Egalet Corp
Form 10-K
March 29, 2019
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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, 2018

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 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	OTCQX

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 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b 2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

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, 2018 (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 $22.7 million based on the last reported sale price of the registrant's Common Stock on June 30, 2018.

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

There were 9,360,968 shares of Common Stock outstanding as of March 26, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our amendment to this Annual Report on Form 10-K ("Form 10-K/A") to be filed within 120 days of December 31, 2018, are incorporated by reference in Part III. Such Form 10-K/A, 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. Egalet Corporation was incorporated in the State of Delaware in 2013. 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, 2018.

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," "goal," "intent," "target," or other words that convey uncertainty of future events or outcomes to identify these forward looking statements. Forward looking statements appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our plans to grow our business, our business strategy, the commercial success of our products and, if partnered and approved, our product candidates, our plans with regard to the commercialization of our products, including through partnerships, our plans to reformulate SPRIX Nasal Spray, 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 and the impact of such regulations, expectations regarding clinical trial data, including the inherent risks in conducting clinical trials for our products, our business development plans, our results of operations, the date through which our existing cash will be sufficient to fund our projected operating requirements, 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 competition and 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 economic or other 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 ability to continue as a going concern;
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the impact of our bankruptcy on our business going forward, including with regard to relationships with vendors and customers, employee attrition, and the costs and expenses resulting from our bankruptcy;

- the impact of our acquisition of five products from Iroko Pharmaceuticals, Inc., including our assumption of related liabilities, potential exposure to successor liability and credit risk of Iroko and its affiliates;

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- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our current and future indebtedness;
- our ability to maintain compliance with the covenants in our debt documents;
- our ability to obtain additional financing or to refinance our existing indebtedness;
- the level of commercial success of our products;
- our ability to execute on our sales and marketing strategy, including developing relationships with customers, physicians, payors and other constituencies;
- the continued development of our commercialization capabilities, including sales, marketing and market access capabilities;
- the rate and degree of market acceptance of any of our products and product candidates;
- the success of competing products that are or become available;
- the entry of any generic products for SPRIX Nasal Spray, Indocin suppositories or any of our other products, or any delay in or inability to reformulate SPRIX;
- recently enacted and future legislation regarding the healthcare system;
- 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 accuracy of our estimates of the size and characteristics of the potential markets for our products and our ability to serve those markets;
- the performance of third parties, including contract research organizations, manufacturers and collaborators;
- our failure to recruit or retain key 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;
- our ability to integrate and grow any businesses or products that we may acquire;
- the success and timing of our preclinical studies and clinical trials;
- litigation related to opioids and public or legislative pressure on the opioid industry; and
- the outcome of any litigation in which we are or may be involved.

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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 place undue reliance on these statements or 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 IQVIA Holdings, Inc. ("IQVIA") is an estimate derived from the use of information under license from the following IQVIA information services: IQVIA National Sales Perspectives and NPA Audits, in each case, for the period 2007 2018. IQVIA expressly reserves all rights, including rights of copying, distribution and republication.

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PART I

ITEM 1. BUSINESS

Overview

On January 31, 2019 we completed the acquisition of five marketed non-narcotic, nonsteroidal anti- inflammatory drug ("NSAID") products from Iroko Pharmaceuticals, Inc. (together with its subsidiaries, "Iroko") (the "Iroko Acquisition"). In exchange for the products, Iroko received $45 million in our new senior secured debt and 49% of our new equity, prior to the dilution associated with our stock-based incentive compensation plan. To facilitate this transaction and reorganize our capital structure, we completed proceedings under Chapter 11 of the United States Bankruptcy Code in the District of Delaware. Our previous convertible debt was equitized, and our previous senior secured holders received $20 million in cash and $50 million in the new senior secured notes, as well as 19.38% of our new equity.

We are a commercial-stage pharmaceutical company commercializing innovative treatments for different types of pain and inflammation. Given the need for acute and chronic pain products and the issue of prescription abuse, we are primarily focused on bringing non-narcotic and abuse-discouraging opioid formulations to healthcare providers. We are currently selling SPRIX® (ketorolac tromethamine) Nasal Spray ("SPRIX Nasal Spray"), ZORVOLEX® (diclofenac), INDOCIN® (indomethacin) suppository, OXAYDO® (oxycodone HCI, USP) tablets for oral use only—CII ("OXAYDO"), VIVLODEX® (meloxicam), TIVORBEX® (indomethacin) and INDOCIN oral suspension. We plan to continue to grow our business through the revenue growth of our seven approved products, business development and advancement of our product candidates from our pipeline with a partner or on our own in the future.

Strategy

Our goal is to become a profitable pharmaceutical company focused on developing, manufacturing and commercializing innovative treatments for pain, inflammation and other conditions. Currently we are focused on commercializing our own products and identifying additional business development opportunities that could accelerate our path to profitability. Key elements of our strategy include:

- Driving revenue growth from all seven of our marketed products. While we are driving growth from all seven of our products, we are primarily focused on SPRIX Nasal Spray, ZORVOLEX and INDOCIN suppositories as key revenue drivers. With our dedicated salesforce that we have expanded to 87 territory representatives, we are targeting approximately 8,000 pain medicine physicians, primary care physicians, nurse practitioners, orthopedic surgeons, urologists, podiatrists and neurologists in the United States with the intent to build awareness, educate and increase adoption of our products.

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- Conducting business development activities to build on our product portfolio. Our business development activities are focused on augmenting our product portfolio through in-licensing and acquisition of late-stage and commercial products. We are looking for products and product candidates that complement our current portfolio, and physician targets, in the pain management space, adjacent to pain management or in a market where our products are primarily used, including in hospital. In addition, we are exploring partnership opportunities for our current products outside of our healthcare professional targets and geographical areas of focus.
- Managing lifecycle of our products. We are working on new formulations that could improve SPRIX Nasal Spray, and potentially add new intellectual property. We anticipate having data on the new formulation in the second half of 2019. We also believe there are potential additional indications for the INDOCIN suppository and are considering doing additional development work to explore these new indications.

Market Opportunity Given the Issue of Pain and Prescription Abuse

According to the National Institutes of Health, pain and inflammation affect more Americans than those with diabetes, heart disease and cancer combined. The millions suffering from different types of pain and inflammation every year greatly impacts the United States with increasing costs associated with health care, rehabilitation and lost worker productivity. With opioids broadly available, prescription opioid abuse has become a significant problem with an estimated 1.7 million people suffering from drug use disorders in the United States according to the Center for Behavioral Health Statistics and Quality's 2017 National Survey on Drug Use and Health. Opioids (both extended release ("ER") and immediate-release ("IR") forms) are prone to being misused or abused through physical and chemical manipulation to increase the speed of the drug release into the bloodstream, accelerating and intensifying its effects. In 2019, the Centers for Disease Control and Prevention ("CDC") estimates that the total economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice involvement.

In reaction to this widespread prescription opioid misuse and abuse, the U.S. government and the U.S. Food and Drug Administration ("FDA") have designated this issue as a high priority. The FDA continues to highlight strategies to combat this issue of prescription opioid abuse with a focus on using and developing new non-narcotic treatment options. Over the past few years, the FDA has revised the indication for both IR and ER opioids to be used when the pain is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. According to the CDC, the first line of therapy should be non-opioid treatments, such as NSAIDs. In a 2018 Strategic Policy Roadmap, the FDA highlighted the development of opioids designed to deter or discourage abuse as a part of the solution. Given the importance of management of pain and inflammation and, the ongoing abuse epidemic, there is a need for non-narcotic options, such as NSAIDs, and opioids designed to discourage abuse.

Our Products

NSAID Market

According to a JAMA Network Open 2019 article, NSAIDs are among the most widely prescribed medications in the world due to their demonstrated efficacy in reducing pain and inflammation, with 70 million prescriptions written annually in the United States. They are used to treat a variety of painful conditions including acute pain, back pain, gout, osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. NSAIDs provide relief from symptoms of many

of these conditions including pain and inflammation. While NSAIDs are generally considered to be safe and effective, they have also been associated with dose-related serious adverse events in some patients, including gastrointestinal, renal and cardiovascular events. The recognized correlation between systemic exposure to NSAIDs and these adverse events led the FDA, to issue its 2005 public health advisory recommending that NSAIDs should be used at their lowest effective dose for the shortest duration of time. The FDA requires companies to provide a medication guide which informs patients of the need to discuss with their doctor the risks and benefits of using NSAIDs and the importance of using the lowest effective dose for the shortest duration possible if treatment with an NSAID is warranted for an individual.

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SoluMatrix® Technology NSAID Products

The SoluMatrix technology platform is used in three of the products we acquired from Iroko. This technology was developed in response to the FDA's support of using the lowest NSAID dose possible. SoluMatrix uses a dry milling process to reduce the NSAID drug particle size by at least ten times. The smaller particle size results in increased surface area relative to mass, which increases the dissolution and absorption rates without changing the chemical structures of the drug molecules themselves. Because of this altered absorption profile, the SoluMatrix NSAID products dissolve and are absorbed at a rate that allows for the rapid onset of pain relief at lower doses and lower systemic exposures than other NSAIDs.

ZORVOLEX is a novel formulation of diclofenac developed using the SoluMatrix technology platform providing patients 23 percent lower overall systemic exposure versus other forms of diclofenac. This low-dose diclofenac is approved for mild to moderate acute pain and osteoarthritis pain. Diclofenac, meloxicam and indomethacin represent 34 percent of the overall NSAID market. According to IMS, there were 20 million diclofenac prescriptions in 2017. ZORVOLEX has shown to be promotionally sensitive and represents an opportunity to garner a larger percentage of the diclofenac market.

VIVLODEX is a SoluMatrix formulation of meloxicam approved for osteoarthritis pain. VIVLODEX is dosed once daily and offers patients low dose and low systemic exposure. According to IMS data in 2017, there were 31 million meloxicam prescriptions.

TIVORBEX, also developed using the SoluMatrix technology, is the first low-dose SoluMatrix indomethacin for mild to moderate acute pain in adults approved by the FDA. TIVORBEX is the lowest FDA-approved dose of indomethacin available.

SPRIX Nasal Spray

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. This non-narcotic provides patients with moderate to moderately severe short-term pain a form of ketorolac that is absorbed rapidly but does not require an injection administered by a healthcare provider ("HCP"). Specialists, including urologists, podiatrists and orthopedic surgeons, use SPRIX Nasal Spray for post-surgery acute-pain management.

Formulated as a nasal 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. SPRIX Nasal Spray has 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. We acquired SPRIX Nasal Spray and certain related assets from Luitpold Pharmaceuticals, Inc. ("Luitpold") in January 2015 for $7.0 million. SPRIX Nasal Spray is currently sold in the United States and the first commercial sale of SPRIX Nasal Spray occurred in May 2011. In 2018, we grew SPRIX Nasal Spray net revenues more than 17 percent over the previous year. We currently believe there is an opportunity for continued revenue growth with this important product given its ability to provide opioid-level pain relief in a non-narcotic.

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INDOCIN Products

We acquired two forms of INDOCIN (indomethacin) from Iroko, an oral solution and a suppository. There are no other branded NSAID suppositories available in the United States. Both products are approved for many indications including: moderate to severe rheumatoid arthritis including acute flares of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) and acute gouty arthritis. We believe there are potential additional indications for the INDOCIN suppository, and we are considering conducting development work to explore these potential additional indications.

IR Oxycodone Market

Oxycodone immediate-release (IR) medication starts to work within a few minutes of administration. It delivers pain relief for up to six hours. According to a 2018 Medpage Today article, Oxycodone IR product prescriptions increased from about 14.5 million in 2013 to about 17.3 million in 2017 in the United States. According to the 2016 National Survey on Drug Use and Health (NSDUH), an estimated 11.8 million Americans age 12 and older misused prescription pain relievers in the past year. Also, according to the Medpage Today article, calls to U.S. Poison Control Centers between 2012-2016 reporting intentional exposure to oxycodone were far more likely to involve IR products than ER ones. With this pattern of IR opioid abuse, we believe it is important to have products designed to discourage abuse. Common methods of manipulating medications in pill or tablet form include crushing to swallow, snort or smoke, and dissolving to inject.

OXAYDO, an abuse-discouraging IR oxycodone product.

OXAYDO is an approved IR oxycodone product designed using an aversion technology to discourage abuse via snorting. It is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. It was approved in 2011 prior to the FDA Guidance for Industry, Abuse-Deterrent Opioids – Evaluation and Labeling (“FDA AD Guidance”) on abuse-deterrent opioids. The label includes results from a Category 3 AD study that evaluated drug liking after snorting crushed OXAYDO compared to crushed Roxicodone (oxycodone hydrochloride tablets USP). We licensed OXAYDO from Acura Pharmaceuticals (“Acura”) in January 2015 for a $5.0 million upfront payment and a $2.5 million milestone payment upon commercial launch. In addition, Acura is entitled to a one-time $12.5 million milestone payment if OXAYDO net sales reach $150.0 million in a calendar year and a tiered royalty percentage based on sales thresholds. We are focused on further educating the approximate 500 current OXAYDO prescribers on the potential benefits of this product. OXAYDO is covered by six U.S. patents that expire between 2023 and 2025. Patents covering OXAYDO in foreign jurisdictions expire in 2024.

U.S. Commercialization Strategy

Since we acquired and licensed SPRIX Nasal Spray and OXAYDO respectively, we have built a fully scaled commercial organization focused on educating providers taking care of individuals with pain, both acute and chronic. As the market demonstrated a greater appetite for non-narcotics, we increased our focus on the promotion of our NSAID SPRIX Nasal Spray. We acquired the Iroko products not only because they are NSAIDs, but because they can be promoted with our existing salesforce at little additional expense. We already had over 80 territories focused on similar targets. We added additional geographies where the Iroko products had been previously marketed. With our dedicated employee sales force, we can cover 99 percent of existing SPRIX targets and 98 percent of existing ZORVOLEX targets. Our 87 sales representatives promote our products to approximately 8,000 healthcare providers in the United States. We believe that our focused targeting, sales force execution, proper brand positioning, message delivery and education, as well as our focus on ensuring proper product access to patients who require our therapies, will help us achieve our promotional goals. As part of our commercial strategy, we are working to enhance patient

access to our products where possible through reducing co-pays, increasing availability of our products in pharmacies and in some cases providing more access to product samples. For approximately the same operating expense, we believe we can significantly increase our potential annual revenue.

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In addition to our own salesforce, we partner with other commercial pharmaceutical companies in therapeutic or geographic areas where our in-house team does not target. In 2017, we signed an agreement with Ascend Therapeutics to promote SPRIX Nasal Spray to approximately 11,000 women's healthcare providers. In early 2018, we announced an agreement with OraPharma to promote SPRIX Nasal Spray along with their own portfolio products to its target dentists, dental specialist, and oral surgeons. OraPharma began promotion of SPRIX Nasal Spray in the first quarter of 2018. On February 26, 2019, OraPharma provided us notice that it was terminating the Co-Promotion Agreement and would cease promotion of SPRIX Nasal Spray effective April 27, 2019. We continue to seek additional partnerships for our approved products to expand our commercial reach.

Global Partnerships

As part of the Iroko Acquisition, Egalet acquired rights with respect to six international distribution arrangements with companies seeking to register and market ZORVOLEX and VIVLODEX in their respective territories. Four of those distribution partners have secured registration of ZORVOLEX in nine territories and of VIVLODEX in one territory. Egalet is evaluating these relationships to determine strategic fit.

Product Candidates and Proprietary Guardian Technology Platform

While our current focus is on our commercial products, we have a pipeline of product candidates. Our primary effort is to identify potential partners to advance these product candidate; however, we may consider developing them ourselves in the future. One of our product candidates, a naproxen product, was developed using the SoluMatrix technology to create a lower dose NSAID. Our other product candidates were developed using our proprietary Guardian technology.

Our proprietary Guardian Technology is a polymer matrix tablet technology that utilizes a novel application of the well-established manufacturing process of injection molding, which results in tablets that are structurally hard and difficult to manipulate for misuse and abuse. While our Guardian Technology creates a tablet that is extremely hard and has AD features, the construct of the tablet allows for controlled release of the active pharmaceutical ingredient ("API") in the gastrointestinal tract. This approach offers the ability to design tablets with controlled-release profiles as well as physical and chemical properties that have been demonstrated to resist both common and rigorous methods of manipulation. Tablets manufactured with Guardian Technology have been shown to have increased resistance to physical methods of manipulation, such as cutting, crushing, grinding or breaking using a variety of mechanical and electrical tools. The tablets are also resistant to chemical manipulation and turn into a viscous hydrogel on contact with liquid, making syringeability difficult.

The Egalet Guardian Technology is a proven technology that was used to develop ARYMO ER, an AD, ER FDA-approved morphine. Due to payor pressure in the ER morphine space, we have discontinued the manufacturing, distribution and promotion of ARYMO ER. In addition to ARYMO ER, we have a pipeline of products developed using our Guardian Technology. Egalet-002, an ER, AD oxycodone formulation, employs a similar matrix system to that is used in ARYMO ER; however, the Egalet-002 tablet is surrounded by a water-impermeable, non-eroding, hard shell containing polylactic acid ("PLA") that creates a cylinder, with the API-containing matrix exposed at both ends. We have two other product candidates that were developed using our Guardian Technology: Egalet-003, an AD stimulant product candidate, and Egalet-004, an AD, ER hydrocodone-based product candidate for which an initial Phase 1 bioavailability study has been conducted. Like Egalet-002 and the SoluMatrix Naproxen, we are not currently investing in these product candidates and are exploring the possibility of their further development with a partner or on our own at some point in the future.

Manufacturing

Our approved products are manufactured at contract manufacturing facilities in the United States. We have agreements with Catalent to manufacture and Patheon to package ZORVOLEX and TIVORBEX capsules, Neolpharma to manufacture and package VIVLODEX capsules, Patheon to manufacture INDOCIN oral suspension and ACP Nimble Buyer Inc. to supply INDOCIN suppositories. Jubilant HollisterStier (“JHS”) manufactures SPRIX Nasal Spray for us

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and we purchase our required quantities of SPRIX Nasal Spray through purchase orders with JHS. We have an agreement with UPM Pharmaceuticals to produce OXAYDO.

In September 2018, we signed an agreement to terminatcs (now part of Cambrex Corporation) related to the manufacture and supply of ARYMO ER. The manufacturing services agreement was terminated in connection with our discontinuation of the manufacture, distribution and promotion of ARYMO ER.

Drug Substances

The active pharmaceutical ingredient ("API") used in SPRIX Nasal Spray is ketorolac tromethamine, in OXAYDO is oxycodone hydrochloride, ZORVOLEX is diclofenac and VIVLODEX is meloxicam. Both INDOCIN oral suspension and suppositories, as well as TIVORBEX all use indomethacin as the API. We currently procure these APIs on a purchase order basis, some of which are pursuant to an agreement with one of our suppliers. We acquire ketorolac tromethamine and indomethacin from a European-based manufacturers, diclofenac and meloxicam from Indian-based manufacturers, while we secure the opioid APIs from a U.S.-based manufacturer.

Oxycodone hydrochloride is classified as narcotic controlled substance under U.S. federal law. OXAYDO is classified as a Schedule II controlled substance by the U.S. Drug Enforcement Administration ("DEA"), meaning that these substances have the highest potential for abuse and dependence among drugs that are recognized as having an accepted medical use. Consequently, the manufacturing, shipping, dispensing and storing of OXAYDO are 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.

In connection with the Iroko Acquisition, we entered into a license agreement with iCeutica Inc. and iCeutica Pty Ltd. (collectively, "iCeutica"). We exclusively license 19 U.S. patents from iCeutica, all of which cover iCeutica's SoluMatrix® technology and relate to composition of matter, process of manufacturing or method of use of three of our products, VIVLODEX, ZORVOLEX and TIVORBEX. Three of the U.S. patents that cover VIVLODEX are listed patents under the Approved Drug Products and Therapeutic Equivalence Evaluations publication, or Orange Book, seven of the U.S. patents are Orange Book listed patents that cover ZORVOLEX and another three of the U.S. patents are Orange Book listed patents that cover TIVORBEX. The remaining U.S. patents relate to the SoluMatrix technology. There are nine pending patent applications in the United States relating to the SoluMatrix technology and the three products. These patents expire between 2030 and 2035. Prior to Iroko Acquisition, Iroko settled patent infringement litigation with Lupin Pharmaceuticals, Inc. ("Lupin"), which settlement will allow Lupin to launch a generic form of ZORVOLEX prior to the expiration of the patents covering ZORVOLEX, no later than the second half of 2023.

Both Lupin and Novitium Pharma have submitted an abbreviated new drug application ("ANDA") with the FDA seeking regulatory approval to market a generic version of VIVLODEX. The notices from Lupin and Novitium Pharma included a "Paragraph IV certification" with respect to the Orange Book VIVLODEX patents alleging that these patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Lupin and Novitium Pharma's proposed generic product. iCeutica and Iroko sued Lupin over its ANDA for a generic version of VIVLODEX. The district court granted Lupin's motion for summary judgment on non-infringement and dismissed the amended complaint. The case is now on appeal to the United States Court of Appeals for the Federal Circuit. As part of our license with iCeutica, we have agreed, and intend, to vigorously enforce iCeutica's rights under the VIVLODEX related patents but cannot predict the outcome of this matter.

In addition, we license seven U.S. patents and five foreign patents from Acura Pharmaceuticals, all of which cover Acura's Aversion Technology and relate to the composition of matter. Six of the seven U.S. patents are Orange Book listed patents that cover OXAYDO. These patents expire between 2023 and 2025. In addition, we license one U.S. and five foreign patent applications relating to OXAYDO and Acura's Aversion Technology, all of which relate to the composition of matter.

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We own two U.S. patents that expire in 2029 and two pending U.S. patent applications, directed to processes of manufacture, devices, and compositions, related to SPRIX Nasal Spray. We held an exclusive license from Recordati to a U.S. patent listed in the Orange Book covering SPRIX Nasal Spray which patent expired in December 2018. We are aware that there is the possibility of generic entrants and if those generic products were to come to market, there could be a material impact on our revenues. We are exploring ways to extend the life of our SPRIX Nasal Spray patents.

We own 23 issued patents within the United States, covering our product candidates incorporating our Guardian technology platform. The term of our overall domestic patent portfolio related to ARYMO ER, Egalet-002 and our Guardian Technology platform, excluding possible patent extensions, extends to various dates between 2022 and 2033.

We own two pending patent applications under active prosecution in the United States covering our product, product candidates and technology platform. We have one pending patent application in the United States relating to ARYMO ER and one pending relating to our Guardian Technology. The types of protection that may be afforded by any patent that may be issued from these applications include composition of matter, process of manufacturing or method of us.

We own two patents within the United States and an additional 25 issued foreign patents covering the Parvulet® technology and relates to composition of matter. The Parvulet technology entails a dosage form that transforms into a “pudding-like” mass within seconds when a small amount of water is added and addresses the growing need for better pediatric and geriatric therapeutics. These patents expire in 2025.

In addition, we own and have one pending international application covering oral delivery of biomacromolecules applying injection molding technology to safely position an active substance into the intestinal wall resulting in effective exposure of active substances.

Competition

We face competition and potential competition from several sources, including pharmaceutical and biotechnology companies, generic drug companies and drug delivery companies. Oral NSAIDs such as celecoxib, diclofenac, ibuprofen, meloxicam and naproxen are the major competitors for our NSAID products. The key competitive factors in this market are product effectiveness, product safety profile, brand awareness and managed care access. According to 2018 data from IQVIA, ibuprofen is the most prescribed NSAID with about a 31% share of prescriptions in the United States in 2018. Meloxicam is the second most commonly prescribed NSAID with approximately a 20% share of U.S. prescriptions in 2018 and is one of the fastest growing among currently marketed NSAIDs, with a compound annual growth rate of 18% from 2007 to 2011, despite the fact that it is generic and not promoted. We believe the growth of meloxicam is due to its perceived safety profile relative to other NSAID products. While celecoxib had the largest share of revenue of NSAID products sold in 2018, we believe its share of prescriptions has declined as a result of physicians continuing to shift prescriptions away from COX-2 inhibitors and due to declining promotional efforts as the product’s patent protection nears expiration.

We expect that OXAYDO will compete with ROXYBOND, an ADF, IR oxycodone developed by Inspirion and to be marketed by Daiichi Sankyo (“Daiichi”) when it is launched. There are a considerable number of opioid product candidates under development that could be potential competitors for OXAYDO, including AD formulations of currently available opioids, novel opioids and alternative delivery forms of various opioids under development at other pharmaceutical companies. The key competitive factors in this market are product effectiveness, product safety profile, brand awareness and managed care access. OXAYDO may also face competition from non-opioid product candidates including new chemical entities (“NCEs”), 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 and QRxPharma Ltd.

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Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act ("FFDCA") and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications ("NDAs") warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The FDA approval process can be time consuming and cost intensive and companies may, and often do, re-evaluate the path of a particular product or product candidate at different points in the approval and post-approval process, even deciding, in some cases, to discontinue development of a product candidate or take a product off the market

Pharmaceutical product development in the United States for a new product or related to changes to an approved product typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application (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, unless the FDA authorizes that the clinical investigations in the IND may begin sooner than 30 days after submission. 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, as long as other necessary approvals (for example, an institutional review board ("IRB") overseeing clinical study sites) have been granted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers and/or to 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 human subjects and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The study protocol and informed consent information for

subjects in clinical trials must also be submitted to an 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, concerns about subjects, 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,

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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 some 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. Another scenario which allows for a single Phase 3 efficacy/safety study is via the 505(b)(2) pathway when the investigational product is not bioequivalent to the RLD but can still utilize other safety data from the reference agent for a submission.

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 United States. 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 $2,6 million for FDA's fiscal year 2019 (October 1, 2018 through September 30, 2019), and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees, currently $310,000 per product in FDA's fiscal year 2019. 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 10-12 months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. The review process for both standard and priority review may be extended by FDA for three additional months to consider major amendments to pending NDAs.

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 takes into consideration the recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices ("cGMP") is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

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.

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Changes to some of the conditions established in an approved application, including most 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

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 may be pursued.

Prescription Drug Marketing Act (“PDMA”)

The Prescription Drug Marketing Act (“PDMA”) of 1987 and the Prescription Drug Amendments of 1992 govern the storage, handling, and distribution of prescription drug samples. The law prohibits the sale, purchase, or trade (including an offer to sell, purchase or trade) of prescription drug samples; it also imposes various requirements upon manufacturers, including but not limited to, proper storage of samples, documentation of request and receipt of samples, validation of requesting practitioner’s licensure, periodic inventory and reconciliation of samples, notification to the FDA of loss or theft of samples, and procedures for auditing sampling activity. In addition, section 6004 of the Patient Protection and Affordable Care Act (“PPACA”) also requires manufacturers to annually report the identity and quantity of drug samples that were requested and distributed to licensed HCPs in a given year.

The Hatch Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant’s product, active ingredient, or method of use. Upon approval of a drug, each of the listed patents covering the approved drug is then published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredient(s) in the same strengths and dosage form, with essentially the same labeling as the listed drug, and that has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are generally 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 or make certain representations 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, unenforceable or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii

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statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding a patented method of use. 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 or unenforceable, 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 earliest 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 an NCE drug product, which is a drug that contains no active moiety that has been previously approved by the FDA in another NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive or review 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. Although NCE exclusivity runs for five years, 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.

A drug may obtain a three year period of exclusivity for a change to the drug for which new clinical investigations (other than bioavailability studies) are required, such as the addition of a new indication to the labeling or a new formulation. During a three-year exclusivity period, the FDA can review, but cannot approve, an ANDA or a Section 505(b)(2) NDA for the exclusivity-protected conditions.

Additional types of exclusivity may be available, depending on the circumstances. For example, orphan drug seven-year exclusivity is available in connection with the approval of drugs for rare diseases. Pediatric exclusivity provides a six-month extension of patents and exclusivities if requested studies in children are performed.

Section 505(b)(2) NDAs

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and effectiveness in the approval of a similar product or published literature in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on 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

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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 an NCEy, 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 earliest 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, orphan drug exclusivity, and pediatric exclusivity, assuming the NDA includes appropriate reports of new clinical studies and other criteria are satisfied.

REMS

The FDA has the authority to require a Risk Evaluation and Mitigation Strategy, commonly called 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 support 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 July 2012, the FDA approved a standardized REMS for all ER and long acting (LA) opioid drug products. ER formulations of morphine, oxycodone, and hydrocodone, among other opioids, are required to have a REMS. This includes ARYMO ER. In September 2017, the FDA issued letters to manufacturers of IR opioid drug products announcing the agency's intention to require a REMS for IR formulations as well.

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 existence and progress of development programs.

DEA Regulation

Our product OXAYDO is and our product candidate, Egalet 002, if approved, 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. In addition to DEA, state-controlled substance agencies and boards of pharmacy apply comparable requirements under state laws. This control extends to the equipment and raw materials used in their manufacture and packaging, accountability

controls, security measures, and other controls in order to prevent loss and diversion into illicit channels of commerce. Controlled substance registrants must monitor for and report suspicious orders, as well as thefts and significant losses of controlled substances.

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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. An approved 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 associated harm, Schedule V substances the lowest relative risk of abuse and associated harm 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 IR 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 Egalet 002, an AD, ER oxycodone product candidate, if approved, will be as well. Other companies' oxycodone products have been subject to recent scrutiny, litigation, and concerns. 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 and may not be refilled without a new prescription.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

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 number of opioids that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our license partners and contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including oxycodone hydrochloride for use in manufacturing Egalet 002 and OXAYDO. 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 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.

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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 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 like 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 for marketing exclusively in one member state may be submitted as well as for marketing in more than one member state. Such marketing authorization for several member states may be submitted under a centralized, a decentralized, or a mutual recognition 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 simultaneous national marketing authorizations in more than one member state. Where a national marketing authorization has already been granted, the holder of a national marketing authorization may apply to the remaining member states for mutual recognition of the marketing authorization. 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, marketing, and commercial distribution of our products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services (“CMS”), other divisions of the U.S. Department of Health and Human Services (“HHS”) (e.g., the Office of Inspector General “OIG”), the U.S. Department of Justice, state Attorneys General and other state and local government agencies. For example, pharmaceutical manufacturers’ activities (including sales and marketing activities, as well as scientific/educational grant programs, among other activities) are subject to 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. These activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The federal Anti Kickback Statute prohibits any person or entity, 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 another to (i) refer an individual for the furnishing of a pharmaceutical product for which payment may be made under a federal healthcare program such as Medicare or Medicaid ("covered product"), (ii) purchase or order any covered product, (iii) arrange for the purchase or order of a covered product, or (iv) recommend a covered product. This statute has been interpreted broadly to apply to a wide range arrangements between

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pharmaceutical manufacturers and others, including, but not limited to, any exchange of remuneration between a manufacturer and prescribers (such as physicians), purchasers, pharmacies, pharmacy benefit managers ("PBMs"), formulary managers, group purchasing organizations, hospitals, clinics and other health care providers, and patients. 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, "value-added" services, the furnishing of supplies or equipment at no charge, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Although there are several 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 referrals, prescribing, purchasing or recommending covered products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Additionally, many states have adopted laws like 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. Violations of fraud and abuse laws such as the Anti-Kickback Statute may be punishable by criminal or civil sanctions and/or exclusion from federal healthcare programs (including Medicare and Medicaid). Our arrangements and practices may not meet all the criteria of applicable exceptions and/or safe harbors for the Anti Kickback Statute in all cases, and thus would not be immune from prosecution under the Statute. Additionally, Anti Kickback Statute and similar state laws are subject to differing interpretations and may contain ambiguous requirements or require administrative guidance for implementation. Finally, some of the safe harbor rules are currently under review for potential revision. Given these variables, our activities could be subject to the penalties under the Anti-Kickback Statute and similar authorities.

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 violated the False Claims Act, 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 based on inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare numbers when detailing the provider of services, improper promotion of off label uses not expressly approved by FDA in a drug's label, and allegations as to misrepresentations with respect to the services rendered. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance. Also, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created several 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 about the delivery of or payment for healthcare benefits, items or services.

In addition, 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. For example, HIPAA and its implementing regulations established standards for "covered entities," which are certain healthcare providers, health plans and healthcare clearinghouses, regarding the security and privacy of protected health information. While we are not a covered entity

under HIPAA, many of our customers are, and this limits the information they can share with us. The American Recovery and Reinvestment Act of 2009 included expansion of HIPAA's privacy, security and breach notification standards, called the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which became effective February 17, 2010. Among other things, HITECH makes HIPAA's security and breach standards (and certain privacy standards) directly applicable to "business associates," which are entities that perform certain services on behalf

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of covered entities involving the exchange of protected health information. 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. While we do not currently perform any services that would render us a business associate under HIPAA/HITECH, it is possible that we may provide such services in the future and would be subject to the applicable provisions of HIPAA/HITECH. Finally, we may be directly subject to state privacy and security laws, regulations and other authorities, which may limit our ability to use and disclose identifiable information, and may impose requirements related to safeguarding such information, as well as reporting on breaches.

Additionally, 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" provided to U.S. physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals. The Open Payments program also requires that manufacturers and applicable group purchasing organizations report annually to HHS ownership and investment interests held in them by physicians (as defined above) and their immediate family members. Manufacturers' reports are filed annually with the CMS by each March 31, covering the previous calendar year. CMS posts disclosed information on a publicly available website. There are also an increasing number of state laws that restrict or prohibit pharmaceutical manufacturers' interactions with health care providers licensed in the respective states, and that require pharmaceutical manufacturers to, among other things, establish comprehensive compliance programs, adopt marketing codes of conduct, file periodic reports with state authorities regarding sales, marketing, pricing, and other activities, and register/license their sales representatives. A number of state laws require manufacturers to file reports regarding payments and items of value provided to health care providers (similar to the federal Open Payments program). Many of these laws contain ambiguities as to what is required to comply with the laws. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. With respect to any of our products sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable privacy laws and 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.

Impact of Public Pressure on Drug Pricing, Healthcare Reform and Legislation Impacting Payor Coverage

In the United States, federal and state authorities, as well as third-party payors, are increasingly attempting to limit or regulate the price of medical products and services. There is increased scrutiny of prescription drug pricing practices

by federal and state lawmakers and enforcement authorities. In addition, there is an emphasis on managed healthcare in the United States, which will put additional pressure on pharmaceutical drug pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

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Drug pricing continues to be an agenda item in the current administration and in the Congress. In 2018, the current administration solicited comments on a proposal being developed to reset Medicare Part B drug payment rates to more closely align with international prices for the drugs paid by other countries. In 2019, the Administration proposed a rule to make clear that the Anti-Kickback Statute's Discount Safe Harbor does not protect manufacturer rebates to PBMs or third-party payors but would create new safe harbors for rebates passed through to the point-of-sale and for fixed payments for services provided by PBMs, in an effort to reduce patient drug costs. In addition, there have been several recent state and federal lawmaker inquiries and proposed legislation as was the case in California designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers and government regulators of price increases and provide an explanation of the reasons for the increase. There have also been actions to review the relationship between drug pricing and manufacturer patient assistance programs and to reform government program reimbursement methodologies for drugs.

The U.S. pharmaceutical industry has already been significantly affected by major legislative initiatives, including, for example, the Affordable Care Act. The Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug medicines. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. Since its enactment, there have been judicial and Congressional challenges to numerous provisions of the Affordable Care Act. Further, since 2017, both the U.S. Congress and current administration have enacted legislative and regulatory changes to repeal or dismantle certain aspects of the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and additional actions by Congress and the current administration to possibly repeal and replace it has on our business.

In the future, there will likely continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of pharmaceutical drugs. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans (also known as the Medicare "Donut Hole"), and increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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 as well as commercial healthcare plans and pharmacy benefits managers. 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 will continue 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 regulatory and 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.

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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.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for influencing any act or decision of the foreign entity to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Other Regulatory Requirements and Challenges to Regulatory Actions

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. Companies may petition governmental agencies, including the FDA, to discuss or take action with regard to regulatory decisions made relating to a product, product candidate or the company itself.

Employees

As of February 28, 2019, we have 130 employees, of which 129 are employed in the United States and one is employed in Denmark. Of our employees, 100 are in sales and marketing, 1 is in research and development and 29 are in administration. Per the Danish Salaried Act, Danish employees have the right to be represented by a labor union. We consider our employee relations to be good.

Available Information

We file electronically with the Securities and Exchange Commission (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 SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Copies of our annual report on Form 10 K, quarterly reports on Form 10 Q, current reports on Form 8 K, ownership reports for insiders and any amendments to these reports filed with or furnished to the SEC are available free of charge through our internet website (www.egalet.com) as soon as reasonably practicable after filing with the SEC. We use the Investor Relations section of our website as a means of disclosing material non public information and for complying with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the Investor Relations section of our website, in addition to following press releases, SEC filings and public conference calls and webcasts.

In addition, 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.

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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 Emergence from Bankruptcy

Our actual financial results may vary significantly from the projections we filed with the bankruptcy court.

In connection with the bankruptcy process, we were required to prepare projected financial information to demonstrate to the bankruptcy court the feasibility of our bankruptcy plan and our ability to continue operations upon emergence from bankruptcy. At the time they were last filed with the bankruptcy court on December 3, 2018, the projections reflected numerous assumptions concerning anticipated future performance and prevailing and anticipated market and economic conditions that were and continue to be beyond our control and that may not materialize. Projections are inherently subject to uncertainties and to a wide variety of significant business, economic and competitive risks. If we do not achieve the financial projections or other assumed results, we may lack sufficient liquidity to continue operating as planned or at all, which could have an adverse impact on the value of our Common Stock, as well as our ability to make scheduled payments on our 13% Senior Secured Notes due 2024.

Because our consolidated financial statements will reflect fresh start accounting adjustments made upon emergence from bankruptcy, financial information in our financial statements will not be comparable to our financial information from prior periods.

Upon our emergence from bankruptcy in January 2019, we will adopt fresh start accounting in accordance with ASC 852—Reorganizations (“ASC 852”), pursuant to which our reorganization value, which represents the fair value of the entity before considering liabilities, will be allocated to the fair value of assets in conformity with the purchase method of accounting for business combinations. We will state our liabilities, other than deferred taxes, at a present value of amounts expected to be paid. Thus, our balance sheets and results of operations will not be comparable in many respects to balance sheets and consolidated statements of operations data for periods prior to our adoption of fresh start accounting. You will not be able to compare information reflecting our post-emergence financial statements to information for periods prior to our emergence from bankruptcy, without making adjustments for fresh start accounting. The lack of comparable historical information may discourage investors from purchasing our Common Stock.

We cannot be certain that the bankruptcy proceeding will not adversely affect our operations going forward.

We operated in bankruptcy from October 31, 2018 to January 31, 2019, and during that time we were required to make only limited payments on our prepetition indebtedness and our pre-petition liabilities. We cannot assure you of our ability to negotiate favorable terms from vendors and suppliers, hedging counterparties and others and to attract and retain customers upon emergence from bankruptcy or that the requirement to make payments on our indebtedness or other liabilities on a current basis will not adversely affect our business. The failure to obtain such favorable terms and retain customers and the requirement to make payments on our debt and other liabilities could adversely affect our financial performance.

Due to these and other uncertainties, many risks exist, including the following:

- we may have difficulty obtaining the capital we need to run and grow our business;
- key suppliers could terminate their relationship with us or require financial assurances, enhanced performance or accelerated payment schedules;
- our ability to renew existing contracts and compete for new business may be adversely affected;

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- our ability to attract, motivate and/or retain key executives and employees may be adversely affected;
- employees may be distracted from performance of their duties or more easily attracted to other employment opportunities; and
- competitors may take business away from us, and our ability to attract and retain customers may be negatively impacted.

The occurrence of one or more of these events could have a material adverse effect on our operations, financial condition and results of operations. We cannot assure you that having our operations in bankruptcy and recent emergence will not adversely affect our operations in the future.

We may be subject to claims that were not discharged in the bankruptcy proceedings, which could have a material adverse effect on our results of operations and profitability.

Substantially all of the material claims against us that arose prior to the date of our bankruptcy filing were addressed during the bankruptcy proceedings or resolved in connection with the bankruptcy plan and the order of the bankruptcy court confirming our bankruptcy plan. In addition, although our plan contemplated the payment of most of our prepetition claims at 100%, the Bankruptcy Code provides that the confirmation of a plan of reorganization discharges a debtor from substantially all debts arising prior to confirmation and certain debts arising afterwards. Circumstances in which claims and other obligations that arose prior to the bankruptcy filing were not discharged primarily relate to pending litigation, as well as, potentially, instances where a claimant had inadequate notice of the bankruptcy filing. To the extent any pre-filing liability remains, the ultimate resolution of such claims and other obligations may have a material adverse effect on our results of operations, profitability and financial condition.

Our long-term liquidity requirements and the adequacy of our capital resources are difficult to predict at this time.

We face uncertainty regarding the adequacy of our liquidity and capital resources and have limited access to additional financing. In addition to the cash requirements necessary to fund ongoing operations, we incurred significant professional fees and other costs in connection with our bankruptcy proceedings and through the consummation of the Iroko Acquisition.

Our liquidity, including our ability to meet our ongoing operational obligations, is dependent upon, among other things, our ability to maintain adequate cash on hand and our ability to generate cash flow from operations. If we are unable to manage cash effectively, our financial condition will suffer. In addition, our indenture provides that we must, commencing December 31, 2019, maintain a minimum level of consolidated liquidity, based on unrestricted cash on hand and availability under any revolving credit facility, equal to the greater of the quotient of the outstanding principal amount of our 13% Senior Secured Notes due 2024 divided by 9.5 and $7,500,000.

As of March 20, 2019, we have put into place a $20.0 million senior secured revolving credit facility ("Revolving Credit Facility"), as permitted under the indenture for our 13% Senior Secured Notes due 2024. Incurrence of additional indebtedness will increase our debt repayment burden.

We may experience increased levels of employee attrition as a result of our bankruptcy proceedings.

As a result of our bankruptcy proceedings, we may experience increased levels of employee attrition, and our employees face uncertainty regarding our ongoing financial situation. A loss of key personnel or material erosion of employee morale could adversely affect our business and results of operations. The loss of services of members of our senior management team could impair our ability to execute our strategy and implement operational initiatives, which would be likely to have a material adverse effect on our business, financial condition and results of operations.

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Risks Related to the Iroko Acquisition

We may not be able to successfully integrate the Iroko Acquisition.

A successful integration of the assets acquired from Iroko with ours will depend substantially on our ability to consolidate operations, corporate cultures, systems and procedures, to potentially restructure certain relationships and to eliminate redundancies and costs. We may not be able to combine our business with these assets without encountering difficulties, such as:

- the disruption of operations and business;
- the retention of the existing suppliers, manufacturers, distributors, customers and other third-party constituencies;
- inability to retain current pharmacy network;
- inability to maintain and increase competitive presence;
- customer loss and revenue loss;
- possible inconsistencies in standards, control procedures and policies;
- unexpected problems with costs, operations, personnel, technology and credit;
- problems with the assimilation of new operations, sites or personnel, which could divert resources from other operations;
- difficulties integrating the products acquired by the Iroko Acquisition into our existing sales channel;
- failure to generate revenues from newly-acquired products that meet our current expectations;
- potential unknown liabilities associated with the Iroko Acquisition, including potential successor liability claims; and
- general market and economic conditions or governmental actions.

Further, the Iroko Acquisition is expected to result in various benefits including, among other things, a strengthened market position, cross selling opportunities, technological efficiencies, cost savings and operating efficiencies. Achieving the anticipated benefits of this acquisition is subject to a number of uncertainties, including whether we integrate the Iroko assets in an efficient and effective manner, and general competitive factors in the marketplace. Failure to achieve these anticipated benefits on the anticipated timeframe, or at all, could result in a reduction in the price of our Common Stock as well as in increased costs, decreases in the amount of expected revenues and diversion of management’s time and energy and could materially and adversely affect our business, financial condition and operating results. In addition, we have made fair value estimates of certain assets and liabilities in recording the Iroko Acquisition. Actual values of these assets and liabilities could differ from estimates, which could result in us not achieving the anticipated benefits of the Iroko Acquisition. Finally, any cost savings that are realized may be offset by losses in revenues or other charges to earnings.

Failure to successfully address these and other issues related to the Iroko Acquisition could have a material adverse effect on our financial condition and results of operations and could adversely affect our ability to successfully implement our business strategy. Also, if our growth occurs more slowly than anticipated or declines, our operating results could be materially adversely affected.

We face possible successor liability due to our acquisition of assets from Iroko.

We may face potential successor liability for liabilities of Iroko. Although we have endeavored to structure the Iroko Acquisition to minimize exposure to unassumed liabilities, it is possible that under common law, certain statutes or otherwise, creditors of Iroko and its subsidiaries could attempt to assert that we have successor liability for obligations of Iroko. Such liabilities may arise in a number of circumstances, including those where: a creditor or other security holder of Iroko did not receive proper notice of, or appropriate consideration from, the Iroko Acquisition or any pre- or post-acquisition transactions undertaken by Iroko in contemplation thereof or in connection therewith; the damage giving rise to an Iroko creditor's claim did not manifest itself in time for the creditor to file the creditor's claim; or fraud on the part of Iroko, its creditors or any of its other constituencies.

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If we are determined to be subject to such liabilities, satisfaction of attempted satisfaction of such liabilities could materially adversely affect our business, financial condition and results of operations. Even if any such claim was unsuccessful, the defense of such claim could be costly.

We are relying upon the creditworthiness of Iroko and its affiliates, which are indemnifying us for certain liabilities excluded from the Iroko Acquisition. To the extent Iroko or its affiliates are unable to satisfy their obligations to us, we bear the risk of these excluded liabilities.

Under and in connection with the asset purchase agreement entered in connection with the Iroko Acquisition (the "Iroko Acquisition Agreement"), Iroko and its affiliates have agreed to indemnify us and our affiliates from any and all claims and losses actually suffered or incurred by us or our affiliates arising out of or relating to the breach of Iroko's representations, warranties or covenants contained in the Iroko Acquisition Agreement, as well as other losses arising out of certain assets and liabilities retained by Iroko as provided in the Iroko Acquisition Agreement. Except for fraud, Iroko's indemnification obligations are subject to certain limitations as provided in the Iroko Acquisition Agreement.

To the extent Iroko and its affiliates are unable to satisfy their indemnification obligations to us, we may bear the risk of incurring liabilities excluded from the Iroko Acquisition, which could materially adversely affect our financial condition, results of operations or cash flows.

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 with a limited operating and commercialization history. To date, we have focused on developing ARYMO ER, our product that was approved in January 2017 and discontinued on September 28, 2018, and our product candidate, Egalet-002, as well as commercializing SPRIX Nasal Spray, OXAYDO and ARYMO ER. Our investment in the development of ARYMO ER and our product candidates required substantial upfront capital expenditures. Similarly, investment in the commercialization of a product may be slow to achieve results. As a result, 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 in a difficult and changing environment.

We have generated substantial net losses and negative cash flow from operations since our inception, filed for bankruptcy protection and we continue to incur significant commercialization and other expenses related to our ongoing operations for our products. For the years ended December 31, 2018 and 2017, we reported a net loss of approximately $95.5 million and $69.4 million, respectively.

We may incur losses and negative cash flow for the foreseeable future. Our ability to generate sufficient revenues from our products, including the five products we acquired from Iroko, any other products that we may in-license or acquire, and, any product candidates that we may develop and partner, will depend on numerous factors described in the following risk factors and elsewhere in this Annual Report. We expect that our gross margin may fluctuate from period to period as a result of changes in product mix sold, potentially by the introduction of new products by us or our competitors, manufacturing efficiencies related to our products, payor reimbursement and rebates 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' deficit and working capital.

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

To date, we have generated $77.5 million in total revenue from SPRIX Nasal Spray, OXAYDO and, prior to its discontinuation, ARYMO ER, and have generated $22.6 million in total revenue since our inception from feasibility and collaboration agreements.

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Our ability to generate additional revenue and become profitable depends upon our ability to, among other things, expand the marketing of our products, as well as any other products that we may develop, in-license or acquire in the future. Further, even if we are able to partner our product candidates and we decide to seek and are able to successfully achieve regulatory approval for them, we do not know when any of these products will generate revenue for us, if at all. Our ability to generate revenue from our products or any partnered product candidates also depends on a number of additional factors, including our ability to:

- successfully satisfy any FDA post-marketing requirements for our products, including studies and clinical trials that have been required for other IR opioid analgesics;
- successfully complete any necessary clinical studies and human abuse liability studies;
- Successfully obtain and maintain all regulatory filings and labels for our products;
- complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- appropriately address generic entry into the markets for our products;
- set a commercially viable price for our products;
- obtain and maintain coverage and adequate reimbursement from third party payors, including government payors;
- address limitations in our marketing ability as a result of the claims that we are permitted to include in the label for our products;
- further penetrate the market for existing products and ultimately increase sales for our products relative to our competition;
- find suitable partners to help us market, sell and distribute our products, including in other markets and maintain our current partnerships;
- maintain our intellectual property rights and defend our intellectual property rights from any challenges;
- obtain commercial quantities of our products at acceptable cost levels;
- maintain the quality of our products such that they are not subject to a product withdrawal;
- continue to develop and/or reconfigure 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 partners to help us to develop and seek regulatory approval for our product candidates; and
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities.

In addition, our commercial infrastructure results in significant expenses. To manage operations effectively, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our operations effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer. Any failure by us to manage our operations effectively could have an adverse effect on our ability to achieve our goals.

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, need to license or abandon one or more of our products and/or be forced to reduce our operations.

Our current significant indebtedness and any 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.

Upon our emergence from bankruptcy on January 31, 2019, we completed our debt restructuring and issued $95.0 million in 13% Senior Secured Notes due 2024. In addition, in March 2019, we put in place the Revolving Credit Facility.

Interest on our 13% Senior Secured Notes due 2024 accrues at a rate of 13% per annum and is payable semi-annually in arrears on May 1 and November 1 of each year. On each such payment date, we will also pay an installment

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of principal on the 13% Senior Secured Notes due 2024 in an amount equal to 15% of the aggregate net sales of OXAYDO, SPRIX Nasal Spray, ARYMO ER, Egalet-002, ZORVOLEX, VIVLODEX, TIVORBEX, INDOCIN suppositories and oral suspension for the two-consecutive fiscal quarterly period most recently ended, less the amount of interest paid on the 13% Senior Secured Notes due 2024 on that payment date. The 13% Senior Secured Notes due 2024 mature on January 31, 2024.

Advances under the Revolving Credit Facility bear interest at the Company's option at either a LIBOR rate (which is subject to a floor of 2%) plus 5%, or a base rate plus 4%. The Revolving Credit Facility matures in March 2022.

Our ability to make payments on the 13% Senior Secured Notes due 2024 and our Revolving Credit Facility 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. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

The indebtedness under the 13% Senior Secured Notes due 2024 and under the Revolving Credit Facility is secured by substantially all of our assets, including our intellectual property. As a result, a default under the 13% Senior Secured Notes due 2024 indenture or the Revolving Credit Facility could result in the loss of some or all of our assets and intellectual property, which would have a material adverse effect on our business and results of operations. 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 and executing the further development, clinical testing, approval and marketing of our products or product candidates, if successfully partnered;
- 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 fund working capital, capital expenditures and other general corporate purposes;
- increase our vulnerability to both general and industry specific adverse economic conditions;
- limit our ability to engage in acquisitions or other business development activities; and
- limit our ability to obtain additional funds.

In addition, as the magnitude of our principal and interest payments on the 13% Senior Secured Notes due 2024 may be proportionate to the revenues generated by our products, the nature of the 13% Senior Secured Notes due 2024 will reduce the amount of cash flow from net product sales that is available for other corporate purposes.

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 our 13% Senior Secured Notes due 2024 and our Revolving Credit Facility, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not 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. Further, the indenture governing our 13% Senior Secured Notes due 2024 and the Revolving Credit Facility each contain cross-default provisions which could be triggered in the event of a default under other material indebtedness, which would adversely impact our cash flow and financial condition.

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We rely on available borrowings under the Revolving Facility for cash to operate our business, which subjects us to market and counterparty risk, some of which is beyond our control.

In addition to cash we generate from our business, our principal existing sources of cash are borrowings available under the Revolving Credit Facility. If our access to such financing was unavailable or reduced, or if such financing were to become significantly more expensive for any reason, we may not be able to fund daily operations, which would cause material harm to our business or could affect our ability to operate our business as a going concern. In addition, if certain of our lenders experience difficulties that render them unable to fund future draws on the Revolving Credit Facility, we may not be able to access all or a portion of these funds, which could have similar adverse consequences.

The report of our independent registered public accounting firm contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2018 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. If we curtail our operations, we may be placed into bankruptcy or undergo liquidation, the result of which will adversely affect the value of our Common Stock.

The consolidated financial statements included in this Form 10-K do not include any adjustments that might be necessary should we be unable to continue as a going concern. If the going concern basis were not appropriate for these financial statements, adjustments would be necessary in the carrying value of assets and liabilities, the reported expenses and the balance sheet classifications used.

If we require additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to successfully market and promote our products, acquire new products or enhance the profiles of our products.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to commercialize our products, as well as to enhance the profiles of our products.

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 commercialization of one or more of our products or delay our ability to acquire or license new products or product candidates. We also could fail to complete our post-marketing requirements, fail to maintain our regulatory approvals or our intellectual property or be required to further curtail our operations, including by

discontinuing the sale of one or more of our products.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- increasing sales of our products;
- complying with and completing FDA post-marketing requirements for our products and PREA commitment for SPRIX Nasal Spray and certain for SoluMatrix products;
- the initiation, progress, timing, costs and results of clinical trials for our products and any future products we may in license or acquire;
- any generic entry into one or more of the markets for our products;
- the number and characteristics of products, any partnered product candidates, and any products that we in license or acquire;
- our ability to maintain regulatory approvals by the FDA and comparable foreign regulatory authorities once obtained;
- our ability to maintain the quality of our products such that they do not become subject to product withdrawals;
- the cost and timing of completion of commercial scale outsourced manufacturing activities for any products we develop, in-license or acquire;

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- the timing and amount of revenue from sales of our products;
- our ability to achieve milestones under any license or collaboration agreement that we have entered or may enter into in the future;
- the size and cost of our commercial infrastructure;
- our ability to maintain coverage and adequate reimbursements from third party payors and to gain inclusion on applicable formularies;
- costs and timing of completion of any outsourced commercial manufacturing supply arrangements that we may establish;
- 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;
- our ability to obtain API through the allocation process handled by the DEA;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to maintain the quality of our products;
- the effect of competing technological and market developments, including pressure on the opioid market and the expected decline in the prescribing of opioids; and
- costs associated with any third-party litigation.

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

Our existing debt places significant limitation on our ability to incur indebtedness. Despite our current consolidated debt levels, we and our subsidiaries may be able to incur certain additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. In certain situations, the terms of the indenture governing the 13% Senior Secured Notes due 2024 and the terms of our Revolving Credit Facility permit us to incur additional debt, secure existing or future debt, recapitalize our debt or take a number of other actions that could have the effect of diminishing our ability to make payments on our existing debt when due. The indenture governing our 13% Senior Secured Notes due 2024 and the Revolving Credit Facility each restrict our ability to incur certain additional indebtedness, including certain secured indebtedness, subject to certain exceptions, but if the 13% Senior Secured Notes due 2024 and the Revolving Credit Facility mature or are 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, products 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. 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 additional indebtedness would result in increased fixed payment obligations and could also result in certain additional

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 are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our commercialization efforts, otherwise significantly curtail operations or grant rights to develop and market our technologies that we would otherwise prefer to develop and market ourselves. 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.

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Risks Related to the Commercialization of Our Products

Our future prospects are dependent on the success of our 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 products, SPRIX Nasal Spray, INDOCIN Suppositories and Oral Suspension, ZORVOLEX, TIVORBEX, VIVLODEX and OXAYDO. Our ability to generate significant product revenues and to achieve commercial success in the near term will initially depend in large part on our ability to successfully commercialize these products in the United States. 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 liquidity, financial condition and results of operations will be adversely affected.

Our products are and 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 and/or maintaining approvals. In addition, 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, in January 2019, the House Oversight Committee launched one of the most wide-ranging investigations in decades into the prescription drug industry's pricing practices. The Oversight Committee sent letters to twelve drug companies seeking detailed information and documents about the companies' pricing practices. The letters seek information and communications on price increases, investments in research and development, and corporate strategies to preserve market share and pricing power. The House Oversight Committee will hold hearings on the matter as well. While we did not receive a letter, the letters and planned hearings demonstrate the continued focus of the U.S. Congress on pricing issues. 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. Further, legislation has been introduced in the U.S. Congress and several state legislatures that allows price controls in various circumstances, requires enhanced transparency in how pricing is established, caps or penalizes price inflation beyond certain parameters and ties pricing to federal supply schedules, among other initiatives. 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 of our products.

Our ability to commercialize our products, including any products we may in-license or acquire, 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, PBMs 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. For example, in late 2017, we were notified by CVS Caremark, a pharmacy benefits manager, that SPRIX Nasal Spray would no longer be on its formulary for a portion of its commercial covered lives beginning January 1, 2018, which had an adverse effect on our revenues. We cannot be sure that coverage and reimbursement will be available for our products, or any product that we commercialize, or that we will obtain such coverage and reimbursement in a timely fashion. 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

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to cover a significant portion of the cost of our products. Coverage and reimbursement may impact the demand for, or the price of, any of our products. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize our products. In addition, if we seek coverage for one or more of our products (which we are currently not actively doing), we may be required to submit bids that include our entire product portfolio for coverage consideration. Such a requirement may result in a demand for, and agreement to, higher rebates on one or more of our products than would occur if each were bid in isolation.

There may be significant delays in obtaining coverage, reimbursement and eligibility. Neither coverage nor reimbursement implies that any drug will be paid for in any instance or paid for 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 third-party 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 our products could hamper our ability to generate widespread prescription demand and would have a material adverse effect on our operating results, our ability to raise capital and our overall financial condition.

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

If our products do not achieve coverage by third party payors and/or broad market acceptance by physicians and patients, the commercial success of those products and revenues that we generate from those products will be limited. Acceptance and use of our products will depend on a number of factors including:

- the timing of market introduction of competitive products;
- any exclusivity rights a competitor's products may have;
- the results of any required post-marketing studies following any product approval to support the continued use of any abuse-discouraging claims for OXAYDO;
- 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 products and, in particular, the efficacy of our abuse discouraging technology in reducing potential risks of unintended use;
- published studies demonstrating the cost effectiveness of our products relative to competing products;
- the potential and perceived advantages of our products and product candidates over alternative treatments;
- availability of coverage and adequate reimbursement for our products from government and third-party payors;
- any negative publicity related to our or our competitors' products that include the same active ingredient as our products;

- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved product labeling;
- legislative, regulatory or administrative enforcement actions against opioid manufacturers;
- any quality issue that may arise in the manufacturing or distribution of our products;
- effectiveness of marketing and distribution efforts by us and other licensees and distributors; and
- the steps that prescribers and dispensers of must take, since our products are controlled substances, as well as the perceived risks based upon their controlled substance status.

Because we expect to rely on sales generated by our products to achieve profitability in the future, the failure of our products to achieve market acceptance would harm our business prospects.

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

Following our acquisition and license in January 2015 of SPRIX Nasal Spray and OXAYDO, respectively, and our acquisition of ZORVOLEX, TIVORBEX, VIVLODEX, and INDOCIN suppositories and oral suspension, we have seven 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 continued to promote ZORVOLEX, TIVORBEX, VIVLODEX, and INDOCIN suppositories and oral suspension after our acquisition of those products from Iroko in the first quarter of 2019. SPRIX Nasal Spray has remained commercially available in the United States following our acquisition of the product in January 2015. To date, sales of our marketed products, while growing, have not been significant, particularly as compared to the costs associated with the commercial infrastructure we have created and the commercialization efforts we have undertaken. 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 our approved products, 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 are a relatively small company with relatively limited sales and marketing capabilities and, if we are unable to effectively utilize our sales and marketing resources or enter into strategic alliances with collaborators, we may not be successful in commercializing our products or any products that we may in-license or acquire.

We have limited sales, marketing, market access and distribution capabilities compared to some of our competitors. We cannot guarantee that we will be successful in marketing our products or any products that we may in license or acquire in the United States. 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 products over competitive products;
- 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
- our inability to secure formulary coverage that provides broad product access; and
- the ability of our existing salesforce to market the products acquired from Iroko along with our existing products.

If we are not successful in effectively deploying our limited sales and marketing capabilities or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing our products or any products that we may in-license or acquire. Outside the United States, where we intend to commercialize our products 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 we are unable to recruit, retain and effectively train qualified sales personnel, our performance could suffer.

While we compete with other pharmaceutical and biotechnology companies, many of those companies are larger or have more resources to recruit, hire, train and retain qualified sales personnel. In addition, as a company that has recently emerged from bankruptcy, we face challenges recruiting due to concerns about our financial situation. If we are not successful in continuing to recruit and retain sales personnel, we may not be successful in commercializing our products or any products that we may in-license or acquire. Further, we will need to provide our salesforce with the quality training, support, guidance and oversight, including with respect to compliance with applicable law, in order for them to be credible and effective. If we fail to perform these commercial functions, our products may not achieve their maximum commercial potential or any significant level of success at all, which could have a material adverse effect on

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our financial condition, stock price and operations. The deterioration or loss of our salesforce would materially and adversely impact our ability to generate sales revenue, which would hurt our results of operations.

If we fail to obtain the necessary regulatory approvals, or if such approvals are limited, we will not be able to fully commercialize our products and our financial performance could suffer.

We have and will submit supplemental applications to the FDA for our products. The FDA may not approve supplemental applications we make to make changes to our products, add dosage strengths or strengthen the labels for our products with additional labeling claims, which we believe are necessary or desirable for the successful commercialization of our products and product candidates. The FDA could also decide that any approval would require us to perform additional clinical studies, which could be costly. For example, in June 2017, we received a complete response letter from the FDA regarding the prior approval supplement of OXAYDO in 10 mg and 15 mg dosage strengths in which the FDA requested more information regarding the effect of food on OXAYDO 15 mg and the intranasal abuse-deterrent properties of OXAYDO 10 mg and 15 mg. In addition, we filed an sNDA with the FDA in December 2016 based on Category 1 AD data that demonstrated that OXAYDO resists syringeability, which could potentially deter abuse through the intravenous route. Based on discussions with the FDA regarding the sNDA, we believe a contemporary intranasal HAP study would be needed to complete the sNDA. Given that the issues involved in both the sNDA and prior approval supplement are intertwined, we are evaluating our options and the costs associated to proceed on the AD label and/or the additional dosage strengths.

Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products if the benefits of such products do not outweigh the risks. 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 labels based on outcomes of on-going Phase 4 commitments for OXAYDO. Addressing these regulatory issues, if any, may impact the commercial availability of these products, which could have an adverse effect on our financial performance.

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

Our products compete against numerous branded and generic products already being marketed and potentially those that are or will be in development. Many of these competitive products are offered in the United States by large, well capitalized companies. The NSAID market is highly competitive and we face competition from branded, generic and over-the-counter products. We cannot be sure that we will be able to sufficiently distinguish SPRIX or our SoluMatrix products to enable them to generate significant revenue.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products, it could reduce our sales of those product. 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. Depending on the product, 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 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 products. Generic equivalents may be significantly less costly than ours to bring to market and companies that produce generic equivalents are often 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 products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products and product candidates. For example, the patent for SPRIX Nasal Spray expired in December 2018 and Indocin currently has no patent protection. We cannot be certain what impact generic products would have on our revenues from SPRIX Nasal Spray, or our operating results generally. Prior to our purchase of products from Iroko, Iroko settled patent infringement litigation with Lupin, which settlement will allow Lupin to

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launch a generic form of ZORVOLEX prior to the expiration of the patents covering ZORVOLEX, no later than the second half 2023. In addition, iCeutica and Iroko sued Lupin over its ANDA for a generic version of VIVLODEX. The district court granted Lupin's motion for summary judgment on non-infringement and dismissed the amended complaint. The case is now on appeal to the United States Court of Appeals for the Federal Circuit.

Our competitors may also develop branded products, devices or technologies 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. While we have our own internal salesforce, which markets our products in the United States, there can be no assurance that we can maintain 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.

Our products may be associated with undesirable adverse reactions or result in significant negative consequences.

Undesirable adverse reactions associated with our products could cause us, our IRBs, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in a restrictive product label or the delay, denial or withdrawal of regulatory approval by the FDA or foreign regulatory authorities. In addition, undesirable side effects can result in the withdrawal of entire classes of drugs.

If we or others identify undesirable adverse events associated with any of our products a number of potentially significant negative consequences could result, including:

- we may have to significantly alter our promotional campaigns or activities or we may be forced to suspend marketing of the product entirely;
- regulatory authorities may withdraw their approvals of the product or impose restrictions on its distribution;
- regulatory authorities may require additional warnings or contraindications in the product label that could diminish the usage or otherwise limit the commercial success of the product;
- we may be required to conduct additional post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products and our business, financial condition and results of operations may be adversely affected.

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 products and our product candidates and hinder or prevent the commercial success.

Before we can market and sell 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 or maintain all of the necessary regulatory approvals, we may never generate significant revenues from any commercial sales of our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent approval of any of our applications, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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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 any product candidates we are able to partner, restrict or regulate post approval activities or affect our ability to profitably sell our products.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act") was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the Affordable Care Act: establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extends manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expands eligibility criteria for Medicaid programs; expands the entities eligible for discounts under the Public Health program; increases the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; creates a new Medicare Part D coverage gap discount program; establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and establishes a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been judicial and political challenges to certain aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While there have been repeated calls and attempts to repeal the Affordable Care Act, 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.

Congress has not passed comprehensive repeal legislation, but two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 (the "Tax Act") includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share. The Bipartisan Budget Act of 2018 (the "BBA"), among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," by increasing from 50 percent to 70 percent the

point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Texas District Court Judge, as well as the current Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

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In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could impose additional financial pressure on our customers, which could in turn diminish demand for our products or result in pricing pressure on us.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. The current administration has indicated that reducing the price of prescription drugs will be a priority of the administration. If healthcare policies or reforms intended to curb healthcare costs are adopted, or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products may be limited, our commercial opportunity.

At the federal level, the current administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the current administration released a "Blueprint" to lower drug prices through proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has begun the process of soliciting feedback on some of these measures and, at the same time, is implementing others under its existing authority. Although some of these, and other, proposals will require authorization through additional legislation to become effective, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

In addition, on February 27, 2018, a bipartisan group of senators introduced Senate Bill 2456 (S.2456). S.2456 is characterized as "CARA 2.0," in reference to the Comprehensive Addiction and Recovery Act of 2016. CARA 2.0 would limit initial prescriptions for opioids to three days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. The bill would increase civil fines from $10,000 to $100,000, and if a manufacturer fails to maintain effective controls or report suspicious orders with knowledge or willful disregard, the bill would double criminal penalties from $250,000 to $500,000. If this bill were signed into law, it could adversely affect our ability to successfully commercialize OXYADO. In addition, in 2017 several states, including Indiana, Louisiana, and Utah, enacted laws that further limit or restrict opioid prescriptions.

In October 2018, President Trump signed the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. Among other things, this legislation provides funding for research and development of non-addictive painkillers that could potentially compete with our products. It also clarifies FDA's authority to require that certain opioids be dispensed in packaging that limits their abuse potential, makes changes to Medicare and Medicaid in an effort to limit over-prescription of opioid painkillers, and increases penalties against manufacturers and distributors related to the over-prescription of opioids, including the failure to report suspicious orders and keep accurate records. Shortly after the bill was signed, the FDA issued a statement discussing the steps it planned to take based on the authority it was granted under the Act. Some of those steps, including requiring certain packaging, such as unit dose blister packs, for opioids and other drugs that pose a risk of abuse or overdose and requiring that opioids be dispensed with a mail-back pouch or other safe disposal option would increase our costs related

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to OXAYDO. The ultimate effect of this legislation is currently not known but could potentially have a material adverse effect on our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. For example, California recently enacted a law restricting manufacturers from paying co-pays for branded products if an AB-rated generic equivalent is available. While this law does not currently impact our products, California's law could spur other states to adopt similar legislation, even legislation that is more restrictive. Any such law could adversely impact the utilization of our products and harm our commercial prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In April 2018, New York enacted a statute called the Opioid Stewardship Act (the "Stewardship Act") that, among other things, requires certain sellers and distributors of certain opioids in the state of New York to make annual payments of $100 million, in the aggregate, to a newly created fund, with each party's share determined in proportion to its share of opioid sales in New York (based on morphine milligram equivalents). While the effect of this legislation remains uncertain, and it has already been challenged as an unconstitutional law, we may be required to make payments to the fund and take additional actions to comply with the Stewardship Act. Compliance with the Stewardship Act, or similar requirements that could be enacted by other jurisdictions, could have an adverse effect on our business, results of operations, financial condition and cash flows.

We expect that the Affordable Care Act, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. 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 prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

We may not be able to obtain three-year FDA regulatory exclusivity for certain aspects of our products and if partnered and approved, our product candidates.

Under certain circumstances, the FDA provides periods of regulatory exclusivity following its approval of an NDA, which provide the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug. Three-year exclusivity is available to the holder of an NDA, including a

505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation or new labeling information for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, were essential to the approval of the application and were conducted or sponsored by the applicant.

We are currently pursuing the reformulation of SPRIX Nasal Spray and hope to obtain three-year exclusivity and/or additional patent protection for such reformulated version. There is a risk that the FDA may take the view that the studies that we are conducting are not clinical trials, other than bioavailability and bioequivalence studies, that are essential to approval and therefore do not support three-year exclusivity. Further, the FDA may decide that any exclusivity is limited (such as to a particular formulation) and does not block approval of subsequent applications for competing products that differ in certain respects from our product. Finally, to the extent that the basis for exclusivity is not clear, the FDA may determine to defer a decision until it receives an application which necessitates a decision.

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If we do obtain three years of exclusivity, such exclusivity will not block any potential competitors from the market. Competitors may be able to obtain approval for similar products with a different mechanism, such a with abuse-deterrent products.

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.

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 or remove opioids from the market entirely. Such efforts may inhibit our ability to commercialize OXAYDO. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of opioid drugs, the limitations or unintended consequences of abuse resistant formulations, the ability of drug abusers to discover previously unknown ways to abuse opioid drugs; public inquiries and investigations into prescription drug abuse, litigation or regulatory activity relating to sales, marketing (including providing meals to doctors), distribution (including with respect to high prescribers of opioids), or storage of our drug products could harm our reputation. In addition, payments to doctors to participate in speaker programs or payments to industry groups could reflect negatively on us. Such negative publicity could reduce the potential size of the market for 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 a less urgent public health issue, regulators and third-party payors may not be willing to pay a premium for abuse deterrent formulations of opioids.

Many state legislatures are considering various bills intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. Further, the FDA is requiring “black-box” warnings on IR opioids highlighting the risk of misuse, abuse, addiction, overdose and death. In March 2017, President Trump announced the creation of a commission, through the Office of National Drug Control Policy (“ONDCP”), to make recommendations to the president on how to best combat opioid addiction and abuse. In August 2017, the commission issued a preliminary report calling on President Trump to officially declare the crisis of opioid abuse a national emergency. On October 26, 2017, President Trump declared the opioid crisis a “national public health emergency.” The commission’s final report was released in early November 2017.

Efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for OXAYDO. In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA’s approach to opioid medications. The plan identifies the FDA’s focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA’s plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic abuse-deterrent opioid formulations, and seeking input from the FDA’s Science Board to broaden the understanding of the public risks of opioid abuse. The FDA’s Science Board met to address these issues on March 1, 2016. In November 2017, FDA issued a final guidance addressing approval standards for generic abuse-deterrent opioid formulations, which included recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. The FDA’s plan is part of a broader initiative led by the HHS to address opioid-related overdose, death and dependence. The HHS initiative’s focus is on improving physician’s use of opioids through education and resources to address

opioid over-prescribing, increasing use and development of improved delivery systems for naloxone, which can reverse overdose from both prescription opioids and heroin, to reduce overdose-related deaths, and expanding the use of Medication-Assisted Treatment, which couples counseling and behavioral therapies with medication to address substance abuse. As part of this initiative, the CDC has launched a state grant program to offer state health departments resources to assist with abuse prevention efforts, including efforts to track opioid prescribing through state-run electronic databases. In March 2016, as part of the HHS initiative, the CDC released a Guideline for Prescribing Opioids for Chronic Pain. The guideline is intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The guideline states that no treatment recommendations about the use of abuse-deterrent opioids can be made at this time. Many of these changes could require us to expend additional resources

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on commercializing OXAYDO to meet additional requirements. Advancements in the development and approval of generic abuse-deterrent opioids could also compete with and potentially impact physician use of our products and product candidates and cause our products to be less commercially successful.

In July 2017, the Pharmaceutical Care Management Association, a trade association representing PBMs, wrote a letter to the commissioner of the FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have either recently enacted, intend to enact, or have pending legislation or regulations designed to, among other things, limit the duration and quantity of initial prescriptions of IR forms of opiates and mandate the use by prescribers of prescription drug databases and mandate prescriber education.

Many of these changes and others could cause us to expend additional resources in developing and commercializing our products and our product candidates to meet additional requirements. Advancements in development and approval of generic abuse-deterrent opioids could also compete with and potentially impact physician use of our product candidates and cause our product candidates to be less commercially successful.

Many states and municipalities, a Native American Tribe and individual consumers have brought lawsuits against manufacturers, pharmacies and distributors of opioids, seeking damages for the costs associated with drug abuse and dependency. We may be brought into actions in the future, which could divert our attention and resources and have an adverse impact on our operations and financial condition.

Several state attorneys general, including Missouri, Ohio, New Hampshire, Arkansas and others, have sued opioid manufacturers, distributors and pharmacies alleging that such parties made false and misleading statements in the promotion of opioids or fueled opioid addition by selling large quantities of opioids in certain areas, resulting in high incidences of opioid overdoses and deaths. The plaintiffs in these cases are seeking to recover costs associated with drug dependency, overdose and death resulting from opioid use. These cases generally involve our larger competitors and largely relate to time periods prior to the time that we first began commercializing OXAYDO, our abuse discouraging IR oxycodone, in 2015. However, we were a defendant in Arkansas' opioid litigation when Arkansas sued all manufacturers who sold opioids in Arkansas. While we were voluntarily dismissed from that litigation, we could be brought into actions in the future if potential plaintiffs view our promotion of opioids as fueling the social problems with opioids.

The U.S. Congress has also investigated opioid manufacturers. In March 2017, the U.S. Senate began investigating the role that manufacturers may have played in the opioid addiction problem in the United States. The Senate requested internal documents from five of our large competitors relating to the marketing tactics for opioids and what, if anything, those manufacturers knew about the dangers of those drugs. While the investigation did not result in serious ramifications against the investigated manufacturers, the House or Senate may determine to open similar investigations in the future. If we were involved in those investigations, such investigations could negatively impact our reputation and potentially raise our profile with other governmental agencies.

Litigation involving governmental entities or class actions and governmental investigations are expensive and time consuming. If we were to be sued again or investigated over our commercialization of opioids, such an action could divert our attention and resources and have an adverse impact on our operations and financial condition.

Guidelines and recommendations published by various organizations can reduce the use of OXAYDO.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Third party payors, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. For example, some governmental and large third-party payors have begun to institute limits on the number of days' worth of opioid medication a patient can receive for the patient's first opioid prescription. Recommendations or

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guidelines suggesting the reduced use of our products or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products.

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 any 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:

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

Risks Related to Our Business and Strategy

We face substantial competition, which may result in others commercializing products more successfully than we do.

We face and will continue to face competition from other companies in the pharmaceutical, medical devices and drug delivery industries. Our products compete a 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, non-narcotic analgesics, local and topical analgesics and antiarthritics. Products of these types are marketed or in development by Collegium Pharmaceuticals, Daichii, Depomed, Horizon Pharma, Boehringer Ingelheim, Pfizer, Almatica Pharma, Novartis 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 competitors have substantially more marketing, manufacturing, financial, technical, human and managerial, and research and development resources than we do, and have more institutional experience than we do.

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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 products. Our competitors may develop products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings.

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

We may not be able to successfully reformulate SPRIX Nasal Spray, which could limit the prospects for that product and have a negative impact on our results of operations and long-term corporate prospects.

We have been pursuing a reformulation of SPRIX Nasal Spray, for which the patent expired in December 2018, in an effort to enhance the long-term prospects of that product. The reformulation process has so far involved preclinical studies and once we choose a formulation to advance, will involve clinical trials. This process, similar to the process for any other new or enhanced product, could encounter issues involved with any clinical trials and even if the clinical trials are successful, we could fail to receive FDA approval for the reformulation. If the FDA does not approve our reformulation, we would have to choose to restart or abandon the process. Even if we do receive FDA approval for a reformulation of SPRIX Nasal Spray, we may fail to obtain three-year exclusivity for the product, which could limit our commercial prospects related to the product. In addition, we would seek to file patent applications covering this new formulation to gain proprietary protection of this formulation and potentially limit competitors from copying this formulation. Our patent applications may not be granted and therefore our new formulation may not have intellectual property protection and therefore not prevent competitors from copying our formulation. As SPRIX Nasal Spray is responsible for a significant portion of our revenue, any limitations on the long-term prospects of SPRIX, could have a negative impact on our results of operations and long-term prospects.

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

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 products and, if partnered, our product candidates.

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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 operating officer, Mark Strobeck, and our chief commercial officer, Patrick Shea. 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, Dr. Strobeck, or Mr. Shea could impede the achievement of our corporate objectives.

We may engage in future acquisitions or business development activities 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 or products that we believe have products or capabilities that are a strategic or commercial fit with our products and business or otherwise offer opportunities for us, including in-licensing technologies. In connection with these acquisitions or investments, we may:

- pay too much for the product or business;
- 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. In addition, we currently have limited capital resources and a significant amount of outstanding debt, the governing documents of which restrict our ability to make certain capital expenditures, each of which could limit our ability to engage in otherwise attractive acquisition or in-license transactions. We may also issue shares of our common stock in such a transaction, which would result in dilution to our stockholders.

If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions could also pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- increases to our expenses;
    - the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day to day responsibilities;

- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to successfully complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition. For example, we recently completed the purchase of 5 marketed products from Iroko Pharmaceuticals. We are in the process of integrating those products into our commercial organization, which takes time and resources. If we are unsuccessful in doing so, our financial condition will suffer.

If we are unable to protect our information systems against service interruption, misappropriation of data or other failures, accidents or breaches of security, our operations could be disrupted, our reputation may be damaged, and our business and operations would suffer.

Despite the implementation of security measures, our internal computer systems, and those of our third-party contract research organizations ("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 any clinical trials, our commercial activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. 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

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reproduce the data. To the extent that any disruption or security breach were 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.

Further, our reliance on information systems and other technology also gives rise to cybersecurity risks, including security breach, espionage, system disruption, theft and inadvertent release of information. We regularly make investments to upgrade, enhance or replace these systems, as well as leverage new technologies to support our growth strategies. Any delays or difficulties in transitioning to new systems or integrating them with current systems or the failure to implement our initiatives in an orderly and timely fashion could result in additional investment of time and resources, which could impair our ability to improve existing operations and support future growth, and ultimately have a material adverse effect on our business.

Changes in tax laws and regulations or in our operations may impact our effective tax rate and may adversely affect our business, financial condition and operating results.

Changes in tax laws in any of the jurisdictions in which we operate, or adverse outcomes from tax audits that we may be subject to in any of the jurisdictions in which we operate, could result in an unfavorable change in our effective tax rate, which could adversely affect our business, financial condition and operating results.

The Tax Act was enacted on December 22, 2017. There are various provisions within the Tax Act that could impact our future tax position. The U.S. corporate tax rate was reduced to 21%, the Alternative Minimum Tax was repealed, and Net Operating Losses (“NOLs”) generated beginning in 2018 may be carried forward indefinitely but, limited to 80% of taxable income for utilization. However, interest deductions could be limited and certain performance-based compensation deductions could be limited. In addition, we will continue to evaluate the potential impacts of the US taxation of its Controlled Foreign Corporation.

We continue to assess the impact of various U.S. federal or state legislative proposals that could result in a material increase to our U.S federal or state taxes. We cannot predict whether any specific legislation will be enacted or the terms of any such legislation. However, if such proposals were to be enacted, or if modifications were to be made to certain existing regulations, the consequences could have a material adverse impact on us, including increasing our tax burden, increasing the cost of tax compliance or otherwise adversely affecting our financial position, results of operations, cash flows and liquidity.

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.

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. Further, pharmaceutical companies have used the Lanham Act, a private right of action that enables a party to sue a competitor for a false or misleading description or representation of fact that misrepresents the nature, characteristics, qualities, or geographic origin of the competitor's goods, services or commercial activities. Any commercial dispute, claim or lawsuit may divert our management's attention away from our

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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.

The change of ownership under Section 382 of the Code, as well as our emergence from bankruptcy, may limit our ability to use net operating loss carryforwards to reduce future taxable income.

Our foreign 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.

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

Pursuant to the Restructuring Plan, our aggregate outstanding indebtedness will be reduced. Generally, the discharge of a debt obligation for cash and property (including common stock) having a value less than the amount owed gives rise to the cancellation of debt ("COD") income. However, an exception is made for COD income arising in a bankruptcy proceeding. The taxpayer in a bankruptcy proceeding does not include the COD income in its taxable income, but must instead reduce the following tax attributes, in order, by the amount of COD income: (i) NOLs (beginning with NOLs for the year of the COD income, then the oldest and then next-to-oldest NOLs, and so on), (ii) general business tax credits (in the order generally taken into account in computing tax liability), (iii) alternative minimum tax credits. (iv) net capital losses (beginning with capital losses for the year of the COD income, then the oldest and then next-to-oldest capital losses, and so on), (v) passive activity losses, and (vi) foreign tax credits (in the order generally taken into account in computing tax liability). Alternatively, a debtor may elect to first reduce the basis of its depreciable and amortizable property. Importantly, the debtor's tax attributes are not reduced until after determination of the debtor's tax liability for the year of the COD income, in this case, the December 31, 2019 tax year. Any COD income in excess of available tax attributes is forgiven but may result in excess loss account recapture income. Based on calculations prepared to date, we do not expect to have COD income that exceeds our available tax attributes, and we expect that any remaining tax attributes will be subject to the Section 382 limitation described above.

An alternate bankruptcy exception applies if qualified creditors acquire 50% of the New Common Stock in exchange for their Claims (the "Bankruptcy Exception"). If the Bankruptcy Exception applied, our use of pre-change losses would not be subject to the Section 382 limitation. Instead, our NOLs would be reduced by the amount of interest deducted, during the taxable year that includes the Effective Date and the three preceding taxable years, on claims exchanged for New Common Stock. In addition, if the Bankruptcy Exception applied and a second ownership change occurred during the two years following the Effective Date, our NOLs at the time of the second ownership change would be effectively eliminated. We have determined that this Bankruptcy Exception will not provide a favorable result and we therefore expect to make an election for the Bankruptcy Exception not to apply.

Risks Related to Our Compliance with Governmental Regulations

Our products are 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

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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 products or the manufacturing facilities for our products 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 Corporate Integrity Agreement ("CIA') or 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; a CIA would require three to five years of ongoing auditing and monitoring internally and through an Independent Review Organization, which is expensive and time consuming;
- seek an injunction, impose civil penalties or monetary fines or pursue criminal prosecution, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve or cause a delay of 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;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- refuse to allow us to enter into government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We currently have Phase 4 study requirements for 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.

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Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti kickback, fraud and abuse, transparency, health information privacy and security 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 third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any commercial products. Our current and future arrangements with healthcare professionals, principal investigators, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, 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. In addition, we are subject to state and federal physician payment transparency laws and may be subject to patient privacy and security regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. 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, including the Medicare and Medicaid programs, 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, including erroneous pricing information on which mandatory rebates, discounts and reimbursement amounts are based, or in the case of the civil False Claims Act, for violations of the Anti-Kickback Statute in connection with a claim for payment or for conduct constituting reckless disregard for the truth;
- the FCPA, which prohibits U.S. firms and individuals from paying bribes to foreign officials in furtherance of a business deal and against the foreign official's duties and specifies required accounting transparency guidelines;
- 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 nongovernmental 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 HITECH 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 that 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 restrict payments that may be made to healthcare providers;
- 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;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our products and may subject us to potentially significant discounts on our products,

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increased infrastructure costs, potential liability for the failure to report such prices in an accurate and timely manner and potentially limit our ability to offer certain marketplace discounts;

- the Prescription Drug Marketing Act (PDMA) of 1987 and the Prescription Drug Amendments of 1992, which govern the storage, handling, and distribution of prescription drugs and prescription drug samples, prohibit the sale, purchase, or trade (including offer to sell, purchase or trade) prescription drug samples and impose various requirements upon manufacturers, including but not limited to, proper storage of samples, documentation of request and receipt of samples, validation of requesting practitioner, periodic inventory and reconciliation of samples, notification to the FDA of loss or theft of samples, and procedures for auditing sampling activity. We began our sampling program with the Iroko Acquisition. If we or one of our sales representatives were to violate the PDMA or similar state laws, such a violation could result in severe implications for both us and the individual involved; 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. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us.

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.

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

Advertising and promotion of our products is 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 unintended 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. In addition, 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 products, even if unlawful promotion is inadvertent, we may become subject to government investigations, inquiries and/or litigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable, and we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged off-label use and has enjoined

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several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our products, we could become subject to significant liability, which could materially adversely affect our business and financial condition.

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 products:

- failure to obtain or maintain requisite governmental approvals;
- failure to obtain or maintain 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.

OXAYDO is subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of OXAYDO.

The FDA has indicated that some opioid drugs formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and others are required to participate in the shared-system Opioid Analgesic Risk Evaluation and Mitigation Strategy ("REMS") program to ensure that the benefits of the drugs continue to outweigh the risks. In September 2017, the FDA announced that IR opioid drugs will be subject to the same REMS as ER opioids. Once of the primary goals of the REMS is to ensure that the benefits of these drugs continue to outweigh the risks.

The FDA has approved a new REMS that covers both ER and IR opioids as part of a federal initiative to address prescription drug abuse and misuse. The goal of the Opioid Analgesic REMS is to educate prescribers and other healthcare providers on the treatment and monitoring of patients with pain. The central component of the REMS consists of education programs for prescribers so that opioid analgesics can be prescribed and used safely and effectively. It is expected that the consortium of companies will satisfy this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS also requires the consortium to make available FDA approved patient education materials on the safe use of these drugs. The consortium must perform periodic assessments of the implementation of the REMS and assess 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.

OXAYDO is subject to the Opioid Analgesic REMS requirement. The REMS includes a Medication Guide that is dispensed with each prescription, physician training based on FDA-identified learning objectives, audits to ensure that the FDA's learning objectives are addressed in the physician trainings, letters to prescribing physicians, professional organizations and state licensing entities alerting each to the REMS, and the establishment of a call center to provide

more information about the REMS. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of products subject to the REMS requirement, which could reduce or remove the commercial benefits to us from the sale of these products and product candidates.

OXAYDO contains a controlled substance, 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 and certain of our product candidates contain controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. OXAYDO contains active ingredients that are classified as controlled substances under the CSA and regulations of the DEA. A number of states also independently regulate these drugs as controlled substances. Chemical compounds are classified by the DEA as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. For OXAYDO, 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

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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 to meet the commercial demand of our products or to complete any additional clinical trials.

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. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. Because of their restrictive nature, these regulations could limit commercialization of our products and product candidates containing controlled substances.

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 manufacture of materials and research and development activities, 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.

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. We are 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

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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 Jumpstart our Business Startups Act ("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 the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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. In addition, 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, principal investigators, CROs, CMOs and other third-party manufacturers, distributors, independent contractors, consultants, collaborators or vendors 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, principal investigators, CROs, CMOs and other third-party manufacturers, independent contractors, consultants, collaborators or vendors. Misconduct by any of these parties could include intentional reckless and/or negligent conduct or failures to:

- comply with FDA, DEA or similar 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

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· 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 Conduct, 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.

We are an “emerging growth company” and a “smaller reporting company” and we take advantage of reduced disclosure and governance requirements applicable to such 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 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 from our initial public offering.

Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements and reduced disclosure obligations regarding executive compensation. 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," which will occur in 2020. Compliance with the Sarbanes Oxley Act of 2002, the Dodd Frank Act of 2010, as well as rules of the Securities and Exchange Commission, 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." 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. It is also

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uncertain what the impact of the new Congress and administration will have on such regulation in light of the President's campaign promises and executive directives to roll back aspects of, among other things, the Dodd-Frank Act.

See – "If we fail to maintain and 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."

Risks Related to Our Dependence on Third Parties

Due to the fact that we currently rely on sole suppliers to manufacture the active pharmaceutical ingredients of our products, and a sole supplier for each of our products, any production problems with our suppliers 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 sole manufacturer of our supply of APIs for each of our products. We also rely on a sole supplier for each of our products. Although we have identified alternate sources for these supplies, it would be time consuming and costly to qualify these sources. If our suppliers were to terminate our arrangements or fail to meet our supply needs, we could face disruptions in the distribution and sale of our products. We currently do not have secondary sources for our products.

If third party manufacturers of our products fail to devote sufficient time and resources to our concerns, or if their performance is substandard, we may be unable to continue to 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. As discussed above, we currently rely on a limited number of experienced personnel and single contract manufacturers ("CMO") to manufacture SPRIX Nasal Spray, OXAYDO, ZORVOLEX, TIVORBEX, VIVLODEX, INDOCIN suppositories and oral suspension. We purchase our required quantities of SPRIX Nasal Spray through purchase orders and while we have an understanding with the manufacturer of SPRIX Nasal Spray regarding an exit strategy if our relationship with that manufacturer were to be terminated, we cannot assure you that a termination of this relationship would not result in a supply disruption. Our reliance on a limited number of vendors and manufacturers exposes us to the following risks, any of which could interrupt commercialization of our products, delay our clinical trials, result in higher costs, or deprive us of potential product revenues:

- CMOs, 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 CMOs could default on or, under certain circumstances, terminate their agreements or purchase orders with us to provide clinical supplies or meet our requirements for commercialization of our products.
- For OXAYDO, the use of alternate CMOs may be difficult because the number of potential CMOs that have the necessary governmental licenses to produce narcotic products is limited. In addition, the FDA and the DEA must approve any alternative manufacturer of our products before we may use the alternative manufacturer to produce our products.
- It may be difficult or impossible for us to find a replacement CMO on acceptable terms quickly, or at all. Our CMOs 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 products be manufactured according to cGMP and similar foreign standards. Any failure by our CMOs to comply with cGMP, including any failure to deliver sufficient quantities of products in a timely manner could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products, or take other regulatory or legal action, including recall or seizure, total or partial suspension of

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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.

Our utilization of CMOs could also result in our lack of visibility throughout our supply chain, which could result in shortages in the supply of our products or, conversely, the build-up of more inventory than we require. 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.

Indocin suppositories are a branded generic product manufactured by the CMO using our trademark. If the CMO decided not to manufacture the product for us, allow us manufacture under its ANDA, or decided to manufacture the product itself, our financial condition would suffer.

The CMO that manufactures Indocin suppositories owns the ANDA for the product and manufactures it under that ANDA using the Indocin trademark that we own. The price that the CMO charges us for the product is fixed for the term of the contract under the terms of the contract (unless otherwise agreed to by the parties), but could be subject to significant increase once the contract term ends. In addition, while we do have a five-year contract with that CMO to manufacture Indocin suppositories, the manufacturer could decide, after the contract expires, to manufacture the product itself without the use of the Indocin trademark. In addition, the agreement could be terminated for material breach and in other limited circumstances. If the cost to manufacture Indocin suppositories increases or the CMO decided to sell indomethacin suppositories itself that it manufactures under its own ANDA or the agreement with the CMO was terminated, our business could suffer.

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 any supplemental drug applications relating to changes to the labels of or new dosage strengths for our products or receive regulatory approval for any product candidate we are able to partner.

We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our 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 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 any supplemental drug applications relating to changes to the labels of or new dosage strengths for our products or receive regulatory approval for or successfully commercialize any of our product

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candidates that we successfully partner. As a result, the commercial prospects for our products or partnered product candidates, as the case may be, would be harmed, our costs could increase and our ability to generate additional 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 any 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.

If we lose our relationships with CROs, our clinical trial efforts could be delayed.

We rely on third party vendors and CROs for preclinical studies and clinical trials related to expanding the labels for our existing products or, if successfully partnered, developing our product candidates. 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 and time consuming. 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.

We may seek collaborations with third parties to market and commercialize our products, including outside of the United States, who may fail to effectively and compliantly market our products and suffer reputational harm.

We have and may continue to rely on third-party collaborators to assist us with marketing our products, including outside of the United States. For example, we have co-promotion arrangements in place in the United States with Ascend Therapeutics to promote SPRIX Nasal Spray to its target women's healthcare practitioners and with OraPharma to promote SPRIX Nasal Spray to dentists, dental specialists and oral surgeons. The OraPharma arrangement will end in April 2019. In addition, we have entered into agreements with pharmaceutical companies in various international markets to market ZORVOLEX and VIVLODEX that we supply. We currently possess limited resources and may not be successful in establishing additional collaborations or co promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co promotion partners. By

entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for commercialization, sales and marketing and regulatory expertise. Our collaborators may fail to market our products in a legally compliant manner, which could subject us to regulatory risk and reputational harm. Any failure of our third party collaborators to successfully market and commercialize our products and product candidates in a legally-compliant manner both in and outside of the United States would diminish our revenues and could harm our reputation.

Risks Related to Our Intellectual Property

The patents and patent applications associated with three of our products are licensed from iCeutica. If iCeutica terminates the license or fails to maintain or enforce the underlying patents, our competitive position and market share will be harmed.

We have licensed the patents and patent applications associated with three of our products, ZORVOLEX, TIVORBEX and VIVLODEX, including the technology that is used to manufacture our products, from iCeutica. iCeutica may not successfully prosecute certain patent applications under which we have licenses and which are material

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to our business. Even if patents are issued from these applications, iCeutica may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. Under the license agreement, we are required to use commercially reasonable diligence efforts to commercialize, market and sell our licensed NSAIDs. If we fail to use such efforts as to any NSAID, iCeutica may terminate our license to that NSAID. If iCeutica were to attempt to terminate the license agreement for this or any other reason, that could remove our ability to market our products covered by the license agreement. In addition, if iCeutica or any other licensor we have in the future were to enter bankruptcy, there is a risk that the license iCeutica or such licensor has granted to us could be terminated or modified in a manner adverse to us. If our license agreement with iCeutica is terminated for any reason, we would be required to cease the commercialization of our products that are subject to such agreement, which would have a material adverse effect on our business.

If we are unable to obtain or maintain intellectual property rights for our technology and products, 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 products, including 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 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. The United States Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents.

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

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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, 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, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post grant proceedings, including post grant review, inter partes review, and derivation proceedings. An adverse determination based on any such submission or proceeding before the USPTO or opposition before a foreign patent agency could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties.

Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection for our technology and products.

If third parties claim that our technology or products infringe 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 in part upon our ability to develop product candidates and commercialize future products without infringing the intellectual property rights of others. Our products and current or future product candidates, 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 morphine or oxycodone products. Since patent applications are published after a certain period of time after filing, and

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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) of the FFDCA for any of our product candidates that we successfully partner, 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 any of our product candidates that we successfully partner 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. For example, we sued a competitor who sent us a Paragraph IV certification related to our now discontinued product, ARYMO ER. We ultimately dismissed the suit when we discontinued ARYMO ER.

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

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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.

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 ZORVOLEX, VIVLODEX and TIVORBEX from iCeutica, to OXAYDO from Acura and to SPRIX Nasal Spray from Recordati, 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 iCeutica, we are subject to commercialization, royalty, patent prosecution and maintenance obligations. 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. Under our agreement with Recordati, which was assigned to us as part of our acquisition of SPRIX Nasal Spray from Luitpold, we are obligated to use best commercial efforts to market and sell SPRIX Nasal Spray and we pay a royalty to Recordati in connection with the SPRIX Nasal Spray license. 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.

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.

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, on non disclosure and confidentiality agreements that we enter into

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

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

We rely upon a combination of patents, trade secret protection (i.e., know-how), and confidentiality agreements to protect the intellectual property of our products, including 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 products 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 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 pharmaceuticals, 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.

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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.

Risks Related to Our International Operations

We are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition.

We, through our distribution partners, sell our products globally. Therefore, we are subject to risks associated with having worldwide operations. These international operations require significant management attention and financial resources.

International operations are subject to inherent risks and our future results could be adversely affected by a number of factors, including:

- Our ability to manufacture the finished product and transport it to locations outside the United States;
- the time and resources required for the oversight of the distribution arrangements in foreign countries, some of which are in the developing world;
- requirements or preferences for domestic products or solutions, which could reduce demand for our solutions;
- differing existing or future regulatory and certification requirements, including with regard to pricing;
- management communication and integration problems related to entering new markets with different languages, cultures and political systems;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties in enforcing contracts, including due to the distribution partner going out of business;
- the uncertainty of protection for intellectual property rights in some countries;
- potentially adverse tax consequences, including regulatory requirements regarding our ability to repatriate profits to the United States;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our solutions in certain non-U.S. markets; and
- political and economic instability and terrorism.

If we do not successfully manage these and other factors, our international distribution arrangements could suffer.

Failure to comply with the FCPA and similar laws associated with our activities outside the United States could subject us to penalties and other adverse consequences.

A portion of our revenue is derived from jurisdictions outside of the United States due to our international distribution arrangements. We face significant risks if we or our distributors fail to comply with the FCPA and other laws that prohibit improper payments or offers of payment to non-U.S. governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business. In many non-U.S. countries, particularly in countries with developing economies, some of which represent markets for us through our distribution arrangements, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees and consultants to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. Although our agreements with our distributors and resellers clearly state our expectations for our distributors' and resellers' compliance with U.S. laws and provide us with various remedies upon any non-compliance, including the ability to terminate the agreement, we also cannot guarantee our distributors' and

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resellers' compliance with U.S. laws, including the FCPA. Therefore, there can be no assurance that none of our employees and agents, or those companies to which we outsource certain of our business operations, will take actions in violation of our policies or of applicable laws, for which we may be ultimately held responsible. As a result of our focus on managing our growth, our development of infrastructure designed to identify FCPA matters and monitor compliance is at an early stage. Any violation of the FCPA and related policies could result in severe criminal or civil sanctions, which could have a material and adverse effect on our reputation, business, operating results and financial condition.

Non-U.S. governments tend to impose strict price controls that may adversely affect our future profitability.

In most non-U.S. countries prescription drug pricing and/or reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, our distribution partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of the products sold by our distribution partners is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability with regard to those international distribution arrangements will be negatively affected.

Risks Related to our Product Candidates

If we do not find suitable partners to assist us with the development and regulatory submissions for our product candidates, we may not be able to further develop or seek regulatory approval for Egalet-002 and our other product candidates and we may not realize any return on our investment in those assets.

Although we have completed our phase 3 studies for Egalet-002, we have determined to delay indefinitely our previously-announced anticipated 2019 filing date for the Egalet-002 NDA, unless we find a partner to share the cost. We have also ceased, for the time being, the research and development of Egalet-003, an AD stimulant, and Egalet-004, an AD, ER hydrocodone, which were developed using our Guardian Technology. We are seeking partners for those product candidates as well. If we are unable to find suitable partners, we not be able to seek regulatory approval for Egalet-002 or perform additional necessary preclinical or clinical studies for our other product candidates. As a result, we may not realize any return on the investments we have made in our product candidates or our Guardian Technology.

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

Our commercialization strategy for our product candidates in clinical and preclinical development will depend on our ability to enter into agreements with partners 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 can be 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.

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- 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.
- 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.

Any delay in the approval process due to our inability to find collaborators quickly or a collaborator's delay in conducting clinical trials or other steps needed for approval could mean that our competitors, especially some of our larger competitors, could discover, develop or commercialize products before, and more successfully than, our product candidates. 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 or that our label cannot reflect certain claims because they are barred by exclusivity. 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. In addition, 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 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.

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.

Even if we are able to partner our product candidates, we may not be able to obtain FDA approval for our product candidates or receive the label we seek, which would prevent or limit the commercialization of our product candidates.

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Even if we successfully partner our product candidates, we may not successfully complete preclinical or clinical studies necessary to obtain FDA 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.

A key element of our strategy with regard to any product candidate that we are able to partner is to seek FDA approval for our product candidates through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Such reliance is typically predicated on a showing of bioequivalence or comparable bioavailability to an approved drug.

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

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.

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Even if we do obtain FDA approval for our partnered product candidates, we may not obtain the labelling that we believe is necessary to fully commercialize the product candidate. While the FDA has issued guidance on requirements for abuse-deterrent labeling, including the studies that must be performed, and although we intend to conduct such studies if we are able to find suitable partners for our product candidates, there can be no assurance that our product candidates that are approved will receive FDA approved labeling that describes any or all of the abuse deterrent features of such product candidates. Any product candidates that we are able to partner may also have other properties that could delay or prevent their regulatory approval or limit the commercial profile of their approved product label. These properties may come to light in the form of adverse events experienced during clinical trials.

We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes may be on the marketing approval of any product candidates we are able to partner. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval of any NDAs we file, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Even if we are able to partner some of our product candidates and obtain regulatory approval for them, they may be subject to mandatory REMs programs, which could increase the cost, burden and liability associated with their commercialization.

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

The regulatory approval processes of the FDA and comparable foreign regulatory authorities can be lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for supplemental applications we may file for our products or for our product candidates that we are able to partner, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable. Any sNDA for our products could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority if there is a disagreement with or disapproval of the design or implementation of our clinical trials; if there is a failure to demonstrate that the product sufficiently deters a particular route of abuse, if any clinical trials fail to meet the level of statistical significance required for approval; or if there are changes in the approval policies or regulations that render our clinical data insufficient to support the submission and filing of a sNDA or to obtain regulatory approval, among others.

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 products or any partnered 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 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 sNDA 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. The FDA may grant deferrals for submission of data or full or partial waivers. We filed a sNDA for SPRIX Nasal Spray 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. The 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. In addition, the FDA denied Iroko's request to be excused from its PREA requirements after Iroko submitted an application.

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The FDA approval process for product candidates 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. 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. It is also possible that we may re-evaluate the path of a particular product or product candidate at different points in the approval and post-approval process, even deciding, in some cases, to discontinue development of a product candidate or take a product off the market. For example, in September 2018, we discontinued the manufacture, distribution and promotion of ARYMO ER after it became clear that the costs associated with the product exceeded the revenues it generated.

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

- disagreement with or disapproval of the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure to sufficiently deter abuse;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- a negative interpretation of the data from our preclinical studies or clinical trials;
- deficiencies in the manufacturing processes or failure of third-party manufacturing facilities with whom we contract for clinical and commercial supplies to pass inspection; or
- insufficient data collected from clinical trials of our product candidates or changes in the approval policies or regulations that render our preclinical and clinical data insufficient to support the submission and filing of an NDA or to obtain regulatory approval.

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, OXAYDO is and we expect that 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 products and 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 include 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 design, conduct and complete clinical trials successfully, we may not be able to receive regulatory approval for products that we are enhancing or any of our partnered product candidates.

In order to obtain FDA approval for any enhancements to our existing products or any product candidates that we partner, we must submit to the FDA substantial evidence that demonstrates that the enhanced product or 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

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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 any of our product candidates that we partner 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 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 fail to approve an enhancement to our product or product label, 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 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 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. In addition, 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 or sNDA as scheduled.

Even if clinical trials are completed as planned, their results may not support expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our product candidates are safe and effective for indicated uses or could fail to support a product enhancement or labeling claim. Such failure may cause us to abandon a product enhancement or labeling claim that we are seeking, abandon a product candidate, 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 our ability to market any product or labeling enhancements;
· delay commercialization of, and product revenues from, our product candidates; and

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

Conducting clinical trials for our products and product candidates and any commercial sales of our products or future 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 products and 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 products, or an applicable foreign regulatory authority.

We currently carry clinical trial and product liability insurance with coverage up to approximately $10 million. We may face product liability claims for our products and product candidates, 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 products or product candidates 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 our products;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- product recall or withdrawal from the market;
- the inability to commercialize any products that we may develop; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

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

Risks Related to Ownership of Our Securities

We have a significant stockholder, which may exert significant control over our operations. As a result, our future strategy and plans may differ materially from those in the past.

Upon our emergence from bankruptcy, approximately 49% of our outstanding Common Stock is owned by Iroko Pharmaceuticals, Inc. and its affiliates, and holders of a significant number of shares of our Common Stock could determine to act as a "group" with respect to their holdings of our Common Stock for securities law purposes. These stockholders have significant control on the outcome of matters submitted to a vote of stockholders, including, but not limited to, electing directors and approving corporate transactions. As a result, our future strategy and plans may differ materially from those of the past, and this concentration of ownership could also facilitate or hinder a negotiated change of control of Egalet and, consequently, have an impact upon the value of our Common Stock.

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Circumstances may occur in which the interests of these significant stockholders could be in conflict with the interests of other stockholders, and these stockholders would have substantial influence to cause us to take actions that align with their interests. Should conflicts arise, we can provide no assurance that these stockholders would act in the best interests of other stockholders or that any conflicts of interest would be resolved in a manner favorable to our other stockholders.

In addition, out of seven directors appointed to our board as of the effective date of our bankruptcy plan, two were selected by Iroko, one was selected by our former secured noteholders, one was selected by our convertible noteholders and one was selected jointly by the mutual agreement of all of our former noteholders. The appointment and removal of the members of our board of directors is governed by the terms of our corporate governance documents, including, our Stockholders' Agreement. Accordingly, those holders of Common Stock may have significant influence or control over our operations and matters presented to our stockholders.

Our Common Stock is listed on the OTC Bulletin Board and could be highly volatile and difficult to sell.

Although our Common Stock is listed on the OTC Bulletin Board, any lack of liquidity may adversely affect the price at which our Common Stock may be sold, if at all. Furthermore, holders of our Common Stock may have difficulty selling or obtaining timely and accurate quotations with respect to such securities. We currently have a small number of stockholders, and our current public float is also small.

The trading price of our Common Stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which will be beyond our control. 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.

There is no trading market for our securities on a national securities exchange and no assurances that an active trading market will develop or that we will list on a national securities exchange.

As of March 6, 2019 our Common Stock currently trades on the OTC Bulletin Board under the symbol "ZCOR", it has not yet been approved for listing on a national securities exchange, and there can be no assurances that we will list on a national securities exchange or that a market for our Common Stock will develop on a national securities exchange. In addition, there can be no assurances as to the liquidity of the trading market for our Common Stock if such a market develops. If our Common Stock begins trading on a national securities exchange, the market price of our Common Stock could be subject to wide fluctuations in response to, and the level of trading that develops with our Common Stock may be affected by, numerous factors beyond our control such as our limited trading history

subsequent to our emergence from bankruptcy, our limited trading volume, the concentration of holdings of our Common Stock, the lack of comparable historical financial information due to our adoption of fresh start accounting principles, actual or anticipated variations in our operating results and cash flow, business conditions in our markets and the general state of the securities markets and the market for energy-related stocks, as well as general economic and market conditions and other factors that may affect our future results, including those described in this Form 10-K. If our Common Stock is listed and begins trading on a national securities exchange, our Common Stock may be traded only infrequently, and reliable market quotations may not be available. Holders of our Common Stock may experience difficulty in reselling, or an inability to sell, their shares. In addition, if an active trading market does not develop or is not maintained, significant sales of our Common Stock, or the expectation of these sales, could materially and adversely affect the market price of our Common Stock.

Future sales of shares by a significant stockholder, including Iroko, could cause our stock price to decline.

If any of our existing stockholders, including Iroko, sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our Common Stock could decline. Sales of a substantial number of shares of our Common Stock in the public market, or the perception that the sales might occur, could depress the market price of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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We are party to ongoing stockholder litigation, and in the future could be party to additional stockholder litigation, which is expensive and could harm our business, financial condition and operating results 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 have been and may be the target of this type of litigation in the future as a result of changes in our stock price, past transactions or other matters. Securities litigation against us, whether or not resolved in our favor, could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business or results of operations. For example, and as further described in Item 3, "Legal Proceedings," and Note 17, "Commitments and Contingencies" to the financial statements accompanying this Annual Report on Form 10-K, we are currently defending two putative securities class actions that were filed in the U.S. District Court for the Eastern District of Pennsylvania on January 27, 2017 and February 10, 2017, respectively. On May 1, 2017, the Court entered an order consolidating the two cases before it and appointing a lead plaintiff. On July 3, 2017, the plaintiffs filed their consolidated amended complaint, which asserts claims for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. The plaintiffs brought their claims individually and on behalf of a putative class of all persons who purchased or otherwise acquired shares of Egalet between November 4, 2015 and January 9, 2017 inclusive. The consolidated amended complaint based its claims on allegedly false and/or misleading statements and/or failures to disclose information about the likelihood that ARYMO ER would be approved for intranasal abuse-deterrent labeling. The defendants moved to dismiss the consolidated amended complaint on September 1, 2017 (the "Motion to Dismiss"), the plaintiffs filed their opposition on October 31, 2017, and the defendants filed their reply on December 8, 2017. The Court heard oral arguments on the Motion to Dismiss on February 20, 2018 and entered an order pursuant to which the plaintiffs filed a motion for leave to file a second amended complaint on March 6, 2018. The defendants responded on March 20, 2018 and the plaintiffs filed their reply on March 27, 2018. The Court heard oral arguments on the plaintiffs' motion for leave to file a second amended complaint on July 12, 2018. On August 2, 2018, the Court granted the defendants' Motion to Dismiss and dismissed the Securities Class Action Litigation with prejudice. Plaintiffs appealed the District Court's decision on August 31, 2018. The appeal was stayed pending our reemergence from bankruptcy. On February 6, 2019, the officer defendants filed a Notice of Lifting of Automatic Stay of Proceedings and Discharge of Subordinated Claims, as plaintiffs' claim against us was extinguished as part of the bankruptcy, which restarted the appellate process. We cannot determine the likelihood of, nor can we reasonably estimate the range of, any potential loss, if any, from these lawsuits.

Future issuances of our Common Stock or rights to purchase Common Stock, including pursuant to our equity incentive plans or the exercise or our outstanding warrants, 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 may 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.

In connection with the Iroko Acquisition and as part of our restructuring, we granted certain customary preemptive rights to Iroko and certain holders of our 13% Senior Secured Notes due 2024, which generally provide for customary preemptive rights in favor of the stockholder parties thereto with respect to certain future issuances of debt or equity securities by us, subject to certain exceptions, for so long as such stockholder party continues to hold certain minimum thresholds of the outstanding shares of our Common Stock. These preemptive rights could impede our ability to raise additional capital and may affect our ability to raise such additional capital on favorable terms. If we that we need to raise additional capital for our business, our inability to do so on favorable terms may have a material adverse effect on our business, consolidated financial condition and results of operations and, as a result, a material adverse effect on our ability to satisfy our debt obligations.

Also, as part of our restructuring, we issued warrants to purchase our Common Stock to certain stockholders who did not want to exceed a certain equity stake in Egalet. In addition, pursuant to our 2019 Stock Based Incentive Compensation Plan (the “2019 Stock Plan”), our compensation committee is authorized to grant equity based incentive

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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 2019 Stock Plan is currently 2,150,000, and future option grants and issuances of common stock under our 2019 Stock Plan may adversely affect the market price of our common stock.

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

The trading market for our Common Stock 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 cover us or provide favorable coverage. If one or more of the analysts who choose to 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.

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 except in certain limited circumstances, 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; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

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

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

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Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated certificate of incorporation provides that, with certain limited exceptions, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any stockholder (including any beneficial owner) to bring (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any director or officer of Egalet owed to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction of the indispensable parties named as defendants. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

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. We also maintained a research laboratory, pilot manufacturing and administrative facility in Vaerlose, Denmark, where we leased 12,895 square feet of space under a lease agreement that automatically renewed every 12 months. We terminated the lease and vacated the facility in February 2019.

We believe that our existing facilities are adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

On January 27, 2017 and February 10, 2017, respectively, two putative securities class actions were filed in the U.S. District Court for the Eastern District of Pennsylvania that named as defendants Egalet Corporation and current officer Robert S. Radie and former officers Stanley J. Musial and Jeffrey M. Dayno (the "Officer Defendants" and together with Egalet Corporation, the "Defendants"). These two complaints, captioned Mineff v. Egalet Corp. et al., No.

2:17-cv-00390-MMB and Klein v. Egalet Corp. et al., No. 2:17-cv-00617-MMB, assert securities fraud claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") on behalf of putative classes of persons who purchased or otherwise acquired Egalet Corporation securities between December 15, 2015 and January 9, 2017 and seek damages, interest, attorneys' fees and other expenses. On May 1, 2017, the Court entered an order consolidating the two cases (the "Securities Class Action Litigation") before it, appointing the Egalet Investor Group (consisting of Joseph Spizzirri, Abdul Rahiman and Kyle Kobold) as lead plaintiff and approving their selection of lead and liaison counsel. On July 3, 2017, the plaintiffs filed their consolidated amended complaint, which named the same Defendants and also asserted claims for purported violations of Sections 10(b) and 20(a) of the Exchange Act. Plaintiffs brought their claims individually and on behalf of a putative class of all persons who purchased or otherwise acquired shares of Egalet between November 4, 2015 and January 9, 2017 inclusive. The consolidated amended complaint based its claims on allegedly false and/or misleading statements and/or failures to disclose information about the likelihood that ARYMO ER would be approved for intranasal abuse-deterrent labeling. The Defendants moved to dismiss the consolidated amended complaint on September 1, 2017 (the "Motion to Dismiss"), the plaintiffs filed their opposition on October 31, 2017, and the Defendants filed their reply on December 8, 2017. The Court heard oral arguments on the Motion to Dismiss on February 20, 2018 and entered an order pursuant to which the plaintiffs filed a motion for leave to

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file a second amended complaint on March 6, 2018. The Defendants responded on March 20, 2018 and the plaintiffs filed their reply on March 27, 2018. The Court heard oral arguments on the plaintiffs' motion for leave to file a second amended complaint on July 12, 2018. On August 2, 2018, the Court granted the Defendants' Motion to Dismiss and dismissed the Securities Class Action Litigation with prejudice. On August 31, 2018, plaintiffs filed their notice of appeal with the United States Court of Appeal for the Third Circuit. On November 7, 2018, the Defendants filed a notice of suggestion of bankruptcy and unopposed motion to stay the appeal as to the Officer Defendants (the appeal was automatically stayed as to the Company upon the Chapter 11 filing). On February 6, 2019, the Officer Defendants filed a Notice of Lifting of Automatic Stay of Proceedings and Discharge of Subordinated Claims, as plaintiffs' claim against us was extinguished as part of the bankruptcy, which restarted the appellate process. We dispute the allegations in the lawsuit and intend to defend these actions vigorously. We cannot determine the likelihood of, nor can it reasonably estimate the range of, any potential loss, if any, from these lawsuits.

In January 2017, Lupin Pharmaceuticals, Inc. and Lupin Limited (together "Lupin") notified iCeutica Pty Ltd. and Iroko Pharmaceuticals, LLC that Lupin had submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Vivlodex® (meloxicam). In the notice, Lupin alleges that U.S. Patent No. 9,526,734 covering meloxicam is invalid as obvious and that Lupin's generic product will not infringe any claim of the patent. On February 10, 2017, Plaintiffs iCeutica Pty Ltd. and Iroko Pharmaceuticals, LLC filed a complaint in the District Court for the District of Maryland alleging infringement of U.S. Patent No. 9,526,734 by Lupin under 35 U.S.C. sections 271(e)(2) and 271(a)-(b). On June 5, 2017, Lupin sent a second notice alleging that U.S. Patent No. 9,649,318 was invalid and not infringed. Plaintiffs filed an amended complaint alleging infringement of U.S. Patent Nos. 9,526,734 and 9,649,318 by the Lupin defendants under 35 U.S.C. sections 271(e)(2) and 271(a)-(b) on July 7, 2017. On February 1, 2018, the district court granted Lupin's motion for summary judgment on non-infringement and dismissed Plaintiffs' amended complaint. Plaintiffs filed a timely notice of appeal to the United States Court of Appeals for the Federal Circuit and filed their opening brief on July 13, 2018. Lupin filed its answering brief on October 22, 2018 and Plaintiffs filed their reply brief on January 4, 2019. With our acquisition of certain assets of Iroko and the assignment of Iroko's exclusive license to U.S. Patent Nos. 9,526,734; 9,526,734; and 9,649,318 to us, we have been substituted for Iroko as a Plaintiff in this matter.

In March 2018, Novitium Pharma LLC ("Novitium") notified iCeutica Pty Ltd. and Iroko Pharmaceuticals, LLC that Novitium had submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Vivlodex® (meloxicam). In the notice, Novitium alleges that its generic product will not infringe any claim of U.S. Patent Nos. 9,526,734; 9,526,734; and 9,649,318. On April 20, 2018, Plaintiffs iCeutica Pty Ltd and Iroko Pharmaceuticals, LLC filed a complaint in the District Court for the District of Delaware alleging infringement of United States Patent Nos. 9,526,734, 9,649,318, and 9,808,468 by Novitium under 35 U.S.C. sections 271(e)(2) and 271(a)-(c). With our acquisition of certain assets of Iroko and the assignment of Iroko's exclusive license to U.S. Patent Nos. 9,526,734; 9,526,734; and 9,649,318 to us, we have been substituted for Iroko as a Plaintiff in this matter.

On October 30, 2018, the Debtors filed the Bankruptcy Petitions in the U. S. Bankruptcy Court for the District of Delaware. The Debtors requested that the Chapter 11 cases (the "Chapter 11 Cases") be jointly administered for procedural purposes only under the caption In re Egalet Corporation, et al., Case No. 18-12439. Upon filing, the Company intended to operate its business as a "debtor-in-possession" under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and orders of the Bankruptcy Court. The Company continued ordinary course operations substantially uninterrupted during the Chapter 11 Cases and sought

approval from the Bankruptcy Court for relief under certain “first day” motions authorizing the Debtors to continue to conduct its business in the ordinary course. On January 14, 2019, the Court entered the Confirmation Order confirming the plan under Chapter 11 of the Bankruptcy Code. On January 31, 2019 (the “Effective Date”), and substantially concurrent with the consummation of the Iroko Acquisition, the Plan became effective. On March 26, 2019, the Bankruptcy Court issued a final decree closing the Chapter 11 Cases. Refer to Note 22 to our Consolidated Financial Statements included in Item 15 of this Form 10-K for additional details.

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 stock was traded on the NASDAQ Global Market under the symbol "EGLT" through July 10, 2018. As of July 11, 2018 our common stock was traded on the NASDAQ Capital Market under the symbol "EGLT". On September 19, 2018 trading in our common stock on the NASDAQ Capital Market was suspended and, as of December 31, 2018, shares of our common stock were quoted by the OTCQX Bulletin Board.

Stockholders

As of March 26, 2019, there were 2 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.

Issuer Purchases of Equity Securities

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

Recent Sales of Unregistered Securities

There were no unregistered sales of our equity securities during the period covered by this Annual Report.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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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

We are a commercial-stage pharmaceutical company commercializing innovative treatments for different types of pain and inflammation. Given the need for acute and chronic pain products and the issue of prescription abuse, we are primarily focused on bringing non-narcotic and abuse-discouraging formulations of opioids to patients and physicians. We are currently selling SPRIX® (ketorolac tromethamine) Nasal Spray ("SPRIX Nasal Spray"), VIVLODEX® (meloxicam), TIVORBEX® (indomethacin) and ZORVOLEX® (diclofenac), INDOCIN® (indomethacin) oral suspension and INDOCIN suppositories and OXAYDO® (oxycodone HCI, USP) tablets for oral use only—CII ("OXAYDO"). We plan to continue to grow our business through the revenue growth of our seven approved products, business development opportunities and development of our product candidates from our pipeline with a partner or on our own in the future.

We use our 87 territory managers to market our seven approved products to over 8,000 healthcare providers treating pain, including pain medicine physicians, primary care physicians, nurse practitioners, orthopedic surgeons and neurologists in the United States, with the intent to build awareness and increase adoption of our products

Using our proprietary Guardian Technology, we developed ARYMO® ER, an extended release morphine product formulated with abuse-deterrent properties, which is approved 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. Due to lack of market adoption of branded abuse-deterrent, ER morphines, we discontinued the manufacturing, distribution and promotion of ARYMO ER on September 28, 2018.

Iroko Acquisition and Restructuring

On October 30, 2018, we entered into an asset purchase agreement with Iroko Pharmaceuticals, Inc. ("Iroko") (the "Iroko Acquisition") pursuant to which, upon the terms and subject to the conditions set forth therein, we agreed to acquire certain assets and rights of Iroko, including assets related to Iroko's marketed products VIVLODEX, TIVORBEX, ZORVOLEX and INDOCIN (indomethacin) oral suspension and suppositories ("INDOCIN"). The Iroko Acquisition closed on January 31, 2019.

The Iroko Acquisition was to be effectuated pursuant to, and was conditioned upon, the occurrence of the effective date of the joint plan of reorganization related to the voluntary petitions for reorganization under the United States Bankruptcy Code filed in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") on October 30, 2018.

On October 30, 2018, we entered into a restructuring support agreement with creditors holding approximately 94% in aggregate principal amount outstanding and in excess of a majority in number of our 13% Notes and approximately 67% in aggregate principal amount outstanding of our existing 5.50% Notes and 6.50% Notes in connection with our filing of the Chapter 11 cases on October 30, 2018.

On January 14, 2019, the Bankruptcy Court entered an order confirming the joint plan of reorganization. On January 31, 2019 (the "Effective Date"), and substantially concurrent with the consummation of the Iroko Acquisition, the plan became effective.

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Pursuant to the plan, on the Effective Date, among other things, the following transactions occurred:

- payment in full, in cash, of all administrative claims, statutory fees, professional fee claims and certain priority other secured claims, and general unsecured claims (or, to the extent not so paid, such amounts shall be paid as soon as practicable after the Effective Date or in the ordinary course of business, subject to the reorganized company's claims and defenses);

- the cancellation of all of the Company's common stock and all other equity interests in the Company outstanding on the Effective Date prior to consummation of the transactions; the conversion of approximately $80.0 million of claims (the "First Lien Secured Notes Claims") related to the Company's 13% Notes into (1) $50.0 million in aggregate principal amount of Series A-1 Notes, (2) the number of shares of the Company's common stock (or warrants) representing, in the aggregate, 19.38% of the shares outstanding as of the Effective Date (subject to dilution only on account of the Management Incentive Plan (the "MIP") (as defined in the Plan)) (the "First Lien Equity Distribution), (3) $20.0 million in cash less certain amounts related to adequate protection payments, and (4) cash in an amount equal to certain unpaid fees and expenses of the trustee under the indenture governing the 13% Notes;

- the conversion of $48.6 million of claims (the "Convertible Notes Claims") related to the Company's 5.50% Notes and its 6.50% Notes into the number of shares of common stock of the Company (or warrants) representing, in the aggregate, 31.62% of the shares outstanding as of the Effective Date (subject to dilution only on account of the MIP);

- the consummation of the Iroko Acquisition and other transaction contemplated by the asset purchase agreement; and

- the effectiveness of the discharge, release, exculpation and injunction provisions for the benefit of the Debtors', certain of the Debtors' claimholders and certain other parties in interest, each in their capacities as such, from various claims and causes of action.

Each of the foregoing percentages of equity in the Company is subject to dilution solely from the shares issued or reserved for issuance under the MIP. On the Effective Date, following the consummation of the Iroko Acquisition and the other transactions contemplated by the plan, there were 9,360,968 shares of common stock issued and outstanding and warrants for an aggregate of 4,972,364 shares of the Company's common stock.

On the Effective Date, the Company issued (i) an aggregate of 4,774,093 shares of common stock to the former holders of First Lien Secured Notes Claims and Convertible Notes Claims and (ii) warrants for an aggregate of 2,535,905 shares of common stock to certain holders of First Lien Secured Notes Claims and Convertible Notes Claims.

Immediately following the completion of the Iroko Acquisition, we currently expect to continue to operate under the "Egalet" name and will market six commercial products: SPRIX Nasal Spray, OXAYDO, INDOCIN, VIVLODEX, TIVORBEX and ZORVOLEX. We have a dedicated internal sales force that will target pain medicine physicians, primary care physicians, nurse practitioners, orthopedic surgeons and neurologists in the United States with the intent to build awareness and increase adoption of our products. We also intend to continue to look for partnerships similar to our ongoing relationships with Ascend to bring SPRIX Nasal Spray to specialists we cannot reach with our internal sales force.

We expect that the Iroko Acquisition will result in cross-selling opportunities for our sales force and various other synergies. More specifically, the Iroko Acquisition enabled the filing of our plan of reorganization in the Chapter 11 Cases, which provided for an increased recovery for our creditors as compared to a liquidation under Chapter 7 of the Bankruptcy Code. We believe the products acquired in the Iroko Acquisition position us well to become a more profitable and financially stable company, better able to compete and respond to the competitive challenges and cyclical business conditions.

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Financial Operations

Our net losses were $95.5 million and $69.4 million for the years ended December 31, 2018 and 2017, respectively. We recognized total revenues of $30.4 million and $26.1 million for the years ended December 31, 2018 and 2017, respectively which were all product sales. As of December 31, 2018, we had an accumulated deficit of $388.9 million. We expect to incur significant expenses and operating losses for the foreseeable future as we incur significant commercialization expenses as we continue to grow our sales, marketing and distribution infrastructure to sell our commercial products in the United States. Additionally, we expect to continue to protect and expand our intellectual property portfolio.

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

The financial operations overview, critical accounting policies and the remainder of the Management's Discussion and Analysis pertain to legacy Egalet only, as the Iroko Acquisition and Plan of Reorganization did not become effective until January 31, 2019.

Revenue

We have generated $77.5 million through December 31, 2018 in net product revenue from our approved products, SPRIX Nasal Spray, OXAYDO, and ARYMO ER, and have generated $22.6 million in total revenue through December 31, 2018, 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

Cost of Sales (excluding amortization of product rights)

Cost of sales includes the cost of inventory sold or reserved, which includes manufacturing, supply chain costs, product shipping and handling costs, and product royalties. In the years ended December 31, 2017 we recognized net product sales when prescriptions were dispensed to patients. The cost of sales associated with the deferred product revenues was recorded as deferred costs, which were included in inventory, until such time the deferred revenue was recognized. Effective January 1, 2018, we recognized net product sales when we ship our products to our customers.

Amortization of Product Rights

Amortization of product rights consists of the amortization expense associated with the intangible product rights related to the SPRIX Nasal Spray 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, regulatory fees, consulting and accounting services. We anticipate that our general and administrative expenses will increase in the future due to 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, regulatory fees, and legal and accounting fees, among other expenses.

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Sales & Marketing Expenses

Sales and marketing expenses 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 and 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 Egalet 002 and life cycle management opportunities for our approved products. Our research and development expenses consist of:

- employee related expenses, including salaries, benefits, and travel expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, other supplies; and
- costs associated with preclinical activities

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.

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 product and product candidates, as shown in the table below.

The following table summarizes our research and development expenses for the years ended December 31, 2018 and 2017:

(in thousands)	Year Ended December 31, 2018	Year Ended December 31, 2017
ARYMO ER	$ 55	$ 663
Egalet 002	383	8,221
OXAYDO	387	225
Other clinical and preclinical development	1,814	2,892
Personnel related	897	2,743
	$ 3,536	$ 14,744

We incurred research and development expenses of $3.5 million and $14.7 million during the years ended December 31, 2018 and 2017, respectively. We anticipate that our future research and development expense will continue to decline as we are seeking partners for each of our 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

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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 our 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.

Due to 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 of our approved products and collaborative research and development agreements that we have entered or may enter into from time to time.

Net Product Sales

In 2017, we recognized revenue under the guidance of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605, Revenue Recognition. Under ASC 605, we recognized net product

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sales when prescriptions were dispensed to patients. We adopted ASC606, Revenue from Contracts with Customers on January 1, 2018. Under ASC 606, revenue is recognized when we ship our products to our customers.

We sell SPRIX Nasal Spray in the United States to a single specialty pharmaceutical distributor subject to rights of return. We recognize revenue of SPRIX Nasal Spray upon delivery of the product to our customer.

We sell OXAYDO and formerly sold ARYMO ER in the United States to several wholesalers, all subject to rights of return. We recognize revenue of OXAYDO and ARYMO ER upon delivery of the product to our customers.

The following table presents an analysis of our provision for product sales allowances and accruals for the year ended December 31, 2018:

(in thousands)	Fees and distribution costs	Co-pay assistance	Rebates	Returns	Total
Balances at December 31, 2017	$ 595	$ 3,644	$ 579	$ —	$ 4,818
Adjustment for ASU 2014-09	—	4,221	656	—	4,877
Allowances for current period sales	8,183	74,530	7,799	2,883	93,395
Adjustment related to prior period sales	—	—	180	—	180
Credits or payments made for prior period sales	(555)	(7,866)	(1,235)	—	(9,656)
Credits or payments made for current period sales	(7,761)	(61,203)	(5,315)	(863)	(75,142)
Balance at December 31, 2018	$ 462	$ 13,326	$ 2,664	$ 2,020	$ 18,472
Total gross product sales					$ 123,928
Total provision for product sales allowances and accruals as a percentage of total gross sales					75%

Intangible and Long-Lived Assets

Intangible assets consist of product rights related to the product acquisition of SPRIX Nasal Spray from Luitpold, 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.

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 are difficult to predict. 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 did not record any impairment charges for the years end December 31, 2017. During the year ended December 31, 2018, we recorded a charge of $113,000 to restructuring and other charges to write

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off the remaining IP R&D intangible asset related to our Guardian Technology due to our decision to discontinue the manufacturing and promotion of ARYMO ER.

Stock Based Compensation Expense

We apply the fair value recognition provisions of FASB ASC Topic 718, Compensation—Stock Compensation. Determining the amount of share-based compensation expense 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.

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. For the year ended December 31, 2018 we estimated our expected volatility based on our actual historical volatility by using daily closing prices over a period of the expected term of the associated award. Prior to January 1, 2017, we utilized data from a representative group of companies to estimate expected stock price volatility. We selected companies from the pharmaceutical 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 Staff Accounting Bulletin ("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, 2018 and 2017:

	2018		2017	
Risk-free interest rate	2.79	%	1.93	%
Expected term of options (in years)	5.90		6.15	
Expected volatility	80.60	%	80.57	%
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 our Consolidated Balance Sheet, and re-measured to fair value at each reporting period. Any changes in fair value are recorded in our 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.

5.50% Notes

We determined the embedded conversion options in the 5.50% Convertible Senior Notes due 2020 (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 shares of our common stock or a combination of cash and shares of our common stock 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

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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.

The fair value of the liability component of the 5.50% Notes was estimated at $40.6 million at issuance in April 2015. 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 is being amortized to interest expense over the term of the 5.50% Notes through April 1, 2020 using the effective interest method.

On a quarterly basis, we perform an assessment 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 our common stock, or a combination of cash and shares of our 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 Consolidated Balance Sheets, with subsequent changes to fair value recorded through earnings at each reporting period on our Consolidated 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 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 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.

6.50% Notes

We determined the embedded conversion options in the 6.50% Convertible Senior Notes due 2024 (the “6.50% Notes”) are required to be separately accounted for as derivatives as we did not have enough available authorized shares to cover the conversion obligation as of the date of issuance, December 27, 2017 or as of December 31, 2017. The value of the liability component is calculated by measuring the fair value of a similar liability that does not have an associated conversion component. 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 6.50% Notes using the effective interest method.

The fair value of the liability component of the 6.50% Notes was estimated at $4.6 million at issuance in December 2017. Therefore, the difference between the $23.9 million face value of the 6.50% Notes and the $4.6 million estimated fair value of the liability component is being amortized to interest expense over the term of the 6.50% Notes through December 31, 2024 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 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 6.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the 6.50% Notes prior to January 1, 2021, 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 6.50% Notes to be converted had such notes remained outstanding from the conversion date through January 1, 2021, 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

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as a liability in our Consolidated Balance Sheets, with subsequent changes to fair value recorded through earnings at each reporting period on our Consolidated 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.

Warrant Liability Accounting

In July 2017, we entered into an underwriting agreement with Cantor Fitzgerald & Co. relating to an underwritten public offering (the "July 2017 Equity Offering") of 16,666,667 shares of our common stock and accompanying warrants to purchase 16,666,667 shares of common stock, at a combined public offering price of $1.80 per share and accompanying warrant, for gross proceeds of $30.0 million. Each warrant has an exercise price of $2.70, subject to adjustment in certain circumstances. As of December 31, 2017, the warrant exercise price was adjusted to $2.14. The shares of common stock and warrants were issued separately. The warrants may be exercised at any time on or after the date of issuance and will expire five years from the date of issuance.

We accounted for the warrants using ASC 480 – Distinguishing Liabilities from Equity and determined that the warrants were a freestanding financial instrument that are subject to liability classification. Pursuant to the terms of the agreement, we could be required to settle the warrants in cash in the event of an acquisition of Egalet, and as a result the warrants are required to be measured at fair value and reported as a current liability in our Consolidated Balance Sheets. The warrant exercise price is subject to adjustment upon the issuance of certain equity securities at a price less than the exercise price of the warrants then in effect.

Accrued Research and Development Expenses

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

Income Taxes

Our income tax expense, deferred tax assets and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We are subject to income taxes in the United States, Denmark, and the United Kingdom ("U.K."). 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, Denmark, and U.K. net operating loss carryforwards will not be realized. At December 31, 2018, in recognition of this risk, we have provided a valuation allowance of approximately $80.4 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, 2018 will be accounted for as a reduction of income tax expense.

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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.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the top U.S. federal corporate tax rate to 21%; requiring companies to pay a one-time transition tax on certain un-repatriated earnings of foreign subsidiaries; generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries; requiring a current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations; eliminating the corporate alternative minimum tax ("AMT") and changing how existing AMT credits can be realized; creating the base erosion anti-abuse tax, a new minimum tax; creating a new limitation on deductible interest expense; and changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

The Tax Act reduces our U.S. corporate income tax rate from 34% to 21%, effective January 1, 2018. 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 reverse. As a result of the reduction in the U.S. corporate income tax rate to 21% under the Tax Act, we revalued our ending net deferred tax assets and liabilities at December 31, 2017.

The Tax Act provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits. We did not have to recognize any income tax expense related to the transition tax due to current and historical losses at its controlled foreign corporation.

The global intangible low-taxed income tax and base erosion provisions are effective for taxable years beginning after December 31, 2017. We do not currently expect these provisions to have a material impact on our tax rate due to losses at our controlled foreign corporation and we are currently below the gross receipts threshold for purposes of the base erosion provisions.

Due to the timing of the new tax law and the substantial changes it brings, the SEC Staff issued SAB 118, which provides registrants a measurement period to report the impact of the new U.S. tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the Tax Act. We have finalized the accounting for the Tax Act and have recorded no additional amount during the current year.

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Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

(in thousands)	Year Ended December 31, 2018	2017	Change
Revenue			
Net product sales	$ 30,353	$ 26,136	$ 4,217
Total revenue	30,353	26,136	4,217
Costs and Expenses			
Cost of sales (excluding amortization of product rights)	7,447	5,153	2,294
Amortization of product rights	2,107	2,082	25
General and administrative	24,079	34,065	(9,986)
Sales and marketing	33,730	35,532	(1,802)
Research and development	3,536	14,744	(11,208)
Restructuring & other charges	17,043	2,760	14,283
Total costs and expenses	87,942	94,336	(6,394)
Loss from operations	(57,589)	(68,200)	10,611
Other (income) expense:			
Change in fair value of derivative liability	(12,292)	(2,546)	(9,746)
Interest expense, net	41,280	17,666	23,614
Other (gain) loss	(144)	(750)	606
Gain on extinguishment of debt	—	(13,221)	13,221
Loss (gain) on foreign currency exchange	(1)	10	(11)
Total other (income) expense	28,843	1,159	27,684
Reorganization charges	9,022	—	9,022
Loss after reorganization charges and before provision (benefit) for income taxes	(95,454)	(69,359)	(26,095)
Provision (benefit) for income taxes	—	—	—
Net loss	$ (95,454)	$ (69,359)	$ (26,095)

Net Product Sales

Net product sales increased by $4.2 million for the year ended December 31, 2018 compared to the year ended December 31, 2017. Net product sales for the year ended December 31, 2017 consisted of $19.9 million for SPRIX Nasal Spray, $5.6 million for OXAYDO and $643,000 for ARYMO ER. Net product sales for the year ended December 31, 2018 consisted of $23.4 million for SPRIX Nasal Spray, $5.8 million for OXAYDO and $1.2 million for ARYMO ER. Due to the adoption of the ASC 606 on January 1, 2018, net product sales for the year ended December 31, 2017 reflected prescriptions dispensed to patients and net product sales for the year ended December 31, 2018 reflected shipments to customers.

Cost of Sales (excluding amortization of product rights)

Cost of sales (excluding amortization of product rights) increased by $2.3 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 related to the product sales of SPRIX Nasal Spray and OXAYDO.

Cost of sales for SPRIX Nasal Spray and OXAYDO for the year ended December 31, 2017 reflects the average cost of inventory produced and dispensed to patients in the period. Cost of sales for ARYMO ER for the year ended December 31, 2017 includes the portion of inventory produced after the FDA approval of ARYMO ER in January 2017.

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The portion of inventory produced before the FDA approval of ARYMO ER was recorded in research and development expense in prior periods.

Cost of sales for SPRIX Nasal Spray, OXAYDO and ARYMO ER for the year ended December 31, 2018 reflects the average cost of inventory shipped to wholesalers and specialty pharmaceutical companies during the period.

Amortization of Product Rights

Amortization of product rights relates to the OXAYDO and SPRIX Nasal Spray intangible assets as well as for the IP R&D intangible asset related to our Guardian Technology. We recorded a charge of $113,000 to restructuring and other charges in September 2018 to write off the remaining In-Process Research and Development ("IP R&D") intangible asset related to our Guardian Technology due to our decision to discontinue the manufacturing and promotion of ARYMO ER.

General and Administrative Expenses

General and administrative expenses decreased by $10.0 million, for the year ended December 31, 2018 compared to the year ended December 31, 2017.

This decrease was attributable to decreases in salaries and stock-based compensation expenses related to reduced headcount of $2.8 million, decreases in administrative expenses of $1.5 million and decreases in ARYMO ER post-marketing study fees of $4.7 million in the year ended December 31, 2018.

Sales and Marketing Expenses

Sales and marketing expenses decreased by $1.8 million for the year ended December 31, 2018 compared to the year ended December 31, 2017.

This decrease was attributable to decreases in sales access funds expense of $1.5 million and decreases in marketing expenses of $1.0 million, partially offset by an increase of $1.0 million in salaries and stock-based compensation expenses in the year ended December 31, 2018.

Research and Development expenses

Research and development expenses decreased by $11.2 million for the year ended December 31, 2018 compared to the year ended December 31, 2017.

This decrease was driven primarily by decreases in clinical studies expense of $8.3 million and decreases in salaries and stock-based compensation expenses of $2.7 million.

Restructuring and Other Charges

Restructuring and other charges of $17.0 million for the year ended December 31, 2018 reflected costs related to the discontinuation of ARYMO ER of $8.2 million and a termination payment to Halo Pharmaceuticals of $3.1 million, and legal and other professional fees of $5.8 million.

Restructuring and other charges of $2.8 million for the year ended December 31, 2017 reflected costs related to the expense reduction plan announced in August 2017 to decrease the operating expenses that do not directly support the growth of our commercial business.

Change in Fair Value of Warrant and Derivative Liability

The interest make-whole provisions of the 6.50% Notes, as well as the warrant liability associated with the warrants issued in our July 2017 Equity offering are subject to re-measurement at each balance sheet date. Refer to Note

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5 to our Consolidated Financial Statements included in Item 15 of this Annual Report for additional details. We recognize any change in fair value in our consolidated statements of operations and comprehensive loss as a change in fair value of the derivative liabilities. During the years ended December 31, 2018 and 2017, we recognized a change in the fair value of our derivative liabilities of $12.3 million and $2.5 million, respectively. The change in fair value of the derivative liability is due to the changes in the value of our common stock during the years ended December 31, 2018 and 2017.

Interest Expense

The increase of $23.6 million was driven primarily by the acceleration of the amortization of the debt discounts related to our 5.50% Notes, 6.50% Notes and 13% Notes due to the reevaluation of the contractual term of these instruments due to the events of default.

Interest expense of $41.3 million for the year ended December 31, 2018 includes non-cash interest and amortization of debt discount totaling $31.1 million. Interest expense of $17.7 million for the year ended December 31, 2017 includes non-cash interest and amortization of debt discount totaling $5.1 million.

Refer to Note 11 to our Consolidated Financial Statements included in Item 15 of this Annual Report for additional details about our long-term debt at December 31, 2018.

Other gain

Other gain of $144,000 for the year ended December 31, 2018 consisted primarily of gains on sale of machinery and equipment in Denmark. Other gain of $750,000 for the year ended December 31, 2017 consisted primarily of Danish research and development tax credit of $880,000 offset by losses of $184,000 for the retirement of a leasehold improvement in the United States.

Gain on Extinguishment of Debt

We recognized a gain of $13.2 million for the year ended December 31, 2017 related to the note exchange of a portion of our 5.50% convertible notes in 2017.

Refer to Note 11 to our Consolidated Financial Statements included in Item 15 of this Annual Report for additional details about our long-term debt at December 31, 2018.

Loss on Foreign Currency Exchange

We recognized a gain on foreign currency exchange of $1,000 during the year ended December 31, 2018.We recognized a loss on foreign currency exchange of $10,000 during the year ended December 31, 2017.

Reorganization Charges

Reorganization charges of $9.0 million for the year ended December 31, 2018 reflected costs related to the Chapter 11 Cases and consist of legal and other professional fees incurred subsequent to the Chapter 11 filing.

Benefit for Income Taxes

We had no tax benefit during the years ended December 31, 2018 and 2017.

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 $95.5 million and $69.4 million for the years ended December 31, 2018 and 2017, respectively. Our operating activities used $54.8 million and $65.2 million of cash during the years ended December 31, 2018 and

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2017, respectively. At December 31, 2018, we had an accumulated deficit of $388.9 million, working capital of $21.4 million and cash, restricted cash, cash equivalents and marketable securities totaling $40.7 million.

Since our initial public offering ("IPO") we have engaged in the following financing transactions.

In January 2015, we entered into the Loan Agreement with Hercules and certain other lenders, pursuant to which we borrowed $15.0 million under a term loan. In August 2016, we repaid all outstanding obligations under the Loan Agreement, using the proceeds from the 13% Notes. Refer to Note 11 to our Consolidated Financial Statements included in Item 15 of this Annual Report for additional details.

In April and May 2015, we issued through a private placement $61.0 million in aggregate principal amount of the 5.50% Notes. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing on October 1, 2015. Refer to Note 11 to our Consolidated Financial Statements included in Item 15 of this Annual Report for additional details.

In July 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.

Through December 31, 2015, we received $4.1 million in payments from our collaborative research and development agreements along with aggregate upfront and milestone payments of $20.0 million under our collaborative research and license agreement with Shionogi Limited.

In August 2016, we issued $40.0 million in aggregate principal amount of the 13% Senior Secured Notes and issued another $40.0 million in aggregate principal amount following FDA approval of ARYMO ER in January 2017 (the "13% Notes"). Interest on the 13% Notes accrues at a rate of 13% per annum and is payable semi-annually in arrears on March 20 and September 20 of each year (each, a "Payment Date") commencing on March 20, 2017. On each Payment Date commencing on March 20, 2018, we will also pay an installment of principal on the 13% Notes in an amount equal to 15% (or 17% if certain sales targets are not met) of the aggregate net sales of OXAYDO (oxycodone HCI, USP) tablets for oral use only – CII, SPRIX Nasal Spray, ARYMO ER and Egalet-002, if approved, for the two consecutive fiscal quarter periods most recently ended, less the amount of interest paid on the 13% Notes on such Payment Date.

In March 2017, we initiated sales of shares under our July 2015 Controlled Equity Offering Sales Agreement ("2015 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") and sold an aggregate of 9,786,622 shares of Common Stock through December 31, 2018, resulting in net proceeds of $9.5 million after deducting commissions of $286,000.

Under the 2015 Sales Agreement, we may, at our discretion, from time to time sell shares of our Common Stock, for an aggregate offering price of up to $30.0 million (inclusive of amounts sold to date). We provided Cantor with customary indemnification rights, and Cantor is entitled to a commission at a fixed rate of 3% of the gross proceeds per share sold. Sales of the shares under the 2015 Sales Agreement have been made and, any additional sales under the 2015 Sales Agreement, will be made in transactions deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act of 1933, as amended. We suspended sales under the 2015 Sales Agreement effective July 27, 2018.

In July 2017, we completed an underwritten public offering of 16,666,667 shares of our Common Stock and accompanying warrants to purchase 16,666,667 shares of our Common Stock, at a combined public offering price of $1.80 per share and accompanying warrant for gross proceeds of $30.0 million. The net offering proceeds were $28.6 million after deducting underwriting discounts and commissions of $1.4 million. Each warrant has an exercise price of $2.70, subject to adjustment in certain circumstances.

In December 2017, we entered into exchange agreements (the "Exchange Agreements") with certain holders (the "Holders") of our 5.50% Notes pursuant to which the Holders agreed to exchange, in the aggregate, approximately $36.4 million of outstanding principal amount of the 5.50% Notes for, in the aggregate, (i) approximately $23.9 million

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of our new 6.50% Notes, (ii) a warrant exercisable for 3.5 million shares of the our Common Stock and (iii) payments, in cash, of all accrued but unpaid interest as of the closing on the 5.50% Notes exchanged in the transaction (the "Exchange"). We are obligated to pay interest on the 6.50% Notes semiannually in arrears on January 1 and July 1 of each year commencing July 1, 2018 at a rate of 6.50% per year.

Cash Flows

Comparison of Years Ended December 31, 2018 and 2017

The following table summarizes our cash flows for the years ended December 31, 2018 and 2017:

(in thousands)	Year Ended December 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	$ (54,814)	$ (65,164)
Investing activities	55,209	(17,584)
Financing activities	3,912	69,353
Effect of foreign currency translation on cash	(74)	530
Net (decrease) increase in cash and restricted cash	$ 4,233	$ (12,865)

Cash Flows from Operating Activities

Net cash used in operating activities was $54.8 million for the year ended December 31, 2018 and included a net loss of $95.5 million. Net non-cash adjustments to reconcile net loss to net cash provided by operations were $40.9 million and included non-cash interest and 13% Notes redemption premium of $38.3 million, the write-down of ARYMO assets for $6.9 million, and depreciation and amortization expenses of $4.2 million, partially offset by a $12.3 million change in fair value of our derivative liability. Net cash inflows from changes in operating assets and liabilities consisted of an increase in accounts receivable of $4.3 million, and a decrease in accounts payable of $1.6 million, offset by an increase an increase in accrued expenses of $6.1 million.

Net cash used in operating activities was $65.2 million for the year ended December 31, 2017 and consisted primarily of a net loss of $69.4 million. This net loss included a non-cash gain on extinguishment of debt of $13.2 million, which was partially offset by $5.9 million in stock-based compensation expense, $5.1 million of non-cash interest and debt discount amortization, $5.0 million of non-cash depreciation and amortization expense, and $3.9 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 $5.5 million primarily driven by our commercial operations, clinical studies and manufacturing operations, and an increase in deferred revenue of $3.5 million related to the product sales of SPRIX Nasal Spray, OXAYDO and ARYMO ER. These inflows were partially offset by cash outflows due to a decrease in accounts receivable of $3.0 million and a decrease in inventory of $1.5 million.

Cash Flows from Investing Activities

Net cash provided by investing activities for the year ended December 31, 2018 was $55.2 million and consisted primarily of the maturity of investments of $74.2 million, offset by cash outflows of $23.5 million for the purchase of investments.

Net cash used in investing activities for the year ended December 31, 2017 was $18.0 million. Cash outflows for the year ended December 31, 2017 consisted of the purchase of investments for $101.3 million and an increase in

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restricted cash of $400,000. These outflows were partially offset by inflows from the sale and maturity of investments of $83.8 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was $3.9 million for the year ended December 31, 2018 and included $5.2 million in net proceeds from the issuance of our common stock under our “at-the-market” offering.

Net cash provided by financing activities was $69.4 million for the year ended December 31, 2017 and consisted of $38.3 million in net proceeds from the issuance of the 13% Notes and Royalty Rights and $32.9 million in net proceeds from the issuance of common stock and warrants pursuant to our July 2017 underwritten public offering and our “at-the-market” offering.

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, sales and marketing expenses, commercial infrastructure, legal and other regulatory expense, business development opportunities and general overhead costs, including interest and principal repayments on indebtedness and, in the near term, costs and expenses related to the Chapter 11 Cases.

To date, we have been unable to achieve profitability, and with just our existing products and product candidates, we believe we are unlikely to achieve profitability in the future.

Following the completion of the Chapter 11 Cases, 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 holders of our common stock. Following the completion of the Chapter 11 Cases, we expect that the indenture that will govern the 13% Senior Secured Notes due 2024 will contain covenants that, among other things, restrict our ability to issue additional indebtedness other than pursuant to the Revolving Credit Facility. Although our ability to issue additional indebtedness is expected to be significantly limited by such covenants, 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. We may also seek to raise additional financing through the issuance of debt which, if available and permitted pursuant to the documents governing the 13% Senior Secured Notes due 2024 and any other indebtedness we may incur in the future, 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. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, certain agreements we entered into in connection with the consummation of the Iroko Acquisition and the Chapter 11 Cases will further restrict and limit our ability to raise additional capital, including agreements with respect to pre-emptive rights. Accordingly, our ability

to raise additional capital may be restricted by these agreements as well. Refer to Note 21 to our Consolidated Financial Statements included in Item 15 of this Annual Report for additional details.

As of December 31, 2018, we had cash and cash equivalents, restricted cash and marketable securities of $40.7 million. Given the uncertainty with respect to the various factors and assumptions underlying the previously disclosed date through which we estimated that our cash and cash equivalents would be sufficient to fund our future cash requirements, including the pendency of the Chapter 11 Cases and the Iroko Acquisition, we are no longer in a position to provide such forward-looking information.

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

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.

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

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.

JOBS Act

As an “emerging growth company” under the JOBS Act, 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 and cash equivalents, restricted cash and marketable securities of $40.7 million and $91.4 million at December 31, 2018 and December 31, 2017, respectively, consisting primarily of money market funds, certificates of deposit, commercial paper, U.S. government agency securities 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 U.S. dollars and Danish Krone.

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All assets and liabilities of our international subsidiary, Egalet Ltd. 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' deficit. 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 2018 net loss from $95.5 million to $95.9 million, an increase of $400,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

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 Accounting 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 Accounting 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 Accounting Officer concluded that our disclosure controls and procedures were effective as of December 31, 2018 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 Accounting 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.

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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 Accounting 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, 2018, the end of our most recent fiscal year.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes Oxley Act. For as long as we remain an “emerging growth company” as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2018, that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

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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 an amendment to this Annual Report on Form 10-K ("Form 10-K/A") and is incorporated herein by reference. The 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 11. EXECUTIVE COMPENSATION

Information with respect to this item will be set forth in the Form 10-K/A and is incorporated herein by reference. The 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 Form 10-K/A and is incorporated herein by reference. The 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 Form 10-K/A and is incorporated herein by reference. The 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 a Form 10-K/A and is incorporated herein by reference. The 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 101.

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ITEM 16. FORM 10-K SUMMARY

None.

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).
2.2	Asset Purchase Agreement, dated October 30, 2018, by and among Egalet Corporation, Egalet US Inc. and Iroko Pharmaceuticals Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed October 31, 2018).
3.1	Fourth Amended and Restated Certificate of Incorporation of Egalet Corporation, as amended (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed February 1, 2019).
3.2	Second 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 1, 2019).
4.1	Form of Certificate of Common Stock (filed herewith).
4.2	Indenture, dated as of January 31, 2019, among the Company, the Guarantors from time to time party thereto and U.S. Bank National Association, as trustee and collateral agent (incorporated by reference to Exhibit 4.1 to Egalet Corporation's current report on Form 8_K filed with the Securities and Exchange Commission on February 1, 2019).
4.3	Promissory Note, dated as of January 31, 2019, by and between Egalet Corporation and Iroko Pharmaceuticals Inc. (incorporated by reference to Exhibit 4.2 to Egalet Corporation's current report on Form 8_K filed with the Securities and Exchange Commission on February 1, 2019).
4.4	Form of Iroko Warrant Agreement. (incorporated by reference to Exhibit 4.3 to Egalet Corporation's current report on Form 8_K filed with the Securities and Exchange Commission on February 1, 2019).
4.5	Form of Non-Iroko Warrant Agreement. (incorporated by reference to Exhibit 4.4 to Egalet Corporation's current report on Form 8_K filed with the Securities and Exchange Commission on February 1, 2019).
10.1*	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 10.4 to Egalet Corporation's annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2015).
10.2*	License Agreement effective as of November 23, 2000 between Recordati Sa Chemical & Pharmaceutical Company and Roxro Pharma LLC (incorporated by reference to Exhibit 10.13 to Egalet Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2018).
10.3*	First Amendment dated March 21, 2001 to License Agreement effective as of November 23, 2000 between Recordati Sa Chemical & Pharmaceutical Company and Roxro Pharma LLC (incorporated by reference to Exhibit 10.14 to Egalet Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2018).
10.4*	Second Amendment dated December 10, 2015 to License Agreement effective as of November 23, 2000 between Recordati Sa Chemical & Pharmaceutical Company and Roxro Pharma LLC (incorporated by reference to Exhibit 10.15 to Egalet Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2018).

10.5*	Drug Product Manufacturing Services Agreement dated as of February 28, 2017 by and among Halo Pharmaceutical, Inc., and Egalet Corporation, Egalet, Ltd, and Egalet US Inc. (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 May 10, 2017).
10.6	Termination and Settlement Agreement, dated October 29, 2018, by and among Halo Pharmaceutical Inc., Egalet Corporation, Egalet US Inc. and Egalet Ltd. (incorporated by reference to Exhibit 10.3 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018).
10.7	Form of Royalty Rights Agreement (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 February 1, 2019).

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10.8	Collateral Agreement, dated as of January 31, 2019, among the Company, the Subsidiary Parties from time to time party thereto and U.S. Bank National Association as trustee and collateral agent (incorporated by reference to Exhibit 10.2 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2019).
10.9	Revolving Credit Agreement, dated as of March 20, 2019, among the Company, Cantor Fitzgerald Securities, as administrative agent and collateral agent, and the lenders 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 March 20, 2019).
10.10	Collateral Agreement, dated as of March 20, 2019, among the Company, the subsidiaries of the Company party thereto as Guarantors, and Cantor Fitzgerald Securities, as collateral agent (incorporated by reference to Exhibit 10.2 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 20, 2019).
10.11	Stockholders' Agreement, dated as of January 31, 2019, among the Company and the stockholder(s) of the Company from time to time party thereto (incorporated by reference to Exhibit 10.3 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2019).
10.12	Form of Preemptive Rights Agreement (incorporated by reference to Exhibit 10.4 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2019).
10.13	Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.6 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2019).
10.14	Registration Rights Agreement, dated as of January 31, 2019, by and between the Company and Iroko Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.7 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2019).
10.15+	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 with the Securities and Exchange Commission on February 11, 2014).
10.16+	Employment Separation Agreement and General Release, dated October 30, 2018, by and among Egalet Corporation and Stanley J. Musial (incorporated by reference to Exhibit 10.2 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018).
10.17+	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 with the Securities and Exchange Commission on February 11, 2014).
10.18+	Employment Agreement by and between Egalet Corporation and Patrick M. Shea (incorporated by reference to Exhibit 10.5 to Egalet Corporation's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 2016).
10.19+	Employment Agreement by and between Egalet Corporation and Barbara Carlin (incorporated by reference to Exhibit 10.24 to Egalet Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2018).
10.20+	Employment Agreement by and between Egalet Corporation and Megan Timmins (incorporated by reference to Exhibit 10.25 to Egalet Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2018).
10.21+	Form of Employment Agreement Amendment (incorporated by reference to Exhibit 10.8 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2019).
10.22+	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)).
10.23+	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)).
10.24	Lease Agreement, dated as of November 30, 2015 by and between Chesterbrook Partners, LP and Egalet US Inc. (incorporated by reference to Exhibit 10.24 to Egalet Corporation's annual report on Form 10_K filed on

	March 11, 2016).
21.1	List of Significant Subsidiaries (filed herewith).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002 (filed herewith).

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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 (filed herewith).
32.2	Certification of Principal Accounting Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 (filed herewith).
99.1	Debtors' First Amended Joint Plan of Reorganization, filed with the Court on January 10, 2018 (incorporated by reference to Exhibit 99.1 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 16, 2019).
99.2	Order Confirming Debtors' First Amended Joint Plan of Reorganization, dated January 14, 2018 (incorporated by reference to Exhibit 99.2 to Egalet Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 16, 2019).
101.INS	XBRL Instance Document (filed herewith)
101.SCH	XBRL Taxonomy Extension Schema (filed herewith)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase (filed herewith)
101.DEF	XBRL Taxonomy Extension Definition Linkbase (filed herewith)
101.LAB	XBRL Taxonomy Extension Label Linkbase (filed herewith)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase (filed herewith)

+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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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 29, 2019 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 29, 2019
	Chief Accounting Officer (Principal Accounting Officer	March 29, 2019
/s/ BARBARA CARLIN Barbara Carlin		
/s/ Timothy P. Walbert Timothy P. Walbert	Chairman, Board of Directors	March 29, 2019
/s/ LUKE DÜSTER Luke Düster	Director	March 29, 2019
/s/ TODD HOLMES Todd Holmes	Director	March 29, 2019
/s/ JOE MCINNIS Joe McInnis	Director	March 29, 2019
/s/ MATTHEW PAULS Matthew Pauls	Director	March 29, 2019
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Director	March 29, 2019

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Egalet Corporation and Subsidiaries
Audited Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Egalet Corporation and Subsidiaries (Debtor-in-Possession)

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Egalet Corporation and Subsidiaries (Debtor-in-Possession) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

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 has incurred recurring operating losses and negative cash flows from operations and filed for relief under Chapter 11 of the United States Bankruptcy Code on October 30, 2018 and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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.

Adoption of New Accounting Standard

As discussed in Note 3 to the consolidated financial statements, the Company changed its method of accounting for revenue in 2018 due to the adoption of Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) and the related amendments, using the modified retrospective approach.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included

examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

Philadelphia, Pennsylvania

March 29, 2019

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Egalet Corporation and Subsidiaries

(Debtor-In-Possession)

Consolidated Balance Sheets

(in thousands, except per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 35,323	$ 31,090
Marketable securities, available for sale	4,988	59,953
Accounts receivable	8,006	4,120
Inventory	2,639	3,225
Prepaid expenses and other current assets	2,715	2,672
Other receivables	846	893
Total current assets	54,517	101,953
Intangible assets, net	4,281	6,583
Restricted cash	400	400
Property and equipment, net	1,059	9,911
Deposits and other assets	1,676	1,011
Total assets	$ 61,933	$ 119,858
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 8,561	$ 10,160
Accrued expenses	24,584	16,104
Deferred revenue	—	7,456
Debt - current, net	—	1,081
Warrant liability	—	8,166
Total current liabilities	33,145	42,967
Debt - non-current portion, net	—	98,890
Deferred income tax liability	24	26
Derivative liability	—	16,623
Other liabilities	536	727
Total liabilities not subject to compromise	33,705	159,233
Liabilities subject to compromise	139,588	—
Commitments and contingencies (Note 17)		
Stockholders' deficit:		
Common stock--$0.001 par value; 275,000,000 and 75,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 56,547,101 and 45,939,663 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	55	46
Additional paid-in capital	276,569	254,871

Accumulated other comprehensive income	869	1,008
Accumulated deficit	(388,853)	(295,300)
Total stockholders' deficit	(111,360)	(39,375)
Total liabilities and stockholders’ deficit	$ 61,933	$ 119,858

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

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Egalet Corporation and Subsidiaries

(Debtor-In-Possession)

Consolidated Statements of Operations

(in thousands, except per share data)

	Year Ended December 31, 2018	2017
Revenue		
Net product sales	$ 30,353	$ 26,136
Total revenue	30,353	26,136
Costs and Expenses		
Cost of sales (excluding amortization of product rights)	7,447	5,153
Amortization of product rights	2,107	2,082
General and administrative	24,079	34,065
Sales and marketing	33,730	35,532
Research and development	3,536	14,744
Restructuring and other charges	17,043	2,760
Total costs and expenses	87,942	94,336
Loss from operations	(57,589)	(68,200)
Other (income) expense:		
Change in fair value of warrant and derivative liability	(12,292)	(2,546)
Interest expense, net	41,280	17,666
Other (gain) loss	(144)	(750)
Gain on extinguishment of debt	—	(13,221)
Loss on foreign currency exchange	(1)	10
Total other (income) expense	28,843	1,159
Reorganization charges	9,022	—
Loss before reorganization charges and provision (benefit) for income taxes	(95,454)	(69,359)
Provision (benefit) for income taxes	—	—
Net loss	$ (95,454)	$ (69,359)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (1.81)	$ (2.05)
Weighted-average shares outstanding, basic and diluted	52,775,116	33,755,462

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

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Egalet Corporation and Subsidiaries

(Debtor-In-Possession)

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,	
	2018	2017
Net loss	$ (95,454)	$ (69,359)
Other comprehensive income (loss):		
Unrealized gain (loss) on available for sale securities	45	(37)
Foreign currency translation adjustments	(184)	945
Comprehensive loss	$ (95,593)	$ (68,451)

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

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Egalet Corporation and Subsidiaries

(Debtor-In-Possession)

Consolidated Statements of Changes in Stockholders' Deficit

(in thousands, except per share data)

	Common stock					
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2016	25,189,125	25	230,379	(225,178)	100	5,326
Cumulative adjustment - ASU 2016-09	—	—	763	(763)	—	—
Forfeiture of restricted shares of common stock	(32,771)	—	—	—	—	—
Issuance of common stock, net of costs	18,283,309	18	23,204	—	—	23,222
Exchange of convertible debt and issuance of warrants	2,500,000	3	(5,393)			(5,390)
Stock-based compensation expense	—	—	5,918	—	—	5,918
Unrealized loss on available for sale securities	—	—	—	—	(37)	(37)
Foreign currency translation adjustment	—	—	—	—	945	945
Net loss	—	—	—	(69,359)	—	(69,359)
Balance, December 31, 2017	45,939,663	46	254,871	(295,300)	1,008	(39,375)
Cumulative adjustment - ASU 2014-09	—	—	—	1,901	—	1,901
Issuance of restricted shares of common stock	1,500,000	—	9	—	—	9
Forfeiture of restricted shares of common stock	(225,000)	—	—	—	—	—
Issuance of common stock, net of costs	8,332,438	8	5,220	—	—	5,228
Conversion feature of 6.50% Notes	—	—	12,496			12,496
Exercise of warrants	1,000,000	1	—	—	—	1

Stock-based compensation expense	—	—	3,973	—	—	3,973
Unrealized gain on available for sale securities	—	—	—	—	45	45
Foreign currency translation adjustment	—	—	—	—	(184)	(184)
Net loss	—	—	—	(95,454)	—	(95,454)
Balance, December 31, 2018	56,547,101	$ 55	$ 276,569	$ (388,853)	$ 869	$ (111,360)

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

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Egalet Corporation and Subsidiaries

(Debtor-In-Possession)

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2018	2017
Operating activities:		
Net loss	$ (95,454)	$ (69,359)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,193	5,062
Non-cash impairment of property and equipment	6,886	—
Change in fair value of warrant and derivative liability	(12,292)	(2,546)
Stock-based compensation expense	3,973	5,918
Non-cash interest and 13% Notes redemption premium	38,307	5,070
Amortization of discount on marketable securities	(209)	(24)
Deferred income taxes	(1)	—
Gain on extinguishment of debt	—	(13,221)
Changes in assets and liabilities:		
Accounts receivable	(4,257)	(3,012)
Inventory	429	(1,525)
Prepaid expenses and other current assets	(46)	(132)
Other receivables	3	219
Deposits and other assets	(666)	(375)
Accounts payable	(1,600)	7,597
Accrued expenses	6,104	(2,132)
Deferred revenue	—	3,475
Other liabilities	(184)	(179)
Net cash used in operating activities	(54,814)	(65,164)
Investing activities:		
Payments for purchase of property and equipment	(9)	(88)
Purchases of investments	(23,465)	(101,338)
Sales of investments	4,509	12,195
Maturity of investments	74,174	71,647
Net cash provided by (used in) investing activities	55,209	(17,584)
Financing activities:		
Net proceeds from issuance of common stock	5,228	32,888
Payments on borrowings	(895)	—
Net proceeds from debt and royalty rights	—	38,304
Exchange of convertible notes	—	(1,532)
Royalty payments in connection with the 13% Notes	(421)	(307)
Net cash provided by financing activities	3,912	69,353
Effect of foreign currency translation on cash and cash equivalents	(74)	530
Net increase (decrease) in cash, cash equivalents and restricted cash	4,233	(12,865)
Cash, cash equivalents and restricted cash at beginning of period	31,490	44,355

Cash, cash equivalents and restricted cash at end of period	$ 35,723	$ 31,490
Supplemental disclosures of cash flow information:		
Cash interest payments	$ 11,896	$ 12,817
Non-cash financing activities:		
Fair value of warrants issued in connection with debt and common stock	$ —	$ 9,667
Reclassification to additional paid-in capital of derivative liability	$ 12,496	$ 9,030
Fair value of warrants issued in connection with common stock	$ —	$ 3,640

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

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Egalet Corporation and Subsidiaries

(Debtor-In-Possession)

Notes to the Consolidated Financial Statements

December 31, 2018 and 2017

1. Organization and Description of the Business

Egalet Corporation (the "Company") is a commercial-stage pharmaceutical company commercializing innovative treatments for different types of pain and inflammation. Given the need for acute and chronic pain products and the issue of prescription abuse, the Company is focused on bringing non-narcotic and abuse-discouraging ("AD") opioid formulations to healthcare providers. The Company is currently selling SPRIX® (ketorolac tromethamine) Nasal Spray ("SPRIX Nasal Spray") and OXAYDO® (oxycodone HCI, USP) tablets for oral use only—CII ("OXAYDO").

SPRIX Nasal Spray is a nonsteroidal anti-inflammatory drug 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") oxycodone product designed to discourage abuse via snorting, indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Using its proprietary Guardian Technology ("GT"), the Company developed ARYMO ER, an extended-release ("ER") morphine product formulated with abuse-deterrent ("AD") properties, which is approved 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. Due to, among other things, lack of market adoption of branded ER morphine products, the Company discontinued the manufacturing and promotion of ARYMO ER on September 28, 2018. In addition to ARYMO ER, the Company developed a pipeline of products also using GT, which it may look to partner. The Company plans to continue to grow revenues of its commercial products, explore business development opportunities and leverage its proprietary technology.

On October 30, 2018, the Company entered into a definitive asset purchase agreement (the "Purchase Agreement") to acquire four non-narcotic marketed pain and inflammation products, VIVLODEX®, TIVORBEX®, ZORVOLEX® and INDOCIN® (indomethacin) oral suspension and suppositories (collectively, the "Iroko Products") and one development product from Iroko Pharmaceuticals Inc. and its subsidiaries ("Iroko"). To facilitate the transactions contemplated by the Purchase Agreement (the "Iroko Acquisition") and to reorganize its financial structure, the Company and its wholly-owned subsidiaries ("the Debtors") filed voluntary petitions for reorganization (the "Bankruptcy Petitions") under Chapter 11 of the United States ("U.S.") Bankruptcy Code in the U.S. Bankruptcy Court for the District of Delaware (the "Court") and a related Joint Plan of Reorganization ("the Plan") on October 30, 2018. The Iroko Acquisition was consummated, and the Plan went effective, on January 31, 2019. Refer to Note 21— Subsequent Events for additional details.

Liquidity and Substantial Doubt in Going Concern

Nasdaq Transfer and Delisting: Tender Offer

On July 18, 2018, the Company filed a Tender Offer Statement on Schedule TO with respect to the right of each holder of its 5.50% Convertible Senior Notes due 2020 (the "5.50% Notes") to sell, and the obligation of the Company to repurchase for cash, all or a portion of each such holder's 5.50% Notes on September 19, 2018, on the terms and

subject to the provisions set forth in the Fundamental Change Company Notice, Make-Whole Fundamental Change Company Notice and Offer to Repurchase to Holders of the 5.50% Convertible Senior Notes due 2020, dated July 31, 2018, as amended August 10, 2018 (the "Offer"). The Offer was commenced in accordance with the requirements of the indenture governing the 5.50% Notes (the "5.50% Notes Indenture") as a result of the determination by The Nasdaq Stock Market LLC ("Nasdaq") that the Company had ceased to meet the requirements for the listing of its common stock on The Nasdaq Global Market and to transfer such listing to the Nasdaq Capital Market effective at the open of business

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on July 11, 2018 (the "Nasdaq Transfer"). The Nasdaq Transfer constituted both a Fundamental Change and a Make-Whole Fundamental Change under the 5.50% Notes Indenture. In accordance with the terms of the 5.50% Notes Indenture, as a result of the Nasdaq Transfer, the Company was required, on or before the 20th calendar day following the Nasdaq Transfer, to give notice of the Fundamental Change and Make-Whole Fundamental Change to the holders of the 5.50% Notes and to make an offer to purchase all of the 5.50% Notes. The scheduled expiration time of the Offer was 5:00 p.m., New York City time, on September 18, 2018 (the "Expiration Time"), and the scheduled repurchase date was September 19, 2018 (the "Fundamental Change Repurchase Date").

On September 18, 2018, the day prior to the Fundamental Change Repurchase Date and shortly before the Expiration Time, the Company received written notification from Nasdaq indicating that, as the Company had not regained compliance with Nasdaq's continued listing requirements for the listing of the Company's common stock on the Nasdaq Capital Market or fulfilled certain of the milestones and conditions contained in a compliance plan originally submitted to the Nasdaq Hearings Panel by the Company in June 2018, the Nasdaq Hearings Panel determined to delist the Company's common stock from the Nasdaq Capital Market and that there would be a suspension of trading in the Company's common stock effective at the open of business on September 19, 2018 (the "Delisting Notice"). As of December 31, 2018, shares of the Company's common stock were quoted by the OTCQX Bulletin Board (the "OTCQX") following the suspension of trading of the Company's common stock on the Nasdaq Capital Market on September 19, 2018.

Events of Default; Forbearance Agreement

On September 18, 2018, following the Company's receipt of the Delisting Notice, the Company and its subsidiaries determined to enter into a Forbearance Agreement (the "Forbearance Agreement") with certain holders (the "FA Supporting Holders") of the Company's 13% Notes. Pursuant to the Forbearance Agreement, the FA Supporting Holders agreed to forbear from exercising their rights and remedies under the indenture governing the Company's 13% Notes (the "13% Notes Indenture") and the related security documents until the earlier of (a) 11:59 p.m. on October 14, 2018 and (b) following an Event of Termination (as defined in the Forbearance Agreement) (such period, the "Forbearance Period") with respect to certain potential events of default arising under the 13% Notes Indenture. On each of October 14, 2018, October 21, 2018 and October 24, 2018, the Company and the FA Supporting Holders entered into amendments to the Forbearance Agreement to extend the Outside Time to 11:59 New York City time on October 21, 2018, October 24, 2018 and October 28, 2018, respectively.

The Events of Termination included, among other things, the Company or any of its subsidiaries making any purchase of the 5.50% Notes or the Company's 6.50% Convertible Senior Notes (the "6.50% Notes"). As a result, the consummation of the Offer would have resulted in an Event of Termination under the Forbearance Agreement and permitted the holders of 13% Notes to exercise all rights and remedies available under the 13% Notes Indenture and related security documents. The expiration, termination and withdrawal of the Offer without payment resulted in none of the 5.50% Notes that were tendered in the Offer being accepted for purchase and no consideration was paid to holders of 5.50% Notes who tendered their 5.50% Notes in the Offer. All 5.50% Notes previously tendered and not withdrawn were returned or credited back to the respective holders thereof. Consequently, the failure of the Company to complete the Offer in accordance with the terms of the 5.50 % Notes Indenture constituted an Event of Default thereunder and resulted in a cross-defaults under the 13% Notes Indenture and the indenture governing the Company's 6.50% Notes (the "6.50% Notes Indenture").

Chapter 11 Cases

On October 30, 2018, the Debtors voluntarily filed the Bankruptcy Petitions in the U. S. Bankruptcy Court for the District of Delaware. The Debtors requested that the Chapter 11 cases (the "Chapter 11 Cases") be jointly administered for procedural purposes only under the caption "In re Egalet Corporation, et al., Case No. 18-12439". Upon filing, the Company intended to operate its business as a "debtor-in-possession" under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and orders of the Bankruptcy Court. The Company continued ordinary course operations substantially uninterrupted during the Chapter 11 Cases and sought approval from the Bankruptcy Court for relief under certain "first day" motions authorizing the Debtors to continue to conduct its business in the ordinary course. On January 14, 2019, the Court entered the Confirmation Order confirming

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the Plan under Chapter 11 of the Bankruptcy Code. On January 31, 2019 (the "Effective Date"), and substantially concurrent with the consummation of the Iroko Acquisition, the Plan became effective. Refer to Note 21—Subsequent Events for additional details.

Significant Bankruptcy Court Actions

On November 1, 2018 after the first-day hearing of the Chapter 11 Cases, the Bankruptcy Court issued certain interim orders relating to the Company's businesses. These orders authorized the Debtors to, among other things, use cash collateral and its existing cash management system on an interim basis and pay certain prepetition debts related to customer programs, critical vendors, insurance programs, taxes, and employee wages and benefits. In addition, on December 3, 2018 the Bankruptcy Court held the second-day hearing and issued final orders related to the matters approved in the interim orders as well as certain other related matters. These orders allowed the Company to operate its business in the normal course.

Substantial Doubt Regarding Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred recurring operating losses since inception. As of December 31, 2018, the Company had an accumulated deficit of $388.9 million and working capital of $21.4 million, which does not reflect the Company's outstanding indebtedness which has been recorded within liabilities subject to compromise at December 31, 2018. Even after the Company's emergence from bankruptcy it will continue to have significant indebtedness and its ability to continue as a going concern is contingent upon the successful integration of the Iroko Acquisition, increasing its revenue, managing its expenses and complying with the terms of its new debt agreements.

These factors, in combination with others described above, result in the conclusion that there is substantial doubt about the ability of the Company to continue as a going concern for the one-year period after the date that these financial statements are issued. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

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.

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 expenses, the outcome of litigation, convertible debt, share-based payments, warrant and derivative liabilities, income taxes and liabilities subject to compromise. The Company is subject to risks and uncertainties due to changes in, among other things, the healthcare environment, regulatory oversight, competition, and legislation that may cause actual results to differ from estimated results.

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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, 2018, long lived assets based upon geographic location were located in both the United States and Denmark, with a net book value of $1.1 million and $4,000 respectively. For the years ended December 31, 2018 and 2017, revenue from product sales was derived entirely from the United States.

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 and accounts receivable. 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.

The below table represents the Company’s accounts receivable concentration by customer at December 31, 2018 and 2017:

	2018	2017
Customer A	70.2 %	10.0 %
Customer B	14.3 %	39.0 %
Customer C	9.0 %	23.0 %
Customer D	5.5 %	26.0 %
Customer E	0.6 %	1.0 %
Total	99.6 %	99.0 %

Cash, Restricted 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 $34.7 million and $1.0 million were maintained at financial institutions in the United States and Denmark, respectively, at December 31, 2018. Bank deposits are insured up to approximately $250,000 and $121,000 for U.S. and Danish financial institutions, respectively.

Marketable Securities, Available-for-Sale

Marketable securities consist of securities with original maturities greater than three months and are composed 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

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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 expenses 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 5 – 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 the Company measures 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.

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, 2018 or 2017.

Financial liabilities that the Company measures at fair value on a recurring basis include derivative liabilities consisting of the interest make whole feature of the 5.50% and 6.50% Notes, the conversion feature of the 6.50% Notes and the warrant liability associated with the July 2017 Equity offering. These financial liabilities are classified as Level 3 within the fair value hierarchy. 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.

The Company’s financial liabilities have been initially and subsequently valued at the end of each reporting period, typically utilizing third-party valuation services. The valuation services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs for similar instruments to determine value, if available. 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 valuations provided by its third-party valuation services by reviewing their pricing valuation and matrices and

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confirming the relevant markets are active. The Company did not adjust or override any fair value measurements provided by its valuation services as of December 31, 2018 and December 31, 2017.

During the years ended December 31, 2018 and 2017, there were no transfers between Level 1, Level 2, or Level 3 financial assets or liabilities. The Company did not have any non-recurring fair value measurements on any assets or liabilities at December 31, 2018 and December 31, 2017.

Stock-Based Compensation

The Company uses 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, the Company measures stock-based compensation cost at the grant date based on the estimated fair value of the award and recognizes it as expense over the requisite service period on a straight-line basis. The Company records 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, the Company expenses 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.

The fair value for restricted stock awards is determined based on the closing market price of the Company’s 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 and long-lived assets consist of in process research and development ("IP R&D") and product rights. IP R&D is considered an indefinite lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets would be written off and the Company would record a non cash impairment loss on its consolidated statement of operations. For those product candidates that reach commercialization, the IPR&D asset will be amortized over its estimated useful life.

Long-lived intangible assets acquired as part of the SPRIX Nasal Spray acquisition and OXAYDO license are being amortized on a straight-line basis over their estimated useful lives of 5 years 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 for 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

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reduction in the carrying value of the related asset and a charge to operating results. During the year ended December 31, 2018, the Company recorded a charge of $113,000 to restructuring and other charges to write off the remaining IP R&D intangible asset related to our Guardian Technology due to the Company's decision to discontinue the manufacturing and promotion of ARYMO ER. For the year ended December 31, 2017, the Company determined that there was no impairment of its intangible and other long lived assets.

Net Product Sales

The Company recognizes revenue in accordance with FASB ASC 606, Revenue from Contracts with Customers, at the time it ships its products to its customers (primarily wholesalers and specialty pharmacies), rather than its historic policy of recognizing net product sales when prescriptions are dispensed to patients.

The Company sells SPRIX Nasal Spray in the United States to a single specialty pharmaceutical distributor subject to rights of return. The Company recognizes revenue from sales of SPRIX Nasal Spray upon delivery of the product to its customer.

The Company sells OXAYDO and formerly sold ARYMO ER in the United States to several wholesalers, all subject to rights of return. The Company recognizes revenue of OXAYDO and ARYMO ER upon delivery of the product to its customers.

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 Fees. The Company offers a discount to a certain specialty pharmaceutical distributor based on a contractually determined rate. The Company records the fees on shipment to the distributor and recognizes the fees as a reduction of revenue in the same period the related revenue is recognized.

Wholesaler Fees. The Company pays certain pharmaceutical wholesalers fees based on a contractually determined rate. The Company accrues the fees on shipment to the respective wholesalers and recognizes the fees 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 each of its products to patients, in which patients receive a co-pay discount on their prescriptions. The Company utilizes data provided by independent third parties to determine the total amount that was redeemed and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Rebates. Managed care rebates are payments to governmental agencies and third parties, primarily pharmacy benefit managers and other health insurance providers. The reserve for these rebates is based on a combination of actual utilization provided by the third party and an estimate of customer buying patterns and applicable contractual rebate rates to be earned over each period. The Company recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

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Inventories and Cost of Sales

Inventories are stated at the lower of cost or market net of reserve for excess and obsolete inventory and cost is determined using the average-cost method. At December 31, 2018, inventory consisted of raw materials, work in process, and finished goods. At December 31, 2017, 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

5.50% Notes

In April and May 2015, the Company issued through a private placement $61.0 million in aggregate principal amount of the 5.50% Notes in two separate closings. 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 convertible at 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).

In December 2017, the Company closed exchange agreements with certain holders of the outstanding 5.50% notes for $36.4 million in principal value of the 5.50% Notes. The total face value of the outstanding 5.50% notes was reduced from $61.0 million to $24.6 million as a result of the Exchange. As part of the exchange, the Company issued $23.9 million in principal amount of new 6.50% convertible notes due December 31, 2024. See below for further information.

13.0% Notes

In August 2016, the Company completed the initial closing (the “Initial Closing”) of its offering (the “Offering”) of up to $80.0 million aggregate principal amount of its 13.0% senior secured notes and entered into an indenture governing the Notes with the guarantors party thereto (the “Guarantors”) and U.S. Bank National Association, a national banking

association, as trustee (the "Trustee") and collateral agent (the "Collateral Agent"). The Company issued $40.0 million aggregate principal amount of the 13% Notes at the Initial Closing and issued an additional $40.0 million aggregate principal amount of the Notes on approval from the Food and Drug Administration ("FDA") of ARYMO ER in January 2017 (the "Second Closing"). Net proceeds from the Initial Closing and Second Closing were $37.2 million and $38.3 million respectively, after deducting offering expenses. The Notes were sold only to qualified institutional buyers within the meaning of Rule 144A under the Securities Act of 1933, as amended (the "Securities Act").

6.50% Notes

In December 2017, the Company issued $23.9 million in principal amount of the 6.50% Notes. The 6.50% notes were issued to existing 5.50% Note holders in exchange for $36.4 million in face value of the 5.50% Notes. Interest on the 6.50% Notes is payable semi-annually in arrears on January 1 and July 1 of each year, commencing July 1, 2018. The 6.50% Notes are convertible at 749.6252 shares per $1,000 principal amount of the 6.50% Notes (equivalent to an initial conversion price of approximately $1.33 per share of common stock).

Refer to Note 11–Long Term Debt for additional information.

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Liabilities Subject to Compromise

The Company's financial statements include amounts classified as Liabilities Subject to Compromise, which represent liabilities that existed prior to the effectiveness of its bankruptcy plans and that were restructured under the Plan of Reorganization. These amounts include amounts related to (i) the 5.50% Notes, (ii) the 6.50% Notes and (iii) the 13.0% Notes, including the accrued interest thereon, and accrued vendor liabilities. Refer to Note 10–Liabilities Subject to Compromise for additional details.

Interest Make-Whole Derivative

The 5.50% Notes include an interest make-whole feature whereby if a noteholder converted any of the 5.50% Notes prior to April 1, 2018, subject to certain restrictions, the noteholder would be 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 has recognized the fair value of this derivative as a liability on the Company's Consolidated Balance Sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's Consolidated 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 6.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the 6.50% Notes prior to January 1, 2021, 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 January 1, 2021, 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 on the Company's Consolidated Balance Sheets, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's Consolidated 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.

Warrant Liability

On July 6, 2017, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co. relating to an underwritten public offering (the "July 2017 Equity Offering") of 16,666,667 shares of the Company's common stock and accompanying warrants to purchase 16,666,667 shares of common stock, at a combined public offering price of

$1.80 per share and accompanying warrant, for gross proceeds of $30.0 million. Each warrant was issued at an exercise price of $2.70, subject to adjustment in certain circumstances. The shares of common stock and warrants were issued separately. The warrants may be exercised at any time on or after the date of issuance and will expire five years from the date of issuance.

The Company accounted for the warrants using ASC 480 – Distinguishing Liabilities from Equity and determined that the warrants were a freestanding financial instrument that are subject to liability classification. Pursuant to the terms of the agreement, the Company could be required to settle the warrants in cash in the event of an acquisition of the Company, and as a result the warrants are required to be measured at fair value and reported as a current liability in the Company's Consolidated Balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's Consolidated Statements of Operations and Comprehensive Loss as change in fair value of derivative liabilities.

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

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exchange rates at the end of each reporting period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive loss or income on the Company’s Consolidated Balance Sheets. Gains and losses resulting from foreign currency transactions are reflected within the Company’s Consolidated Statements 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’ deficit exclusive of transactions with owners (such as capital contributions and distributions). Comprehensive loss is composed of net loss, foreign currency translation adjustments 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 the Company estimates 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 the entire 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 Company’s Consolidated Statement of Operations and Comprehensive Loss. Accrued interest and penalties are included within the related tax liability line in the Company’s Consolidated Balance Sheets. The Company did not have any accrued interest or penalties associated with any unrecognized tax positions at December 31, 2018 and 2017, and there were no such interest or penalties recognized during the years ended December 31, 2018 and 2017.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the top U.S. federal corporate tax rate to 21 percent; requiring companies to pay a one-time transition tax on certain un-repatriated earnings of foreign subsidiaries; generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries; requiring a current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations; eliminating the corporate alternative minimum tax and changing how existing such credits can be realized; creating the base erosion anti-abuse tax, a new minimum tax; creating a new limitation on deductible interest expense; and changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

The Tax Act reduces the Company's U.S. corporate income tax rate from 34% to 21%, effective January 1, 2018. 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 reverse. As a result of the reduction in the U.S. corporate income tax rate to 21% under the Tax Act, the Company revalued its ending net deferred tax assets and liabilities at December 31, 2017.

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The Tax Act provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits. The Company did not have to recognize any income tax expense related to the transition tax due to current and historical losses at its controlled foreign corporation.

The global intangible low-taxed income tax and base erosion provisions are effective for taxable years beginning after December 31, 2017. The Company does not currently expect these provisions to have a material impact on its tax rate due to losses at its controlled foreign corporation and they are currently below the gross receipts threshold for purposes of the base erosion provisions.

Due to the timing of the new tax law and the substantial changes it brings, the Staff of the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin (“SAB”) No. 118 which provides registrants a measurement period to report the impact of the new US tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the Tax Act. The Company finalized the accounting for the Tax Act and has recorded no additional amount during the current year.

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% and 6.50% 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, 2018 and 2017.

Customer Concentration

Customer concentration for the years ended December 31, 2018 and 2017 are as follows:

	2018	2017
Customer A	76.3 %	76.0 %

Customer B	9.9	%	9.7	%
Customer C	6.4	%	5.8	%
Customer D	6.0	%	7.2	%
Customer E	0.6	%	—	%
Total	99.2	%	98.7	%

Recent Accounting Pronouncements

In March 2016, the FASB issued Accounting Standards Update ("ASU") 2016-09, Improvements to Employee Share-Based Payment Accounting, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 became effective for the Company in the first quarter of 2017 and was applied using a modified retrospective transition approach. Under ASU 2016-09, the Company has elected to no longer estimate forfeiture rates as part of its stock-based compensation expense and will true up forfeitures as they occur. As a result of the adoption of ASU 2016-09, the Company recorded a cumulative adjustment of $763,000, which increased its accumulated deficit as of January 1, 2017.

In November 2016, the FASB issued Accounting Standards Update ("ASU") 2016-18, Statement of Cash Flows: Restricted Cash. The new standard requires changes in restricted cash during the period to be included with cash

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and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the Company's Consolidated Statements of Cash Flows. If cash, cash equivalents and restricted cash are presented in more than one line on the Company's Consolidated Balance Sheets, the new guidance requires a reconciliation of the total in the statements of cash flows to the related captions in the Company's Consolidated Balance Sheets. ASU 2016-18 was effective for annual and interim periods beginning after December 15, 2017 with early adoption permitted. The amendments in this ASU increased the beginning and ending cash balances in the Company's Consolidated Statements of Cash Flows. The Company adopted the standard in the first quarter of 2018. The adoption had no material impact on the Company's Consolidated Statements of Cash Flows and had no impact on the Company's Consolidated Balance Sheets or Statements of Operations.

In February 2016, the FASB issued ASU No. 2016-02, Leases, that requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The standard is effective on January 1, 2019, with early adoption permitted. The Company adopted the new standard on January 1, 2019 and is using the effective date as its date of initial application. In July 2018, the FASB issued an update that provided an additional transition option that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the consolidated financial statements. Companies that elect this option would record a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption. The Company elected this optional transition method. The Company also elected the "package of practical expedients", which permits it to not reassess the Company's prior conclusions about lease identification, lease classification and initial direct costs. The Company continues to evaluate other practical expedients available under the standard.

The Company has substantially completed its assessment of the standard. The Company continues to finalize its calculations, including its discount rate assumptions, related to the new standard. The Company is also continuing to establish new processes and internal controls that may be required to comply with the new lease accounting and disclosure requirements set by the new standard.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 was effective for annual periods and interim periods within those annual periods beginning after December 15, 2017. The Company adopted the standard in the first quarter of 2018 and determined there to be no material impact of the adoption in the year ended December 31, 2018.

In May 2014, the FASB issued new guidance related to revenue recognition, ASU 2014-09, Revenue from Contracts with Customers ("ASC 606"), which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new guidance requires an entity to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASC 606 defines a five-step approach for recognizing revenue, which may require an entity to use more

judgment and make more estimates than under the current guidance. The new guidance becomes effective in calendar year 2018 and early adoption in calendar year 2017 is permitted. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented; or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening retained earnings balance.

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, Revenue From Contracts with Customers: Principal Versus Agent Considerations, ASU No. 2016-10, Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing, and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12 Revenue from Contracts with Customers, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement

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date for non-cash consideration and completed contracts at transition (collectively “ASC 606”). These standards are effective for the Company beginning in the first quarter of 2018.

The Company formed a task force that analyzed the Company’s customer contracts and the impact the standard had on previously reported revenues and future revenues. Under ASC 606, the Company recognizes net product sales at the time it ships its products to its customers (primarily wholesalers and specialty pharmacies), rather than its historic policy of recognizing net product sales when prescriptions are dispensed to patients. As a result, the Company now recognizes net product sales under such contracts earlier under ASC 606 than it would have recognized under historic guidance.

The Company adopted the new standard effective January 1, 2018 using the modified retrospective approach. As a result of the adoption of ASU 2014-09, the Company recorded a cumulative adjustment of $1.9 million, which reduced its accumulated deficit as of January 1, 2018. Refer to Note 3 - Revenue from Contracts with Customers for further details.

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and Other: Simplifying the Accounting for Goodwill Impairment. ASU 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit’s carrying value exceeds its fair value, not exceed the carrying amount of goodwill. This standard, which will be effective for the Company beginning in the first quarter of fiscal year 2020, is required to be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact this new accounting guidance will have on its consolidated financial statements, if any.

3. Revenue from Contracts with Customers

Adoption of ASC Topic 606, Revenue from Contracts with Customers

The Company adopted ASC 606 on January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption, referred to herein as the “new guidance”. The reported results as of, and for the year ended December 31, 2018 reflect the application of ASC 606 guidance while the reported results as of, and for the year ended December 31, 2017 were prepared under the guidance of ASC 605, Revenue Recognition (“ASC 605”), which is also referred to herein as “legacy GAAP” or the “previous guidance”. The adoption of ASC 606 had a material impact on the Company’s Consolidated Balance Sheets, Statements of Operations and Stockholders’ Deficit as of the adoption date and for the year ended December 31, 2018. The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of the Company's products to its customers and will provide financial statement readers with enhanced disclosures.

Financial Statement Impact of Adopting ASC 606

The cumulative effect of applying the new guidance to all contracts with customers for which all performance obligations were satisfied as of January 1, 2018, was recorded as an adjustment to accumulated deficit as of the adoption date. For contracts which were modified before the adoption date, the Company has not restated the contract for those modifications. Rather, the Company has reflected the aggregate effect of all modifications when identifying the satisfied and unsatisfied performance obligations, determining the transaction price and allocating the transaction price, if

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necessary. As a result of applying the modified retrospective method in adopting the new revenue guidance, the following adjustments were made to accounts on the Company's Consolidated Balance Sheets as of January 1, 2018:

	December 31, 2017	Adjustments due to ASU 2014-09	January 1, 2018
Accounts receivable	4,120	(371)	3,749
Inventory	3,225	(157)	3,068
Accrued expenses	16,104	5,028	21,132
Deferred revenue	7,456	(7,456)	-
Accumulated deficit	(295,300)	1,901	(293,399)

Under ASC 606, the Company recognizes net product sales at the time it ships its products to its customers (primarily wholesalers and specialty pharmacies), rather than the legacy GAAP policy of recognizing net product sales when prescriptions are dispensed to patients. As a result, the adjustments reflect the recognition of all deferred revenue related to product shipped to the Company's customers, but not yet dispensed to patients and the related decrease in inventory. In addition, the Company recorded accrued expenses for patient discount programs, commercial and government rebates and a reduction in accounts receivable for estimated returns. An adjustment to accumulated deficit was recorded for the net impact of the preceding adjustments as of January 1, 2018.

Revenue Recognition

Under ASC 606, revenue is recognized when, or as, performance obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. To recognize revenue pursuant to the provisions of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect substantially all the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses whether the goods or services promised within each contract are distinct to determine those that are performance obligations.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. To the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price to which the Company expects to be entitled after giving effect to returns, rebates, sales allowances and other variable elements with contracts between the Company and its customers. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance under the contract and all information (historical, current and forecasted) that is reasonably available. Sales taxes and other taxes collected on behalf of third parties are excluded from revenue.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the significant financing practical expedient, the Company does not assess whether a significant financing component

exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2018.

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The Company's existing contracts with customers contain only a single performance obligation and, as such, the entire transaction price is allocated to the single performance obligation. Should future contracts contain multiple performance obligations, those would require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on observable prices or a cost-plus margin approach when one is not available.

The Company's performance obligations are to provide pharmaceutical products to several wholesalers or a single specialty pharmaceutical distributor. All of the Company's performance obligations, and associated revenue, are generally transferred to customers at a point in time. Revenue is recognized at the time the related performance obligation is satisfied by transferring control of a promised good to a customer, which is typically upon delivery. Payments for invoices are generally due within 30 to 65 days of invoice date.

Disaggregation of Revenue

The following table summarizes revenue by revenue source for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
(in thousands)	2018	2017
Product lines		
SPRIX Nasal Spray	$ 23,424	$ 19,920
OXAYDO	5,767	5,576
ARYMO ER	1,162	640
Total	$ 30,353	$ 26,136

Reserves for Variable Consideration

Revenues from product sales are recorded at the transaction price, which includes estimates of variable consideration for which reserves are established and which result from returns, rebates and sales allowances that are offered within or impacted by contracts between the Company and its customers. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract as of the date of determination. The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Product Returns

Consistent with industry practice, the Company generally offers customers a limited right of return for its products. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company estimates product return liabilities using the expected value method based on its historical sales information and other factors that it believes could significantly impact its expected returns, including product discontinuations, product recalls and expirations, of which it becomes aware. These factors include its estimate of actual and historical return rates for

non-conforming product and open return requests.

Specialty Pharmacy Fees

The Company pays certain specialty pharmaceutical distributor fees based on a contractually determined rate. The Company records the fees on shipment to the distributor and recognizes the fees as a reduction of revenue in the same period the related revenue is recognized.

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Wholesaler Fees

The Company pays certain pharmaceutical wholesalers fees based on a contractually determined rate. The Company accrues the fees on shipment to the respective wholesalers and recognizes the fees as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discount

The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company estimates cash discounts using the mostly likely amount method by reducing accounts receivable by the prompt pay discount amount. The discount is recognized as a reduction of revenue in the same period as the related revenue.

Patient Discount Programs

The Company offers co-pay discount programs to patients for each of its products, in which patients receive a co-pay discount on their prescriptions. For discount amounts that are not immediately available, the Company estimates the total amount that will be redeemed using the expected value method based on the quantity of product shipped. The Company recognizes the discount as a reduction of revenue in the same period as the related revenue.

Commercial and Government Rebates

The Company contracts with various commercial and government payor organizations, primarily private insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates using the expected value method and records such estimates in the same period the related revenue is recognized, resulting in a reduction of net product sales and the establishment of an accrued expense.

The following table summarizes activity in each of the net product sales allowance and reserve categories for the year ended December 31, 2018:

(in thousands)	Fees and distribution costs	Co-pay assistance	Rebates	Returns	Total
Balances at December 31, 2017	$ 595	$ 3,644	$ 579	$ —	$ 4,818
Adjustment for ASU 2014-09	—	4,221	656	—	4,877
Allowances for current period sales	8,183	74,530	7,799	2,883	93,395
Adjustment related to prior period sales	—	—	180	—	180
Credits or payments made for prior period sales	(555)	(7,866)	(1,235)	—	(9,656)
Credits or payments made for current period sales	(7,761)	(61,203)	(5,315)	(863)	(75,142)
Balance at December 31, 2018	$ 462	$ 13,326	$ 2,664	$ 2,020	$ 18,472
Total gross product sales					$ 123,928
Total provision for product sales allowances and accruals as a percentage of					75%

total gross sales

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Impact of New Revenue Guidance on Financial Statement Line Items

The following table compares the Company's reported Consolidated Balance Sheet as of December 31, 2018 to the pro forma amounts had the previous guidance been in effect:

	As reported	Adjustments Due to ASU 2014-09	Pro Forma if the previous accounting was in effect
Accounts receivable	8,006	371	8,377
Inventory	2,639	495	3,134
Accrued expenses	24,584	(10,104)	14,480
Deferred revenue	-	13,582	13,582
Accumulated deficit	(388,853)	(2,612)	(391,465)

Under ASC 606, the Company recognizes net product sales at the time it ships its products to its customers (primarily wholesalers and specialty pharmacies), rather than the legacy GAAP policy of recognizing net product sales when prescriptions are dispensed to patients. As a result, the adjustments reflect the accrual of deferred revenue related to product shipped to the Company's customers, but not yet dispensed to patients and the related increase in inventory for deferred cost of goods sold. In addition, the Company would not have accrued expenses for patient discount programs, commercial and government rebates or a reduction in accounts receivable for estimated returns until the product was dispensed to patients. The adjustment to accumulated deficit represents the net impact of these items.

The following table compares the Company's reported Consolidated Statement of Operations for the year ended December 31, 2018 to the pro forma amounts had the previous guidance been in effect:

	As reported	Adjustments Due to ASU 2014-09	Pro Forma if the previous accounting was in effect
Net product sales	$ 30,353	$ (1,117)	$ 29,236
Cost of sales (excluding amortization of product rights)	7,447	(406)	7,041
Net loss	(95,454)	(711)	(96,165)
Per share information:			
Net loss per share of common stock, basic and diluted	$ (1.81)	$ (0.01)	$ (1.82)
Weighted-average shares outstanding, basic and diluted	52,775,116	52,775,116	52,775,116

Amounts reported on certain line items within net cash used in operating activities on the Company's Consolidated Statement of Cash Flows changed as a result of the adoption of ASU 2014-09, but there was no change in the reported amounts of total operating, investing and financing cash flow.

Transaction Price Allocated to Future Performance Obligations

ASC 606 requires that the Company disclose the aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied as of December 31, 2018. The guidance provides certain

practical expedients that limit this requirement including performance obligations that are part of a contract that has an original expected duration of one year or less. All of the Company's contracts are eligible for the practical expedient provided by ASC 606, therefore the Company elected not to disclose any remaining performance obligations.

Contract Balances from Contracts with Customers

When the Company receives consideration from a customer, or such consideration is unconditionally due from a customer prior to the transfer of goods or services to the customer under the terms of a contract, the Company records a contract liability. Contract liabilities are recognized as revenue after control of the products is transferred to the customer and all revenue recognition criteria have been met. The Company classifies contract liabilities as deferred revenue. The Company had no deferred revenue as of January 1, 2018 or December 31, 2018.

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Contract assets primarily relate to rights to consideration for goods or services transferred to the customer when the right is conditional on something other than the passage of time. Contract assets are transferred to accounts receivable when the rights become unconditional. The Company had no contract assets as of January 1, 2018 or December 31, 2018.

Costs to Obtain and Fulfill a Contract

The Company accounts for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products. When shipping and handling costs are incurred after a customer obtains control of the products, the Company has elected to account for these as costs to fulfill the promise and not as a separate performance obligation. Shipping and handling costs associated with the distribution of finished products to customers are expensed as incurred and are recorded in costs of goods sold in the Company's Consolidated Statements of Operations. The Company expenses incremental costs of obtaining a contract with a customer (for example, commissions) when incurred as the period of benefit is less than one year.

4. Investments

Marketable securities consisted of the following as of December 31, 2018:

(in thousands)	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	$ 4,990	$ —	$ (2)	$ 4,988
Total	$ 4,990	$ —	$ (2)	$ 4,988

Marketable securities consisted of the following as of December 31, 2017:

(in thousands)	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	$ 60,000	$ —	$ (47)	$ 59,953
Total	$ 60,000	$ —	$ (47)	$ 59,953

At December 31, 2018, the Company held 2 marketable securities, 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 existed at December 31, 2018.

The fair value of marketable securities at December 31, 2018 with a maturity of less than one year was $5.0 million. The Company had no marketable securities with a maturity of greater than one year as of December 31, 2018.

5. 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, 2018			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents (money market funds and commercial paper)	$ 22,996	$ —	$ —	$ 22,996
Marketable securities, available-for-sale	—	4,988	—	4,988
Total assets	$ 22,996	$ 4,988	$ —	$ 27,984
Liabilities				
Interest make-whole derivatives	$ —	$ —	$ —	$ —
Warrant liability	—	—	—	—
Total liabilities	$ —	$ —	$ —	$ —

(in thousands)	Fair Value Measurements as of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents (money market funds)	$ 16,973	$ —	$ —	$ 16,973
Marketable securities, available-for-sale	—	59,953	—	59,953
Total assets	$ 16,973	$ 59,953	$ —	$ 76,926
Liabilities				
Interest make-whole derivatives	$ —	$ —	$ 2,589	$ 2,589
Conversion feature, 6.50% Notes	—	—	14,034	14,034
Warrant liability	—	—	8,166	8,166
Total liabilities	$ —	$ —	$ 24,789	$ 24,789

The 5.50% Notes included and 6.50% Notes include an interest make-whole feature whereby if a noteholder had converted any of the 5.50% Notes prior to April 1, 2018, or converts any of the 6.50% Notes prior to July 1, 2021, 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 (5.50% Notes), or July 1, 2021 (6.50% Notes), computed

using a discount rate equal to 2%.

The embedded conversion options in the 6.50% Notes are required to be separately accounted for as derivatives as the Company did not have enough available authorized shares to cover the conversion obligation as of the date of issuance as of December 31, 2017. In February 2018, the Company held a special meeting of stockholders (the "Special Meeting"). At the Special Meeting, the Company's stockholders approved an amendment to the Company's Third Amended and Restated Certificate of Incorporation to increase the number of shares of the Company's authorized common stock from 75,000,000 to 275,000,000 shares. As the Company had reserved sufficient shares of its common stock to satisfy the conversion provisions of the 6.50% Notes, the conversion feature was considered indexed to its stock and the fair value of the conversion feature was reclassified from a liability into stockholders' deficit in the first quarter of 2018.

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The Company has determined that the above features are embedded derivatives and has recognized the fair value of the derivatives as liabilities in the Company's Consolidated Balance Sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's Consolidated Statements of Operations and Comprehensive Loss as change in fair value of derivative liabilities.

The following tables set forth a summary of changes in the fair value of Level 3 liabilities for the year ended December 31, 2018:

(in thousands)	December 31, 2017	Additions	Reclassification to Additional Paid in Capital	Fair Value Change in 2018	December 31, 2018
Interest make-whole derivatives	2,589	$ —	$	$ (2,589)	$ —
Conversion feature, 6.50% Notes	14,034	—	(12,497)	(1,537)	—
Warrant liability	8,166	—		(8,166)	—
Total liabilities	$ 24,789	$ —	$ (12,497)	$ (12,292)	$ —

The following tables set forth a summary of changes in the fair value of Level 3 liabilities for the year ended December 31, 2017:

(in thousands)	December 31, 2016	Additions	Fair Value Change in 2017	December 31, 2017
Interest make-whole derivatives	$ 12	$ 2,683	$ (106)	$ 2,589
Conversion feature, 6.50% Notes	—	14,973	(939)	14,034
Warrant liability	—	9,667	(1,501)	8,166
Total liabilities	$ 12	$ 27,323	$ (2,546)	$ 24,789

Interest make-whole derivative

The 6.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the 6.50% Notes prior to July 1, 2021, the Company is obligated to, 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 6.50% Notes to be converted had such notes remained outstanding from the conversion date through July 1, 2021, computed using a discount rate equal to 2%.

The fair value of the 6.50% Notes interest make-whole features was calculated 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:

Credit spread at the valuation date

Discount yield as of the valuation date

As of December 31, 2018, the Company determined that the 6.50% Notes interest make-whole features had a fair value of $0 based primarily on the value of the Company's equity securities and the liquidity events discussed in Note 1 – Organization Description of the Business.

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Conversion feature

The embedded conversion options in the 6.50% Notes were required to be separately accounted for as derivatives as at December 31, 2017 as the Company did not have sufficient available authorized shares to cover the conversion obligation as of the date of issuance as of December 31, 2017. In February 2018, the Company received stockholder approval for the Charter Amendment, which increased the Company's authorized shares of its common stock by 200,000,000. As the Company had reserved sufficient shares of its common stock to satisfy the conversion provisions of the 6.50% Notes, the conversion feature is considered indexed to its stock and the fair value of the conversion feature at the date of approval, $12.5 million, was reclassified from a liability into stockholders' deficit during the first quarter of 2018.

The Company has determined that the above features of the interest make-whole provision and conversion features are embedded derivatives and has recognized the fair value of the derivatives as liabilities in the Company's Consolidated Balance Sheets, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's Consolidated Statements of Operations and Comprehensive Loss as change in fair value of derivative liabilities.

Warrant liability

The fair value of the Company's warrant liability was estimated utilizing a lattice tree model both for the initial valuation and as of December 31, 2018. 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. As of December 31, 2018, the Company determined the warrant liability had a fair value of $0 based primarily on the value of the Company's equity securities and the liquidity events discussed in Note 1 – Organization and Description of the Business.

As of December 31, 2018, the fair value of the Company's 5.50% Notes and 6.50% Notes and the included interest make whole features, along with the conversion feature of the 6.50% Notes were 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:

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 and 6.50% Notes at December 31, 2018 were as follows and are included in liabilities subject to compromise on the Company's Consolidated Balance Sheet:

(in thousands)	Fair Value	Carrying Value	Face Value
5.50% Notes due 2020	$ —	$ 24,650	$ 24,650
6.50% Notes due 2024	$ —	$ 23,888	$ 23,888

As of December 31, 2018, the Company determined that the fair value of the 13% Notes is significantly below the current $79.1 million carrying value given the liquidity events discussed in Note 1 – Organization and Description of the Business.

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6. 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, 2018 and 2017.

	December 31,	
(in thousands)	2018	2017
Raw materials	$ 1,374	$ 850
Work in process	665	772
Finished goods	600	1,446
Deferred cost of sales	—	157
Total	$ 2,639	$ 3,225

As a result of the discontinuation of manufacturing and promotion of ARYMO ER effective September 28, 2018, the Company recognized a write-down of the remaining inventory of ARYMO ER of $707,000 in the year ended December 31, 2018, which is included in Restructuring and other charges on the Company's Consolidated Statements of Operations.

During the years ended December 31, 2018 and 2017 the Company recorded a reserve for excess and obsolete inventory of $57,000 and $542,000, respectively.

7. Property and Equipment

Property and equipment and related accumulated depreciation are as follows:

	December 31,	
(in thousands)	2018	2017
Leasehold improvements	$ 1,431	$ —
Laboratory and manufacturing equipment	—	14,911
Furniture, fixtures and other property	867	888
Construction in process	—	241
Less accumulated depreciation	(1,239)	(6,129)
Property and equipment, net	$ 1,059	$ 9,911

As a result of the discontinuation of manufacturing and promotion of ARYMO ER effective September 28, 2018, the Company recognized a write-down of equipment related to the manufacture of ARYMO ER of $6.8 million in the year ended December 31, 2018, which is included in Restructuring and other charges on the Company's Consolidated Statements of Operations.

Depreciation expense was $2.1 million and $2.8 million for the years ended December 31, 2018 and 2017, respectively.

8. Intangible Assets

The following represents the balance of the intangible assets including accumulated amortization at December 31, 2018:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	$ 7,623	$ (4,330)	$ 3,293	3.00
SPRIX Nasal Spray product rights	4,831	(3,843)	988	1.00
Total	$ 12,454	$ (8,173)	$ 4,281	

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The following represents the balance of the intangible assets including accumulated amortization at December 31, 2017:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	$ 7,695	$ (3,273)	$ 4,422	4.00
SPRIX Nasal Spray product rights	4,978	(2,964)	2,014	2.00
IP R&D	183	(36)	147	4.00
Total	$ 12,856	$ (6,273)	$ 6,583	

There was no impairment to the OXAYDO and SPRIX Nasal Spray intangible assets recognized in the years ended December 31, 2018 and 2017. As a result of the discontinuation of manufacturing and promotion of ARYMO ER effective September 28, 2018, the Company recognized a write-down of the remaining intangible asset value of the IP R&D intangible asset associated with the Guardian Technology of $113,000 in September 2018, which is included in Restructuring and other charges on the Company's Consolidated Statements of Operations.

Estimated amortization of the intangible assets for the five years subsequent to December 31, 2018 is as follows:

(in thousands)	
2019	$ 2,055
2020	$ 1,111
2021	$ 1,089
2022	$ 26
2023	$ —

Collaboration and License Agreement with Acura Pharmaceuticals, Inc. ("Acura")

In January 2015, the Company entered into a Collaboration and License Agreement with Acura to commercialize OXAYDOTM (oxycodone hydrochloride) tablets containing Acura's Aversion® Technology (the "OXAYDO License Agreement"). The Company paid Acura an upfront payment of $5.0 million in January 2015 and a $2.5 million milestone payment 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. The Company recorded an intangible asset of $7.7 million related to the transaction. Refer to Note 19—Acquisitions and License and Collaboration agreements for additional details.

During each of the years ended December 31, 2018 and 2017, the Company recognized amortization expense of $1.1 million related to the OXAYDO product right intangible asset.

Purchase Agreement with Luitpold Pharmaceuticals, Inc. (“Luitpold”)

In January 2015, the Company entered into and consummated the transactions contemplated by the Purchase Agreement with Luitpold to purchase SPRIX Nasal Spray (the “SPRIX Purchase Agreement”). Pursuant to the SPRIX 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 19–Acquisitions and License and Collaboration agreements for additional details.

During the years ended December 31, 2018 and 2017, the Company recognized amortization expense of $985,000 and $960,000, respectively, related to the SPRIX Nasal Spray product rights intangible asset.

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In-Process Research and Development ("IP R&D")

In connection with the acquisition of Egalet A/S in 2010, 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 Guardian Technology. Through December 31, 2016, the IP R&D was considered an indefinite-lived intangible asset and was assessed for impairment annually or more frequently if impairment indicators existed. Following the approval of ARYMO ER in January 2017, the Company began to amortize the intangible asset over a useful life of five years.

During the years ended December 31, 2018 and 2017, the Company recognized amortization expense of $27,000 and $36,000. The remaining IP R&D intangible asset was written off due to the Company's decision to discontinue the manufacturing and promotion of ARYMO ER in the year ended December 31, 2018.

9. Accrued Expenses

Accrued expenses were as follows:

(in thousands)	December 31, 2018	December 31, 2017
Sales allowances	$ 17,174	$ 4,721
Payroll and related	3,567	4,349
Interest	—	3,270
Professional services	1,847	627
Royalties	1,049	800
Sales and marketing	81	1,247
Manufacturing services	34	579
Clinical research	—	355
Other	832	156
	$ 24,584	$ 16,104

10. Liabilities Subject to Compromise

As of December 31, 2018, the Company has segregated liabilities and obligations whose treatment and satisfaction were dependent on the outcome of its reorganization under the Chapter 11 Cases and has classified these items as liabilities subject to compromise. Generally, all actions to enforce or otherwise effect repayment of prepetition liabilities of the Debtors, as well as all pending litigation against the Debtors, were stayed while the Company is subject to the Chapter 11 Cases. The ultimate amount and treatment for these types of liabilities will be subject to the claims resolution processes in the Chapter 11 Cases and the terms of the Plan confirmed by the Bankruptcy Court in the Chapter 11 Cases. Liabilities subject to compromise may vary significantly from the stated amounts of claims filed with the Bankruptcy Court. Although prepetition claims are generally stayed, at hearings held on November 1, 2018, the Bankruptcy Court approved the Debtors' "first day" motions generally designed to stabilize the Debtors' operations and cover, among other things, human capital obligations, supplier relations, customer relations, business operations, tax matters, cash management, utilities and retention of professionals.

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Liabilities subject to compromise consist of the following:

(in thousands)	December 31, 2018
13.0% Senior Secured Debt	$ 79,104
5.50% Convertible Notes	24,650
6.50% Convertible Notes	23,888
13.0% Senior Secured Debt redemption premium	7,200
Accrued interest	2,464
Accrued royalty rights	2,119
Accrued expenses	163
Liabilities subject to compromise	$ 139,588

In December 2018, the Company made an adequate protection payment of $896,000 to the holders of the Senior Secured Debt that reduced the outstanding principal balance of the Notes as of December 31, 2018. The payment was made as part of the First Lien Cash Distribution arrangement required by the Plan of Reorganization.

On the Effective Date of the Company's Plan of Reorganization on January 31, 2019, the accrued interest was cancelled, the Convertible Notes were converted to equity and the Senior Secured Debt was converted to newly issued notes, equity and partially repaid in cash. See Note 21–Subsequent Events for additional details.

11. Long Term Debt

5.50% Convertible Senior Notes Due 2020

In April and May 2015, the Company issued through a private placement $61.0 million in aggregate principal amount of the 5.50% Notes. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year and commenced on October 1, 2015. As of December 31, 2018, a total of $24.7 million in principal amount of the 5.50% Notes remained outstanding.

The 5.50% Notes are general, unsecured and unsubordinated obligations of the Company and rank senior in right of payment to all of the Company's indebtedness that is expressly subordinated in right of payment to the 5.50% Notes. The 5.50% Notes are effectively subordinated to any secured indebtedness of the Company 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 was subject to adjustment upon the occurrence of certain specified events but would not be adjusted for accrued and unpaid interest. The Company was obligated to 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.

Holders would have the right to 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 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 5.50% 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 5.50% Notes for each trading day of the

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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, including Fundamental Changes, as defined in the indenture governing the 5.50% Notes (the "5.50% Notes Indenture").

Under the 5.50% Notes, holders are permitted to convert all or any portion of their 5.50% Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances, on or after January 1, 2020 until the close of business on the second scheduled trading day immediately preceding the maturity date (April 1, 2020).

Upon conversion, the Company would have been obligated to pay or deliver cash, shares of the Company's 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 Company's common stock, if applicable. If the Company satisfied the conversion obligation solely in cash or through payment and delivery, as the case may be, of a combination of cash and shares of the Company's common stock, the amount of cash and shares of the Company's 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 would have been obligated to increase the conversion rate for a holder who elects to convert its 5.50% Notes in connection with such a corporate event in certain circumstances. Holders would not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a 5.50% Note, except in limited circumstances. Instead, interest would be deemed to be paid in full, rather than cancelled, extinguished or forfeited from the consideration paid to the holders upon conversion of a 5.50% Note.

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 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 was greater than or equal to the conversion price for the 5.50% Notes on each applicable trading day, the Company was obligated to, 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%. The Company would have been obligated to 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 have delivered in connection with a conversion of the 5.50% Notes, including those delivered in connection with an interest make-whole payment, would not exceed 77.3395

shares of the Company's common stock per $1,000 principal amount of 5.50% Notes, subject to adjustment. The Company would 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 stock or pay any cash in excess of the threshold described above. In addition, if in connection with any conversion the conversion rate was adjusted, then such holder would not receive the interest make-whole payment with respect to such 5.50% Notes.

Certain provisions in the 5.50% notes could have required accelerated payment of principal and interest. The 5.50% Notes provide that the delisting of the Company's common stock from the Nasdaq Global Market would have constituted a "fundamental change" under the 5.50% Notes, which would have entitled the holder, at the holder's option, to require the Company to repurchase for cash all or any portion of such holder's 5.50% Notes at a repurchase price equal to 100% of the principal amount thereof, plus accrued and unpaid interest thereon.

On July 31, 2018, the Company filed a Tender Offer Statement on Schedule TO with respect to the Offer in accordance with the requirements of the indenture governing the 5.50% Notes Indenture. The expiration, termination and withdrawal of the Offer without payment on September 19, 2018 resulted in none of the 5.50% Notes that were

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tendered in the Offer being accepted for purchase and no consideration was paid to holders of the 5.50% Notes who tendered their 5.50% Notes in the Offer. All 5.50% Notes previously tendered and not withdrawn were returned or credited back to the respective holders thereof. Consequently, the failure of the Company to complete the Offer in accordance with the terms of the 5.50% Notes Indenture constituted an Event of Default thereunder. Refer to Note 1—Organization and Description of the Business —Liquidity and Substantial Doubt in Going Concern – Nasdaq Transfer and Delisting: Tender Offer.

As a result of the Nasdaq Transfer and the corresponding Fundamental Change under the 5.50% Notes Indenture, the conversion criteria for the 5.50% Notes was met as of July 11, 2018 and, as an Event of Default (as defined in the 5.50% Indenture) occurred on September 19, 2018 when the Company failed to consummate the Offer and was continuing, the trustee or the holders of at least 25% in aggregate principal amount of the outstanding 5.50% Notes have the right pursuant to the 5.50% Note Indenture to declare all the outstanding 5.50% Notes to be due and payable immediately. However, any efforts to enforce such payment obligations under the 5.50% Notes Indenture were automatically stayed as a result of the Bankruptcy Petitions and as of the Petition Date, the creditors' rights of enforcement in respect of the 5.50% Notes Indenture were subject to the applicable provisions of the Bankruptcy Code.

On October 30, 2018, the Company entered into a restructuring support agreement (the "Support Agreement") with creditors holding approximately 94% in aggregate principal amount outstanding and in excess of a majority in number of our 13% Notes and approximately 67% in aggregate principal amount outstanding of our existing 5.50% notes and 6.50% Notes (the "Supporting Noteholders") in connection with the Company's filing of the Chapter 11 Cases on October 30, 2018.

Pursuant to the Support Agreement, the Supporting Noteholders agreed to forbear from exercising any of their rights and remedies under the applicable Existing Debt Instruments (as defined below) pending the outcome of the Bankruptcy Petitions. Under the Plan, the claims under the 5.50% Notes were converted into equity interests in the Company. Refer to Note 21—Subsequent Events for further details.

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 amortization of the discount on the 5.50% Notes was accelerated in the year ended December 31, 2018 due to the reevaluation of the contractual term of the 5.50% Notes due to the events of default.

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 the transaction costs were allocated to equity and the remaining $2.8 million was recorded as debt discount at issuance.

In September 2016, in connection with the issuance of the 13% Notes (as defined below), the Company and its subsidiaries entered into supplemental indentures with the trustee for the 5.50% Notes pursuant to which the Company’s subsidiaries became guarantors under the 5.50% Notes Indenture.

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In December 2017, the Company exchanged, with certain existing 5.50% Noteholders, $36.4 million in principal value of the 5.50% Notes for (i) approximately $23.9 million of the Company's new 6.50% Notes, (ii) a warrant exercisable for 3.5 million shares of the Company's common stock, and (iii) payments, in cash, of all accrued but unpaid interest as of the closing of the 5.50% Notes exchanged in the transaction. This exchange was accounted for as a debt extinguishment and the gain on debt extinguishment of $13.2 million, inclusive of the make-whole payments and write-off of deferred financing fees is reflected in the Company's Consolidated Statements of Operations during the year ended December 31, 2017.

The following table summarizes how the issuance of the 5.50% Notes is reflected in the Company's Consolidated Balance Sheets at December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
(in thousands)		
Principal	$ 24,650	$ 24,650
Unamortized debt discount	—	(4,222)
Carrying value	$ 24,650	$ 20,428

The carrying value of the 5.50% Notes was classified as a non-current liability on the Company's consolidated balance sheets at December 31, 2017. Given the Events of Default, the Company reevaluated the remaining contractual term of the 5.50% Notes and recorded a charge to interest expense of $2.9 million in September 2018. The carrying value of the 5.50% Notes was included in Liabilities Subject to Compromise on the Company's Consolidated Balance Sheet at December 31, 2018. Refer to Note 1—Organization and Description of the Business and Note 10—Liabilities Subject to Compromise for further details.

The Company did not record interest expense for the 5.50% Notes subsequent to the Chapter 11 filing as the Plan of Reorganization included the cancellation of accrued interest upon the Plan becoming effective.

6.50% Convertible Notes due 2024

In December 2017, the Company entered into exchange agreements (the "Exchange Agreements") with certain holders (the "Holders") of the Company's 5.50% Notes pursuant to which the Holders agreed to exchange, in the aggregate, approximately $36.4 million of outstanding principal amount of the 5.50% Notes for, in the aggregate, (i) approximately $23.9 million of the Company's new 6.50% Notes, (ii) a warrant exercisable for 3.5 million shares of the Company's common stock at an exercise price of $0.01 per share and (iii) payments, in cash, of all accrued but unpaid interest as of the closing on the 5.50% Notes exchanged in the transaction (the "Exchange"). At the closing of the Exchange, 2.5 million warrants were exercised. The remaining 1.0 million warrants were exercised in January 2018.

The Company consummated the Exchange in reliance upon the exemption from registration provided by Section 4(a)(2) under the Securities, and pursuant to an indenture (the "Indenture"), dated December 27, 2017, by and among the Company, the subsidiary guarantors party thereto as of the date thereof, and The Bank of New York Mellon, as trustee (the "Trustee").

At the date of Exchange, December 27, 2017, the Company did not have sufficient unissued authorized shares to cover the conversion of the outstanding 6.50% Notes and as a result was required to account for the bifurcated conversion feature as a derivative liability which results in a debt discount on the 6.50% Notes. The fair value of the derivative liability for the conversion feature at the date of Exchange was determined to be approximately $15.0 million and was classified as a liability in the Company's consolidated balance sheet as of December 31, 2017, with subsequent changes to fair value recorded through earnings at each reporting period on the Company's consolidated statements of operations and comprehensive loss as change in fair value of derivative liabilities.

As a result of the Charter Amendment, as of February 14, 2018, the Company had reserved sufficient shares of its common stock to satisfy the conversion provisions of the 6.50% Notes and accordingly, the conversion feature is

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considered indexed to the Company's common stock and the fair value of the conversion feature at the date of approval, $12.5 million, was reclassified from a liability into stockholders' deficit during the first quarter of 2018.

Under the 6.50% Notes, the Company is obligated to pay interest on the 6.50% Notes semiannually in arrears on January 1 and July 1 of each year commencing July 1, 2018 at a rate of 6.50% per year, which rate was subject to adjustment in accordance with the terms of the Indenture (the "6.50% Notes Indenture") and as described below. The 6.50% Notes are general unsecured obligations of the Company and ranked equally in right of payment with all of its other existing and future senior unsecured indebtedness and senior in right of payment to all of its existing and future subordinated indebtedness. The 6.50% Notes would mature on December 31, 2024, unless earlier repurchased, redeemed or converted in accordance with the terms of the 6.50% Notes Indenture prior to such date. Subject to certain conditions, on or after January 1, 2021, the Company may redeem for cash all or a part of the 6.50% Notes. The 6.50% Notes will be convertible at any time until the close of business on the business day immediately preceding the maturity date. Upon conversion and subject to certain conditions, holders of the 6.50% Notes were entitled to receive shares of the Company's common stock at an initial conversion rate of 749.6252 shares of common stock per $1,000 principal amount of 6.50% Notes, which is equivalent to an initial conversion price of approximately $1.33 per share and is subject to adjustment under the terms of the 6.50% Notes Indenture. Similar to the 5.50% Notes, the 6.50% Notes provide for an interest make-whole payment in connection with conversions that occur prior to January 1, 2021. For any Conversion Date that occurred prior to the close of business on the business day immediately preceding January 1, 2021, the Company was obligated to, in addition to the other consideration payable or deliverable in connection with any conversion of Notes, make an interest make-whole payment in cash or in shares of common stock, at the Company's election, to such 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 January 1, 2021. The present values will be computed using a discount rate equal to 2% by a U.S. nationally recognized independent investment banking firm.

If an event of default (as defined in the 6.50% Notes Indenture) occurred and was continuing (other than specified events of bankruptcy or insolvency with respect to the Company), the Trustee or the holders of at least 25% in aggregate principal amount of the outstanding 6.50% Notes could declare all the outstanding 6.50% Notes to be due and payable immediately. If an event of default relating to specified events of bankruptcy or insolvency with respect to the Company occurs, all the outstanding 6.50% Notes will immediately become due and payable without any declaration or other act on the part of the trustee or any holders of the 6.50% Notes. Notwithstanding the foregoing, the 6.50% Notes Indenture provides that, to the extent the Company elects, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the 6.50% Notes Indenture will, for the first 180 days after such event of default, consist exclusively of the right to receive additional interest on the 6.50% Notes. Events of default under the 6.50% Notes Indenture included, among other things, a default in payment of principal on the 6.50% Notes (including upon any required repurchase), a default in payment of any other indebtedness for money borrowed in excess of $5,000,000 if such default is not cured or waived within 30 days and certain events of bankruptcy or insolvency, both voluntary and involuntary.

In addition, the 6.50% Notes Indenture required the Company to use its reasonable best efforts to (i) seek stockholder approval of an amendment to the Company's Third Amended & Restated Certificate of Incorporation, as amended, in order to increase the amount of authorized shares available for issuance thereunder, and (ii) if and when such approval is obtained, to reserve from such amount the number of shares that may be issued in respect of the 6.50% Notes and any other securities issued in connection with the Exchange. In February 2018, the Company held a special meeting of stockholders (the "Special Meeting") and received stockholder approval of an amendment to the Company's Third Amended and Restated Certificate of Incorporation (the "Charter Amendment") to increase authorized shares by 200,000,000 shares. Refer to Note 20—Stockholders' Deficit for further details. The Exchange Agreements also provide that, for a period of nine months, the Company will not enter into additional exchange transactions with the other holders of the 5.50% Notes the economic terms of which, taken as a whole, are more favorable to the 5.50% Note

holders than the December 2017 Exchange.

Certain provisions in the 6.50% notes could require accelerated payment of principal and interest. The 6.50% Notes provide that the delisting of the Company's common stock from the Nasdaq exchange would constitute a "fundamental change" under the 6.50% Notes, which would entitle the holder, at the holder's option, to require the

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Company to repurchase for cash all or any portion of such holder's 6.50% Notes at a repurchase price equal to 100% of the principal amount thereof, plus accrued and unpaid interest thereon. The Nasdaq Transfer did not constitute a fundamental change under the 6.50% Notes, but the Company's delisting from the Nasdaq Capital Market on September 19, 2018 constituted a fundamental change under the 6.50% Notes Indenture.

The failure of the Company to complete the Offer in accordance with the terms of the 5.50% Notes Indenture constituted a cross-default under the 6.50% Notes Indenture. Accordingly, the holders of the 6.50% Notes (or the trustee under the applicable indenture) would have the right to accelerate and declare due and payable immediately all principal and accrued but unpaid interest with respect to the 6.50% Notes if the 5.50% Notes holders (or trustee under the 5.50% Notes Indenture). The filing of the Chapter 11 Cases on October 31, 2018 also constituted an Event of Default under the 6.50% Indenture.

However, any efforts to enforce such payment obligations under the 6.50% Notes Indenture were automatically stayed as a result of the Bankruptcy Petitions and the creditors' rights of enforcement in respect of the 6.50% Notes Indenture and as of the Petition Date, were subject to the applicable provisions of the Bankruptcy Code. In addition, pursuant to the Support Agreement, the Supporting Noteholders have agreed to forbear from exercising any of their rights and remedies under the applicable Existing Debt Instruments pending the outcome of the Bankruptcy Petitions. Refer to Note 1—Organization and Description of the Business. Under the Plan, the claims under the 6.50% Notes were converted into equity interests in the Company. Refer to Note 21—Subsequent Events for further details.

Transaction costs of $1.7 million were incurred related to the issuance of the 6.50% Notes were accounted for as debt discount.

The following table summarizes how the issuance of the 6.50% Notes is reflected in the Company's Consolidated Balance Sheets at December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
(in thousands)		
Principal	$ 23,888	$ 23,888
Unamortized debt discount	—	(20,919)
Carrying value	$ 23,888	$ 2,969

The carrying value of the 6.50% Notes was classified as a non-current liability on the Company's consolidated balance sheet at December 31, 2017. Given the Event of Default, the Company reevaluated the remaining contractual term of the 6.50% Notes and recorded a charge to interest expense of $20.8 million during the third quarter of 2018. The carrying value of the 6.50% Notes was included in Liabilities Subject to Compromise on the Company's Consolidated Balance Sheet at December 31. 2018. Refer to Note 1—Organization and Description of the Business and Note 10— Liabilities Subject to Comprise for additional details.

The Company did not record interest expense for the 6.50% Notes subsequent to the Chapter 11 filing as the Plan of Reorganization included the cancellation of accrued interest upon the Plan becoming effective.

13% Senior Secured Notes (the "13% Notes")

In August 2016, the Company completed the initial closing (the "Initial Closing") of its offering (the "Offering") of up to $80.0 million aggregate principal amount of its 13% Notes and entered into an indenture (the "Indenture") governing the 13% Notes with the guarantors party thereto (the "Guarantors") and U.S. Bank National Association, a national banking association, as trustee (the "Trustee") and collateral agent (the "Collateral Agent").

The Company issued $40.0 million aggregate principal amount of the 13% Notes at the Initial Closing and issued an additional $40.0 million aggregate principal amount upon the FDA's approval of ARYMO™ ER in January 2017 (the "Second Closing"). Net proceeds from the Initial Closing and Second Closing were $37.2 million, and $38.3 million respectively, after deducting the estimated Offering expenses payable by the Company in connection with the

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Initial Closing and Second Closing. The 13% Notes were sold only to qualified institutional buyers within the meaning of Rule 144A under the Securities Act of 1933, as amended.

Prior to the Second Closing, interest on the 13% Notes accrued at a rate of 13% per annum and was payable semi-annually in arrears on March 20 and September 20 of each year (each, a "Payment Date") commencing on March 20, 2017. On each Payment Date commencing on March 20, 2018, the Company was required to also pay an installment of principal of the Notes pursuant to a straight-line fixed amortization schedule. Following the Second Closing in January 2017, in lieu of the straight-line fixed amortization schedule, on each Payment Date commencing on March 20, 2018, the Company is obligated to pay an installment of principal on the 13% Notes in an amount equal to 15% (or 17% if certain sales targets are not met) of the aggregate net sales of SPRIX Nasal Spray, OXAYDO, ARYMO ER and if approved, Egalet-002 for the two consecutive fiscal quarterly period most recently ended, less the amount of interest payable on the 13% Notes on such Payment Date.

The 13% Notes are senior secured obligations of the Company and equal in right of payment to all existing and future pari passu indebtedness of the Company (including the 5.50% Notes), will be senior in right of payment to all existing and future subordinated indebtedness of the Company, have the benefit of a security interest in the Notes collateral and are junior in lien priority in respect of any collateral that secures any first priority lien obligations incurred, which includes intellectual property, from time to time in accordance with the indenture governing the 13% Notes (the "13% Notes Indenture"). Following the Second Closing, the stated maturity date of the 13% Notes became September 30, 2033. Upon the occurrence of a Change of Control, subject to certain conditions, or certain Asset Sales events (each, as defined in the13% Notes Indenture), holders of the 13% Notes may require the Company to repurchase for cash all or part of their 13% Notes at a repurchase price equal to 101.00% of the principal amount of the 13% Notes to be repurchased, plus accrued and unpaid interest to the date of repurchase.

The Company was entitled to redeem the 13% Notes at its option, in whole or in part from time to time, prior to August 31, 2018, at a redemption price equal to 100.00% of the principal amount of the 13% Notes being redeemed, plus accrued and unpaid interest, if any, through the redemption date, plus a make-whole premium computed using a discount rate equal to the treasury rate in respect of such redemption date plus 100 basis points. The Company may redeem the 13% Notes at its option, in whole or in part from time to time, on or after August 31, 2018 at a redemption price equal to: (i) from and including August 31, 2018 to and including August 30, 2019, 109.00% of the principal amount of the 13% Notes to be redeemed, (ii) from and including August 31, 2019 to and including August 30, 2020, 104.50% of the principal amount of the 13% Notes to be redeemed, and (iii) from and including August 31, 2020 and thereafter, 100.00% of the principal amount of the 13% Notes to be redeemed, in each case, plus accrued and unpaid interest to the redemption date. In addition, prior to August 31, 2018, the Company may redeem, at its option, up to 35% of the aggregate principal amount of the 13% Notes with the proceeds of one or more public or private equity offerings at a redemption price equal to 113.50% of the aggregate principal amount of the 13% Notes to be redeemed, plus accrued and unpaid interest to the date of redemption in accordance with the Indenture; provided that at least 65% of the aggregate principal amount of 13% Notes issued under the Indenture remains outstanding immediately after each such redemption and provided further that each such redemption occurs within 90 days of the date of closing of each such equity offering. No sinking fund is provided for the 13% Notes, which means that the Company is not required to periodically redeem or retire the 13% Notes.

The obligations of the Company under the 13% Notes Indenture and the 13% Notes are unconditionally guaranteed on a secured basis by the Guarantors. Under the terms of the 13% Notes Indenture, the Company may designate entities within its corporate structure as unrestricted subsidiaries, which entities will therefore not be guarantors provided that certain conditions set forth in the Indenture are met.

Pursuant to the 13% Notes Indenture, the Company and its restricted subsidiaries must also comply with certain affirmative covenants, such as furnishing financial statements to the holders of the 13% Notes, and negative covenants, including limitations on the following: the incurrence of debt; the issuance of preferred and/or disqualified stock; the payment of dividends, the repurchase of shares and under certain conditions making certain other restricted payments; the prepayment, redemption or repurchase of subordinated debt; the merger, amalgamation or consolidation involving the Company; engaging in certain transactions with affiliates; and the making of investments other than those permitted by the 13% Notes Indenture.

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The 13% Notes Indenture contains customary events of default with respect to the 13% Notes and upon certain events of default occurring and continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding 13% Notes by notice to the Company and the Trustee, may (subject to the provisions of the 13% Notes Indenture) declare 100% of the principal of and accrued and unpaid interest, if any, on all of the 13% Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, as well as the then-applicable optional redemption premium under the 13% Notes Indenture, will be due and payable immediately. In the case of certain events of bankruptcy, insolvency or reorganization involving the Company or a Restricted Subsidiary (as defined in the 13% Notes Indenture), the 13% Notes will automatically become due and payable. Events of default under the 13% Notes Indenture include, among other things, a default in payment of principal on the 13% Notes (including upon any required repurchase or redemption), a default in payment of any other indebtedness for money borrowed in excess of $2,000,000 and certain events of bankruptcy or insolvency, both voluntary and involuntary. The Company accrued the redemption premium of $7.2 million upon filing for bankruptcy in October 2018.

In connection with the filing of the Bankruptcy Petitions, which constituted an event of default under the 13% Notes Indenture, with the principal and accrued but unpaid interest thereunder subject to acceleration to be due and payable, the Company reclassified the principal and accrued but unpaid interest balance to current liabilities. However, any efforts to enforce such payment obligations under the 13% Notes Indenture were automatically stayed as a result of the Bankruptcy Petitions and as of the Petition Date the creditors' rights of enforcement in respect of the 13% Notes Indenture were subject to the applicable provisions of the Bankruptcy Code. In addition, pursuant to the Restructuring Support Agreement, the Supporting Noteholders have agreed to forbear from exercising any of their rights and remedies under the applicable Existing Debt Instruments pending the outcome of the Bankruptcy Petitions. Refer to Note 1 — Organization and Description of the Business. Under the Plan, the claims under the 13% Notes were converted into newly issued notes, equity interests in the Company and cash. Refer to Note 21—Subsequent Events for further details.

In connection with the Initial Offering in August 2016, the Company entered into royalty rights agreements with each of the 13% Notes Purchasers pursuant to which the Company sold to such Purchasers the right to receive, in the aggregate, a payment equal to 1.5% of the aggregate net sales of OXAYDO and SPRIX Nasal Spray from the Initial Closing through December 31, 2019, inclusive (the "Royalty Rights"). Following the approval of ARYMO ER in January 2017, Royalty Rights will continue through December 31, 2020 and include royalties of ARYMO ER as described below.

The Company also entered into separate royalty rights agreements with each of the Purchasers pursuant to which the Company sold to such Purchasers the right to receive 1.5% of the aggregate net sales of ARYMO ER payable from the date of first sale of ARYMO ER through December 31, 2020, inclusive. The royalty rights agreements also include other terms and conditions customary in agreements of this type.

The Company incurred fees and legal expenses of $4.5 million in connection with the issuance of the 13% Notes, which have been recorded as a discount on the debt in the Company's Consolidated Balance Sheets and are amortized using the effective interest method. The Company calculated an effective interest rate of 14.6% upon origination of the 13% Notes based on its best estimate of future cash outflows.

The Royalty Rights were determined to be a freestanding element with respect to the 13% Notes and the Company is accounting for the Royalty Rights obligation relating to future royalties as a debt instrument. The Company has Royalty Rights obligations of $1.9 million and $4.1 million as of December 31, 2018 and 2017, respectively, which are classified as current and non-current debt in the consolidated balance sheet.

The accounting for the 13% Notes requires the Company to make certain estimates and assumptions about the future net sales of OXAYDO and SPRIX Nasal Spray in the United States, and prior to the discontinuation of ARYMO ER, future net sales of ARYMO ER. The estimates of the magnitude and timing of OXAYDO and SPRIX Nasal Spray net sales are subject to significant variability due to the recent product launch and the extended time period associated with the financing transaction and are thus subject to significant uncertainty. Therefore, these estimates and assumptions

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are likely to change as the Company continues to gain experience marketing OXAYDO and SPRIX Nasal Spray. The fair value of the Royalty Rights associated with certain net product sales was estimated to be approximately $5.0 million using a probability-weighted present value analysis. Upon informing he FDA in September 2018 that the Company was discontinuing the manufacturing and promotion of ARYMO ER, the Company adjusted the fair value of the Royalty Rights associated with ARYMO ER by reducing the liability by $691,000 and interest expense in the third quarter of 2018.

The following table summarizes how the issuance of the 13% Notes is reflected in the Company's Consolidated Balance Sheet at December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
(in thousands)		
Gross proceeds	$ 79,104	$ 80,000
Unamortized debt discount	—	(7,572)
Carrying value	$ 79,104	$ 72,428

The carrying value of the 13% Notes was classified as a non-current liability on the Company's Consolidated Balance Sheets at December 31, 2017. Given the Event of Default, the Company reevaluated the remaining contractual term of the 13% Notes and recorded a charge to interest expense of $7.6 million in September 2018. The carrying value of the 13% Notes was included in Liabilities Subject to Compromise on the Company's Consolidated Balance Sheets at December 31, 2018. Refer to Note 1—Organization and Description of the Business and Note 10—Liabilities Subject to Compromise for further details. The Royalty Rights remaining at December 31, 2018 based on net sales of OXAYDO and SPRIX total $1.9 million and are included in Liabilities Subject to Compromise on the Company's Consolidated Balance Sheets. The Royalty Rights issued in connection with the 13% Notes at December 31, 2017 were $4.1 million

Current and non-current debt on the Company's Consolidated Balance Sheet at December 31, 2017 includes the carrying value of the 5.50% Notes and the 13% Notes, as well as $4.1 million for the Royalty Rights issued in connection with the debt.

The Company did not record interest expense for the 13.0% Notes subsequent to the Chapter 11 filing as the Plan of Reorganization included the cancellation of accrued interest upon the Plan becoming effective.

The following table sets forth the Company's net interest expense incurred for the years ended December 31, 2018 and 2017:

	For the Year Ended December 31,	
(in thousands)	2018	2017
5.50% Notes	$ 5,355	$ 7,998
6.50% Notes	22,209	50
13% Notes	14,632	10,506
Amortization of premium on marketable securities	(234)	(38)
Interest income on investments	(682)	(850)

Total	$ 41,280	$ 17,666

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12. Stock-Based Compensation Expense

Chapter 11 Cases

On the Effective Date of the Company's Plan of Reorganization (January 31, 2019) all of its outstanding equity interests and, accordingly, each of the plans described below, were terminated in accordance with the terms of the Reorganization Plan. Refer to Note 21—Subsequent Events for additional details

2013 Stock-Based Incentive Compensation Plan

In November 2013, the Company adopted its 2013 Stock-Based Incentive Compensation Plan (as subsequently amended and restated from time to time, the "2013 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 the Company's common stock initially reserved for issuance under the 2013 Plan was 1,680,000, in the form of restricted stock and stock options. Share increases of 2,000,000, 2,600,000 and 6,000,000 to the number of shares originally reserved for issuance under the 2013 Plan were authorized by the Company's stockholders in June 2014, June 2016 and May 2018, respectively. The amount, terms of grants and exercisability provisions are determined by the compensation committee. The term of the stock options may be up to 10 years, and stock options are exercisable in cash or as otherwise determined by the compensation committee. All stock options vest over time as stipulated in the individual award agreements. In September 2015, the compensation committee voted to amend the 2013 Plan to, among other things, allow for monthly vesting of stock options granted thereunder.

2017 Inducement Plan

In December 2016, the Company adopted its 2017 Inducement Plan (the "Inducement Plan"), which became effective in January 2017. Pursuant to the Plan, the Company's compensation committee is authorized to grant equity-based incentive awards to its employees, including employees of its subsidiaries, who were not previously employees or Non-Employee Directors of the Company or any of its subsidiaries (or who have had a bona fide period of non-employment with the Company and its subsidiaries) in compliance with Rule 5635(c)(4) of the Nasdaq Global Market. The number of shares of the Company's common stock initially reserved for issuance under the Plan was 300,000, in the form of common stock, deferred stock, restricted stock, restricted stock units and stock options. The amount, terms of grants and exercisability provisions are determined by the compensation committee of the Company's board of directors. The term of stock options issued under the Inducement Plan may be up to 10 years, and stock options are exercisable in cash or as otherwise determined by the compensation committee of the Company's board of directors. All stock options vest over time as stipulated in the individual award agreements.

Employee Stock Purchase Plan

In January 2016, the Company established an Employee Stock Purchase Plan (the "Purchase Plan"), which was approved by the Company's stockholders in June 2016. A total of 750,000 shares of common stock were originally approved for future issuance under the Purchase Plan pursuant to purchase rights granted to the Company's employees. Under the Company's Purchase Plan, eligible employees can purchase the Company's common stock through accumulated payroll deductions at such times as are established by the administrator. The Purchase Plan is administered by the compensation committee. Under the Purchase Plan, eligible employees may purchase the Company's common stock at 85% of the lower of the fair market value of a share of the Company's common stock on the first day of an offering period or on the last day of the offering period. Eligible employees may contribute up to

10% of their eligible compensation. A participant may purchase a maximum of 1,500 shares of common stock per offering period. Under the Purchase Plan, a participant may not accrue rights to purchase more than $25,000 worth of the Company's common stock for each calendar year in which such right is outstanding.

At the end of each offering period, shares of the Company's common Stock may be purchased at 85% of the lower of the fair market value of the Company's common stock on the first or last day of the respective offering period. In accordance with the guidance in ASC 718-50 – Compensation – Stock Compensation, the ability to purchase shares of

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the Company's common stock at the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the Purchase Plan is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company has recognized stock-based compensation expense of $18,000 and $107,000 for the years ended December 31, 2018 and 2017, respectively, related to the Purchase Plan.

The Company terminated the Purchase Plan effective September 30, 2018. No purchases were made at the end of the offering period that ended December 31, 2018.

Shares Reserved for Future Issuance

As of December 31, 2018, the Company has reserved the following shares of the Company's common stock for issuance:

Shares initially reserved under the 2013 Plan	1,680,000
Shares reserved under the Inducement Plan	300,000
Shares reserved under the Purchase Plan	750,000
Authorized increase to the 2013 Plan	10,600,000
Common stock options granted under the 2013 Plan	(6,314,688)
Common stock options granted under the Inducement Plan	(212,500)
Restricted stock awards granted under the 2013 Plan	(3,043,660)
Restricted stock units granted under the 2013 Plan	(600,000)
Common stock issued under the Purchase Plan	(184,961)
Stock options and restricted stock awards forfeited	2,435,265
Remaining shares available for future grant	5,409,456

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:

	Year Ended December 31,	
(in thousands)	2018	2017
General and administrative	$ 3,537	$ 4,460
Sales and marketing	231	524
Research and development	205	570
Restructuring and other charges	—	364
Total stock-based compensation expense	$ 3,973	$ 5,918

Stock Options Outstanding Under Equity Compensation Plans

	Stock Options Outstanding	
		Weighted-average Remaining

	Number of Shares	Weighted-Average Exercise Price	Contractual Term (in years)
Outstanding at December 31, 2017	4,110,612	$ 6.41	
Granted	1,123,750	0.66	
Exercised	—	—	
Forfeited	(558,677)	4.28	
Cancelled	(253,139)	8.86	
Outstanding at December 31, 2018	4,422,546	$ 5.08	7.53
Vested or expected to vest at December 31, 2018	4,422,546	$ 5.08	7.53
Exercisable at December 31, 2018	2,332,882	$ 6.63	6.53

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The intrinsic value of the Company's 4,422,546 stock options outstanding as of December 31, 2018 was $0 based on a per share price of $0.00, the Company's closing stock price on that date, and a weighted-average exercise price of $5.08 per share.

There were no options exercised in the years ended December 31, 2018 and 2017.

The Company uses 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, the Company measures stock-based compensation cost at the grant date based on the estimated fair value of the award and recognizes it as expense over the requisite service period on a straight-line basis. The Company records 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, the Company expenses 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.

On June 8, 2017, the Company granted stock options for 630,000 shares of the Company's common stock to nine senior executives (the "June 2017 Grant"). The contractual term of each of the grants made in the June 2017 Grant is 10 years and the exercise price is $2.38 per share. Provided that the grantee is still employed by the Company, the vesting terms of the June 2017 Grant include a combination of market and service-based conditions as follows:

- 25% of the award will vest on the later of (i) the six-month anniversary of the grant and (ii) the date on which the average closing price of the Company's common stock on Nasdaq is at least $3.33 for 30 consecutive trading days.

- 25% of the award will vest on the later of (i) the twelve-month anniversary of the grant and (ii) the date on which the average closing price of the Company's common stock on Nasdaq is at least $4.05 for 30 consecutive trading days.

- 50% of the award will vest on the later of (i) the twenty-four-month anniversary of the grant and (ii) the date on which the average closing price of the Company's common stock on Nasdaq is at least $4.76 for 30 consecutive trading days.

The Company used the binomial model to estimate the compensation cost for the June 2017 Grant. Key assumptions used in calculating the total estimated compensation cost of $1.3 million included (i) an estimated term of 5.6 years, (ii) expected volatility of 95.54%, (iii) expected dividends of $0.00 and (iv) a risk-free return of 1.80%. Stock-based compensation expense related to the June 2017 Grant will be recognized ratably over the requisite service period of 5.6 years. The Company recognized stock-based compensation expense of $204,000 and $136,000 for the years ended December 31, 2018 and 2017, respectively.

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The per-share weighted-average grant date fair value of the options granted to employees during the years ended December 31, 2018 and 2017 was estimated at $0.46 and $3.62, respectively, per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	2018		2017	
Risk-free interest rate	2.79	%	1.93	%
Expected term of options (in years)	5.90		6.15	
Expected volatility	80.60	%	80.57	%
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 stock options: The Company estimated the expected life of its employee stock options using the "simplified" method, as prescribed in SAB No. 107, Share Based Payments, 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 its actual historical volatility of the Company's stock price. The Company calculated the historical volatility by using daily closing prices over a period of the expected term of the associated award. A decrease in the expected volatility would have decreased the fair value of the underlying instrument.

Prior to January 1, 2017, 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 impact of this change had an immaterial effect on the Company's financial results for the year ended December 31, 2017.

- 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, 2018, there was $3.7 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 1.88 years.

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Restricted Stock Granted under the 2013 Stock-Based Incentive Plan

A summary of the status of the Company's restricted stock awards at December 31, 2018 and of changes in restricted stock awards outstanding under the Plan for the year ended December 31, 2018 is as follows:

	Number of Shares	Weighted-average Grant Date Fair Value per Share
Unvested at December 31, 2017	25,047	$ 7.07
Granted	2,100,000	$ 0.55
Forfeited	(305,000)	$ 0.55
Vested restricted stock awards	(9,104)	$ 7.07
Unvested at December 31, 2018	1,810,943	$ 0.61

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 of the Company, 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 awards vested for the years ended December 31, 2018 and 2017, was $2,000 and $1.8 million, respectively.

As of December 31, 2018, there was $451,000 of total unrecognized stock-based compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 0.73 years.

13. Income Taxes

Income taxes have been recorded on the following losses before income taxes:

(in thousands)	As of December 31,	
	2018	2017
Domestic operations	$ (91,262)	$ (52,568)
Foreign operations	(4,192)	(16,791)
Loss before provision for income taxes	$ (95,454)	$ (69,359)

The benefit for income taxes consists of the following for 2018 and 2017:

(in thousands)	As of December 31,	
	2018	2017
Current:		
U.S. federal	$ —	$ —
State and local	—	—
Foreign	—	—

Total current taxes	—	—
Deferred:		
U.S. federal	$ —	$ —
State and local	—	—
Foreign	—	—
Total deferred taxes	—	—
Total income tax benefit	$ —	$ —

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For the years ended December 31, 2018 and 2017, 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,	
	2018	2017
Beginning balance	$ 73	$ 73
Increase related to prior tax years	—	—
Increase related to current year	—	—
Ending balance	$ 73	$ 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 Company's 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,	
	2018	2017
Deferred tax assets:		
Inventory	$ 75	$ 96
Accrued expenses	874	725
Deferred revenue	—	1,843
Stock-based compensation expense	1,146	1,072
Intangible assets	1,112	969
Other	152	341
Other debt	552	1,149
Interest 163(j)	7,489	—
Sales returns and rebates	1,154	—
Fixed assets	2,206	—
Convertible notes	940	—
Net operating losses	64,669	56,943
Deferred tax assets	80,369	63,138
Deferred tax liabilities:		
Fixed assets	$ —	$ (747)
Convertible notes	—	(1,445)
Deferred tax liabilities	—	(2,192)
Net deferred tax assets	80,369	60,946
Less: valuation allowance	(80,389)	(60,966)
Net deferred tax liabilities after valuation allowance	$ (20)	$ (20)

As of December 31, 2018, the Company had foreign net operating loss ("NOL") carry forwards of $91.4 million 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 Limited (“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 the NOLs will ever be realized. As

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of December 31, 2018, the Company had U.S. federal and state NOL's of $176.0 million and $111.8 million, respectively. These domestic NOL carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three year period in excess of 50%. This could limit the amount of NOLs that the Company can utilize annually to offset future domestic taxable income or tax liabilities, if any. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. These federal and state NOL's will begin to expire in 2033 and through 2036. As a result of the Tax Act, the Federal NOL incurred in 2018 will have an indefinite life.

ASC 740 – Tax Provisions 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, 2018 and 2017, respectively, because the Company 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 $19.4 million and $27.9 million, which includes the impact of the Tax Reform for the years ended December 31, 2018 and 2017, respectively.

At December 31, 2018, no provision has been made for U.S. federal and state income taxes of foreign earnings due to the history of foreign losses and the Company does not expect to incur any future United States federal and state income tax with respect to its foreign companies.

The Company files income tax returns in Denmark, the U.K., the United States, and in various U.S. states. The foreign tax returns are subject to tax examinations for the tax years ended July 31, 2013 through December 31, 2018. The domestic tax returns are subject to tax examinations for the tax years ended December 31, 2015 through December 31, 2018. 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, 2018		2017	
Federal income tax at the statutory rate	21.0	%	34.0	%
Permanent tax items	(0.4)		(0.3)	
State income tax, net of federal benefit	5.1		2.6	
Change in foreign tax rate	(1.0)		(3.1)	
Equity compensation shortfall	—		(0.7)	
Tax reform rate change	—		(25.8)	
Change in valuation allowance	(24.7)		(6.7)	
Effective income tax rate	—	%	—	%

The Tax Act was enacted on December 22, 2017 and was the driver of the rate change item above.

14. Employee Benefit Plans

The Company's 401(k) Employee Savings Plan (the "401(k) Plan") is available to all U.S. 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 $591,000 and $617,000 to the 401(k) Plan in the years ended December 31, 2018 and 2017, respectively.

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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 expense for the financial year is equal to the contributions called by, and thus payable to, such plan. Under Denmark's state plan, contributions paid by the Company are in full discharge of the Company's liability and are recognized as an expense for the period. For the years ended December 31, 2018 and 2017 the Company recorded $107,000 and $202,000 respectively, for contributions under its state plan for Denmark employees.

15. Restructuring and Other Charges

The following table presents a summary of the Company's restructuring and other charges for the years ended December 31, 2018 and 2017:

(in thousands)	Year Ended December 31,	
	2018	2017
ARYMO write down of assets	$ 8,184	$ —
Halo termination fee	3,100	—
Legal fees	4,331	—
Other professional fees	1,428	—
Severance	—	2,760
Total restructuring and other costs	$ 17,043	$ 2,760

Restructuring and other charges for the year ended December 31, 2018 reflect the write-down of assets related to the discontinuation of ARYMO ER, a termination payment to Halo Pharmaceuticals also related to the discontinuance of ARYMO ER and legal and professional fees relating to, but incurred prior to the bankruptcy filing. Restructuring and other charges for the year ended December 31, 2017 reflect costs related to the Company's expense reduction plan announced in August 2017 to decrease the operating expenses that did not directly support the growth of the Company's commercial business.

16. Reorganization Charges

The Company incurred reorganization charges of $9.0 million subsequent to the bankruptcy filing in the year ended December 31, 2018 related to its Chapter 11 filing. The charges were comprised of a redemption premium on the 13% Notes, legal, professional and court fees.

(in thousands)	For the Year Ended December 31, 2018
13% Notes redemption premium	$ 7,200

Legal fees	1,003
Other professional fees	528
U.S. Bankruptcy Court fees	214
Other fees	77
Total reorganization charges	$ 9,022

17. Commitments and Contingencies

Operating Leases

The Company’s corporate U.S. 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. The Company also maintained a research laboratory, pilot manufacturing and administrative facility in Vaerlose, Denmark, where it leased

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12,895 square feet of space under a lease agreement that automatically renewed every 12 months. The Company has terminated the Denmark lease and vacated the facility in February 2019.

The following is a schedule by year of the future minimum rental payments required under non-cancelable leases as of December 31, 2018:

(in thousands)	
2019	533
2020	543
2021	553
2022	92
Total minimum lease payments	$ 1,721

Rent expense was $574,000 and $617,000 for the years ended December 31, 2018 and 2017, respectively.

Legal Proceedings

On January 27, 2017 and February 10, 2017, respectively, two putative securities class actions were filed in the U.S. District Court for the Eastern District of Pennsylvania that named as defendants Egalet Corporation and current officer Robert S. Radie and former officers Stanley J. Musial and Jeffrey M. Dayno (the “Officer Defendants” and together with Egalet Corporation, the “Defendants”). These two complaints, captioned Mineff v. Egalet Corp. et al., No. 2:17-cv-00390-MMB and Klein v. Egalet Corp. et al., No. 2:17-cv-00617-MMB, assert securities fraud claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) on behalf of putative classes of persons who purchased or otherwise acquired Egalet Corporation securities between December 15, 2015 and January 9, 2017. On May 1, 2017, the Court entered an order consolidating the two cases (the “Securities Class Action Litigation”) before it, appointing the Egalet Investor Group (consisting of Joseph Spizzirri, Abdul Rahiman and Kyle Kobold) as lead plaintiff and approving their selection of lead and liaison counsel. On July 3, 2017, the plaintiffs filed their consolidated amended complaint, which named the same Defendants and also asserted claims for purported violations of Sections 10(b) and 20(a) of the Exchange Act. Plaintiffs brought their claims individually and on behalf of a putative class of all persons who purchased or otherwise acquired shares of the Company between November 4, 2015 and January 9, 2017 inclusive. The consolidated amended complaint based its claims on allegedly false and/or misleading statements and/or failures to disclose information about the likelihood that ARYMO ER would be approved for intranasal abuse-deterrent labeling. The Defendants moved to dismiss the consolidated amended complaint on September 1, 2017 (the “Motion to Dismiss”), the plaintiffs filed their opposition on October 31, 2017, and the Defendants filed their reply on December 8, 2017. The Court heard oral arguments on the Motion to Dismiss on February 20, 2018 and entered an order pursuant to which the plaintiffs filed a motion for leave to file a second amended complaint on March 6, 2018. The Defendants responded on March 20, 2018 and the plaintiffs filed their reply on March 27, 2018. The Court heard oral arguments on the plaintiffs’ motion for leave to file a second amended complaint on July 12, 2018. On August 2, 2018, the Court granted the Defendants’ Motion to Dismiss and dismissed the Securities Class Action Litigation with prejudice. On August 31, 2018, plaintiffs filed their notice of appeal with the United States Court of Appeal for the Third Circuit. On November 7, 2018, the Defendants filed a notice of suggestion of bankruptcy and unopposed motion to stay the appeal as to the Officer Defendants (the appeal was automatically stayed as to the Company upon the Chapter 11 filing). On February 6, 2019, the Officer Defendants filed a Notice of Lifting of Automatic Stay of Proceedings and Discharge of Subordinated Claims, as plaintiffs’ claim against the Company was extinguished as part of the bankruptcy, which restarted the appellate process. The Company disputes the allegations in the lawsuit and intends to defend these actions vigorously. The Company cannot determine the likelihood of, nor can it reasonably estimate the range of, any potential loss, if any, from these lawsuits.

On October 30, 2018, the Debtors filed the Bankruptcy Petitions in the U.S. Bankruptcy Court for the District of Delaware. The Debtors requested that the Chapter 11 cases (the “Chapter 11 Cases”) be jointly administered for procedural purposes only under the caption In re Egalet Corporation, et al., Case No. 18-12439. Upon filing, the Company intended to operate its business as a “debtor-in-possession” under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and orders of the Bankruptcy Court. The Company continued ordinary course operations substantially uninterrupted during the Chapter 11 Cases and sought approval from

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the Bankruptcy Court for relief under certain "first day" motions authorizing the Debtors to continue to conduct its business in the ordinary course. On January 14, 2019, the Court entered the Confirmation Order confirming the plan under Chapter 11 of the Bankruptcy Code. On January 31, 2019 (the "Effective Date"), and substantially concurrent with the consummation of the Iroko Acquisition, the Plan became effective. On March 26, 2019, the Bankruptcy Court issued a final decree closing the Chapter 11 Cases. Refer to Note 21—Subsequent Events for additional details.

18. 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, 2018 and 2017:

(in thousands, except share and per share data)	Year Ended December 31,	
	2018	2017
Basic and diluted net loss per common share calculation:		
Net loss	$ (95,454)	$ (69,359)
Weighted average common stock outstanding	52,775,116	33,755,462
Net loss per share of common stock—basic and diluted	$ (1.81)	$ (2.05)

The following outstanding securities for the year ended December 31, 2018 and 2017 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti dilutive:

	Year Ended December 31,	
	2018	2017
Stock options outstanding	4,422,546	4,110,612
Unvested restricted stock awards	1,810,943	25,047
Common shares issuable upon conversion of the 5.50% Notes	1,657,757	1,657,757
Common shares issuable upon conversion of the 6.50% Notes	17,907,047	17,907,047
Common shares issuable upon exercise of warrants	16,666,667	17,666,667
Total	42,464,960	41,367,130

19. Acquisitions and License and Collaboration Agreements

Collaboration and License Agreement with Acura

In January 2015, the Company entered into the OXAYDO License Agreement with Acura to commercialize OXAYDO tablets containing Acura's Aversion Technology. OXAYDO (formerly known as Oxecta®) is currently approved by the FDA for marketing in the United States in 5 mg and 7.5 mg strengths, but was not actively marketed at the time of the OXAYDO License Agreement Under the terms of the OXAYDO License Agreement, Acura transferred the approved New Drug Application("NDA") for OXAYDO to the Company and the Company was granted an exclusive license under Acura's intellectual property rights for development and commercialization of OXAYDO worldwide in all strengths.

The Company paid Acura an upfront payment of $5.0 million in January 2015 and a $2.5 million milestone payment 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 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 License Agreement. The OXAYDO 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 receives from the Company, a tiered royalty percentage based on sales thresholds. Based on the Company's current level of net sales, the royalty percentage payable to Acura is in the mid-single digits; however, the percentage may increase in future years in the event the Company achieves the higher sales thresholds set forth in the

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License Agreement. In addition, in any calendar year in which net sales exceed a specific threshold, Acura is entitled to receive a double-digit royalty on all OXAYDO net sales in that year. The Company's royalty payment obligations commenced on the first commercial sale of OXAYDO and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering OXAYDO in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by the Company to acquire intellectual property rights to commercialize OXAYDO, with an aggregate minimum floor. The term of the Acura license agreement expires, in its entirety, upon the final expiration of any such patent claim in any country. OXAYDO is currently sold in the United States and is covered by six U.S. patents that expire between 2023 and 2025. Patents covering OXAYDO in foreign jurisdictions expire in 2024. Either the Company or Acura may terminate the license agreement for certain customary reasons, including cause, insolvency or patent challenge. The Company may terminate the license agreement upon 90 days prior written notice. During the pendency of the Chapter 11 Cases, any efforts by Acura to terminate the agreement pursuant to the provisions described above are automatically stayed as a result of the Bankruptcy Petitions and Acura's rights of enforcement are subject to the applicable provisions of the Bankruptcy Code.

Purchase Agreement with Luitpold

In January 2015, the Company entered into and consummated the transactions contemplated by the SPRIX Nasal Spray Purchase Agreement with Luitpold (the "SPRIX Purchase Agreement"). Pursuant to the SPRIX Purchase Agreement, the Company acquired specified assets and liabilities associated with SPRIX Nasal Spray for a purchase price of $7.0 million. 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. Based on the projected future cash flows of SPRIX Nasal Spray through December 31, 2019, the SPRIX Nasal Spray intangible asset is being amortized over a useful life of 5 years.

Under the SPRIX Purchase Agreement pursuant to which the Company acquired certain assets and liabilities associated with SPRIX Nasal Spray, the Company was assigned an exclusive license with Recordati Ireland Ltd. ("Recordati") for intranasal formulations of ketorolac tromethamine (the "Licensed Product"), the active ingredient in SPRIX Nasal Spray. The Company is required to pay a fixed, single-digit royalty to Recordati on net sales of the Licensed Product. The exclusive term of the license agreement expires, on a country-by-country basis, on the later of the final expiration of any patent right in such country that contains a valid claim covering the Licensed Product, or ten years from the date of the first commercial sale of the Licensed Product in such country, and thereafter the Company will retain a non-exclusive, perpetual license in such country. In addition, during the exclusivity period with respect to the United States, Canada and Latin America, the royalty payable to Recordati is decreased if no patent containing a valid claim is in force in the country at the time of sale. SPRIX Nasal Spray is currently sold in the United States and is covered by a patent that expired in December 2018 and the first commercial sale of SPRIX Nasal Spray in the United States occurred in May 2011.

During the pendency of the Chapter 11 Cases, any efforts by Recordati to terminate the license agreement pursuant to the provisions thereof are automatically stayed as a result of the Bankruptcy Petitions and Recordati's rights of

enforcement are subject to the applicable provisions of the Bankruptcy Code.

The Company accounted for the SPRIX Purchase Agreement as a business combination.

20. Stockholders' Deficit

Chapter 11 Cases

On the Effective Date of the Company's Plan of Reorganization, January 31, 2019, all of its outstanding equity interests were extinguished in accordance with the terms of the Reorganization Plan. Refer to Note 21—Subsequent Events for additional details.

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At the Market Offering

In July 2015, the Company entered into a Controlled Equity Offering Sales Agreement ("2015 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), under which the Company could, at its discretion, from time to time, sell shares of its common stock, for an aggregate offering price of up to $30.0 million. The Company provided Cantor with customary indemnification rights, and Cantor is entitled to a commission at a fixed rate of 3% of the gross proceeds per share sold. Sales of the shares under the 2015 Sales Agreement have been and, if there are additional sales under the 2015 Sales Agreement, will be, made in transactions deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act of 1933, as amended.

The Company initiated sales of shares under the 2015 Sales Agreement at various times beginning in March 2017 and sold an aggregate of 9,786,622 shares of common stock resulting in net proceeds of $9.5 million after deducting commissions of $286,000, through July 27, 2018, the date on which the Company suspended all sales under the 2015 Sales Agreement.

July 2017 Equity Offering

On July 6, 2017, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co. relating to an underwritten public offering (the "July 2017 Equity Offering") of 16,666,667 shares of the Company's common stock and accompanying warrants to purchase 16,666,667 shares of common stock, at a combined public offering price of $1.80 per share and accompanying warrant, for gross proceeds of $30.0 million. The net offering proceeds were $28.6 million after deducting underwriting discounts and commissions and offering-related costs of $1.4 million. Each warrant has an exercise price of $2.70, subject to adjustment in certain circumstances. As of December 31, 2018, the warrants had an exercise price of $1.92. The shares of common stock and warrants were issued separately. The warrants may be exercised at any time on or after the date of issuance and will expire five years from the date of issuance.

The Company accounted for the warrants using ASC 480 – Distinguishing Liabilities from Equity and determined that the warrants were a freestanding financial instrument that are subject to liability classification. Pursuant to the terms of the agreement, the Company could be required to settle the warrants in cash in the event of an acquisition of the Company, and as a result the warrants are required to be measured at fair value and reported as a liability in the Company's Consolidated Balance Sheets. The warrant exercise price is subject to adjustment upon the issuance of certain equity securities at a price less than the exercise price of the warrants then in effect.

The fair value of the warrants to purchase shares of the Company's common stock in connection with the July 2017 Equity Offering was $9.7 million on the date of issuance, which was determined using a lattice model that takes into account various future financing scenarios and the impact of those scenarios on the fair value of the warrants. The fair

value of the warrants of $9.7 million on the date of issuance was recorded as a liability which will be marked to its estimated fair value at each reporting period. Refer to Note 5—Fair Value Measurements for further details. As of December 31, 2018, the Company determined the warrant liability had a fair value of $0 based primarily on the value of the Company's equity securities and the liquidity events discussed in Note 21 – Subsequent Events.

Reclassification of the Derivative Liability

In February 2018, the Company received shareholder approval to increase the number of its authorized shares of its common stock by 200,000,000 additional shares. Prior to this approval, the embedded conversion options in the 6.50% Notes were required to be separately accounted for as a derivative liability. Upon the shareholder approval to increase the number of authorized shares, the Company had sufficient authorized shares of its common stock to satisfy the conversion provisions of the 6.50% Notes. The fair value of the derivative liability of $12.5 million was reclassified from a liability into stockholders' deficit during the first quarter of 2018.

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21. Subsequent Events

Chapter 11 Cases

On January 14, 2019, the Court entered the Confirmation Order confirming the Plan under Chapter 11 of the Bankruptcy Code. On January 31, 2019 (the "Effective Date"), and substantially concurrent with the consummation of the Iroko Acquisition, the Plan became effective.

Pursuant to the Plan, on the Effective Date, among other things, the following transactions occurred:

payment in full, in cash, of all administrative claims, statutory fees, professional fee claims and certain priority claims, other secured claims, and general unsecured claims (or, to the extent not so paid, such amounts shall be paid as soon as practicable after the Effective Date or in the ordinary course of business, subject to the reorganized company's claims and defenses);

the cancellation of all of the Company's common stock and all other equity interests in the Company outstanding on the Effective Date prior to the consummation of the transactions;

the conversion of approximately $80.0 million of claims (the "First Lien Secured Notes Claims") related to the Company's old 13% Notes into

- $50.0 million in aggregate principal amount of Series A-1 Notes,
- The number of shares of the Company's common stock (or warrants) representing, in the aggregate, 19.38% of the shares outstanding as of the Effective Date (subject to dilution only on account of the Management Incentive Plan (as defined in the Plan)) (the "First Lien Equity Distribution"),
- $20.0 million in cash less certain amounts related to adequate protection payments, and
- cash in an amount equal to certain unpaid fees and expenses of the trustee under the indenture governing the Old 13% Notes;

the conversion of $48.6 million of claims (the "Convertible Notes Claims") related to the Company's 5.50% Convertible Senior Notes due 2020 and its 6.50% Convertible Senior Notes due 2023 into the number of shares of common stock of the Company (or Warrants) representing, in the aggregate, 31.62% of the shares outstanding as of the Effective Date (subject to dilution only on account of the Management Incentive Plan);

the consummation of the Iroko Acquisition and other transactions contemplated by the Purchase Agreement; and

the effectiveness of the discharge, release, exculpation and injunction provisions for the benefit of the Debtors', certain of the Debtors' claimholders and certain other parties in interest, each in their capacities as such, from various claims and causes of action.

Each of the foregoing percentages of equity in the Company is subject to dilution solely from the shares issued or reserved for issuance under the Management Incentive Plan (as defined in the Plan). On the Effective Date, following the consummation of the Iroko Acquisition and the other transactions contemplated by the Plan, there were 9,360,968 shares of common stock issued and outstanding and warrants for an aggregate of 4,972,364 shares of the Company's common stock.

On the Effective Date, the Company issued (i) an aggregate of 4,774,093 shares of common stock to the former holders of First Lien Secured Notes Claims and Convertible Notes Claims and (ii) warrants for an aggregate of 2,535,905 shares of common stock to certain holders of First Lien Secured Notes Claims and Convertible Notes Claims. Based on the Confirmation Order and the Plan, the issuance of such shares of common stock of the Company and the warrants (including shares of common stock issuable upon the exercise thereof) are exempt from registration requirements of the Securities Act, in reliance on Section 1145 of the Bankruptcy Code.

Iroko Acquisition

Also, on the Effective Date, the Company issued an aggregate of 4,586,875 shares of its common stock and warrants for an aggregate of 2,436,459 shares of common stock to Iroko and certain of its affiliates pursuant to the Purchase Agreement. The issuance of the common stock pursuant to the Purchase Agreement was exempt from the

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registration requirements of the Securities Act, pursuant to Section 4(a)(2) thereof and Regulation D promulgated thereunder.

Upon the effectiveness of the Plan and the Iroko Acquisition, (i) Iroko, together with certain of its affiliates, owns approximately 49% of the outstanding common stock of the Company and (ii) the former holders of First Lien Secured Notes Claims and Convertible Notes Claims own, in the aggregate, approximately 51% of the outstanding common stock of the Company. Pursuant to the Plan, Iroko and the Supporting Noteholders (as defined in the Plan) have designated certain new members of the board of directors of the Company.

iCeutica License Agreement

Pursuant to the Purchase Agreement, on the Effective Date, the Company assumed the rights and obligations of Iroko and its subsidiaries pursuant to the Amended and Restated Nano-Reformulated Compound License Agreement, dated October 30, 2018 (the "iCeutica License"), with iCeutica Inc. and iCeutica Pty Ltd. (collectively, "iCeutica") to license certain technology, intellectual property and expertise related to iCeutica's SoluMatrix® technology, meloxicam and certain other rights of iCeutica.

Pursuant to the iCeutica License, iCeutica grants to the Company (as the assignee of Iroko) a sole and exclusive, world-wide right and license under certain iCeutica intellectual property to make, use, sell, offer and import certain products made from the compounds indomethacin, diclofenac, naproxen and meloxicam. In consideration of the grant of the iCeutica License, the Company is obligated to pay to iCeutica a mid-single digit royalty on all Net Sales of any licensed products, including pro rata portions of any combination products that include a licensed product.

The iCeutica License will terminate on a country-by-country basis until the expiration of the last-to-expire of any patent rights in such country, and otherwise twenty years after the date of the first commercial introduction of a licensed product in such country. Either party may terminate the license in its entirety if the other party materially breaches the License Agreement, subject to applicable cure periods. The iCeutica License also contains customary provisions for an agreement of this type related to intellectual property matters, confidentiality, representations and warranties and indemnification.

Interim Promissory Note

On the Effective Date, pursuant to the Purchase Agreement, the Company issued a $4.5 million promissory note to an affiliate of Iroko in respect of certain inventory purchases by Iroko during the pendency of the Iroko Acquisition (the "Interim Promissory Note"). The Interim Promissory Note bears interest at a rate of 8% per annum (payable by way of

increasing the principal amount of the Interim Promissory Note on each interest payment date), is subordinate to the Notes, and matures on July 31, 2020.

Transition Services Agreement

On the Effective Date, the Company and Iroko Pharmaceuticals LLC ("Iroko LLC"), a subsidiary of Iroko, entered into a transition services agreement (the "Transition Services Agreement") pursuant to which Iroko LLC has agreed to provide or cause to be provided certain services related to the Transferred Assets and the related business for a period of time following the Effective Date. The Transition Services Agreement includes customary provisions regarding fees, reimbursement of expenses, confidentiality and indemnification.

13% Senior Secured Notes Indenture

On the Effective Date, the Company issued $95.0 million aggregate principal amount of its 13% senior secured notes (the "Notes") and entered into an indenture (the "Indenture") governing the Notes with the guarantors party thereto (the "Guarantors") and U.S. Bank National Association, a national banking association, as trustee (the "Trustee") and collateral agent (the "Collateral Agent"). The Notes were issued in two series: (x) $50 million of "Series A-1 Notes", issued pursuant to the Plan to former holders of First Lien Secured Notes Claims and which will be subject to an interest holiday from the Effective Date through November 1, 2019 and (y) $45 million of "Series A-2 Notes," issued to Iroko

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and certain of its affiliates and which are subject to the rights of set-off and recoupment and related provisions set forth in the Purchase Agreement. The obligations of the Company under the Indenture and the Notes are unconditionally guaranteed on a secured basis by the Guarantors.

Interest on the Notes accrues at a rate of 13% per annum and is payable semi-annually in arrears on May 1 and November 1 of each year (each, a "Payment Date") commencing on May 1, 2019 (subject to the interest holiday referred to above with respect to the Series A-1 Notes). On each Payment Date, the Company will also pay an installment of principal on the Notes in an amount equal to 15% of the aggregate net sales of OXAYDO (oxycodone HCI, USP) tablets for oral use only —CII, SPRIX (ketorolac tromethamine) Nasal Spray, ARYMO ER, Egalet-002, and the Iroko Products for the two consecutive fiscal quarter period most recently ended, less the amount of interest paid on the Notes on such Payment Date.

The Notes are senior secured obligations of the Company and will be equal in right of payment to all existing and future pari passu indebtedness of the Company, will be senior in right of payment to all existing and future subordinated indebtedness of the Company, will have the benefit of a security interest in the Notes collateral and will be junior in lien priority in respect of any collateral that secures any first priority lien obligations incurred from time to time in accordance with the Indenture. The stated maturity date of the Notes is January 31, 2024. Upon the occurrence of a Change of Control, subject to certain conditions, or certain Asset Sales events (each, as defined in the Indenture), holders of the Notes may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 101.00% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to the date of repurchase.

The Company may redeem the Notes at its option, in whole or in part from time to time, prior to January 31, 2020, at a redemption price equal to 100.00% of the principal amount of the Notes being redeemed, plus accrued and unpaid interest, if any, through the redemption date, plus a make-whole premium computed using a discount rate equal to the treasury rate in respect of such redemption date plus 100 basis points. The Company may redeem the Notes at its option, in whole or in part from time to time, on or after January 31, 2020, at a redemption price equal to: (i) from and including January 31, 2020 to and including January 30, 2021, 103.00% of the principal amount of the Notes to be redeemed and (ii) from and including January 31, 2021 and thereafter, 100.00% of the principal amount of the Notes to be redeemed, in each case, plus accrued and unpaid interest to the redemption date. In addition, prior to January 31, 2020, the Company may redeem, at its option, up to 35% of the aggregate principal amount of the Notes with the proceeds of one or more public or private equity offerings at a redemption price equal to 113.50% of the aggregate principal amount of the Notes to be redeemed, plus accrued and unpaid interest to the date of redemption in accordance with the Indenture; provided that at least 65% of the aggregate principal amount of Notes issued under the Indenture remains outstanding immediately after each such redemption and provided further that each such redemption occurs within 90 days of the date of closing of each such equity offering. No sinking fund is provided for the Notes, which means that the Company is not required to periodically redeem or retire the Notes.

Pursuant to the Indenture, the Company and its restricted subsidiaries must also comply with certain affirmative covenants, such as furnishing financial statements to the holders of the Notes, and negative covenants, including limitations on the following: the incurrence of debt; the issuance of preferred and/or disqualified stock; the payment of

dividends, the repurchase of shares and under certain conditions making certain other restricted payments; the prepayment, redemption or repurchase of subordinated debt; the merger, amalgamation or consolidation involving the Company; engaging in certain transactions with affiliates; and the making of investments other than those permitted by the Indenture. In addition, commencing December 31, 2019, the Company must maintain a minimum level of consolidated liquidity, based on unrestricted cash on hand and availability under any revolving credit facility, equal to the greater of (1) the quotient of the outstanding principal amount of the Notes divided by 9.5 and (2) $7,500,000.

The Indenture governing the Notes contains customary events of default with respect to the Notes (including the Company's failure to make any payment of principal or interest on the Notes when due and payable or the Company's failure to comply with the minimum consolidated liquidity covenant described above), and upon certain events of default occurring and continuing, the Trustee by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Notes by notice to the Company and the Trustee, may (subject to the provisions of the Indenture) declare 100% of the principal of and accrued and unpaid interest, if any, on all the Notes to be due and payable. Upon such a

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declaration of acceleration, such principal and accrued and unpaid interest, if any, as well as the then-applicable optional redemption premium under the Indenture, will be due and payable immediately. In the case of certain events of bankruptcy, insolvency or reorganization involving the Company or a Restricted Subsidiary (as defined in the Indenture), the Notes will automatically become due and payable. With respect to any event of default due to the Company's non-compliance with the minimum liquidity covenant, the Company may, within ten business days, cure such default through the issuance of equity securities, subordinated debt securities or certain other capital contributions.

Preemptive Rights Agreements

On the Effective Date, the Company entered into preemptive rights agreements (the "Preemptive Rights Agreements") with certain of the Supporting Noteholders. The Preemptive Rights Agreements provide for customary preemptive rights in favor of the stockholder parties thereto with respect to certain future issuances of debt or equity securities by the Company, subject to certain exceptions, for so long as such stockholder party continues to hold at least 2.5% of the outstanding shares of the Company's common stock.

Collateral Agreement

On the Effective Date and in connection with its entry into the Indenture, the Company entered into a collateral agreement, dated as of the Effective Date, with the Collateral Agent and the subsidiary parties from time to time party thereto (the "Collateral Agreement"). Pursuant to the terms of the Collateral Agreement, the Notes and the related guarantees are secured by a first priority lien on substantially all of the Company's and the Guarantors' assets, in each case, subject to certain prior liens and other exclusions, and a pledge of 65% of the voting equity interests and 100% of the non-voting equity interests of the Company's foreign subsidiaries (other than Egalet Limited and any Specified IP Subsidiary (as defined in the Indenture), of which 100% of the voting equity interests have been pledged) to the extent and only for so long as the Company determines in good faith that permitting a pledge of 100% of such voting Equity Interests would result in material adverse tax consequences for the Company or any of its subsidiaries, it being understood that, if a percentage less than 100% but greater than 65% of such voting equity interests may be pledged without any such material adverse tax consequences, then such percentage shall be pledged.

Stockholders' Agreement

On the Effective Date, the Company entered into a stockholders' agreement (the "Stockholders' Agreement") with Iroko and certain of its affiliates. Pursuant to the Stockholders' Agreement, Iroko and the other stockholder parties have agreed to a customary lock-up with respect to their shares of common stock for a period of 90 days following the Effective Date and a customary standstill provision for a period of 24 months following the Effective Date, in each case, subject to certain exceptions. In addition, pursuant to the Stockholders' Agreement, the stockholder parties are

entitled to designate two nominees to the Company's board of directors for so long as such entities hold 25% of the equity consideration received on the Effective Date. The Stockholders' Agreement also provides for customary preemptive rights in favor of the stockholder parties with respect to certain future issuance of equity securities by the Company, subject to certain exceptions.

Warrant Agreements

On the Effective Date, the Company entered into warrant agreements (the "Warrant Agreements") with Iroko, certain of Iroko's affiliates and certain other parties entitled to receive shares of the Company's common stock as consideration pursuant to the Purchase Agreement or in satisfaction of certain claims pursuant to the Plan. Pursuant to the Warrant Agreements, the Company issued warrants to purchase up to an aggregate of 2,436,459 shares of the Company's common stock. The warrants are exercisable at any time at an exercise price of $0.001 per share, subject to certain ownership limitations including, with respect to Iroko and its affiliates, that no such exercise may increase the aggregate ownership of such parties above 49% of the number of shares of its common stock then outstanding for a period of 18 months.

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Royalty Rights Agreements

On the Effective Date, the Company (i) entered into royalty rights agreements with Iroko and certain of its affiliates and (ii) amended and restated its existing royalty rights agreements with each of the other holders of the 13% Notes (collectively, the "Royalty Rights Agreement"). Pursuant to the Royalty Rights Agreements, the Company sold the right to receive, in the aggregate, a payment equal to 1.5% of the aggregate net sales of the Products through December 31, 2022, inclusive (the "Royalty Rights"). The Royalty Rights Agreements also include other terms and conditions customary in agreements of this type.

Lock-Up Agreements

On the Effective Date, the Company entered into lock-up agreements with Iroko, certain of Iroko's Affiliates and certain of the Supporting Noteholders (as defined in the Plan) pursuant to which such entities agreed, for 90 days after the Effective Date, not to sell, pledge, encumber or take certain other actions with respect to 50% of the shares of common stock issued to such entity on the Effective Date, subject to certain customary exceptions.

Registration Rights Agreement

On the Effective Date, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with Iroko pursuant to which the Company agreed to file with the SEC, upon Iroko's request at any time following the date which is 180 days following the date on which any equity securities of the Company are accepted for listing on any national securities exchange, a registration statement on Form S-1 or Form S-3, and thereafter to use its commercially reasonable efforts to cause to be declared effective as promptly as practicable, one or more registration statements for the offer and resale of the Company's common stock held by Iroko and certain of its affiliates. The Registration Rights Agreement contains other customary terms and conditions, including, without limitation, provisions with respect to blackout periods, underwrite cutbacks, reimbursement of expenses and indemnification.

Amended and Restated Charter and Bylaws

On February 1, 2019, in accordance with the Plan, the Company's Fourth Amended and Restated Certificate of Incorporation (as amended and restated, the "A&R Charter") was filed with the Secretary of State of the State of Delaware, at which time the A&R Charter became effective. Among other things, the A&R Charter decreases the

number of shares of authorized common stock of the Company from 275,000,000 to 100,000,000 and decreases the maximum number of directors that may serve on the Board to seven.

On the Effective Date, pursuant to the Plan, the Company's Second Amended and Restated Bylaws (the "A&R Bylaws") became effective. Among other things, the A&R Bylaws provide for special director nomination procedures, related party transaction approval procedures and independence requirements with respect to certain directors appointed by the Supporting Noteholders pursuant to the Plan (or such directors successors), in each case, for a two-year period following the Effective Date.

Employment Agreement Amendments

On the Effective Date, the Company entered into amendments to the employment agreements of each of Robert S. Radie, Mark Strobeck, Barbara Carlin, Megan Timmins and Patrick Shea (the "Employment Agreement Amendments"). The Employment Agreement Amendments provide that, as consideration for such employee's ability to participate in the Management Incentive Plan (as defined in the Plan), such employee waives any increased benefits pursuant to such employment agreement as a result of any "Change in Control" (as defined in the applicable employment) effected as a result of the consummation of the Iroko Acquisition and the other transactions contemplated by the Plan.

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Impact on Net Operating Loss Carryforwards

On October 30, 2018, the Company filed voluntary chapter 11 petitions under Title 11 of the United States Code (the "Bankruptcy Code"). On January 14, 2019, the Bankruptcy Court approved the Company's Joint Pre-Packaged Plan of Reorganization of the Debtors (the "Restructuring Plan").

The Company's emergence from bankruptcy pursuant to the Restructuring Plan, effective January 31, 2019, will result in cancellation of indebtedness income that will reduce the Company's net operating loss carryforwards ("NOLs") under Section 108 of the Internal Revenue Code of 1986, as amended (the "Code"). Additionally, the Company's emergence will cause an Ownership Change, as of January 31, 2019, for purposes of Section 382, further limiting our ability to utilize the Company's NOLs.

Generally, under Section 382, a change in ownership of a company of greater than 50% within a three-year period results in an annual limitation on that company's ability to utilize its carryforwards from the tax periods prior to the Ownership Change. Under Section 382(l)(6), where an ownership change is pursuant to a Chapter 11 bankruptcy reorganization, the amount of the annual limitation that applies is equal to the "long-term tax-exempt rate" (published monthly by the IRS) for the month in which the ownership change occurs, multiplied by the Company's equity value immediately following the Ownership Change.

By taking into account the Company's equity value immediately after consummation of the Restructuring Plan, the limitation is increased as a result of cancellation of indebtedness pursuant to the Chapter 11 Filing. Any portion of the annual limitation that is not used in a particular year may be carried forward and used in subsequent years, subject to expiration.

The annual limitation is increased by certain built-in income and gains recognized (or treated as recognized) during the five years following an Ownership Change (up to the total amount of net built-in income and gain that existed at the time of the Ownership Change). Built-in income for this purpose includes the amount by which the Company's tax depreciation and amortization expense during this five-year period is less than it would have been if the Company's assets had a tax basis on the date of the ownership change equal to their fair market value. The Company expects any NOL limitation for the five years following the ownership change to be increased by built-in income and to result in a carryforward of excess limitation to future periods.

Adoption of Stock-Based Incentive Compensation Plan

On February 7, 2019, the Company's Board of Directors approved and adopted the Egalet Corporation 2019 Stock-Based Compensation Plan (the "2019 Stock Plan"). Subject to the approval of the 2019 Stock Plan by the stockholders of the Company, the Company shall reserve for issuance 1,433,333 shares of common stock available for

awards under the 2019 Stock Plan (subject to adjustment pursuant to and in accordance with the 2019 Stock Plan).

Revolving Credit Agreement

On March 20, 2019, (the "Closing Date"), the Company entered into a credit agreement (the "Revolving Credit Agreement") with Cantor Fitzgerald Securities as administrative agent and collateral agent (in such capacities, the "Agent") and certain funds managed by Highbridge Capital Management, LLC, as lenders (collectively, the "Lenders"), which Revolving Credit Agreement consists of a $20.0 million revolving line of credit. The Company drew $5.0 million on the Closing Date and must maintain at least 25% of the commitment amount outstanding at all times. The Company will use the proceeds of the loans under the Revolving Credit Agreement for working capital purposes and to pay costs and expenses incurred by the Revolving Credit Agreement and related transactions. This arrangement will be recognized as a related party transaction as the Lenders are holders of a portion of the Company's 13% Notes that were issued on January 31, 2019.

Advances under the Revolving Credit Agreement bear interest at the Company's option at either the LIBOR Rate (as defined in the Revolving Credit Agreement) plus 5.00% or the Base Rate (as defined in the Revolving Credit Agreement) plus 4.00%. The Revolving Credit Agreement matures on March 20, 2022.

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The obligations of the Company under the Revolving Credit Agreement are unconditionally guaranteed on a senior secured basis by the Company's wholly-owned subsidiaries, Egalet US Inc. and Egalet Ltd. (collectively, the "Guarantors"). As security for the Company's obligations under the Revolving Credit Agreement, the Company and the Guarantors have granted to the Agent, for the benefit of the Lenders and other secured parties, a first priority lien on substantially all of their tangible and intangible personal property (other than certain specified excluded assets), including proceeds and accounts related to this property and the capital stock of the Guarantors, pursuant to the terms of that certain Collateral Agreement, dated as of the Closing Date (the "Collateral Agreement"), among the Company and the Guarantors in favor of the Agent for the benefit of the Lenders and other secured parties. The Revolving Credit Agreement will (i) be equal in right of payment to all existing and future pari passu indebtedness of the Company, (ii) be senior in right of payment to the obligations of the Company pursuant to that certain Indenture, dated as of January 31, 2019 (the "Indenture"), among the Company, the Guarantors and U.S. Bank National Association, as trustee and collateral agent, and (iii) be senior in right of payment to all existing and future subordinated indebtedness of the Company.

The Company may terminate the commitments under the Revolving Credit Agreement at its option, in whole or in part from time to time, subject to a termination fee equal to (x) 1.0% from the Closing Date through March 20, 2020 and (y) 0.50% from March 20, 2020 through March 20, 2021.

Pursuant to the Revolving Credit Agreement, the Company and its subsidiaries must also comply with certain customary affirmative covenants, such as furnishing financial statements to the Lenders, and negative covenants, including limitations on the following: incurring debt; issuing preferred and/or disqualified stock; paying dividends, repurchasing shares and, under certain conditions, making certain other restricted payments; prepaying, redeeming or purchasing subordinated debt; conducting a merger or consolidation involving the Company; engaging in certain transactions with affiliates; disposing of assets under certain circumstances; and making certain investments, in each case, other than those permitted by the Revolving Credit Agreement. In addition, commencing with the fiscal quarter ending on December 31, 2019, the Company must maintain a minimum level of consolidated liquidity, based on unrestricted cash on hand and availability under any revolving credit facility, equal to the greater of (1) the quotient of the outstanding principal amount of the senior secured notes issued pursuant to the Indenture divided by 9.5 and (2) $7,500,000.

The Revolving Credit Agreement contains customary events of default (including the Company's failure to make any payment of principal or interest when due and payable, the failure to comply with the minimum consolidated liquidity covenant or other covenants described above, or upon a Change of Control (as defined in the Revolving Credit Agreement)), and, upon such events of default occurring and continuing, the Lenders may accelerate the loans. In the event of certain events of bankruptcy, insolvency or reorganization involving the Company or its subsidiaries, the obligations under the Revolving Credit Agreement will automatically become due and payable. With respect to any event of default due to the Company's non-compliance with the minimum liquidity covenant (described above), the Company may, within ten business days, cure such default through the issuance of equity securities, subordinated debt securities or certain other capital contributions.

Collateral Agreement

On the Closing Date and in connection with its entry into of the Revolving Credit Agreement, the Company and the Guarantors entered into the Collateral Agreement, which granted a first priority lien on substantially all of the Company's and the Guarantors' assets, in each case subject to certain existing liens and other exclusions.