI") tract.

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Below is a diagram that illustrates how Egalet 002 delivers the API in the GI tract. The pill's shell, which is permeable and remains unchanged, is shown in gray and the matrix containing the API is shown in light gray.

Our Guardian Technology employs a proven, reproducible, scalable and cost efficient manufacturing process. While other pharmaceutical companies typically manufacture their AD products using conventional compression methods, our injection molding technology involves the simultaneous use of both pressure and heat to form tablets using a customized mold. This injection molding technology used to create our matrix and shell is also used in the manufacture of medical devices, including implants and diagnostics, to create the 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.

AD Features of Guardian Technology

Misusers and 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 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's Guardian Technology

Type of Abuse	Abuse-Deterrent Features	Comment
Chewing	Hardness of the tablet	The matrix composition and the manufacturing process result in a very hard tablet that is difficult to chew.
Crushing and swallowing	Resistant to particle size reduction	Tablet maintains some ER properties after attempted manipulation.
Injection	Matrix not easily solubilized	High amount of polyethylene oxide results in a highly viscous hydrogel when attempting to solubilize, preventing ability to draw and inject with a syringe.
	API not easily accessible	Composition and hydrophilic nature of the matrix make isolating the API difficult.
Snorting	Resistant to particle size reduction	The injection molded tablet is difficult to crush/grind/mill, yielding particle sizes that are large and difficult to snort.
Smoking	Poor combustion	Formulation combusts to a solid black mass with limited yield of the API.

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Ability to Tailor Release

In addition to its AD 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, delayed release and sustained release 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 AD products with other classes of APIs with known abuse liability (e.g. stimulants, benzodiazepines). Our Guardian Technology also enables the development of combination products containing two APIs that can be designed to release at different rates. This allows for rational drug development that can address specific clinical situations, some of which may represent unmet medical needs. We have developed prototypes and conducted feasibility studies of additional applications, including combination products both independently and in collaboration with major pharmaceutical companies.

ARYMO ER 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

Overview

Our lead product candidate, ARYMO ER, an AD, ER oral morphine formulation, was developed using our Guardian Technology to address common methods of abuse and misuse, such as crushing in order to swallow, snort or smoke, or dissolving in order to inject. We have developed ARYMO ER for twice or three times a day dosing. In December of 2015, we submitted an NDA for ARYMO ER tablets 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 are seeking U.S. regulatory approval of ARYMO ER pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. In February 2016, the FDA accepted the submission and with the PDUFA goal date for a decision of October 14, 2016, we believe ARYMO ER could be on the market, if approved, before the end of 2016.

Product Features of ARYMO ER

We believe that ARYMO ER, if approved, will provide patients and physicians with the following benefits when compared to existing morphine based products:

- AD features: Due to our Guardian Technology ARYMO ER tablets are extremely hard, very difficult to chew, resistant to particle size reduction and inhibit/block attempts at chemical extraction of the API, morphine sulfate.
- No alcohol dose dumping: In the presence of alcohol, the release of morphine from ARYMO ER is slowed and there was no evidence of alcohol dose dumping in our clinical trials. This is 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. For example, Embeda, the only commercially available AD morphine product, has a black box warning regarding alcohol dose dumping.

· No food effect. Results from a clinical study demonstrated that there was no evidence of clinically relevant food effect for ARYMO ER in healthy subjects following single-dose administration compared to when dosed in the fasted state.

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Completed Clinical Studies

The clinical development program for ARYMO ER was designed to demonstrate bioequivalence to MS Contin based on the PK parameters of area under the curve ("AUC") and maximum or peak plasma concentration ("Cmax"). In order to demonstrate bioequivalence, as defined by the FDA, the 90 percent confidence interval ("CI") of the ratio for both of these parameters must fall within 80 percent to 125 percent of the reference drug. Our NDA submission included data from the pivotal PK studies that demonstrated bioequivalence of ARYMO ER 15 mg, 30 mg and 60 mg to equivalent doses of MS Contin, a commonly prescribed ER oral morphine that is currently on the market. Below is a table summarizing these results:

Completed Abuse Deterrent Studies

In addition to the pivotal PK studies that demonstrated bioequivalence to MS Contin, the ARYMO ER NDA submission included a series of AD studies conducted in accordance with the April 2015 FDA AD Opioid Guidance. Below is a summary of certain findings from the AD studies:

- Resistance to common forms of abuse: Category 1 studies of ARYMO ER show that the formulation is unusually resistant to most common forms, and rigorous multi-step attempts, of manipulation of the product, including chewing, crushing, physical manipulation, and chemical extraction. These Category 1 studies suggest that the physio-chemical properties of ARYMO ER, such as its tablet bulk, density, hardness, ER properties, and gelling properties in various solvents, would deter attempts to abuse the product by any of the known routes of abuse.
- High level of effort required: In order to evaluate the degree of effort required to bypass or defeat the AD properties of a product, a laboratory investigation of ARYMO ER using the Assessing Labor, Effort and Resources Required for TamperingSM ("ALERRT") Scale was conducted. This investigation demonstrated that it takes a significant amount of time, effort, and resources to try to manipulate ARYMO ER compared to MS Contin to get it into an abusable form and, even following such manipulation, the output of such efforts either failed to defeat the product in any way or only yielded large, coarse particle sizes that would not be favorable for use via common routes of abuse.
- Positive Category 2/3 intranasal results: Category 2/3 studies of ARYMO ER demonstrated that intranasal administration of manipulated ARYMO ER, in both a high volume version which included all particle sizes

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and a manipulated/sieved low volume version consisting of only small particles amenable to snorting, had significantly lower subjective drug liking and physiologic effects compared to manipulated MS Contin administered intranasally. This was supported by a statistically significant decrease in the primary outcome of maximum drug liking. With regard tom the secondary outcomes of Overall Drug Liking and Take Drug Again Assessment ("TDAA"), both the high volume and low volume ARYMO ER arms of the study had scores similar to the placebo arm on both of these measures, with the exception of TDAA for high volume ARYMO ER which was greater than for placebo, but significantly lower than MS Contin. The PK parameters also demonstrated that manipulated ARYMO ER maintains many of its ER properties compared to manipulated MS Contin, and this resulted in a significantly lower abuse quotient for both the high volume and low volume ARYMO ER treatments compared to MS Contin.

- Positive Category 2/3 oral results: Category 2/3 studies of ARYMO ER have demonstrated that, when administered by the oral route as intact or manipulated tablets, ARYMO ER had significantly lower subjective and physiologic effects compared to intact or manipulated MS Contin administered orally, respectively. This resulted in a statistically significant decrease in the primary outcome of maximum drug liking. ARYMO ER was associated with a delay in onset of effects and lower peak exposure compared to manipulated MS Contin. This suggests that, even after the more rigorous manipulation required to manipulate ARYMO ER that requires an increased level of effort compared to what it takes to defeat MS Contin, ARYMO ER maintains a higher proportion of its ER and AD properties.

Together, we believe the results of these studies demonstrate that ARYMO ER, with its AD properties, has lower potential for accidental misuse via chewing and abuse via oral, intravenous, and intranasal routes compared to MS Contin.

In addition, results from a study conducted with to-be-marketed product demonstrated that there was no evidence of a clinically relevant food effect for ARYMO ER in healthy subjects following single-dose oral administration and under naltrexone blockade.

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

Overview

Egalet 002, an AD, ER, oral oxycodone formulation, is currently in Phase 3 development 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. Using our Guardian Technology, we developed Egalet 002 to address common methods of abuse and misuse, including crushing in order to swallow, snort or smoke, or dissolving in order to inject. In particular, Egalet-002 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. We plan to seek approval of Egalet 002 through the FDA's Section 505(b)(2) approval pathway, using OxyContin as the reference listed drug ("RLD"). In parallel, we are conducting a full set of AD studies in accordance with the FDA AD Guidance, with the goal of obtaining AD claims in Egalet-002's product label. Because of the different PK profile of Egalet-002, a single Phase 3 efficacy/safety study is being conducted, along with a one-year open-label safety study to assess the long-term exposure of the outer shell component, as required by the FDA.

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 polylactic acid ("PLA") and PEO—the physical hardness of the tablet and the gelling effect of the matrix combine to give Egalet-002 its AD characteristics. The primary component

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making up the outer shell, has been used extensively in the medical devices industry, including in the manufacture of implants and diagnostics.

Product Features of Egalet 002

We believe that Egalet 002, if approved, would provide patients and physicians with the following benefits:

- Abuse deterrent features: Egalet 002 was developed to address the most common methods of abuse and misuse, 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 is not bioequivalent to OxyContin and produces less peak to trough concentration variability in drug exposure.
- No alcohol dose dumping: In a clinical alcohol interaction study, the release of oxycodone from Egalet 002 was slowed in the presence of increasing concentrations of alcohol demonstrating no evidence of alcohol dose dumping.

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 have conducted Phase 1 PK trials of Egalet 002, a battery of Category 1 AD studies comparing Egalet-002 to OxyContin and a clinical alcohol interaction study. In 2016, we plan to conduct a head to head Category 3 intranasal HAP study comparing Egalet-002 to OxyContin and in early 2017 we plan to conduct an oral HAP study. We have initiated a pivotal Phase 3 program which includes a safety and efficacy trial, as well as an open-label, long-term safety study. The FDA has granted 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 mid-2017.

Completed Clinical Trials

We have performed three Phase 1 clinical trials of Egalet 002 as part of the formulation development and optimization program. The results of these studies demonstrated that Egalet-002 exhibited improved PK characteristics relative to OxyContin. In particular, the plasma concentration of oxycodone 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 in plasma oxycodone concentration.

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]		

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Results from the Phase 1 clinical program also demonstrated dose proportionality of Egalet 002 across the dosage range of 10, 20, 40 and 80 mg. In addition, one of the PK studies included a fed arm with the highest dose, 80 mg, to assess the food effect of Egalet 002. A food effect was observed which was consistent with the magnitude of food effect observed in previous OxyContin studies.

Completed Abuse Deterrent Studies

In accordance with the FDA AD Guidance, we commissioned a third party to conduct Category 1 AD studies of Egalet 002 to evaluate the physical and chemical properties of Egalet 002 compared to the AD formulation of OxyContin. These experiments included the full battery of Phase 1 physical manipulations and Phase 2 chemical manipulations as referenced in the FDA AD Guidance to fully interrogate the AD 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 the shell. The result of this Category 1 study with regard to particle size reduction showed that, for Egalet 002, 12.5 percent of particles were less than 500 microns (suitable for snorting) compared to 74.2 percent of the particles for OxyContin ($p < 0.0001$).

Ongoing/Planned Clinical Trials and Abuse Deterrent Studies

- 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 has been initiated.
- 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 one year. This trial has been initiated.
- A randomized, double blind, double dummy, active and placebo controlled, crossover study comparing the abuse potential of manipulated Egalet 002 versus manipulated immediate-release oxycodone and manipulated OxyContin following intranasal administration in nondependent recreational opioid users; This trial is expected to be completed in the second half of 2016.
- A study comparing the abuse potential of manipulated and intact Egalet 002 tablets versus manipulated IR oxycodone and manipulated OxyContin following oral administration in nondependent recreational opioid users; This study is expected to be conducted in 2017.

Additional Product Candidates

Developed using our Guardian Technology, we have two other product candidates. We have Egalet-003, an AD stimulant product candidate, for which we plan to file an IND application in the fourth quarter of 2016. In addition, we have Egalet-004, an AD, ER hydrocodone based product candidate for which an initial Phase 1 bioavailability study has been conducted. We have the opportunity to further develop these product candidates on our own or with a partner.

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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. We have developed prototypes, conducted feasibility studies and are exploring additional applications of our technology, both on our own and in collaboration with other pharmaceutical companies.

Commercialization

In the second quarter of 2015, we launched a 50-person sales force and began the promotion of SPRIX Nasal Spray. In the third quarter, we launched OXAYDO and at the same time announced that we would be expanding the sales force. As of the beginning of 2016, we have an additional 21 territory managers or sales representatives and are now targeting 11,500 physicians in the high decile of pain medicine prescribers in the United States. Given that the current physician targets are the same for ARYMO ER and Egalet-002, if approved, we will plan to use the same 71-person sales force to promote our Guardian Technology products.

Beyond the sales force, we also added to our marketing, medical affairs, managed markets and distribution functions in 2015. We have developed positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies for both of our approved products.

We intend to promote SPRIX and OXAYDO, and, if approved, ARYMO ER and Egalet 002 to pain care specialists in the United States, while out licensing commercialization rights for regions outside the United States and partner with other companies to reach other physician specialists.

Manufacturing

Overview

Our approved products are manufactured at contract manufacturing facilities in the United States. We have an agreement with Jubilant Hollister Stier to manufacture SPRIX Nasal Spray and with UPM Pharmaceuticals to manufacture OXAYDO.

Our Guardian Technology 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.

We use our contract manufacturer Halo Pharmaceuticals, Inc. (“Halo”) to produce ARYMO ER and Egalet-002. To prepare for the potential commercial launch of ARYMO ER, we are expanding the manufacturing capacity and investing in two more injection molding machines at Halo.

Drug Substances

The API used in SPRIX is ketorolac tromethamine, in OXAYDO is oxycodone hydrochloride, in ARYMO ER 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 ARYMO ER 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

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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 February 29, 2016, we owned fourteen issued patents within the United States, and an additional 70 issued foreign patents covering our product candidates or technology platform. The terms of the issued U.S. patents, extend to various dates between 2018 and 2033. We have acquired three U.S. patents, four pending U.S. patent applications and two pending Canadian patent 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 our ARYMO ER and Egalet 002 product candidates and our Guardian Technology platform, excluding possible patent extensions, extends to various dates between 2022 and 2033, if pending patent 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 February 29, 2016, we owned ten pending patent applications under active prosecution in the United States, and an additional 34 pending foreign patent applications covering our product candidates and technology platform. We have one pending patent application in the United States and eleven pending foreign patent applications relating to ARYMO ER. 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 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 and ARYMO ER in the United States, Canada and the European Union, and SPRIX in United States 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.

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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 AD 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 products being marketed by companies such as Endo Pharmaceuticals Holdings Inc., Mallinckrodt, Pfizer, Purdue, Teva 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 ER hydrocodone product candidates, which include abuse deterrent and tamper resistant formulations, being developed by Pfizer, Purdue and Teva. 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, 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 Nasal Spray

SPRIX Nasal Spray 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 in this market; 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 IR opioids such as oxycodone, hydrocodone and tapentadol.

ARYMO ER

If approved, ARYMO ER 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 commercially available as of the date of this report.

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Inspirion Delivery Technologies' MorphaBond received FDA approval in October of 2015 and it is expected to become commercially available by the end of 2016.

We believe there are AD morphine products in clinical development by Purdue and Elite. In addition, any company that has developed an AD technology could initiate an AD 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. Collegium's XTAMPZA ER received tentative FDA approval in November of 2015. 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 AD features could be developed to mirror OxyContin, in which case Egalet 002 would compete also with any such generic oxycodone products.

Additionally, we are aware of companies in late stage development of AD oxycodone product candidates, including Pain Therapeutic's Remoxy® and Pfizer's ALO 02. 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 AD technology could initiate an abuse deterrent oxycodone program at any time.

Government Regulations

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The 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

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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 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 NDA 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 NDAs. 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

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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.

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 the 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 the 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.

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

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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 the 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 REMS for these opioid medications to ensure their safe use. ER 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.

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DEA Regulation

Our product OXAYDO is and our product candidates, ARYMO ER 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 designed to discourage abuse via snorting, is listed by the DEA as a Schedule II controlled substance under the CSA and we expect that ARYMO ER, an AD, ER morphine product candidate, and Egalet 002, an AD, ER oxycodone product candidate, 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 ARYMO ER, and Egalet 002 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.

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 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

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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 ARYMO ER 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 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.

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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 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

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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 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,

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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.

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

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likely be lower than the prices we might otherwise obtain. Moreover, while the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by HHS, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third party payors do not consider our products to be cost effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In March 2010, the Affordable Care Act was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1 percent and 13 percent 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 percent 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 percent 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;

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- new requirements under the federal Open Payments program for drug manufacturers to report information related to payments and other transfers of value made to physicians and other healthcare providers as well as ownership or investment interests held by physicians and their immediate family members;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, President Obama 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 percent 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.

Employees

As of February 29, 2016, we had 78 employees, of which 52 were employed in the United States and 26 were located in Denmark. According to the Danish Salaried Act, Danish employees have the right to be represented by a labor union. We consider our employee relations to be good. In addition, to our employees we have 71 sales representatives contracted through Inventiv for our dedicated specialty sales force.

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

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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 securities 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 any investment decision regarding our securities. 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. As a result, the trading price of our securities could decline and you may lose part or all 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.

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, 2015 and 2014, we reported a net loss of $57.9 million and $43.2 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 approved products, and ARYMO and Egalet 002 and any other product candidates that we may develop, 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 losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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We currently generate limited revenue from the sale of products and may never become profitable.

To date, we have not generated any revenues from ARYMO and Egalet 002, our lead product candidates, and only limited revenues from our approved products, and have generated $22.5 million in total revenue since our inception from feasibility and collaboration agreements. Under our collaboration agreement with Shionogi, we received a $10.0 million upfront payment in December 2013 and an additional $10.0 million milestone payment in April 2015, but as this agreement as terminated in December 2015, we will not generate any additional revenue under this agreement. Our ability to generate additional revenue and become profitable depends upon our ability to expand the marketing of our approved 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 approved 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 and HAL 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;

•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 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 ARYMO 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 approved 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

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projected operating requirements at least through December 31, 2016. 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 approved 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 ARYMO and Egalet 002, and any future product candidates we may in license or acquire;

•increasing sales of our marketed products, SPRIX and OXAYDO;

•the clinical development plans we establish for these product candidates;

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

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

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

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

•the effect of competing technological and market developments;

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

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

•our ability to achieve milestones under any license or collaboration agreement that we may enter into in the future;

Complying with and completing FDA post-marketing requirements on OXAYDO

•the size and cost of our commercial infrastructure; and

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•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.

In January 2015 we entered into a loan and security agreement, or the Senior Secured Loan Agreement, with Hercules Technology Growth Capital, Inc., or Hercules, pursuant to which we have borrowed $15.0 million from Hercules. We must repay the indebtedness under the Senior Secured Loan Agreement on or before July 1, 2018, and we must make interest only payments on the amounts borrowed until at least June 2016, after which we must make 25 equal monthly payments of principal plus interest. The interest only period may be further extended to January 2017 subject to our satisfaction of certain conditions during the first half of 2016. Additionally, in April 2015, we completed an offering of $61.0 million aggregate principal amount of our 5.50 % convertible senior notes due 2020, or the Convertible Senior Notes. Interest on the Convertible Senior Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing in October 2015, and the Convertible Senior Notes mature on April 1, 2020. As of December 31, 2015, our total consolidated indebtedness was approximately $76 million.

Our ability to make payments on the Senior Secured Loan Agreement and the Convertible Senior Notes 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. In addition, the indebtedness under the Senior Secured Loan Agreement is secured by substantially all of our assets other than intellectual property on which we have given Hercules a negative pledge. Both the Senior Secured Loan Agreement and the indenture governing the Convertible Senior Notes also contain 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 prior consent. The terms of the agreements governing any of our future indebtedness may have similar or additional limitations and restrictions.

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 approved products or product candidates;

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

•reduce the amount of funds available to pay interest on the Senior Secured Credit Facility and the Convertible Senior Notes;

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

•limit our ability to engage in acquisitions; and

•limit our ability to obtain additional funds.

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 and the Convertible Senior Notes offering.

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Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Senior Secured Loan Agreement and the Convertible Senior Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations

Despite our current debt levels, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.

Despite our current consolidated debt levels, we and our subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. We will not be restricted under the terms of the indenture governing the notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the notes that could have the effect of diminishing our ability to make payments on the notes when due. The Senior Secured Loan Agreement restricts our ability to incur additional indebtedness, including secured indebtedness, subject to certain exceptions, but if the facility matures or is repaid, we may not be subject to such restrictions under the terms of any subsequent indebtedness.

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 sources of funds. 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

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use our pre change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

In addition to the level of commercial success of our approved 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 aggregate sales of our marketed products of approximately $4.2 million and an aggregate of $22.5 million in revenues from various collaborative and research and development arrangements, including aggregate payments of $20.0 million under our prior collaboration and licensing agreement with Shionogi that was terminated in December 2015. 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, ARYMO 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.

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 ARYMO and Egalet 002 or any

of our other product candidates, we will not be able to earn revenue from them.

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If we 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 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.

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 post-marketing requirement or REMS, which could limit the labeling, distribution or promotion of a drug product.

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

If we 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 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 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 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

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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 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 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 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 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 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 FDA may also require us to perform lengthy Phase 4 post approval clinical efficacy or safety trials. These trials could be very expensive. The FDA may also require us to amend our label based on outcomes of on-going Phase 4 commitment for OXAYDO. 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

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approved drug. For example, in December 2015 we submitted an NDA for our product candidate ARYMO pursuant to Section 505(b)(2).

If the FDA does not allow us to pursue the Section 505(b)(2) approval pathway as anticipated, or if we cannot demonstrate bioequivalence or comparable bioavailability of our 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 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

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•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 . Any FDA determination that our NDA or supplemental NDA ("sNDA") submission is incomplete or insufficient for filing, results in FDA refusing to file the NDA or sNDA. A refusal to file by the FDA requires us to expend additional time and resources to revise and resubmit our NDA or sNDA. There is no guarantee that any revised or resubmitted NDA or sNDA filing we make will be accepted by the FDA.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. FDA may grant deferrals for submission of data or full or partial waivers. We filed a supplemental NDA for SPRIX in December 2015, based on pediatric data initially generated and submitted by former sponsors. We received a refusal to file notice from the FDA on February 25, 2016. FDA indicated that the filing review represents a preliminary review of the application and is not indicative of deficiencies that would be identified if FDA performed a complete review. We will work with FDA during upcoming meetings to address the identified issues.

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 ARYMO and Egalet 002, if approved, will be subject to REMS or other post-marketing requirements, such as lengthy and costly post-marketing studies. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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.

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.

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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,

Additionally, recent public comments from FDA and members of Congress have highlighted the importance of addressing the opioid abuse epidemic. Given the changing legislative and regulatory environment, it is difficult to predict how existing laws and regulations may affect the future approval and continued marketing of opioids, including those that fulfill current abuse-deterrent FDA guidance. FDA notified us upon acceptance of the ARYMO NDA, that it will require an Advisory Committee to discuss our ARYMO application. At this time we cannot speculate how the Advisory Committee will affect our approval process

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 submit 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.

We anticipate that ARYMO 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

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

Our 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 civil and criminal laws and civil monetary penalty laws, including the False Claims Act, which impose 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;

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

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

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

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 approved 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;

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•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.

Risks Related to the Commercialization of Our Products and Product Candidates

Our future prospects are dependent on the success of our approved 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 approved 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 products. We began the commercial activities for 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 approved

products, or if approved, ARYMO, 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

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retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates in the United States include:

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

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

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

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

If we are not successful in continuing to recruit 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 approved products or product candidates, we will not achieve sufficient product revenues and our business will suffer.

If our approved 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 approved 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 approved 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 approved products and product candidates in reducing potential risks of unintended use;

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

•availability of coverage and adequate reimbursement for our approved products and our product candidates from government and healthcare payors;

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

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

Because we expect to rely on sales generated by our products and, if approved, our product candidates to achieve profitability in the future, the failure of either product candidate to find market acceptance would harm our business prospects.

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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 approved products compete, and if approved, ARYMO 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, 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 approved 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 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 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;

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•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 to commercialize our product candidates, may reduce the prices we are able to obtain for our approved 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 approved products or any product candidates for which we obtain marketing approval.

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, modify the definition of "average manufacturer price" for Medicaid reporting purposes thus affecting manufacturers' Medicaid drug rebates payable to states 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 that will remain in effect through 2024 unless additional Congressional action is taken, 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,

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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 approved 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. For example, recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisitions of the rights to certain drug products. In particular, U.S. federal prosecutors recently issued subpoenas to a pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies relating to post-acquisition drug-price increases. Our revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products. 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 approved products and, if approved, our product candidates, successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and other third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for our approved 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 approved products or any product candidate for which we obtain marketing approval.

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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. Private 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 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.

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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.

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.

The members of our sales force have limited experience promoting our approved products, SPRIX and OXAYDO. 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

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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 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.

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

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

If third party manufacturers of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, we may be unable to continue to develop our product candidates and commercialize our products, 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 ARYMO and Egalet 002. With respect to our approved products, we 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 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

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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 approved 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 approved 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 approved products.

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. Collaborations involving our product candidates pose the following risks to us:

•Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.

•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.

•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

•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.

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•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.

•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.

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

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

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

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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 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 medication, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available

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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 financial officer, Stan Musial, our chief operating officer, Mark Strobeck, our chief medical officer, Jeffrey Dayno, our Chief Commercial Officer, Deanne Melloy, our General Counsel, Paul Varki, 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 any of Mr. Radie, Mr. Musial, Dr. Strobeck, Dr. Dayno, Ms. Melloy, Mr. Varki, and Dr. Lindhardt could impede the achievement of our research, development, clinical, business, legal compliance and commercialization objectives.

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

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

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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 approved products, we have increased our number of full time employees to 78 as of February 29, 2016, 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 approved products and, if approved, ARYMO, Egalet 002 and our other product candidates effectively and in a cost effective manner, including managing our contract sales force;

•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.

We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

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

•incur debt and assume liabilities; and

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

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

•problems integrating the purchased business, products or technologies;

•increases to our expenses;

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•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 approved 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 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 approved products or product candidates or the manufacturing facilities for our approved 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 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

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efficacy of the product. We currently have Phase 4 study requirements for OXAYDO. We will collect data on OXAYDO for one year post marketing, and, depending on the results of the study, additional post-marketing investigations may be required to evaluate the effect of OXAYDO. 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.

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.

One of our approved 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.

OXAYDO, ARYMO and Egalet 002 each 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, ARYMO and Egalet 002 contain active ingredients that

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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. For our products and 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 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.

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

The Sarbanes Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with our annual report on Form 10 K for the year ended December 31, 2014, we have been 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 is required 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. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, 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.

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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.

Our employees, independent contractors, consultants or collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants or collaborators. Misconduct by any of these parties 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 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. Misconduct by these parties 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 misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Our 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

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security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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

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

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.

We may incur increased compliance costs and our management will be required to devote substantial time to new compliance initiatives once we are no longer an “emerging growth company.”

We expect to incur significant expense and to 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.” 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, accounting, administrative and other 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 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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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. 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.

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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.

If third parties claim that our intellectual property or 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. For example, in April 2015 we became aware that Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, “Purdue”) filed a lawsuit against us and our collaboration partner Acura Pharmaceuticals, Inc. alleging that our OXAYDO product infringes a patent held by Purdue. The complaint seeks injunctive relief as well as awards of damages and attorneys’ fees. In January 2016, as part of a Claims Construction hearing, the Court ruled that the term polyvinylpyrrolidone, as that term is defined in the claims of the Purdue patent, covers all polymeric forms of vinylpyrrolidone, including crospovidone used in Oxaydo. We deny the allegations in the complaint, As is the case with patent litigation, there is a risk that the Court may enjoin the making, using, selling and offering for sale Oxaydo and/or may find that Oxaydo infringes the ‘007 patent. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to this matter as of December 31, 2015.

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

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications related to morphine or oxycodone drugs and formulations, including those listed in the FDA’s Orange Book for oxycodone products. Since patent applications are published 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.

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In connection with any NDA that we file under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, we will also be required to notify the patent holder that we have certified to the FDA that any patents listed for the reference label 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. 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 have been, and in the future 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 have been, and may in the future 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 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.

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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 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

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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 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

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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. 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 Securities

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

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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, as amended, or the 2013 Stock 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 Plan is 3,680,000, and future option grants and issuances of common stock under our 2013 Stock Plan may adversely affect the market price of our common stock. Subject to the approval of our stockholders, the Company may seek to increase the number of shares of our common stock reserved for issuance under our 2013 Stock Plan at the Company's 2016 Annual Meeting of Stockholders.

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 March 9, 2016, approximately 78.5% 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.

Our share price has been and may continue to 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;

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•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.

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

As of March 9, 2016, our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately 78.5% 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 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.

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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.

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 19,797 square feet of office space under a lease agreement that expires in February 2022 unless terminated earlier. In addition, we are leasing 2,510 square feet of office space in Whippany, 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 2016 unless terminated earlier). We also have existing leases from previous US headquarters totaling 6,599 square feet, of which leases for 3,190 expires in November 2016 and of which 3,409 square feet expires in December 2017.

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

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 SprayThe action was dismissed without cost and without prejudice on January 6, 2016 as a result of a settlement between Apotex and Egalet. The parties have agreed to settle the matter on terms consistent with the prior settlement with Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC ("Amneal") related to SPRIX. The parties are currently drafting the settlement agreement and accompanying documents.

In April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, “Purdue”) commenced a patent infringement lawsuit against us and our OXAYDO product licensor, Acura, in the United States District Court for the District of Delaware alleging our OXAYDO product infringes Purdue’s patent, U.S. Patent No. 8,389,007 (the “’007 patent”). A pre-trial claims construction hearing was held in November 2015 to determine the meaning of the terms in the lawsuit. In January 2016, the Court ruled in favor of Purdue with regard to the pre-trial claims construction hearing. No date has been set for the full hearing. We continue to deny the allegations in the complaint, believe they are without merit, and defend the action vigorously. At the current time, we are proceeding with defending the lawsuit as well as evaluating other options. As is the case with any outcome of a patent litigation, there is a risk that the Court may enjoin the making, using, selling and offering for sale OXAYDO and/or may find that Oxaydo infringes the ‘007 patent.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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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:

	Year ended December 31, 2015	
	High	Low
Year Ended December 31, 2015		
Fourth Quarter	$ 13.20	$ 7.61
Third Quarter	16.59	8.27
Second Quarter	16.0	8.71
First Quarter	17.03	4.81

	Year ended December 31, 2014	
	High	Low
Year Ended December 31, 2014		
Fourth Quarter	$ 7.53	$ 3.81
Third Quarter	14.26	5.42
Second Quarter	15.5	9.54
First Quarter (beginning February 5, 2014)	19.85	11.82

Stockholders

As of March 9, 2016, there were 28 record holders for shares of our common stock.

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, 2015, with the cumulative return of the NASDAQ Composite Index and NASDAQ Biotechnology Index.

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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, 2015

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.

Issuer Purchases of Equity Securities

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

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.

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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, 2013, 2014 and 2015 and balance sheet data as of December 31, 2014 and 2015 from our audited financial statements included elsewhere in this report. The statements of comprehensive income data for the year ended December 31, 2012 and the balance sheet data as of December 31, 2013 and 2012 are derived from our audited financial statements, which are not included herein. 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.

(in thousands)	Year Ended December 31,			
	2012	2013	2014	2015
Consolidated Operations Data:				
Revenues	$ 1,201	$ —	$ 1,920	$ 22,830
Cost and Expenses				
Cost of sales (excluding amortization of product rights)	—	—	—	3,271
Amortization of product rights	—	—	—	1,958
General and administrative	2,241	5,095	15,715	26,474
Sales and marketing	—	—	946	16,289
Research and development	4,256	6,280	22,395	27,054
Total costs and expenses	6,497	11,375	39,056	75,046
Loss from operations	(5,296)	(11,375)	(37,136)	(52,216)
Change in fair value of derivative liability	—	—	—	(260)
Interest expense, net	75	8,842	7,079	7,477
Other gain	—	(222)	(1,045)	(864)
(Gain) loss on foreign currency exchange	27	190	(3)	82
	102	8,810	6,031	6,435
Loss before provision (benefit) for income taxes	(5,398)	(20,185)	(43,167)	(58,651)
Provision (benefit) for income taxes	—	22	47	(718)
Net loss	$ (5,398)	$ (20,207)	$ (43,214)	$ (57,933)

(in thousands)	As of December 31, 2012	As of December 31, 2013	As of December 31, 2014	As of December 31, 2015
Consolidated Balance Sheet Data:				
Cash, cash equivalents and marketable securities, available for sale	$ 3,404	$ 15,700	$ 52,738	$ 145,707
Total assets	5,593	20,363	60,570	172,416
Long term liabilities	—	9,614	8,880	54,530
Total liabilities	1,934	30,236	16,309	83,194
Convertible preferred stock	14,957	14,957	—	—
Accumulated deficit	(13,192)	(33,399)	(76,613)	(134,546)
Total stockholders’ equity (deficit)	(11,298)	(24,830)	44,261	89,222

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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

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 Com 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, 2015.

Our Business

We are a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative treatments for pain and other conditions. Egalet was founded around our proprietary Guardian™ Technology that can be applied broadly across different classes of pharmaceutical products. Using this technology, we have two late-stage product candidates in development; ARYMO ER™, formerly known as Egalet-001, an abuse-deterrent ("AD"), extended-release ("ER"), oral morphine formulation, which, if approved by the U.S. Food and Drug Administration ("FDA"), could be on the market in 2016, and Egalet-002, an AD, ER, oral oxycodone formulation, which is in a Phase 3 program (our "lead product candidates"). Both lead product candidates are in development 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 January 2015, we acquired and in-licensed two FDA-approved products—SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO® (oxycodone HCI, USP) tablets for oral use only—CII (our "approved products")—that complement our pain portfolio. With the addition of these products, we built our commercial organization ahead of the anticipated launch of our lead product candidates and market our approved products to the same target high decile pain medicine prescribers to whom we expect to market ARYMO ER and Egalet-002, if approved. In addition, we have Egalet-003, an AD stimulant, for which we plan to file an investigational new drug ("IND") application in the fourth quarter of 2016 and Egalet-004, an AD hydrocodone based product candidate, that has completed a Phase 1 study—both of which were formulated using our proprietary technology. Our Guardian Technology also can be used to develop combination products that include multiple active pharmaceutical ingredients ("APIs") with similar or different release profiles and offers us a number of long term growth opportunities. We plan to continue to grow Egalet through business development and organic development leveraging our proprietary Guardian Technology.

With the approximately 100 million Americans suffering from chronic pain according to the Institute of Medicine—more than those affected by heart disease, cancer, and diabetes combined—there is a substantial need for effective pain treatments. The millions suffering from acute or chronic pain every year greatly impact our country with increasing health care costs, rehabilitation and lost worker productivity. Pain is a significant public health problem that costs society between $560 and $635 billion annually according to the Institute of Medicine. Opioids are powerful analgesics which are commonly used and found to be effective for many types of pain according to the American

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Academy of Pain Medicine. IMS prescription data from 2015 shows that opioids are the most widely prescribed products for pain, with prescriptions exceeding 200 million in 2015.

The combination of the pervasive issue of chronic pain and the use of opioids to treat chronic pain has led to an epidemic of prescription drug misuse and abuse. According to the American Society of Addiction Medicine, between 26 and 36 million people abuse opioids worldwide. According to the Centers for Disease Control and Prevention ("CDC"), opioids cause 75 percent of prescription drug overdoses. Importantly, 70 percent of Americans misusing painkillers obtained them from a friend or relative according to a 2013 National Survey on Drug Use and Health. This issue of prescription misuse and abuse is a costly one with 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—up to $72.5 billion annually according to the American Journal of Managed Care.

Prescription medications, particularly opioids (both ER and immediate-release ("IR") forms), are prone to being misused or abused through physical and chemical manipulation for the purpose of increasing the speed of the drug release into the bloodstream in order to accelerate and intensify their effects. A study of prescription opioid abusers in a drug rehabilitation program published in the Journal of Pain & Palliative Care Pharmacotherapy found that 80 percent tampered with opioid tablets to accelerate drug release by chewing or administering the drug intranasally or intravenously. 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.

In reaction to this widespread prescription opioid misuse and abuse, the U.S. government and the FDA have established this issue as a top priority. In February of 2016, President Obama proposed $1.1 billion in new funding to address the prescription opioid misuse and abuse and heroin use epidemic. In addition, just days later the FDA announced an action plan to combat the growing problem of prescription abuse, importantly highlighting the development of AD formulations as a part of the solution.

According to RADARS System's 3rd Quarter 2015 Technical Report, 91 percent of prescription opioid abusers have abused IR opioids. In the case of IR oxycodone, data from the Addiction Severity Index-Multimedia Version shows the preferred route of abuse is snorting (61 percent of the respondents). With the large issue of intranasal abuse, we believe OXAYDO, an IR oral formulation of oxycodone indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate, represents an important treatment option. OXAYDO is the first and only approved IR oxycodone product designed to discourage abuse via the route of snorting. OXAYDO, which was approved in 2011, has data in its label from a Category 3 intranasal human abuse liability ("HAL") study. In that study, after snorting crushed OXAYDO and crushed Roxicodone, an IR oxycodone product manufactured by Mallinckrodt Pharmaceuticals ("Mallinckrodt"), a population of recreational non dependent opioid users responded that both "take drug again" and drug liking were lower for OXAYDO compared to Roxicodone.

SPRIX Nasal Spray is the first and only approved nasal spray formulation of a nonsteroidal anti-inflammatory drug ("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. While providing analgesia at the opioid level, SPRIX Nasal Spray does not have the side effects or issues of misuse or abuse common to opioids.

To commercialize SPRIX and OXAYDO and ultimately our pipeline products candidates, we are using a 71-person specialty sales force targeting approximately 11,500 physicians in the high decile of pain medicine prescribers in the United States. We also 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. To expand the commercial reach of SPRIX, we have signed agreements with two third parties. Teva Pharmaceutical Industries Ltd. ("Teva") has exclusive marketing and commercialization rights to SPRIX Nasal Spray in Israel, Gaza and the West Bank and Septodont has the rights to

promote SPRIX Nasal Spray exclusively to dentists in the United States using its focused specialty sales force.

A critical part of our commercial strategy is to ensure patient access to our products by using our IMPACT-Rx (IMproving Patients ACcess To Medicines) initiative which we launched in conjunction with the launch of OXAYDO in the third quarter of 2015. The IMPACT-Rx initiative is applied to each of our commercial products to ensure that

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virtually no barrier exists to patients gaining access to these critical medicines they need. This national initiative employs three key features: 1) reimbursement support, 2) easier access to fill a prescription and 3) patient education. As part of this initiative, we established the My OXAYDO Patient Savings Program. All eligible patients receive ongoing savings through this program and will pay no more than $15 for a prescription of OXAYDO at all pharmacies. Similarly all eligible SPRIX patients will have a $0 co-pay for SPRIX.

Formulated using our proprietary Guardian Technology, we have two product candidates specifically designed to deter misuse and abuse by physical and chemical manipulation in late-stage of development. Having concluded our bioequivalence and AD studies, we submitted a new drug application ("NDA") for our lead program ARYMO ER in December of 2015 which the FDA accepted in February 2016 and we have initiated a Phase 3 program for our second product candidate Egalet 002. We will conduct AD studies on Egalet-002 as well which will be submitted in combination with the Phase 3 data to support an anticipated NDA filing in mid-2017.

ARYMO ER and Egalet 002 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 12.4 million prescriptions in the aggregate resulting in sales of more than $3.5 billion in the United States in 2015.

Developed using our Guardian Technology, we have Egalet-003, an AD stimulant product candidate, and Egalet-004, an AD hydrocodone product candidate. In addition, we have completed initial research and development efforts on 13 potential other product candidates. We have developed prototypes, conducted feasibility studies and are exploring additional applications of our technology, both independently and in collaboration with other pharmaceutical companies, for the development of both tailored precision oral drug delivery of single agent products 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 84 issued and 44 pending patent applications worldwide as well as unpatented know how and trade secrets.

Financial Operations

Our net losses were $20.2 million, $43.2 million and $57.9 million for the years ended December 31, 2013, 2014 and 2015, respectively. We recognized related party revenues of $1.9 million in the year ended December 31, 2014 and related party revenues and net product sales of $18.6 million and $4.2 million, respectively, for the year ended December 31, 2015. We had no revenues for the year ended December 31, 2013. As of December 31, 2015, we had an accumulated deficit of $134.5 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 continue to incur significant commercialization expenses as we grow our sales, marketing and distribution infrastructure to sell our products in the U.S.

Until we become profitable, if ever, 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.

Financial Operations Overview

Revenue

To date, we have generated no revenues from ARYMO ER and Egalet 002, our clinical stage product candidates, and only limited revenues from our approved products, and have generated $22.5 million in total revenue since our inception from feasibility and collaboration agreements. Our ability to generate additional revenue and become profitable depends upon our ability to expand the marketing of our approved products and commercialize our product candidates, or other product candidates that we may in license or acquire in the future.

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Cost of Sales (excluding amortization of product rights)

Cost of sales includes the cost of inventory sold or reserved; manufacturing, supply chain costs, product shipping and handling costs, and product royalties. The cost of sales associated with the deferred product revenues are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized.

Amortization of Product Rights

Amortization of product rights consists of the amortization expense associated with the intangible product rights related to the SPRIX acquisition and OXAYDO license. These expenses are recognized on a straight line basis over the useful life of the related intangible asset.

General & Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in our executive, finance and other administrative areas. Other general and administrative expenses include facility costs and professional fees for legal, patent, consulting and accounting services. We anticipate that our general & administrative expenses will increase in the future to fund continued research and development, with the growth of our commercialization efforts for our approved products and, if approved, our product candidates and to fund ongoing public company costs. These increases will likely include increased costs for insurance, costs related to the hiring of additional personnel and payments to outside consultants, investor relations, legal and accounting fees, among other expenses.

Sales & Marketing Expenses

Sales and marketing costs consist primarily of salaries and related costs for personnel in our sales and marketing departments, along with our third party contracted sales force. Other sales and marketing costs include professional fees for consulting and promotional materials. We anticipate that our sales & marketing expenses will continue to increase as we grow our commercial operations for our approved products and, if approved, our product candidates. These increases will likely include increased costs for hiring of additional personnel, outside consultants and marketing programs, among other expenses.

Research and Development Expenses

Research and development expenses consist primarily of costs associated with the development and clinical testing of ARYMO ER, 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 Clinical Research Organizations ("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.

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

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

We do not currently utilize a formal time allocation system to capture personnel related expenses on a project by project basis because we record expenses by functional department. However, we do allocate third party 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, 2013, 2014 and 2015:

(in thousands)	Year Ended December 31, 2013	Year Ended December 31, 2014	Year Ended December 31, 2015
ARYMO ER	$ 2,552	$ 10,547	$ 7,777
Egalet 002	382	3,397	11,613
Other clinical and preclinical development	1,767	2,634	3,853
Personnel related	1,579	5,817	3,811
	$ 6,280	$ 22,395	$ 27,054

We incurred research and development expenses of $6.3 million, $22.4 million and $27.1 million during the years ended December 31, 2013, 2014 and 2015, 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 ARYMO ER, Egalet 002, or any other product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if regulatory authorities were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of our clinical pipeline or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

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

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

- clinical trial results;
- the terms and timing of regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

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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.

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. Generally Accepted Accounting Principles ("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, debt, stock based compensation, income taxes and accrued research and development 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 filing. 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 from product sales and our collaborative research and development agreements.

Net Product Sales

We recognize revenue in accordance with FASB ASC 605, Revenue Recognition, when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable and collectability is reasonably assured. We determine that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. Pursuant to the contract terms, we determine when title to products and associated risk of loss has passed on to the customer. We assess whether the price is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer's payment history and creditworthiness.

We sell SPRIX in the U.S. to a single specialty pharmaceutical distributor subject to rights of return. We have limited SPRIX sales history under the current distribution model and pricing, and have determined that at this time we cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on product shipments of SPRIX until the right of return no longer exists, which occurs at the earlier of the time SPRIX units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. We calculate patient prescriptions dispensed using an analysis of third-party information. As of December 31, 2015, we had deferred revenue of $9.6 million related to sales of SPRIX to its specialty pharmaceutical distributor. In the event the related units are not dispensed pursuant to patient prescriptions prior to their expiration in April and May of 2016, they may be returned to the Company for replacement product.

We sell OXAYDO in the U.S. to several wholesalers, all subject to rights of return. We have limited OXAYDO sales history under the current distribution model and pricing, and have determined that at this time we cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on product shipments of OXAYDO until the right of return no longer exists, which occurs at the earlier of the time OXAYDO units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in

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transit. We calculate patient prescriptions dispensed using an analysis of third-party information. As of December 31, 2015, we had deferred revenue of $526,000 related to sales of OXAYDO to the wholesalers.

Collaborative research and development agreements

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 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 $1.9 and $18.6 million during the years ended December 31, 2014 and 2015 respectively. We did not recognize any revenue during the year ended December 31, 2013.

Intangible and Long Lived Assets

Intangible assets consist of product rights related to the SPRIX acquisition, product rights associated with the Collaboration and License Agreement with Acura to commercialize OXAYDO tablets, and in process research and development ("IP R&D") related to our drug delivery platform technology we acquired as part of the acquisition of Egalet A/S.

Long lived assets, including intangible assets and property and equipment, 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, 2014 and 2015.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

Stock Based Compensation

We apply the fair value recognition provisions of FASB ASC Topic 718, Compensation—Stock Compensation. Determining the amount of share-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. We recognize share-based compensation expense ratably over the requisite service period, which in most cases is the vesting period of the award. Calculating the fair value of share-based awards requires that we make highly subjective assumptions.

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We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, and the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are a publicly held company with a limited operating history, we utilize data from a representative group of companies to estimate expected stock price volatility. We selected companies from the biopharmaceutical industry with similar characteristics to us, including those in the early stage of product development and with a therapeutic focus, to comprise our representative group.

We use the simplified method as prescribed by the SEC SAB No. 107, Share-Based Payment, to calculate the expected term of stock option grants to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows for the year ended December 31, 2014 and 2015:

	2014	2015
Risk-free interest rate	1.81 %	1.76 %
Expected term of options (in years)	6.24	6.27
Expected volatility	74.88%	72.93%
Dividend yield	—	—

Convertible Debt Accounting

We perform an assessment of all embedded features of a debt instrument to determine if (1) such features should be bifurcated and separately accounted for, and (2) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the consolidated balance sheet, and re-measured to fair value at each reporting period. Any changes in fair value are recorded in the consolidated statement of operations. We monitor, on an ongoing basis, whether events or circumstances could give rise to a change in our classification of embedded features.

We determined the embedded conversion options in the 5.50% convertible Senior Notes (the “5.50% Notes”) are not required to be separately accounted for as derivatives. However, since the 5.50 % Notes can be settled in cash or common shares or a combination of cash and common shares at our option, we are required to separate the 5.50 % Notes into a liability and equity component. The carrying amount of the liability component is calculated by

measuring the fair value of a similar liability that does not have an associated equity component. The carrying amount of the equity component representing the embedded conversion option is determined by deducting the fair value of the liability component from the initial proceeds. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense over the expected life of the 5.50 % Notes using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification for contracts in an entity's own equity.

The fair value of the liability component of the 5.50% Notes was estimated at $40.6 million at issuance. Therefore, the difference between the $61.0 million face value of the 5.50 % Notes and the $40.6 million estimated fair value of the liability component will be amortized to interest expense over the term of the 5.50 % Notes through April 1, 2020 using the effective interest method.

The estimated fair value of the liability component at the date of issuance was determined using valuation models that are complex and subject to judgment. Significant assumptions within the valuation models included an

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implied credit spread, the expected volatility and dividend yield of our common stock and the risk free interest rate for notes with a similar term.

The 5.50% Notes are convertible prior to maturity, subject to certain conditions described below, into shares of our common stock:

Holders may convert all or any portion of their notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the business day immediately preceding January 1, 2020 only under the following circumstances:

on or after the date that is six months after the last date of original issuance of the 5.50% notes, if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending within the five trading days immediately preceding a conversion date is greater than or equal to the conversion price for the notes on each applicable trading day;

during the five business day period after any five consecutive trading day period, the measurement period, in which the trading price per $1,000 principal amount of the 5.50% notes for each trading day of the measurement period was less than 98 % of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

upon the occurrence of specified corporate events.

We will satisfy the conversion obligation by paying or delivering, as the case may be, cash, shares of our common stock or a combination thereof, at our election.

On a quarterly basis, we perform an assessment in order to determine whether the 5.50% Notes have become convertible at the option of the holder, based on meeting any of the conversion criteria described above. Should the 5.50% Notes become convertible, we then assess our intent and ability to settle the 5.50% Notes in cash, shares of common stock, or a combination of cash and shares of common stock.

The 5.50 % Notes include an interest make-whole feature whereby if a noteholder converts any of the 5.50 % Notes prior to April 1, 2018, we will, in addition to the other consideration payable or deliverable in connection with such conversion, make an interest make-whole payment to the converting holder equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the 5.50% Notes to be converted had such notes remained outstanding from the conversion date through April 1, 2018, computed using a discount rate equal to 2%. We have determined that this feature is an embedded derivative and have recognized the fair value of this derivative as a liability in our balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on our statements of operations and comprehensive loss as change in fair value of derivative liabilities. The fair value of this embedded derivative was determined based on a binomial tree lattice model.

Accrued Research and Development Expenses

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

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performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not anticipate the future settlement of existing accruals to differ materially from our estimates.

Income Taxes

Our income tax expense, deferred tax assets and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in Denmark, the United Kingdom and the U.S. 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, 2015, in recognition of this risk, we have provided a valuation allowance of approximately $25.8 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, 2015 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. We are not aware of any such changes that would be expected to have a material effect on our results of operations, cash flows or financial position.

We recognize tax liabilities in accordance with ASC Topic 740 – Tax Provisions 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.

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Results of Operations

Comparison of Years Ended December 31, 2014 and 2015

(in thousands)	Year ended December 31, 2014	2015	Change
Revenues			
Net product sales	$ —	$ 4,184	$ 4,184
Related party revenues	1,920	18,646	16,726
Total revenue	1,920	22,830	20,910
Cost and Expenses			
Cost of sales (excluding amortization of product rights)	—	3,271	3,271
Amortization of product rights	—	1,958	1,958
General and administrative	15,715	26,474	10,759
Sales and marketing	946	16,289	15,343
Research and development	22,395	27,054	4,659
Total costs and expenses	39,056	75,046	35,990
Loss from operations	(37,136)	(52,216)	(15,080)
Other (income) expense:			
Change in fair value of derivative liability	—	(260)	(260)
Interest expense, net	7,079	7,477	398
Other gain	(1,045)	(864)	181
(Gain) loss on foreign currency exchange	(3)	82	85
	6,031	6,435	404
Loss before provision for income taxes	(43,167)	(58,651)	(15,484)
Provision (benefit) for income taxes	47	(718)	(765)
Net loss	$ (43,214)	$ (57,933)	$ (14,719)

Net Product Sales

Net product sales increased from $0 for the year ended December 31, 2014 to $4.2 million for the year ended December 31, 2015. The increase was due to the launch of SPRIX and OXAYDO in 2015.

Related party revenues

Related party revenues increased from $1.9 million for the year ended December 31, 2014 to $18.6 million for the year ended December 31, 2015. The increase was due to the termination of the collaboration agreement with Shionogi which resulted in the recognition of $16.9 million in related party revenues that otherwise would have been classified as deferred revenue as of December 31, 2015 and recognized as revenue over the life of the agreement.

Cost of Sales (excluding Amortization of Product Rights)

Cost of sales (excluding product amortization rights) were $3.3 million for the year ended December 31, 2015 related to the sales of SPRIX and OXAYDO, which began in 2015. The cost of sales in 2015 included $1.6 million related to an inventory write down predominantly due to SPRIX product expiration which was purchased from Luitpold as part of the initial acquisition of the product. The cost of sales for SPRIX (excluding product amortization rights) reflects the fair value of finished goods inventory that was acquired as part of the acquisition and was dispensed to patients during the period. The cost of sales for OXAYDO (excluding product amortization rights) reflects the average costs of inventory dispensed to patients during the period.

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Amortization of Product Rights

Amortization of product rights was $2.0 million for the year ended December 31, 2015 and was comprised of $1.1 million and $903,000 related to intangible assets acquired in the OXAYDO and SPRIX acquisitions, respectively. There was no intangible amortization in 2014.

General and administrative expenses

General and administrative expenses increased by $10.8 million, or 68.5%, from $15.7 million for the year ended December 31, 2014 to $26.5 million for the year ended December 31, 2015. This was primarily attributable to FDA regulatory fees of $3.9 million, increases in salary and benefits of $3.8 million, due to an increase in headcount, as well as professional and administrative fees of $3.9 million as we expanded our operations in 2015. These increases were offset by a decrease in stock compensation expense of $1.1 million due to the timing of restricted stock vesting schedules.

Sales and marketing expenses

Sales and marketing expenses increased by $15.3 million, from $946,000 for the year ended December 31, 2014 to $16.3 million for the year ended December 31, 2015 related to the establishment of the commercial operations in the United States and launch activities for SPRIX and OXAYDO. Expenses for the year ended December 31, 2015 consisted primarily of $8.3 million in salary, benefits and our contract sales force as well as sales and marketing operations for SPRIX and OXAYDO of $4.7 million. Sales and marketing costs were de minimis for 2014.

Research and development expenses

Research and development expenses increased by $4.7 million, or 20.8%, from $22.4 million for the year ended December 31, 2014 to $27.1 million for the year ended December 31, 2015. This increase was driven primarily by an increase in our development costs for EG-002 of $8.2 million and was offset by decrease in ARYMO ER development expenses of $2.8 million and a decrease in stock compensation expense of $2.9 million due to timing of restricted stock vesting schedules.

Change in fair value of derivative liability

The interest make whole provision of the 5.50% Notes is subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations and comprehensive loss as a change in fair value of the derivative liability. The change in the fair value of the derivative liability of $260,000 is due primarily to the decrease in the value of our common stock during the year ended December 31, 2015 following the issuance of the

5.50% Notes. There was no change in derivative liability for the year ended December 31, 2014.

Interest expense, net

Interest expense increased from $7.1 million for the year ended December 31, 2014 to $7.5 million for the year ended December 31, 2015. Interest expense for the year ended December 31, 2014 was primarily attributable to the recognition of the unamortized premium upon conversion of related party senior convertible debt in connection with Egalet's initial public offering in February 2014. Interest expense for the year ended December 31, 2015 was primarily attributable to the interest expense on the 5.50% convertible notes and the Hercules loan, Refer to Note 9 — Long Term Debt in the Notes to our Consolidated Financial Statements, for additional information about our long term debt at December 31, 2015.

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Other gain

Other gain was $1.0 million and $864,000 for the years ended December 31, 2014 and 2015, respectively, and in both years consisted entirely of a Danish research and development tax credit.

(Gain) loss on Foreign Currency Exchange

We recognized a gain on foreign currency exchange of $3,000 during the year ended December 31, 2014 compared to a loss of $82,000 during the year ended December 31, 2015. The change was primarily attributable a change in the average rates of currency in which we transacted during 2014 when compared to 2015.

Provision (benefit) for Income Taxes

We had a provision for income taxes of $47,000 during the year ended December 31, 2014 and a tax benefit of $718,000 during the year ended December 31, 2015. The tax benefit in the year ended December 31, 2015 relates to a state tax benefit associated with the 5.50% Notes.

Comparison of Years Ended December 31, 2013 and 2014

	Year ended December 31,		
	2013	2014	Change
Revenues			
Related party revenues	$ —	$ 1,920	$ 1,920
Total revenue	—	1,920	1,920
Cost and Expenses			
General and administrative	5,095	15,715	10,620
Sales and marketing	—	946	946
Research and development	6,280	22,395	16,115
Total costs and expenses	11,375	39,056	27,681
Loss from operations	(11,375)	(37,136)	(25,761)
Other (income) expense:			
Interest expense, net	8,842	7,079	(1,763)
Other gain	(222)	(1,045)	(823)
(Gain) loss on foreign currency exchange	190	(3)	(193)
	8,810	6,031	(2,779)
Loss before provision for income taxes	(20,185)	(43,167)	(22,982)
Provision for income taxes	22	47	25
Net loss	$ (20,207)	$ (43,214)	$ (23,007)

Related party revenues

Related party 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.

General and administrative expenses

General and administrative expenses increased by $10.6 million, or 208.4%, from $5.1 million for the year ended December 31, 2013 to $15.7 million for the year ended December 31, 2014. The increase was driven primarily by the

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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.

Sales and marketing expenses

Sales and marketing expenses increased were $946,000 for the year ended December 31, 2014 as a result of the formation of a marketing department in the United States to support the growth of our commercialization function. There were no sales and marketing costs for the year ended December 31, 2014.

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 ARYMO ER and Egalet-002 of $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.

Other (gain) loss

Other gain 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 a 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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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 $43.2 million and $57.9 million for the years ended December 31, 2014 and 2015, respectively. Our operating activities used $25.1 million and $36.8 million of cash during the years ended December 31, 2014 and 2015, respectively. At December 31, 2015, we had an accumulated deficit of $134.5 million, a working capital surplus of $121.6 million and cash, cash equivalents and marketable securities totaling $145.7 million.

From our inception and through the completion of our IPO on February 11, 2014, we received gross proceeds of $31.1 million from the issuance of preferred stock and convertible debt.

On February 11, 2014, 4,200,000 shares of our common stock were sold at an 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 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 previous collaboration partner, purchased 1,250,000 shares of our 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, for aggregate gross proceeds of $15.0 million. 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.

In January 2015, we entered the Loan Agreement with Hercules Technology Growth Capital (“Hercules”) and certain other lenders, pursuant to which we borrowed $15.0 million under a term loan. Refer to Note 9 — Long Term Debt in the Notes to our Consolidated Financial Statements, for additional information.

In April 2015, we issued through a private placement $60.0 million in aggregate principal amount of 5.50% Notes due April 1, 2020. On May 6, 2015, we issued an additional $1.0 million in principal amount pursuant to the initial purchasers’ exercise of their 30-day over-allotment for the aggregate gross proceeds of $61.0 million. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year. Refer to Note 9 — Long Term Debt in the Notes to our Consolidated Financial Statements, for additional information.

On July 2, 2015, we entered into a sales agreement to offer shares of our common stock from time to time in an “at-the-market” offering. We may offer and sell shares of common stock for an aggregate offering price of up to $30.0 million. No shares have been sold pursuant to this agreement as of the date of this report.

On July 31, 2015, we completed an underwritten public offering of 7,666,667 shares of common stock (including the exercise in full of the underwriters’ option to purchase additional shares) at an offering price of $11.25 per share for gross proceeds of $86.3 million. The net offering proceeds from the sale were $80.8 million, after deducting

underwriting discounts and commissions of $5.2 million and offering costs of $293,000.

During the year ended December 31, 2015, we had cash outflows related to the purchase of SPRIX and license of OXAYDO of $8.1 million and $7.7 million, respectively. Refer to Note 15 - Acquisitions and License and Collaboration Agreements in the Notes to our Consolidated Financial Statements, for additional information.

Through December 31, 2015 we have also financed our operation with the $4.0 million in payments from our collaborative research and development agreements along with aggregate upfront and milestone payments of $20.0 million from Shionogi under a collaboration agreement.

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Cash Flows

Comparison of Years Ended December 31, 2014 and 2015

The following table summarizes our cash flows for the years ended December 31, 2014 and 2015:

(in thousands)	Year Ended December 31,	
	2014	2015
Net cash (used in) provided by:		
Operating activities	$ (25,074)	$ (38,906)
Investing activities	(3,743)	(119,787)
Financing activities	66,982	152,293
Effect of foreign currency translation on cash	(1,127)	327
Net increase (decrease) in cash	$ 37,038	$ (6,073)

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 $38.9 million for the year ended December 31, 2015 and consisted primarily of a net loss of $57.9 million. These outflows were partially offset by $5.2 million in stock compensation expense, $4.0 million of non-cash interest and debt discount amortization, $3.0 million of noncash depreciation and amortization expense and $7.0 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 accounts payable and accrued expenses of $6.3 million primarily driven by our commercial operations, clinical studies and manufacturing operations, and an increase due to deferred revenue related to the sale of SPRIX and OXAYDO.

Cash Flows from Investing Activities

Net cash used in investing activities for the years ended December 31, 2014 and 2015 was $3.7 million and $119.8 million, respectively. Cash flows for the year ended December 2014 consisted primarily of purchases of property and equipment as well as deposits on future related purchases. Cash outflows for the year ended December 31, 2015 consisted of the purchase of investments for $110.2 million, purchase of SPRIX for $8.1 million, license of OXAYDO for $7.7 million, and payments and deposits for property and equipment of $4.0 million. These outflows were partially offset by inflows from the maturity and sales of investment of $10.2 million.

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 $152.3 million for the year ended December 31, 2015 and consisted of the net proceeds from Hercules Loan Agreement of $14.7 million, net proceeds from the issuance of the 5.50% Notes of $56.7 million and the net proceeds from the July 2015 equity offering of $80.8 million.

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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:

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

Cash Flows from Operating Activities

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.

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.

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 $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.

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.

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Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, commercial infrastructure development, legal and other regulatory expense, business development opportunities and general overhead costs. We expect our cash expenditures to increase in the near term as we continue to grow our commercialization efforts around SPRIX and OXAYDO, and if approved, ARYMO ER, and the clinical development of Egalet-002.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements. 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. We may also seek to raise additional financing through the issuance of debt which, if available, may involve agreements that include restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We believe that our existing capital resources, including the net proceeds from our IPO and the concurrent private placement with Shionogi, our loan agreement with Hercules, the issuance of the 5.50% Notes and our 2015 July 2015 equity offering, will be sufficient to fund our operations at least through December 31, 2016. However, our future operating and capital requirements will depend on many factors, including:

· the results of our clinical trials;

· the costs, timing and outcome of regulatory review;

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

- our ability to establish collaborations or product acquisitions 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.

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Contractual Obligations and Commitments

The following table represents our contractual obligations and commitments as of December 31, 2015.

(in thousands)	Payments Due By Period				
		Less than			More than
	Total	1 year	1 to 3 years	3 to 5 years	5 years
Operating lease obligations(1)	$ 3,302	$ 425	$ 1,156	$ 1,076	$ 645
Hercules debt (2)	17,354	4,724	12,630	—	—
5.50% convertible notes (3)	76,098	3,355	6,710	66,033	—
Other (4)	11	7	4	—	—
Total	$ 96,765	$ 8,511	$ 20,500	$ 67,109	$ 645

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

(2) In January 2015, we entered into the Loan Agreement with Hercules, pursuant to which we borrowed $15.0 million. 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, we 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, we 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. On December 9, 2015, the Company entered into an amendment to the Loan Agreement which provides that the interest-only period of the term loan will be extended for an additional six months to July 1, 2016. The amendment also provides that the interest-only period may be further extended to January 1, 2017, subject to the FDA's acceptance of the Company's new drug application for its product candidate ARYMO ER, formerly known as Egalet-001, the Company's receipt of at least $5 million of product revenue for any consecutive three month period prior to June 30, 2016 and there being no default or event of default under the Loan Agreement.

(3) On April 1, 2015, we issued, through a private placement, $60.0 million in aggregate principal amount of the 5.50% Notes. On May 6, 2015, we issued an additional $1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment for aggregate gross proceeds of $61.0 million. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing October 1, 2015.

(4) 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, commercial 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 SEC rules.

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JOBS Act

As an “emerging growth company” under the JOBS 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.

Interest Rate Risk

We had cash, cash equivalents and marketable securities of $52.7 million and $145.7 million at December 31, 2014 and December 31, 2015, respectively, consisting primarily of funds in cash, money market accounts and corporate debt securities. 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 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 2015 net loss from $57.9 million to $59.0 million, an increase of $1.1 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.

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ITEM 9A. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

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 SEC 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 SEC 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, 2015 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 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 (2013)” 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, 2015, 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

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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 our internal control over financial reporting (as defined in Exchange Act Rule 13a 15(f)) that occurred during year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information with respect to this item will be set forth in the Proxy Statement for the 2015 Annual Meeting of Stockholders ("Proxy Statement") or an amendment to this Annual Report on Form 10-K ("Form 10-K/A") 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 will be set forth in the Proxy Statement or Form 10-K/A under the headings "Executive Compensation" and "Director Compensation," and is incorporated herein by reference. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

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

Information with respect to this item will be set forth in the Proxy Statement or Form 10-K/A under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation," and is incorporated herein by reference. The Proxy Statement of Form 10-K/A 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 will be set forth in the Proxy Statement or Form 10-K/A under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance" and is incorporated herein by reference. The Proxy Statement of Form 10-K/A 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 will be set forth in the Proxy Statement or Form 10-K/A under the heading "Ratification of the Selection of Independent Registered Public Accounting Firm," and is incorporated herein by reference. The Proxy Statement Form 10-K/A 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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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 99.

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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 11, 2016 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 11, 2016
/s/ Stan Musial Stan Musial	Chief Financial Officer (Principal Financial Officer)	March 11, 2016
/s/ Barbara Carlin Barbara Carlin	Chief Accounting Officer (Principal Accounting Officer)	March 11, 2016
/s/ Timothy P. Walbert Timothy P. Walbert	Chairman, Board of Directors	March 11, 2016
/s/ Jean François Formela Jean François Formela	Director	March 11, 2016
/s/ Nicholas Nicolaides Nicholas Nicolaides	Director	March 11, 2016
/s/ John Osborn John Osborn	Director	March 11, 2016
/s/ Gregory Weaver Gregory Weaver	Director	March 11, 2016

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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. (incorporated by reference to Exhibit 2.1 to Egalet Corporation's annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2015).
3.1	Third Amended and Restated Certificate of Incorporation of Egalet Corporation, as amended (incorporated by reference to Exhibit 3.1 to Egalet Corporation's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2015).
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	Indenture dated April 7, 2015 between the Company and The Bank of New York Mellon, as trustee (incorporated by reference to Exhibit 4.1 to the Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2015).
4.2	Registration Rights Agreement, dated as of November 20, 2015, by and among Egalet Corporation and the stockholders party thereto (incorporated by reference to Exhibit 4.1 to the Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on November 27, 2015).
4.3	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)).
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. (incorporated by reference to Exhibit 10.1 to Egalet Corporation's annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2015).
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. (incorporated by reference to Exhibit 10.2 to Egalet Corporation's annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2015).
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. (incorporated by reference to Exhibit 10.3 to Egalet Corporation's annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2015).
10.4	Letter Amendment, dated April 2, 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 (incorporated by reference to Exhibit 10.1 to Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2015).
10.5	Amendment No. 3., dated December 9, 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 (incorporated by reference to Exhibit 10.1 to Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2015).
10.6*	Collaboration and License Agreement, dated as of January 7, 2015, by and among Egalet Corporation, Egalet US, Inc., Egalet Ltd. and Acura Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to

Egalet Corporation's annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2015).

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10.7	Purchase Agreement, dated April 1, 2015, by and among Egalet Corporation and the initial purchasers named therein. (incorporated by reference to Exhibit 10.1 to Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on April 2, 2015).
10.8	Controlled Equity OfferingSM Sales Agreement, dated July 2, 2015, by and between Egalet Corporation and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 to Egalet Corporation's current report on Form 8-K filed with the Securities and Exchange Commission on July 2, 2015).
10.9*	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)).
10.10+	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).
10.11+	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).
10.12+	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).
10.13+	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).
10.14+	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).
10.15+	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).
10.16+	Employment Agreement by and between Egalet Corporation and Paul Varki (filed herewith).
10.17+	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)).
10.18+	Amended & Restated Egalet Corporation 2013 Stock Based Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.2 to Egalet Corporation's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on November 6, 2015).
10.19+	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)).
10.20+	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)).
10.21+	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)).
10.22+	Form of Egalet Corporation Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.2.
10.23	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)).
10.24	Lease Agreement, dated as of November, 30, 2015 by and between Chesterbrook Partners, LP and Egalet US Inc. (filed herewith).
21.1	List of Significant Subsidiaries.
23.1	Consent of Grant Thornton LLP.
23.2	Consent of Ernst & Young 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

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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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Egalet Corporation and Subsidiaries
Audited Financial Statements

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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 sheet of Egalet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2014, and the related consolidated statements of operations, comprehensive loss, changes in convertible preferred stock and stockholders' deficit, and cash flows for the years ended December 31, 2013 and 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, 2014, and the results of their operations and their cash flows for the years ended December 31, 2013 and 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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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Egalet Corporation

We have audited the accompanying consolidated balance sheet of Egalet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2015, and the related consolidated statements of operations, comprehensive loss, changes in convertible preferred stock and stockholders' equity, and cash flows for the year ended December 31, 2015. 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 audit.

We conducted our audit 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 audit 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Egalet Corporation and subsidiaries at December 31, 2015, and the results of its operations and its cash flows for the year ended December 31, 2015 in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG

Philadelphia, PA

March 11, 2016

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Egalet Corporation and Subsidiaries

Consolidated Balance Sheets

(in thousands, except per share data)

	December 31, 2014	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 52,738	$ 46,665
Marketable securities, available for sale	-	99,042
Accounts receivable	-	295
Related party receivable	679	57
Inventory	-	1,837
Prepaid expenses and other current assets	698	1,295
Other receivables	1,011	1,047
Total current assets	55,126	150,238
Intangible assets, net	184	10,380
Property and equipment, net	4,417	7,801
Deposits and other assets	843	3,997
Total assets	$ 60,570	$ 172,416
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	$ 4,209	$ 7,417
Accrued expenses	2,554	7,616
Deferred revenue	588	10,128
Debt - current	-	3,320
Other current liabilities	78	183
Total current liabilities	7,429	28,664
Debt - non-current portion, net	-	52,442
Deferred income tax liability	25	1,084
Deferred revenue - non-current portion	8,855	-
Derivative liability	-	656
Other liabilities	-	348
Total liabilities	16,309	83,194
Commitments and contingencies (Note 13)		
Stockholders’ equity		
Common stock--$0.001 par value; 75,000,000 shares authorized at December 31, 2014 and 2015; 17,283,663 and 25,085,554 shares issued and outstanding at December 31, 2014 and 2015, respectively	17	25
Additional paid-in capital	121,028	223,784
Accumulated other comprehensive loss	(171)	(41)
Accumulated deficit	(76,613)	(134,546)
Total stockholders' equity	44,261	89,222
Total liabilities and stockholders’ equity	$ 60,570	$ 172,416

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

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Egalet Corporation and Subsidiaries

Consolidated Statements of Operations

(in thousands, except per share data)

	Year Ended December 31,		
	2013	2014	2015
Revenues			
Net product sales	$ —	$ —	$ 4,184
Related party revenues	—	1,920	18,646
Total revenue	—	1,920	22,830
Cost and Expenses			
Cost of sales (excluding amortization of product rights)	—	—	3,271
Amortization of product rights	—	—	1,958
General and administrative	5,095	15,715	26,474
Sales and marketing	—	946	16,289
Research and development	6,280	22,395	27,054
Total costs and expenses	11,375	39,056	75,046
Loss from operations	(11,375)	(37,136)	(52,216)
Other (income) expense:			
Change in fair value of derivative liability	—	—	(260)
Interest expense, net	8,842	7,079	7,477
Other gain	(222)	(1,045)	(864)
(Gain) loss on foreign currency exchange	190	(3)	82
	8,810	6,031	6,435
Loss before provision (benefit) for income taxes	(20,185)	(43,167)	(58,651)
Provision (benefit) for income taxes	22	47	(718)
Net loss	$ (20,207)	$ (43,214)	$ (57,933)
Per share information:			
Net loss per share of common stock, basic and diluted	$ (15.64)	$ (2.97)	$ (2.94)
Weighted-average shares outstanding, basic and diluted	1,292,307	14,556,927	19,738,042

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

(in thousands)

	Year Ended December 31,		
	2013	2014	2015
Net loss	$ (20,207)	$ (43,214)	$ (57,933)
Other comprehensive income (loss):			
Unrealized gain (losses) on available for sale securities	-	-	(147)
Foreign currency translation adjustments	854	(1,296)	277
Comprehensive loss	$ (19,353)	$ (44,510)	$ (57,803)

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) Equity

(in thousands, except per share data)

Convertible Preferred Stock								Stockholders' (Deficit) Equity		
	Series A-2		Series B		Series B-1			Common Stock		
Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Total	Number of Shares	$0.001 Par Value	Additional Paid-in Capital
1,443	593,106	770	2,327,301	12,628	113,916	116	14,957	1,292,307	13	1,610
—	—	—	—	—	—	—	—	—	—	5,000
—	—	—	—	—	—	—	—	—	—	1,478
—	—	—	—	—	—	—	—	—	—	(657)
—	—	—	—	—	—	—	—	—	—	—
—	—	—	—	—	—	—	—	—	—	—
1,443	593,106	770	2,327,301	12,628	113,916	116	14,957	1,292,307	13	7,431
—	—	—	—	—	—	—	—	2,585,745	3	24,710
—	—	—	—	—	—	—	—	600,000	1	(1)
—	—	—	—	—	—	—	—	4,830,000	5	51,458

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4)	(1,443)	(593,106)	(770)	(2,327,301)	(12,628)	(113,916)	(116)	(14,957)	5,329,451	(7)	14,964	—
	—	—	—	—	—	—	—	—	1,250,000	1	13,949	—
	—	—	—	—	—	—	—	—	1,396,160	1	(1)	—
	—	—	—	—	—	—	—	—	—	—	8,518	—
	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	(43,
	—	—	—	—	—	—	—	—	17,283,663	17	121,028	(76,
	—	—	—	—	—	—	—	—	—	—	329	—
	—	—	—	—	—	—	—	—	61,644	—	—	—
	—	—	—	—	—	—	—	—	75,000	—	—	—
	—	—	—	—	—	—	—	—	(13,920)	—	—	—
	—	—	—	—	—	—	—	—	7,666,667	8	80,775	—
	—	—	—	—	—	—	—	—	—	—	16,341	—
	—	—	—	—	—	—	—	—	12,500	—	112	—
	—	—	—	—	—	—	—	—	—	—	5,199	—
	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	—
	—	—	—	—	—	—	—	—	—	—	—	(57,

$	—	—	$	—	—	$	—	—	$	—	—	25,085,554	$	25	$	223,784	$	(134

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

(in thousands)

	Year Ended December 31,		
	2013	2014	2015
Operating activities:			
Net loss	$ (20,207)	$ (43,214)	$ (57,933)
Adjustment to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	483	641	3,014
Change in fair value of derivative liability	—	—	(260)
Stock-based compensation expense	—	8,518	5,199
Noncash interest and amortization of debt discount	8,431	6,987	3,957
Amortization of premium on marketable securities	—	—	829
Deferred income taxes	22	6	(718)
Changes in assets and liabilities:			
Related party receivable	34	(744)	563
Accounts receivable	—	—	(295)
Inventory	—	—	1,571
Prepaid expenses and other current assets	350	(540)	(631)
Other receivables	99	(883)	(144)
Deposits and other assets	(7)	—	(2,050)
Accounts payable	(378)	3,268	1,147
Accrued expenses	706	1,412	5,123
Deferred revenue	10,000	(557)	1,485
Other current liabilities	34	32	116
Other liabilities	—	—	121
Net cash used in operating activities	(433)	(25,074)	(38,906)
Investing activities:			
Payments for purchase of property and equipment	(1,791)	(2,889)	(2,747)
Deposits for purchases of property and equipment	—	(854)	(1,223)
Purchases of investments	—	—	(110,216)
Sales of investments	—	—	3,400
Maturity of investments	—	—	6,799
Purchase of SPRIX	—	—	(8,128)
License of OXAYDO	—	—	(7,672)
Net cash used in investing activities	(1,791)	(3,743)	(119,787)
Financing activities:			
Net proceeds from issuance of common stock	—	66,982	80,896
Payment of deferred financing fees	(1,443)	—	—
Net proceeds from debt	15,000	—	71,397
Net cash provided by financing activities	13,557	66,982	152,293
Effect of foreign currency translation on cash and cash equivalents	963	(1,127)	327
Net increase (decrease) in cash and cash equivalents	12,296	37,038	(6,073)
Cash at beginning of period	3,404	15,700	52,738
Cash at end of period	$ 15,700	$ 52,738	$ 46,665

Supplemental disclosures of cash flow information:			
Non-cash purchases of property and equipment	$ (62)	$ —	$ 2,084
Non-cash financing activities:			
Gain (loss) on extinguishment of debt	$ (657)	$ —	$ —
Beneficial conversion features	$ 5,000	$ —	$ —
Issuance of warrants	$ —	$ —	$ 329
Cash interest payments	$ —	$ —	$ 3,461
Conversion of convertible preferred stock	$ —	$ 14,957	$ —
Conversion of related party convertible debt	$ —	$ 24,713	$ —

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, 2013, 2014 and 2015

1. Organization and Description of the Business

Egalet Corporation (the "Company") is a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative treatments for pain and other conditions. 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 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 discourage 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 HCl, USP) tablets for oral use only, —CII, both approved by the United States ("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 an immediate-release ("IR") oral formulation of oxycodone HCl indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. OXAYDO is the first and only approved IR oxycodone product formulated to discourage abuse via snorting. In addition, using its proprietary Guardian™ Technology, the Company is developing a pipeline of clinical-stage, opioid-based product candidates, as well as a stimulant product candidate, 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 patents and filed patent applications to protect its inventions covering both the Guardian technology and its products.

Stock Offerings

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"), 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, 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

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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.

Follow On Offering

On July 31, 2015, the Company completed an underwritten public offering (the “Follow-On Offering”) of 7,666,667 shares of common stock (including the exercise in full of the underwriters’ option to purchase additional shares) at an offering price of $11.25 per share for gross proceeds of $86.3 million. The net offering proceeds to the Company from the sale were $80.8 million, after deducting underwriting discounts and commissions of $5.2 million and offering costs of $293,000.

At the Market Offering

On July 2, 2015, the Company entered into a sale agreement with Cantor Fitzgerald & Co. (“Cantor”) to offer shares of the Company’s common stock from time to time through Cantor, as the Company’s sales agent for the offer and sale of the shares, in an “at-the-market” offering. The Company may offer and sell shares of common stock for an aggregate offering price of up to $30.0 million.

Liquidity

The Company has incurred recurring operating losses since inception. As of December 31, 2015, the Company had an accumulated deficit of $134.5 million and will require substantial additional capital to fund its research and development of its proprietary product candidates and commercialization strategies for SPRIX and OXAYDO. The Company reasonably expects that its cash and cash equivalents and marketable securities at December 31, 2015, will enable it to fund its operating expenses and capital expenditure requirements at least through December 31, 2016. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research and development of its preclinical and clinical product candidates, and the development of its administrative organization. As the Company continues to incur losses, a transition to profitability is dependent upon the successful commercialization of its approved products, 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, until profitability is achieved, if ever. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

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.

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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 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, revenue recognition, useful lives of assets, accrued research and development expenses, the outcome of litigation, convertible debt, share-based payments, 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 performance. As of December 31, 2015, long lived assets based upon geographic location were located in both the United States and Europe, with a net book value of $6.9 million and $949,000 respectively. For the year ended December 31, 2014 revenue based upon geographic location was derived substantially from Europe. For the year ended December 31, 2015 revenue from product sales was derived entirely from the United States, while related party revenue was derived entirely 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 and investments in marketable securities. The Company maintains its cash balances in accounts with financial institutions that management believes are creditworthy. The Company invests cash that is not currently being used for operational purposes in accordance with its investment policy. The policy allows for the purchase of low-risk debt securities issued by U.S. government agencies and very highly rated corporations, subject to certain concentration limits. The Company believes its established guidelines for investment of its excess cash maintain safety and liquidity through its policies on diversification and investment maturity.

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Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash balances of $36.0 million and $10.7 million are maintained at financial institutions in the United States and Denmark, respectively, at December 31, 2015. Bank deposits are insured up to approximately $250,000 and $122,000 for U.S. and Danish financial institutions, respectively. The Company had uninsured cash balances at December 31, 2014 and 2015 of approximately $52.1 million and $45.7 million, respectively.

Marketable Securities, Available-for-Sale

Marketable securities consist of securities with original maturities greater than three months, and are comprised of securities issued by U.S. government agencies and corporate debt securities. Marketable securities have been classified as current assets in the accompanying Consolidated Balance Sheets based upon the nature of the securities and their intended use to fund operations.

Management determines the appropriate classification of securities at the time of purchase. The Company has classified its investment portfolio as available-for-sale in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 320, Investments—Debt and Equity Securities. The Company's available-for-sale securities are carried at fair value with unrealized gains and losses reported in other comprehensive income (loss). Realized gains and losses are determined using the specific identification method and are included in interest expense. Marketable securities are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, then the carrying amount of the investment is written down to fair value and the write-down is included in the Consolidated Statements of Comprehensive Loss as a loss.

Fair Value Measurements

The carrying amounts reported in the Company's consolidated financial statements for cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. The carrying value of the derivative liabilities are the estimated fair value of the liability as further described in Note 4 – Fair value measurements.

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.

Financial assets that we measure at fair value on a recurring basis include cash equivalents and marketable securities. These financial assets are generally classified as Level 1 or 2 within the fair value hierarchy. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices (adjusted), interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The fair value hierarchy level is determined by the lowest level of significant input.

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The Company's financial assets have been initially valued at the transaction price and subsequently valued at the end of each reporting period, typically utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. The Company did not adjust or override any fair value measurements provided by its pricing services as of December 31, 2015 and December 31, 2014.

During the years ended December 31, 2015 and 2014, there were no transfers between Level 1 and Level 2 financial assets. We did not have any non-recurring fair value measurements on any assets or liabilities at December 31, 2015 and December 31, 2014.

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.

Stock-Based Compensation

We use the Black-Scholes valuation model in determining the fair value of equity awards. For stock options granted to employees and directors with only service-based vesting conditions, we measure stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the requisite service period on a straight-line basis. We record the expense of services rendered by non-employees based on the estimated fair value of the stock option as of the respective vesting date. Further, we expense the fair value of non-employee stock options that contain only service-based vesting conditions over the requisite service period of the underlying stock options. Stock-based compensation expense is determined including estimated forfeitures, and is adjusted each period to reflect actual forfeitures.

The fair value for restricted stock awards is determined based on the closing market price of our common stock on the grant date of the awards. The expense is recognized over the requisite service period on a straight-line basis.

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 and Long Lived Assets

Intangible assets consists of in process research and development ("IPR&D") and product rights. IPR&D is 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

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operations. For those product candidates that reach commercialization, the IPR&D asset will be amortized over its estimated useful life.

Long-lived intangible assets acquired as part of the SPRIX acquisition and OXAYDO license are being amortized on a straight-line basis over their estimated useful lives of 5 and 7 years respectively. The Company estimated the useful life of the assets by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of the life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review.

The Company assesses the recoverability of its long lived assets, which include property and equipment and product rights whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset and a charge to operating results. For the years ended December 31, 2014 and 2015, the Company determined that there was no impairment of its intangible and other long lived assets.

Revenue Recognition

During 2013, the Company entered into a collaborative research and license agreement with Shionogi. The agreement contains multiple deliverables which may include (i) licenses, (ii) research and development activities, and (iii) royalty and related commissions. Revenue is recognized when the Company has satisfied our service obligations under a written contract with the Company's 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. The Company has 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, the Company considers 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.

Net Product Sales

The Company recognizes revenue in accordance with FASB ASC 605, Revenue Recognition, when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable and collectability is reasonably assured. The Company determines that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. Pursuant to the contract terms, the Company determines when title to products and associated risk of loss has passed on to the customer. The Company assesses whether the price is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. The Company assesses collectability based primarily on the customer's payment history and creditworthiness.

The Company sells SPRIX in the United States to a single specialty pharmaceutical distributor subject to rights of return. The Company has limited SPRIX sales history under the current distribution model and pricing, and the Company has determined that at this time it cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of SPRIX until the right of

return no longer exists, which occurs at the earlier of the time SPRIX units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. The Company calculates patient prescriptions dispensed using an analysis of third-party information. As of December 31, 2015, the Company had deferred revenue of $9.6 million related to sales of SPRIX to its specialty pharmaceutical distributor. In the event the related units are not dispensed pursuant to patient prescriptions prior to their expiration in April and May of 2016, they may be returned to the Company for replacement product.

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The Company sells OXAYDO in the U.S. to several wholesalers, all subject to rights of return. The Company has limited OXAYDO sales history under the current distribution model and pricing, and has determined that at this time it cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of OXAYDO until the right of return no longer exists, which occurs at the earlier of the time OXAYDO units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. The Company calculates patient prescriptions dispensed using an analysis of third-party information. As of December 31, 2015, the Company had deferred revenue of $526,000 related to sales of OXAYDO to the wholesalers.

Product Sales Allowances

The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company's agreements with customers and third-party payors that may result in future rebates or discounts taken. In certain cases, such as patient discount programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company's product sales allowances include:

Specialty Pharmacy Discounts. The Company offers a discount to a certain specialty pharmaceutical distributor based on a contractually determined rate. The Company accrues the discount on shipment to the respective distributor and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. The Company offers co-pay discount programs for SPRIX and OXAYDO to patients, in which patients receive a co-pay discount on their prescriptions. The Company estimates the total amount that will be redeemed based on the quantity of product shipped and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Inventories and Cost of Sales

Inventories are stated at the lower of cost or market net of reserve for excess and obsolete inventory. At December 31, 2015, inventory consisted of raw materials, work in process, finished goods and deferred cost of goods.

Cost of sales includes the cost of inventory sold or reserved, which includes manufacturing and supply chain costs, product shipping and handling costs, and product royalties. The cost of sales associated with the deferred product revenues are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized.

Long Term Debt

Long term debt consists of the Loan Agreement with Hercules Technology Growth Capital, Inc. and certain other lenders, and the 5.50% convertible senior notes due April 1, 2020 (the "5.50% Notes").

Pursuant to the Loan Agreement with Hercules, the Company borrowed $15.0 million in January 2015 under a term loan (see Note 9 – Long term debt). 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%. On December 9, 2015, the Company entered into an amendment to the Loan Agreement which provides that the interest-only period of the term loan will be extended for an additional six months to July 1, 2016. The amendment also provides that the interest-only

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period may be further extended to January 1, 2017, subject to the FDA's acceptance of the Company's new drug application for its product candidate ARYMO ER, formerly known as Egalet-001, the Company's receipt of at least $5 million of product revenue for any consecutive three month period prior to June 30, 2016 and there being no default or event of default under the Loan Agreement.

On April 1, 2015, the Company issued the 5.50% notes through a private placement, which consisted of $60.0 million in aggregate principal amount. On May 6, 2015, the Company issued an additional $1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment, for aggregate gross proceeds of $61.0 million. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year. Refer to Note 9 - Long term debt for additional information.

Interest Make-Whole Derivative

The 5.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the 5.50% Notes prior to April 1, 2018, subject to certain restrictions, they are entitled, in addition to the other consideration payable or deliverable in connection with such conversion, to an interest make-whole payment equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the notes to be converted had such notes remained outstanding from the conversion date through April 1, 2018, computed using a discount rate equal to 2%. The Company has determined that this feature is an embedded derivative and have recognized the fair value of this derivative as a liability on the Company's balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's statements of operations and comprehensive loss as change in fair value of derivative liabilities. The fair value of this embedded derivative was determined based on a binomial tree lattice model.

Common Stock Warrants

The Company issued warrants to Hercules in connection with the Loan Agreement with Hercules and certain other lenders. The Company evaluated the warrants under ASC 480 - Distinguishing Liabilities from Equity and determined the warrants are classified as equity. The fair value of the warrants on the date of grant was recorded as a debt discount. On August 3, 2015, Hercules exercised the warrant in full, electing the net issuance option. As a result, the Company issued 61,644 shares of the Company's common stock to Hercules.

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

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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.

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 Loss within the Company's Consolidated Balance Sheets.

Comprehensive Loss

Comprehensive loss is defined as changes in stockholders’ equity exclusive of transactions with owners (such as capital contributions and distributions). Comprehensive loss is comprised of net loss, foreign currency translation gains or losses and unrealized gains or losses on marketable securities classified as available for sale.

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, 2014 and 2015, and there were no such interest or penalties recognized during the year ended December 31, 2014 and 2015.

Clinical Trial Expense Accruals

As part of the process of preparing its consolidated financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company’s objective is to reflect the appropriate trial expenses in its consolidated financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company’s clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third party vendors. Although the Company does not

expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2014 and 2015, there were no material adjustments to the Company’s prior period estimates of accrued expenses for clinical trials.

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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. 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 common stock options and warrants outstanding during the period calculated in accordance with the treasury stock method, plus the potential dilutive effects of the 5.50% Notes using the if converted method. 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, 2014 and 2015.

Customer Concentration

For the year ended December 31, 2015, the Company had two significant customers that accounted for the majority of consolidated total revenues as follows:

Customer A	81.7%
Customer B	17.1%
Total	98.8%

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”). The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will have.

On April 7, 2015, the FASB issued ASU 2015-03,1 Interest — Imputation of Interest which changes the presentation of debt issuance costs in financial statements. Under the ASU, an entity presents such costs in the balance sheet as a direct deduction from the related debt liability rather than as an asset. Amortization of the costs is reported as interest expense. The Company adopted this standard during the second quarter of 2015 and as a result reclassified $171,000 in deferred financing fees associated with the Hercules Loan Agreement to debt discount.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities (“ASU 2016-1”), which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2017 and early adoption is not permitted. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will have.

In November 2015, the FASB issued ASU 2015-17, Income Taxes: Balance Sheet Classification of Deferred Taxes. ASU 2015-17 simplifies the balance sheet classification of deferred taxes and requires that all deferred taxes be presented as noncurrent. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016 with early adoption permitted. The adoption of this update is not expected to have a material effect on the Company's financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern. ASU 2014-15 requires management of all entities to evaluate whether there are conditions and events that raise substantial

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doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued, and to make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 is effective for the Company for annual reporting periods beginning in 2016 and for interim reporting periods starting in the first quarter of 2017. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will have.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. ASU 2014-09 will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance, including industry-specific guidance. The guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods therein. The Company is evaluating ASU 2014-09 and has not yet determined what, if any, effect ASU 2014-09 will have on its results of operations or financial condition.

3. Investments

Marketable securities consisted of the following as of December 31, 2015:

(in thousands)	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	$ 99,189	$ —	$ (147)	$ 99,042
Total	$ 99,189	$ —	$ (147)	$ 99,042

At December 31, 2015, the Company held 49 marketable securities, all of which were in a continuous loss position for less than one year. The unrealized losses are the result of current economic and market conditions and the Company has determined that only a temporary impairment exists at December 31, 2015.

The Company had no marketable securities at December 31, 2014.

The fair value of marketable securities with a maturity of less than one year is $75.9 million. The fair value of marketable securities with a maturity of greater than one year is $23.1 million.

4. Fair Value Measurements

The Company measures certain assets and liabilities at fair value in accordance with ASC 820, Fair Value Measurements and Disclosures. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

· Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

· Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

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· Level 3—Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

The following fair value hierarchy table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis:

(in thousands)	Fair Value Measurements as of December 31,			
	Level 1	Level 2	Level 3	Balance as of December 31, 2015
Assets				
Cash equivalents (money market funds)	$ 29,992	$ —	$ —	$ 29,992
Marketable securities, available-for-sale	—	99,042	—	99,042
Total assets	$ 29,992	$ 99,042	$ —	$ 129,034
Liabilities				
Interest make-whole derivative	$ —	$ —	$ 656	$ 656
Total liabilities	$ —	$ —	$ 656	$ 656

(in thousands)	Fair Value Measurements as of December 31, 2014			
	Level 1	Level 2	Level 3	Balance as of December 31, 2014
Assets				
Cash equivalents (money market funds)	$ 45,011	$ —	$ —	$ 45,011
Marketable securities, available-for-sale	—	—	—	—
Total assets	$ 45,011	$ —	$ —	$ 45,011

There were no financial liabilities subject to fair value measurement on a recurring basis at December 31, 2014.

The 5.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the 5.50% Notes prior to April 1, 2018, the Company will, in addition to the other consideration payable or deliverable in connection with such conversion, make an interest make-whole payment to the converting holder equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the notes to be converted had such notes remained outstanding from the conversion date through April 1, 2018, computed using a discount rate equal to 2%. The Company has determined that this feature is an embedded derivative and has recognized the fair value of this derivative as a liability in the Company’s balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company’s statements of operations and comprehensive loss as change in fair value of derivative liabilities. The fair value of this embedded derivative was determined based on a

binomial tree lattice model.

The following tables set forth a summary of changes in the fair value of Level 3 liabilities for the year ended December 31, 2015:

(in thousands)	December 31, 2014	Additions	Fair Value Change in 2015	December 31, 2015
Interest make-whole derivative	—	$ 916	$ (260)	$ 656
Total liabilities	$ —	$ 916	$ (260)	$ 656

As of December 31, 2015, the fair value of our convertible debt, was estimated utilizing the binomial lattice tree model. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value measurement was based on several factors including:

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Credit spread at the valuation date

Discount yield as of the valuation date

The fair value and carrying value of the Company's 5.50% Notes at December 31, 2015 were as follows:

(in thousands)	Fair Value	Carrying Value	Face Value
5.50% Notes due April 1, 2020	$ 38,573	$ 41,266	$ 61,000

The fair value of the Company's Hercules Term Loan approximates its carrying value of $14.5 million as the interest rate is reflective of the interest rates on debt we could currently obtain with similar terms and conditions.

There were no items that were accounted for at fair value on a non-recurring basis for the years ended December 31, 2015 and 2014.

5. Inventory

Inventory is stated at the lower of cost or market using actual cost net of reserve for excess and obsolete inventory. The following represents the components of inventory at December 31, 2015. There was no inventory at December 31, 2014.

(in thousands)	December 31, 2015
Raw materials	$ 589
Work in process	349
Finished goods	230
Deferred cost of sales	669
Total	$ 1,837

During the year ended December 31, 2015 the Company recorded a reserve for excess and obsolete inventory of $1.6 million.

6. Property and Equipment

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

(in thousands)	December 31,	
	2014	2015
Laboratory and manufacturing equipment	$ 6,879	$ 7,286
Furniture, fixtures and other property	827	912
Construction in process	—	3,585
Less accumulated depreciation	(3,289)	(3,982)
Property and equipment, net	$ 4,417	$ 7,801

Depreciation expense was $641,000 and $1.1 million for the years ended December 31, 2014 and 2015, respectively.

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7. Intangible Assets

The following represents the balance of the intangible assets at December 31, 2015:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	$ 7,552	$ (1,055)	$ 6,497	6.00
SPRIX product rights	4,620	(903)	3,717	4.00
IP R&D	166	—	166	Indefinite
Total	$ 12,338	$ (1,958)	$ 10,380	

The following represents the balance of the intangible assets at December 31, 2014:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
IP R&D	$ 184	—	$ 184	Indefinite
Total	$ 184	$ —	$ 184	

There was no impairment to intangible assets recognized in the years ended December 31, 2014 and 2015.

Estimated amortization for the five years subsequent to December 31, 2015 is as follows:

(in thousands)	
2016	$ 2,003
2017	$ 2,003
2018	$ 2,003
2019	$ 2,003
2020	$ 1,100

Collaboration and License Agreement with Acura

In January 2015, the Company entered into a Collaboration and License Agreement with Acura Pharmaceuticals, Inc. (“Acura”) to commercialize OXAYDO™ (oxycodone hydrochloride) tablets containing Acura’s Aversion® Technology.

The Company paid Acura an upfront payment of $5.0 million in January 2015 and a $2.5 million milestone in October 2016 as a result of the first commercial sale of OXAYDO. The Company also incurred transaction costs of $172,000 associated with the transaction. Refer to Note 15 — Acquisitions and license and collaboration agreements for additional details.

During the year ended December 31, 2015, the Company recognized amortization expense of $1.1 million related to the OXAYDO product right intangible. There was no amortization expense recognized in 2014 related to OXAYDO.

Purchase Agreement with Luitpold

In January 2015, the Company entered into and consummated a purchase agreement with Luitpold Pharmaceuticals, Inc. (“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 $7.0 million. The Company recorded an intangible asset of $4.6 million related to this transaction. Refer to Note 15 – Acquisitions and license and collaboration agreements for additional details.

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During the year ended December 31, 2015, the Company recognized amortization expense of $903,000 related to the SPRIX product rights intangible asset. There was no amortization expense recognized in 2014 related to SPRIX.

IP R&D

In connection with the acquisition of Egalet A/S, the Company recognized an IP R&D asset related to the drug delivery platform specifically designed to help deter physical abuse of pain medications. The IP R&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, 2014 and December 31, 2015, the carrying value of IP R&D was $184,000, and $166,000, respectively. The change in value was entirely due to fluctuation in foreign currency exchange rates.

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8. Accrued Expenses

Accrued expenses were as follows:

(in thousands)	December 31,	
	2014	2015
Payroll	$ 1,078	$ 2,363
Manufacturing services	—	1,680
Marketing and sales	—	1,148
Interest	—	962
Clinical research	970	787
Professional services	304	334
Sales allowances	—	296
Other	202	46
	$ 2,554	$ 7,616

9. Long Term Debt

Hercules Loan and Security Agreement

In January 2015, the Company entered into the Loan Agreement with Hercules and certain other lenders, pursuant to which the Company borrowed $15.0 million under a term loan. 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 beginning on February 1, 2015, and then repay the principal balance of the loan in 30 equal monthly payments of principal and interest through the scheduled maturity date of 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. At December 31, 2015 the interest rate on the loan was 9.65%.

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

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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 considered a standalone instrument since it may be exercised separately from the Loan Agreement. The Warrant is exercisable for a period of five years beginning on the date of issuance and has a fair value of $328,610 that is included in stockholders' equity. The fair value of the Warrant was recorded as a debt discount and was determined through the use of a Black-Scholes calculation using the below assumptions:

Risk-free interest rate	1.5 %
Expected term (in years)	5
Expected volatility	71.68%
Dividend yield	—

On August 3, 2015, Hercules exercised the warrant in full, electing the net issuance option. As a result, the Company issued 61,644 shares of the Company's common stock to Hercules.

On December 9, 2015, the Company entered into an amendment (the "Amendment") to the Loan agreement which, among other things, provides that the interest-only period of the term loan will be extended for an additional six months to July 1, 2016. The Amendment also provides that the interest-only period may be further extended to January 1, 2017, subject to the FDA's acceptance of the Company's new drug application for its product candidate ARYMO ER, formerly known as Egalet-001, the Company's receipt of at least $5.0 million of product revenue for any consecutive three month period prior to June 30, 2016 and there being no default or event of default under the Loan Agreement.

5.50% Convertible Senior Notes Due 2020

On April 7, 2015, the Company completed the issuance through a private placement of $60.0 million in aggregate principal amount of the 5.50% Notes. On May 6, 2015, the Company issued an additional $1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment for aggregate gross proceeds of $61.0 million. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing October 1, 2015.

The 5.50% Notes are general, unsecured and unsubordinated obligations and will rank senior in right of payment to all of the Company's indebtedness that is expressly subordinated in right of payment to the notes. The 5.50% Notes rank equal in right of payment to the Company's existing and future indebtedness and other liabilities that are not so subordinated. The 5.50% Notes are effectively subordinated to any of the Company's future secured indebtedness to the extent of the value of the assets securing such indebtedness, and rank structurally junior to all indebtedness and other liabilities incurred by the Company's subsidiaries, including trade payables.

The 5.50% Notes are effectively junior to the $15.0 million principal amount of secured indebtedness outstanding under the Senior Secured Loan Agreement with Hercules and certain other lenders, to the extent of the value of the assets securing such indebtedness.

The Company may not redeem the 5.50% Notes prior to maturity. The 5.50% Notes are convertible prior to maturity, subject to certain conditions described below, into shares of the Company's common stock at an initial conversion rate of 67.2518 shares per $1,000 principal amount of the 5.50% Notes (equivalent to an initial conversion price of approximately $14.87 per share of common stock). This conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. The Company will satisfy the conversion obligation by paying or delivering, as the case may be, cash, shares of the Company's common stock or a combination thereof, at the Company's election.

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Holders may convert all or any portion of their notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the business day immediately preceding January 1, 2020 only under the following circumstances:

on or after the date that is six months after the last date of original issuance of the notes, if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending within the five trading days immediately preceding a conversion date is greater than or equal to the conversion price for the notes on each applicable trading day;

during the five business day period after any five consecutive trading day period, the measurement period in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day; or

upon the occurrence of specified corporate events.

On or after January 1, 2020 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

The conversion rate for the 5.50% notes is initially 67.2518 shares of common stock per $1,000 principal amount of notes (equivalent to an initial conversion price of approximately $14.87 per share of common stock), subject to adjustment.

Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of the Company's common stock, at the Company's election, and an interest make-whole payment in shares of the common stock, if applicable. If the Company satisfies the conversion obligation solely in cash or through payment and delivery, as the case may be, of a combination of cash and shares common stock, the amount of cash and shares of common stock, if any, due upon conversion will be based on a daily conversion value calculated on a proportionate basis for each trading day in a 50 trading day observation period.

In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its notes in connection with such a corporate event in certain

circumstances. Holders will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, interest will be deemed to be paid by the cash, shares the Company's common stock or a combination of cash and shares of the Company's common stock paid or delivered, as the case may be, to the holders upon conversion of a note.

On or after the date that is six months after the last date of original issuance of the notes, if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending within the five trading days immediately preceding a conversion date is greater than or equal to the conversion price for the notes on each applicable trading day, the Company will, in addition to the other consideration payable or deliverable in connection with such conversion, make an interest make-whole payment to the converting holder equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the notes to be converted had such notes remained outstanding from the conversion date through April 1, 2018, computed using a discount rate equal to 2%. The Company will pay any interest make-whole payment by delivering shares of the Company's common stock valued at 95% of the simple average of the daily volume weighted average price for the 10 trading days ending on and including the trading day immediately preceding the conversion date. Notwithstanding the foregoing, the number of shares the Company may deliver in connection with a conversion of the notes, including those delivered in connection with an interest make-whole payment, will not exceed 77.3395 shares of common stock per $1,000 principal amount of notes, subject to adjustment. The Company will not be required to make any cash payments in lieu of any fractional shares or have any further obligation to deliver any shares of common

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stock or pay any cash in excess of the threshold described above. In addition, if in connection with any conversion the conversion rate is adjusted, then such holder will not receive the interest make-whole payment with respect to such note.

The Company accounts for convertible debt instruments by recording the liability and equity components of the convertible debt separately. The liability is computed based on the fair value of a similar debt instrument that does not include the conversion option. The liability component includes both the value of the embedded interest make-whole derivative and the carrying value of the 5.50% Notes. The equity component is computed based on the total debt proceeds less the fair value of the liability component. The equity component is also recorded as debt discount and amortized as interest expense over the expected term of the 5.50% Notes, using the effective interest method.

The liability component of the 5.50% Notes on the date of issuance was computed as $41.6 million, including the value of the embedded interest make-whole derivative of $0.9 million and the carrying value of the 5.50% Notes of $40.6 million. Accordingly, the equity component on the date of issuance was $19.4 million. The discount on the 5.50% Notes is being amortized to interest expense over the term of the Notes, using the effective interest method.

The conversion criteria for the 5.50% Notes have not been met at December 31, 2015. Should the Notes become convertible, management will determine whether the intent is to settle in cash which would result in the liability component of the convertible notes being classified as a current liability and the equity component being presented as redeemable equity if the liability is considered current.

Transaction costs of $4.1 million related to the issuance of the 5.50% Notes are allocated to the liability and equity components in proportion to the allocation of the proceeds and accounted for as debt discount and equity issuance costs, respectively. Approximately $1.3 million of this amount was allocated to equity and the remaining $2.8 million was recorded as debt discount.

The following table summarizes how the issuance of the 5.50% Notes is reflected in the Company’s balance sheet at December 31, 2015:

(in thousands)	December 31, 2015
Gross proceeds	$ 61,000
Unamortized debt discount	(19,734)
Carrying value	$ 41,266

The following table sets forth the Company's net interest expense incurred for the year ended December 31, 2015:

(in thousands)	Year Ended December 31, 2015
Hercules Loan and Security Agreement	$ 2,005
5.50% Senior Convertible Notes	5,865
Amortization of premium on marketable securities	832
Interest income on investments	(1,225)
Total	$ 7,477

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There was no interest expense from long term debt in 2014.

The following table sets forth the Company's future principal payments:

(in thousands)	
2016	$ 3,320
2017	7,149
2018	4,531
2019	—
2020	61,000

10. 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. In September 2015, the Compensation Committee of the Board of Directors voted to amend the Plan to, among other things, allow for monthly vesting of options granted thereunder.

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Shares Reserved for Future Issuance

As of December 31, 2015, 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 granted	(1,832,593)
Restricted stock awards granted	(1,457,240)
Stock options and awards forfeited	78,205
Remaining shares available for future issuance	468,372

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:

(in thousands)	Year Ended December 31,	
	2014	2015
Research and development	$ 3,348	$ 932
General and administrative	5,170	4,049
Sales and marketing	—	218
Total stock-based compensation expense	$ 8,518	$ 5,199

There was no stock-based compensation expense for the year ended December 31, 2013.

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)
Outstanding at December 31, 2014	638,548	$ 7.47	—
Granted	1,188,910	9.79	
Exercised	(12,500)	8.73	
Forfeited	(53,737)	10.49	
Cancelled	(5,413)	11.62	
Outstanding at December 31, 2015	1,755,808	$ 8.93	9.31
Vested or expected to vest at December 31, 2015	1,712,415	$ 8.93	9.30
Exercisable at December 31, 2015	154,094	$ 7.58	8.79

The intrinsic value of the Company's 1,755,808 options outstanding as of December 31, 2015 was $4.3 million based on a per share price of $11.02, the Company's closing stock price on that date, and a weighted-average exercise price

of $8.93 per share. The intrinsic value of the Company's 638,548 options outstanding 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 $7.47 per share.

The intrinsic value of options exercised during the year ended December 31, 2015 was $64,000.

We use the Black-Scholes valuation model in determining the fair value of equity awards. For stock options granted to employees and directors with only service-based vesting conditions, we measure stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the requisite service period on a straight-line basis. We record the expense of services rendered by non-employees based on the

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estimated fair value of the stock option as of the respective vesting date. Further, we expense the fair value of non-employee stock options that contain only service-based vesting conditions over the requisite service period of the underlying stock options. Stock-based compensation expense is determined including estimated forfeitures, and is adjusted each period to reflect actual forfeitures.

The per-share weighted-average grant date fair value of the options granted to employees during the years ended December 31, 2014 and 2015 was estimated at $4.93 and $6.44, respectively, per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	2014	2015
Risk-free interest rate	1.81 %	1.76 %
Expected term of options (in years)	6.24	6.27
Expected volatility	74.88%	72.93%
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, 2015, there was $8.6 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 3.38 years.

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Restricted stock

A summary of the status of the Company's restricted stock awards at December 31, 2015 and of changes in restricted stock awards outstanding under the Plan for the year ended December 31, 2015 is as follows:

	Number of Shares	Weighted-average Grant Date Fair Value per Share
Unvested at December 31, 2014	832,535	$ 11.75
Granted	75,000	$ 6.53
Forfeited	(13,920)	$ 13.04
Vested restricted stock awards	(213,749)	$ 11.64
Unvested at December 31, 2015	679,866	$ 11.19

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.

The fair value of restricted stock vested for the years ended December 31, 2014 and 2015, was $6.7 million and $2.5 million, respectively.

As of December 31, 2015, there was $5.0 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.55 years.

11. Income Taxes

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

(in thousands)	As of December 31,		
	2013	2014	2015
Domestic operations	$ (4,087)	$ (21,829)	$ (45,361)
Foreign operations	(16,098)	(21,338)	(13,290)
Loss before provision for income taxes	$ (20,185)	$ (43,167)	$ (58,651)

The provision (benefit) for income taxes consists of the following for 2014 and 2015:

(in thousands)	As of December 31,		
	2013	2014	2015
Current:			
U.S. Federal	$ —	$ —	$ —
State and local	—	44	—
Foreign	—	—	—

Total Current	—	44	—
Deferred:			
U.S. federal	$ —	$ —	$ —
State and local	—	—	(700)
Foreign	22	3	(18)
Total deferred	22	3	(718)
Total expense (benefit)	$ 22	$ 47	$ (718)

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Through December 31, 2015, 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:

(in thousands)	For the Year Ended December 31,		
	2013	2014	2015
Beginning balance	$ 67	$ 46	$ 59
Increase/(Decrease) related to prior tax years	(21)	13	14
Increase related to current year	—	—	—
Ending balance	$ 46	$ 59	$ 73

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.

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

(in thousands)	As of December 31,	
	2014	2015
Deferred tax assets:		
Fixed assets	$ —	$ 353
Accrued expenses	218	573
Deferred revenue	2,079	3,736
Stock compensation	351	642
Intangibles	—	460
Other	—	2
Net operating losses	11,401	25,312
Deferred tax assets	14,049	31,078
Deferred tax liabilities:		
Fixed assets	$ (26)	$ (73)
Convertible debt	—	(6,318)
Indefinite-lived intangibles	(25)	—
Deferred tax liabilities	(51)	(6,391)
Net deferred tax assets	13,998	24,687
Less: valuation allowance	(14,023)	(25,771)
Net deferred tax liabilities after valuation allowance	$ (25)	$ (1,084)

As of December 31, 2015, the Company had foreign net operating loss ("NOL") carry forwards of $42,512,000 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, 2015, the Company had U.S. federal and state NOL's of $43,444,000 and $21,454,000, 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

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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 2035.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its net deferred tax assets at December 31, 2014 and 2015, 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 $8,799,000 and $11,747,000, for the year ended December 31, 2014 and 2015, respectively. Included in the net change of the valuation allowance from 2014 to 2015 is a reduction in the amount of $6,200,000 that was offset directly to equity in connection with the issuance of the convertible debt in April, 2015.

At December 31, 2015, 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 various states. The foreign tax returns are subject to tax examinations for the tax years ended July 31, 2011 through December 31, 2015. The domestic tax returns are subject to tax examinations for the tax years ended December 31, 2012 through December 31, 2015. 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:

(in thousands)	For the Year Ended December 31,	
	2014	2015
Federal income tax at the statutory rate	34.0 %	34.0 %
Permanent items	(3.9)	(0.3)
Convertible note interest expense	(5.6)	—
State income tax, net of federal benefit	1.7	2.7
Change in valuation allowance	(20.4)	(32.3)
Change in foreign rate	(5.9)	(2.9)
Indefinite-lived intangible	—	—
Increase in tax reserves	—	—
Effective income tax rate	(0.1) %	1.2 %

12. 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 and $199,000 to the 401(k) Plan in the years ended December 31, 2014 and 2015, respectively. 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

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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, 2014 and 2015, the Company recorded $225,000, and $230,000, respectively, for contributions under its state plan for Denmark employees.

13. Commitments and Contingencies

Operating Leases

The Company's corporate headquarters are located in Wayne, Pennsylvania, where it leases 19,797 square feet of office space under a lease agreement that expires in February 2022 unless terminated earlier. In addition, the Company is leasing 2,510 square feet of office space in Whippany, New Jersey in close proximity to its contract manufacturer Halo. The Company also maintains a research laboratory, pilot manufacturing and administrative facility in Vaerlose, Denmark, where it leases 12,895 square feet of space under a lease agreement that automatically renews every 12 months (currently through August 2016 unless terminated earlier). The Company also has existing leases from previous US headquarters totaling 6,599 square feet, of which leases for 3,190 expire in November 2016 and of which 3,409 square feet expire in December 2017.

The following is a schedule by year of the future minimum rental payments required under non-cancelable leases as of December 31, 2015:

(in thousands)	
2016	$ 425
2017	633
2018	523
2019	533
2020	543
2021	553
2022	92
Total minimum lease payments	$ 3,302

Rent expense was $223,000, $325,000 and $408,000 for the years ended December 31, 2013, 2014 and 2015, respectively.

Legal Proceedings

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, the Company was substituted for Luitpold as plaintiff in a patent litigation against Apotex Corp. and Apotex, Inc. (collectively, "Apotex"), involving the SPRIX Nasal Spray. The action was dismissed without cost and without prejudice on January 6, 2016 as a result of a settlement between Apotex and the Company. The parties

have agreed to settle the matter on terms consistent with the prior settlement with Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC ("Amneal") related to SPRIX as discussed above. The parties are currently drafting the settlement agreement and accompanying documents.

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In April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, "Purdue") commenced a patent infringement lawsuit against us and our OXAYDO product licensor, Acura, in the United States District Court for the District of Delaware alleging the Company's OXAYDO product infringes Purdue's patent, U.S. Patent No. 8,389,007 (the "'007 patent"). A pre-trial claims construction hearing was held in November 2015 to determine the meaning of the terms in the lawsuit. In January 2016, the Court ruled in favor of Purdue with regard to the pre-trial claims construction hearing. No date has been set for the full hearing. The Company continues to deny the allegations in the complaint, believe they are without merit, and defend the action vigorously. At the current time, the Company is proceeding with defending the lawsuit as well as evaluating other options. As is the case with any outcome of a patent litigation, there is a risk that the Court may enjoin the making, using, selling and offering for sale OXAYDO and/or may find that Oxaydo infringes the '007 patent.

14. Net Loss Per Share of Common Stock

The following table sets forth the computation of basic and diluted loss per share of the Company's common stock for the years ended December 31, 2014 and 2015:

(in thousands, except per share data)	Year Ended December 31,		
	2013	2014	2015
Basic and diluted net loss per common share calculation:			
Net loss	$ (20,207)	$ (43,214)	$ (57,933)
Weighted average common stock outstanding	1,292,307	14,556,927	19,738,042
Net loss per share of common stock—basic and diluted	$ (15.64)	$ (2.97)	$ (2.94)

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	2015
Redeemable convertible preferred stock	5,329,451	—	—
Options outstanding	—	638,458	1,755,808
Unvested restricted stock awards	—	832,535	679,866
Common shares issuable upon conversion of the 5.50% notes	—	—	4,102,360
Total	5,329,451	1,470,993	6,538,034

15. Acquisitions and License and Collaboration Agreements

License and collaboration agreement with Shionogi

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 (“AD”) hydrocodone-based product candidates using certain of the Company’s core technologies. The collaboration allows Shionogi to develop and commercialize an AD single-agent hydrocodone-based product and up to 20 different AD combination product candidates containing hydrocodone. In December 2015 the Company received notice from Shionogi that Shionogi was terminating for convenience its collaboration and license agreement with the Company.

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Under the terms of the agreement, the Company received an upfront payment of $10.0 million and payment of $10.0 million in April 2015 upon submission of an investigational new drug ("IND") application by Shionogi. Prior to the termination of the agreement, the Company was eligible to receive regulatory milestone payments under the agreement as follows: (i) up to an additional $50.0 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 was 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 AD 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, 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 and IND payments were recorded as deferred revenue and were being recognized ratably using the straight line method through November 2030, the expected term of the agreement. As a result of the termination of the agreement, the Company recognized all remaining deferred revenue related to the Shionogi agreement as revenue in the fourth quarter of 2015 as the Company had no further material obligations under the agreement at that time. For the years ended December 31, 2014 and 2015, the Company recognized revenues of $557,000 and $17.9 million, respectively, related to the amortization of deferred revenue.

Additionally, during the years ended December 31, 2014 and 2015 the Company recognized revenue of $1.4 million and $699,000, respectively, related to certain development costs incurred under the Company's collaborative research and license agreement.

Collaboration and License Agreement with Acura

In January 2015, the Company entered into a Collaboration and License Agreement with 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 Staets in 5 and 7.5 mg strengths, but was not actively marketed. Under the terms of the Collaboration and 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.

The Company paid Acura an upfront payment of $5.0 million in January 2015 and a $2.5 million milestone in October 2015 as a result of the first commercial sale of OXAYDO. In addition, Acura will be entitled to a one-time $12.5 million milestone payment when OXAYDO net sales reach a specified level of $150.0 million in a calendar year.

The Company has recorded a product rights intangible asset of $7.7 million related to the arrangement, which includes $172,000 of transaction costs related to the agreement. The intangible asset is being amortized over a useful life of 7 years, which coincides with the patent protection of the product in the United States.

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 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

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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 U.S.). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by Egalet to acquire intellectual property rights to commercialize OXAYDO, with an aggregate minimum floor.

Purchase Agreement with Luitpold

In January 2015, the Company entered into and consummated a purchase agreement with 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 $7.0 million, of which $315,000 was deposited into an escrow account to secure Luitpold's indemnification obligations under the purchase agreement. The Company concurrently purchased an additional $1.1 million of glassware, equipment and active pharmaceutical ingredient ("API") from Luitpold, and agreed to purchase an additional $340,000 of API after closing.

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

(in thousands)	Allocation
Inventory	$ 3,408
Property, plant & equipment	100
Finite lived intangible-intellectual property	4,620
Net assets acquired	$ 8,128

During the year ended December 31, 2015, management determined that the allocation of the purchase price to inventory and the intangible should be adjusted based on the valuation of the acquired assets. As a result, an adjustment was recorded to increase the allocation of the purchase price of the acquired finished goods inventory by $827,000 and increase the fair value of the intellectual property by $2.5 million. These adjustments reduced goodwill related to the acquisition to $0.

The Company incurred $1.1 million of SPRIX acquisition-related costs, which were recorded as general and administrative expense in the consolidated statement of operations.

The following table presents supplemental pro forma information for the year ended December 31, 2014 as if the acquisition of SPRIX had occurred on January 1, 2014 (unaudited). Due to the acquisition date of January 8, 2015, there is no material difference between the Company's results presented in the consolidated statement of operations

and the pro forma results for the year ended December 31, 2015:

(in thousands)	Year Ended December 31, 2014 (unaudited)
Pro forma product sales	3,622
Pro forma net loss	(47,134)
Pro forma net loss per share	(3.24)

16. Related Party Transactions

Related Party Receivables

As of December 31, 2014 and 2015, related party receivables with Shionogi were $679,000 and $57,000,

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respectively, related to certain development costs incurred under the Company's collaborative research and license agreement.

17. Quarterly Financial Information (unaudited)

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

(in thousands)	March 31,	June 30,	September 30,	December 31,
2015 Quarter Ended				
Revenues	$ 805	$ 959	$ 1,686	$ 19,380
Operating expenses	17,152	14,783	17,254	25,857
Other expense	348	3,265	1,790	1,032
Net loss	(16,721)	(17,066)	(17,359)	(6,787)
Net loss per share of common stock, basic and diluted (1)	(1.02)	(1.03)	(0.81)	(0.28)
2014 Quarter Ended				
Revenues	$ 256	$ 490	$ 346	$ 826
Operating expenses	6,049	12,089	10,540	10,365
Other expense (income)	(7,088)	(43)	51	1,035
Net loss	(12,916)	(11,658)	(10,178)	(8,467)
Net loss per share of common stock, basic and diluted (1)	(1.34)	(0.73)	(0.63)	(0.52)

(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.