ZOGENIX, INC.
Form 10-K
March 11, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

or

¨ 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: 001-34962

Zogenix, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	20-5300780
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
12400 High Bluff Drive, Suite 650 San Diego, California	92130
(Address of Principal Executive Offices)	(Zip Code)

858-259-1165
(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	The NASDAQ Global Market

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

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

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

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x 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 the 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. x

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer o Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ¨ No x

As of June 30, 2014, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $201,484,185, based on the closing price of the registrant's common stock on the Nasdaq Global Market of $2.01 per share.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of March 6, 2015 was 153,363,743.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2014 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2014.

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PART I

Forward-Looking Statements and Market Data

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve substantial risks and uncertainties. These forward looking statements include, but are not limited to, statements about:

- our ability to maintain and increase market demand for, and sales of, Zohydro ER;
- our ability to successfully execute our sales and marketing strategy for the commercialization of Zohydro ER;
- the progress and timing of clinical trials for ZX008, Relday and our other product candidates;
- adverse side effects or inadequate therapeutic efficacy of Zohydro ER that could result in product recalls, market withdrawals or product liability claims;
- the safety and efficacy of our product candidates;
- the market potential for extended-release/long-acting (ER/LA) opioid products, and our ability to compete within that market;
- the goals of our development activities and estimates of the potential markets for our product candidates, and our ability to compete within those markets;
- the ability to develop an abuse deterrent formulation of Zohydro ER;
- estimates of the capacity of manufacturing and other facilities to support our products and product candidates;
- our ability to ensure adequate and continued supply of Sumavel DosePro and Zohydro ER to successfully meet anticipated market demand;
- our and our licensors ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of our products and product candidates and the ability to operate our business without infringing the intellectual property rights of others;
- our ability to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for Zohydro ER or any of our product candidates that may be approved for sale, the extent of such coverage and reimbursement and the willingness of third-party payors to pay for our products versus less expensive therapies;
- the impact of healthcare reform legislation; and
- projected cash needs and our expected future revenues, operations and expenditures.

The forward-looking statements are contained principally in the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” In some cases, you can identify forward-looking statements by the following words: “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “p “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or otl comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading “Item 1A — Risk Factors.” Given these risks, uncertainties and other factors, we urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for Zohydro ER, ZX008 Relday and other drugs, including data regarding the estimated size of those markets, their projected growth rates, the incidence of certain medical conditions, statements that certain drugs, classes of drugs or dosages are the most widely prescribed in the United States or other markets, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber

and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. In particular,

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unless otherwise specified, all prescription, prescriber and patient data in this Annual Report on Form 10-K is from Source Healthcare Analytics, Source® Pharmaceutical Audit Suite (PHAST) Institution/Prescription, Source® PHAST Prescription, Source® Prescriber or Source® Dynamic Claims. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

DosePro®, Relday™, Zogenix™ and Zohydro ER® are our trademarks. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Use or display by us of other parties' trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Zogenix," "we," "us" and "our" refer to Zogenix, Inc., including, as of June 7, 2010, its consolidated subsidiary.

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Item 1. Business

Overview

Zogenix is a pharmaceutical company committed to developing and commercializing therapies to address specific clinical needs for people living with central nervous system, or CNS, disorders who need innovative treatment alternatives to help them return to normal daily functioning. Our current areas of focus are pain, epilepsy and schizophrenia. We received marketing approval in October 2013 from the U.S. Food and Drug Administration. or the FDA, for Zohydro® ER (hydrocodone bitartrate) extended-release capsules, CII, an opioid agonist, extended-release oral formulation of hydrocodone without acetaminophen, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. We launched Zohydro ER in March 2014 with our own sales force and had double-digit quarter-over-quarter growth during the launch year. Total revenues for Zohydro ER for the first ten months of launch ending December 31, 2014 were $11.6 million. On September 30, 2014, we submitted a supplemental New Drug Application, or sNDA, for a modified formulation of Zohydro ER with BeadTek™ which was developed using safe, well-known excipients and proprietary manufacturing processes to create an inactive ingredient that immediately forms a viscous gel when crushed and dissolved in liquids or solvents. All of the beads within the medication capsule are indistinguishable in color, shape, density and size, and do not impact the drug release profile when taken as directed. The FDA approved this application on January 30, 2015. We anticipate a transition from the currently marketed product to this capsule reformulation of Zohydro ER in the second quarter of 2015. On March 10, 2015, we entered into an asset purchase agreement, or the Asset Purchase Agreement, with Pernix Ireland Limited and Pernix Therapeutics Holdings, Inc., or Pernix Therapeutics, and, together with Pernix Ireland Limited, Pernix, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell our Zohydro ER business to Pernix.

We sold our SUMAVEL® DosePro® (sumatriptan injection) Needle-free Delivery System business in May 2014, to Endo International Plc, or Endo, for $85.0 million in cash and milestone payments of up to $20.0 million. In connection with the sale, we entered into a supply agreement, pursuant to which we retain the sole and exclusive right and obligation to manufacture SUMAVEL DosePro for Endo, subject to Endo's right to qualify and maintain a back-up manufacturer.

In October 2014, Zogenix Europe Limited, our wholly-owned subsidiary, acquired Brabant Pharma Limited, or Brabant, a privately-held company organized under the laws of England and Wales for $20.0 million cash and $15.2 million in stock, potential future regulatory milestone payments of up to $50.0 million plus up to $45.0 million in potential future sales milestones. With the acquisition, we obtained worldwide development and commercialization rights to a product candidate, ZX008 (previously referred to as Brabafen™), a low-dose fenfluramine for the treatment of Dravet syndrome. Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and for which current treatment options are very limited. ZX008 has received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome. As of December 31, 2014, plans are underway to support the initiation of Phase 3 clinical trials in both Europe and the United States in the third quarter of 2015.

We have an additional product candidate in development, Relday™ (risperidone once-monthly long-acting injectable) for the treatment of schizophrenia. We began enrolling patients in a multi-dose clinical study for Relday in February 2015. We continue to evaluate worldwide partnering opportunities for Relday.

Recent Developments

On March 10, 2015, we entered into the Asset Purchase Agreement with Pernix, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell our Zohydro ER business to Pernix, including the registered patents and trademarks, certain contracts, the NDA and other regulatory approvals, documentation and authorizations, the books and records, marketing materials and product data relating to Zohydro ER.

Under the terms of the Asset Purchase Agreement, Pernix will pay us $30.0 million in cash upon the closing, or the Closing, of the transaction, $3.0 million of which will be deposited into escrow to fund potential indemnification

claims for a period of 12 months, or the Escrow Period. At the Closing, we will also receive $50.0 million in the form of a secured promissory note, or the Note, and $20.0 million in common stock consideration from Pernix (based on the $11.89 per share closing price of Pernix Therapeutics' common stock on the trading day immediately preceding the execution date). The Note will mature four months after the Closing, which maturity date may be extended in Pernix's sole discretion by up to an additional two months and, in the event of certain intellectual property matters, by up to an additional four months, for an aggregate extension of the maturity date to ten months from the Closing. The Note is subject to customary events of default,

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including cross-defaults to certain defaults under Pernix's debt facilities, and will be secured by substantially all of the purchased assets. Upon repayment of the Note, an additional $7.0 million of the $50.0 million payable thereunder will be deposited into escrow to fund potential indemnification claims through the Escrow Period. In addition, we have agreed to indemnify Pernix for certain intellectual property matters up to an aggregate amount of $5.0 million.

In addition to the upfront cash payment, we are eligible to receive cash payments of up to $283.5 million based on the achievement of pre-determined milestones, including a $12.5 million payment upon approval by the FDA of an abuse-deterrent extended-release hydrocodone tablet (currently in development in collaboration with Altus) and up to $271.0 million in potential sales milestone payments. Pursuant to the Asset Purchase Agreement, Pernix has agreed to use commercially reasonable efforts (as defined in the Asset Purchase Agreement) to meet such milestones.

Furthermore, Pernix will assume responsibility for our obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Zohydro ER business arising after the Closing date. We will retain all liabilities associated with the Zohydro ER business arising prior to the Closing date.

In connection with the stock consideration we will receive pursuant to the Asset Purchase Agreement, Pernix Therapeutics will use commercially reasonable efforts to file a resale shelf registration statement and to have such registration statement declared effective no later than five months after the Closing date. We will agree not to sell our shares in Pernix Therapeutics for a period of six months after such Closing date.

The Asset Purchase Agreement contains customary representations, warranties and covenants, including covenants to cooperate in seeking regulatory approvals, as well as our agreement not to compete in the single entity, extended release hydrocodone market for five years following the closing. The obligation of Pernix to purchase the Zohydro ER business is subject to the satisfaction or waiver of a number of conditions set forth in the Asset Purchase Agreement, including (i) the accuracy of the representations and warranties and compliance with covenants contained in the Asset Purchase Agreement, (ii) the absence of any law or order by any governmental authority that would make illegal or otherwise prohibit the consummation of the transactions under the Asset Purchase Agreement, (iii) all required consents of, notifications to and filings with any governmental authority shall have been made and any waiting periods shall have expired, including the expiration or termination of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iv) the absence of any actions or proceedings challenging or seeking to restrain or prohibit any of the transactions under the Asset Purchase Agreement, (v) there not having been a material adverse effect with respect to our Zohydro ER business, (vi) the delivery to Pernix of a transition services agreement, registration rights agreement, escrow agreement and other ancillary transaction documents and receipt of third party consents, and (vii) other customary conditions. In addition, we are required to extinguish all encumbrances on the assets to be sold to Pernix, including the security interests previously granted to Oxford Finance LLC, or Oxford and Silicon Valley Bank, or SVB, pursuant to our loan and security agreement, dated December 30, 2014, with Oxford and SVB. We are currently in discussions with Oxford and SVB to amend the loan and security agreement to remove the security interests on the assets to be sold to Pernix. However, if we are unable to reach an agreement with Oxford and SVB, we expect to eliminate its existing debt obligation to Oxford and SVB by repaying all amounts owed under the loan and security agreement, including applicable termination fees, which as of December 31, 2014 was $23.3 million.

We expect the Closing to occur during April 2015, subject to the satisfaction of the foregoing closing conditions. Either party may terminate the Asset Purchase Agreement if the Closing has not occurred by May 9, 2015, provided that if the Closing has not occurred due to lack of governmental approval, the Closing may be extended up to 60 additional days to obtain such approval. We and Pernix may also terminate the Asset Purchase Agreement by mutual consent, for a material uncured breach by the other party, or if a final governmental order prohibiting the transaction is issued.

Our Products and Product Candidates

Zohydro ER for the Treatment of Severe Chronic Pain

Zohydro ER is a 12-hour extended-release formulation of hydrocodone without acetaminophen for the treatment of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternate treatment options are inadequate. The FDA approved the New Drug Application, or NDA, for Zohydro ER in October 2013 and

we launched the product in March 2014. Zohydro ER, via its unique extended-release profile, is designed to provide consistent relief of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate over a 12-hour period per dose.

On January 30, 2015, the FDA approved a sNDA for Zohydro ER with BeadTek. BeadTek was developed using safe, well-known excipients and proprietary manufacturing processes to create an inactive ingredient that immediately forms a viscous gel when crushed and dissolved in liquids or solvents. All of the beads within the medication capsule are

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indistinguishable in color, shape, density and size, and do not impact the drug release profile when taken as directed. We expect to have updated label information for Zohydro with BeadTek in the fourth quarter of 2015.

We believe Zohydro ER has the potential to be an important therapeutic alternative to existing extended-release opioids as well as immediate-release hydrocodone products which contain the analgesic combination ingredient acetaminophen and, if taken in high quantities over time, may lead to adverse events such as liver toxicity. We believe Zohydro ER will generate prescriptions from both patients who use immediate-release opioids to treat their severe chronic pain and patients requiring a different alternative to their existing extended-release prescription opioid products. Following the recent approval of the sNDA for Zohydro ER with BeadTek, we entered into the Asset Purchase Agreement with Pernix pursuant to which we agreed to sell our Zohydro ER business to Pernix.

Zohydro ER, like all extended-release and long-acting opioid analgesics, or ER/LA opioids, is designated as a U.S. Drug Enforcement Administration, or DEA, Schedule II product and is subject to the Risk Evaluation and Mitigation Strategy, or REMS, program for ER/LA opioids. The REMS program requires a medication guide for patients and training for prescribers to facilitate appropriate prescribing, dispensing and use of ER/LA opioids like Zohydro ER, and manufacturers of products that are subject to REMS must monitor and submit periodic assessments of the program to FDA. Like all other opioids, Zohydro ER also bears a boxed warning that highlights the risks of addiction, abuse, and misuse; life-threatening respiratory depression; accidental exposure; neonatal opioid withdrawal syndrome; and interaction with alcohol.

In November 2013, we entered into a development and option agreement with Altus Formulation, Inc., or Altus, for the development of an additional abuse deterrent formulation of hydrocodone, ZX007, using Altus' Intellitab™ drug delivery platform. We believe that ZX007 will provide a novel abuse deterrent technology with robust resistance to manipulation and abuse, and with the potential ability to match the pharmacokinetic profile of Zohydro ER, thereby eliminating additional Phase 3 clinical trial requirements.

The Chronic Pain Market

Pain is a worldwide problem with serious health and economic consequences. Chronic pain may be defined as pain that lasts beyond the healing of an injury or that persists beyond three months. Common types of chronic pain include lower back pain, arthritis, and face and jaw pain.

Chronic pain treatment depends on the individual patients, their diagnosis and their pain severity. Chronic pain patients typically first attempt to self-medicate with over-the-counter drugs such as acetaminophen, aspirin or another non-steroidal anti-inflammatory drug, or NSAID. Patients with more constant and/or moderate to severe pain typically seek medical attention and prescription pain medication from a primary care physician and, if necessary, are referred to a neurologist or a physical medicine or pain specialist. Physicians generally assess the patient and, if appropriate, may start treatment with a trial of opioid therapy after other therapies have failed. The general objective of the physician is to safely achieve adequate control of pain with improvement in the patient's function.

A trial of opioid therapy may at times begin with short-acting opioids taken on an as-needed basis. This allows the clinician and patient to assess whether chronic opioid therapy is warranted, and if so, what the patient's daily total opioid requirement is. Patients taking substantial doses of short-acting opioids multiple times per day may find substitution of an extended-release agent, taken two times per day, helpful to provide more constant and consistent pain relief. We believe the more constant opioid blood levels of extended-release products may provide better pain relief and better sleep quality than short-acting opioids. In addition, individual patients may do poorly on one opioid due to either poor pain relief or intolerable side effects, but find they do better after switching to another opioid molecule. This practice is called opioid rotation and is regularly employed in chronic pain management. All opioids, while generally effective for pain treatment, can be associated with numerous potential adverse effects, including opioid induced constipation, sedation, nausea, vomiting, decreased respiratory function, and addiction.

Hydrocodone is often used as a “starter” opioid to initiate opioid therapy because many physicians prescribe it regularly as a short-acting combination product with acetaminophen. Historically, hydrocodone preparations in the United States have been utilized primarily for treatment of acute pain following surgery or injury. For this purpose, they were combined with non-opioid analgesics, including acetaminophen or an NSAID, which treat the acute inflammatory component of the pain. These non-opioid analgesics are generally safe when used at lower doses or for short periods of time. However, at higher doses or over extended periods of time, they may significantly increase patient risk for

gastrointestinal, liver and kidney damage. In particular, chronic use of acetaminophen in high doses is the number one cause of acute liver failure in the United States.

As the practice of pain management has broadened to include chronic therapy for moderate to severe pain, physicians continue to broadly use hydrocodone combinations. In the United States, market research conducted by Answers&Insights in 2014 on our behalf indicates that approximately 17% of patients are using immediate-release combination products that

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include hydrocodone for their treatment of chronic pain and approximately 40% of those prescriptions might be replaced by an extended-release opioid. However, the non-opioid analgesic component in combination hydrocodone products can create a ceiling effect when physicians wish to escalate doses due to reaching the 4g FDA maximum recommended daily dose for acetaminophen. If a further increase in opioid dose is warranted, a physician is compelled to transition to a single-entity opioid not in combination, such as oxycodone, or more potent opioids such as fentanyl or oxymorphone. Transitioning to a single-entity hydrocodone does not require a need for any dose calculation, and allows the patient to continue on the same opioid that has been producing adequate pain relief.
In the twelve months ended December 2014, our target market, which we define as prescription non-injectable codeine-based and extended-release morphine-based pain products, generated sales of approximately $18.4 billion in the United States on approximately 199 million prescriptions. Of the $18.4 billion, hydrocodone products, the most commonly prescribed opioid and the most commonly prescribed pharmaceutical products in the United States, generated $4.2 billion in sales on approximately 115 million prescriptions. (Source® PHAST Prescription January 2014 - December 2014).

In June 2009, the FDA organized a joint meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Advisory Committee to discuss how to address the public health problem of liver injury related to the use of acetaminophen in both over-the-counter and prescription products. The expert panel specifically considered the elimination of combination prescription products containing acetaminophen (including Vicodin and its generics) from the U.S. market. Twenty of the 37 working group members (ten saying this was a high priority) voted in favor of removing such products from the market. The working group ultimately did not recommend withdrawal of these products stating that the benefits of access to Schedule III acetaminophen/ hydrocodone combination products over Schedule II opioids outweighed the risk of removing the combinations from the market. The working group also noted that the logical choice to substitute for the combination products would be a single-entity formulation of hydrocodone. Subsequently, in January 2011, the FDA asked manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule and announced that it would require manufacturers to update labels of all prescription combination acetaminophen products to warn of the potential risk for severe liver injury. Along with this announcement, the FDA issued letters to sponsors of prescription acetaminophen drugs proposing various modifications to the drug labeling, including adding a boxed warning for hepatoxicity. Within 30 days of the date of the letters, the holders of approved applications for prescription acetaminophen drugs were required to submit a supplemental NDA to the FDA proposing labeling changes that reflect the new safety information about acetaminophen and liver toxicity, or a statement detailing the reasons why such change would not be warranted.

The DEA published a final rule moving hydrocodone combination products from Schedule III to Schedule II effective October 6, 2014. It is not known how the rescheduling of all hydrocodone combination products will affect prescribing to patients with regards to these hydrocodone combination products or other pain relieving medications.

ZX008 (low-dose fenfluramine) for the Treatment of Dravet syndrome
In October 2014, Zogenix Europe acquired Brabant for $20.0 million cash and $15.2 million in stock, potential future regulatory milestone payments of up to $50.0 million plus up to $45.0 million in potential future royalties. With the acquisition, we obtained worldwide development and commercialization rights to a product candidate, ZX008 (previously referred to as Brabafen), a low-dose fenfluramine for the treatment of Dravet syndrome. Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and for which current treatment options are very limited. ZX008 has received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome. Plans are currently underway to support the initiation of Phase 3 clinical trials in both Europe and the United States in the third quarter of 2015. The main objective of the clinical trials will be to compare the reduction in seizures experienced by enrollees after treatment with ZX008 compared to treatment with a placebo. In addition, the patients completing the Phase 3 trials will be given the opportunity to enroll in an open label long-term extension safety study.

There are currently no FDA-approved treatments specifically indicated for Dravet syndrome. The standard of care usually involves a combination of the following anticonvulsant drugs: clobazam, clonazepam, leviteracetam, topirimate, valproic acid, ethosuximide or zonisamide. Stiripentol is approved in Europe for the treatment of Dravet syndrome in conjunction with clobazam and valproate. In Europe, stiripentol was granted an orphan drug designation for the treatment of Dravet syndrome in 2001. In the United States, the drug is not FDA approved and can only be obtained via the FDA's Personal Importation Policy, or PIP. Potent sodium channel blocker anticonvulant drugs often used to treat most other epilepsy conditions actually increase seizure frequency in patients with Dravet syndrome. Management of this disease may also include a ketogenic diet and vagal nerve stimulations.

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Dravet syndrome is a form of intractable epilepsy that begins in infancy. Children with Dravet syndrome experience debilitating, persistent and potentially life-threatening seizures beginning in the first year of life. Seizures continue throughout their lifetime and are drug resistant, meaning that currently available medications are not able to achieve complete seizure control. Individuals with Dravet syndrome face a higher incidence of Status Epilepticus and Sudden Unexplained Death in Epilepsy. These children often suffer from increasingly severe cognitive and developmental impairment throughout life. The prognosis for children with Dravet syndrome to become seizure free is poor.

Fenfluramine was originally developed and approved as an anorectic agent for the treatment of obesity. However, pre-clinical and clinical evidence of the drug's ability to abolish epileptic seizures was first described in the 1980's. When fenfluramine was withdrawn from the market in 1997 because of an unacceptable risk in the treated adult patient population of serious heart valve defects, academic clinicians in Belgium continued to evaluate low doses of fenfluramine in a small number of Dravet patients under a government approved protocol. Their open-label study, which continues today, evaluated the safety and effectiveness of low-dose fenfluramine to reduce seizures in Dravet patients. The most recent longitudinal analysis of the study was conducted in June 2014 and demonstrated the following:

- Longest duration of treatment is now 26 years;
- Average duration of treatment is 12.4 years;
- 67% of patients (n=10 out of 15) were seizure free at the latest assessment;
- Average seizure free period is 5.5 years; and
- 87% of patients (n=13 out of 15) had greater than 75% reduction in seizure frequency at last assessment.

Because of the known cardiac side effects of fenfluramine, the ongoing study has also required periodic evaluations using echocardiography. Overall, low-dose fenfluramine has been shown to be well tolerated and side-effects of treatment were mild and transient over the entire 26-year study period. There were no clinically significant findings related to cardiac valvulopathy. In addition, there were no reports of pulmonary hypertension and there were no deaths.

Through our acquisition of Brabant, we have obtained rights to an exclusive supply of fenfluramine from a synthetic process developed to be consistent with current regulatory standards for drug substances. Formal meetings have been held with the regulatory agencies in the United States and European Union to obtain concurrence on remaining pre-clinical and clinical requirements for approval. Based upon this information, we believe two successful pivotal placebo-controlled studies in Dravet syndrome, one in the United States and one in the European Union, will support regulatory approval of ZX008. We expect to begin enrollment in Phase 3 clinical trials as early as the third quarter of 2015. We also will be concurrently developing the appropriate elements of a specific REMS program to support and maintain a long-term favorable benefit-risk profile for ZX008; this is consistent with other drugs with known safety issues that are approved for serious diseases with high unmet need. We aim to submit an NDA for ZX008 in the fourth quarter of 2016.

Relday for the Treatment of Schizophrenia

Relday is a proprietary, long-acting injectable formulation of risperidone using Durect's SABER™ controlled-release formulation technology. If successfully developed and approved, we believe Relday may be the first subcutaneous antipsychotic product with once-monthly dosing. We believe Durect's SABER controlled-release technology will allow Relday to be delivered subcutaneously on a once-monthly basis with a simplified dosing regimen, improved

pharmacokinetic profile and significant reduction in injection volume versus currently marketed long-acting injectable antipsychotics. Based upon these characteristics, Relday may provide an important alternative to currently marketed long-acting injectable antipsychotics as well as a new long-acting treatment option for patients that currently use daily oral antipsychotic products. In May 2012, we filed an IND application with the FDA. In July 2012, we initiated our first clinical trial for Relday. This Phase 1 clinical trial was a single-center, open-label, safety and pharmacokinetic trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. We announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, we extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation. We announced positive top-line results from the extended Phase 1 clinical trial in May 2013. The results from the extended Phase 1 clinical trial showed risperidone blood concentrations in the therapeutic range were achieved on the first day of dosing and maintained throughout the one-month period. In addition, dose proportionality was demonstrated across the full dose range studied. In February 2015, we began a multi-dose Phase 1b clinical trial, which we believe will provide the required steady-

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state pharmacokinetic and safety data prior to initiating Phase 3 development studies. The results of this trial and the ongoing activities around manufacturing scale-up will put us in position to have an end of Phase 2 meeting with the FDA by the first quarter of 2016.

The Antipsychotic Market

Schizophrenia is a complex, chronic, severe and debilitating mental disorder that often develops between the ages of 16 and 30 years, and the National Institute of Mental Health, or NIMH, estimated in 1993 that the 12-month prevalence of schizophrenia is 1.1% of the U.S. adult population. The symptoms of schizophrenia are often categorized as positive, negative or cognitive in nature. Positive symptoms include hallucinations, delusions, disorganized thinking and movement disorders. Negative symptoms of schizophrenia can include flat affect, inability to feel pleasure and speaking little, and the cognitive symptoms of schizophrenia can include poor executive function, problems with working memory and attention deficits. This combination of symptoms often makes it challenging for many schizophrenic patients to care for themselves or hold jobs, resulting in significant societal costs. The direct and indirect costs of schizophrenia in the United States in 2002 were estimated at $62.7 billion, including $22.7 billion in direct medical costs for outpatient care, medications, inpatient care, and long-term care, according to an article published in 2005 in The Journal of Clinical Psychiatry.

Bipolar disorder, or manic depressive illness, is another chronic, recurring psychiatric illness that is characterized by extreme or unusual shifts in mood, energy and activity levels. In general, patients with bipolar disorder suffer over time from episodes of both mania and depression. The NIMH estimated in 2005 that the average age of onset for bipolar disorder is 25 years, and the 12-month prevalence of bipolar disorder is 2.6% of the U.S. adult population. In many cases, the recurring episodes of mania and depression are so severe that the patient cannot maintain normal relationships or function normally at home, work or school, and suicide attempts occur in 25-50% of bipolar disorder patients.

First line therapy for most schizophrenia patients today are drugs generally known as atypical or second generation antipsychotics. These antipsychotics have been named atypical for their ability to treat a broader range of negative symptoms with improved side effect profiles versus the first-generation or typical antipsychotics, which were mostly introduced in the 1950s with drugs such as chlorpromazine and haloperidol. The first atypical antipsychotics to be approved by FDA in the United States were Clozaril (clozapine) in 1989, followed by Risperdal (risperidone) in 1993 and Zyprexa (olanzapine) in 1996. Similarly, over the last decade, atypical antipsychotics have become increasingly utilized in the treatment of bipolar disorder, either as monotherapy or as part of a polytherapy regimen, most often being prescribed in conjunction with a mood stabilizer such as lithium or valproic acid, and sometimes in conjunction with both a mood stabilizer and additional medications.

Patient compliance with medication has been a long-standing problem in the treatment of both schizophrenia and bipolar disorder. Results from the Clinical Antipsychotic Trials in Intervention Effectiveness conducted between 2001 and 2004, and published in The New England Journal of Medicine in 2005, indicated that over 70% of schizophrenia patients became non-compliant with their medication within 18 months of commencing therapy. Similarly a 2004 study of the VA National Psychosis Registry published in the journal Bipolar Disorder in October 2006 found that, of the 45% of bipolar patients who were being prescribed an antipsychotic, just over half of individuals appeared to be fully adherent with their antipsychotic medications, while the remaining individuals were either partially adherent or non-adherent with their antipsychotic medications.

In an attempt to improve patient compliance, physicians increasingly administer antipsychotic drugs through long-acting depot injections. Long-acting depot injections release medication slowly over weeks rather than over hours or days for conventional injections or oral medications, thereby dramatically reducing the number of times a patient needs to take their medication. Currently available long-acting injectable products include Risperdal Consta and Invega Sustenna, both marketed by Johnson & Johnson, Zyprexa Relprevv, marketed by Eli Lilly & Co, and Abilify Maintena, marketed by Otsuka America Pharmaceutical, Inc. These drugs provide two to four weeks of therapy per dose.

Overall, the global atypical antipsychotic market was estimated to be in excess of $17.1 billion in 2011, based upon published sales reports of certain pharmaceutical companies. In 2014, atypical antipsychotics comprised approximately 91% of all antipsychotic prescriptions in the United States, according to data from Source Healthcare

Analytics (Source® PHAST Prescription, January 2014 — December 2014). The existing long-acting injectable risperidone product, Risperdal Consta, achieved global net sales of $1.2 billion in 2014, according to industry reports, and has a wholesale acquisition cost of approximately $341 per bi-weekly dose, or near $700 per month, for the 25 mg dosage strength (Source: Gold Standard). Finally, in the United States, prescribers of long-acting antipsychotics are highly concentrated with approximately 19,200 total prescribers of long-acting injectable products, including approximately 10,900 psychiatrists in 2014 (Source® PHAST Prescription, January 2014 — December 2014).

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The Relday Opportunity

Market research conducted on our behalf by bioStrategies Group in 2013 indicates that psychiatrists in the United States and Europe see significant potential advantages for Relday over the currently marketed long-acting risperidone injectable, specifically identifying the first-day therapeutic plasma levels, once monthly dosing and subcutaneous features of Relday as important differentiators versus the currently marketed long-acting antipsychotics. We believe on the basis of our clinical development work and market research that, if successfully developed and approved, Relday could potentially provide a significant improvements over existing treatment options for patients suffering from schizophrenia as a result of:

- Therapeutic Plasma Levels on First Day: Relday has demonstrated in a Phase 1 single-dose clinical trial in schizophrenic patients the ability to achieve therapeutic plasma levels of risperidone within 24 hours of initial dosing with an acceptable initial burst (i.e., plasma levels less than the comparable oral dose). Achieving first-day therapeutic plasma levels avoids the need for oral supplementation in connection with the initiation of therapy or following a missed or delayed dose. Risperdal Consta requires supplementation with oral risperidone for the first three weeks following initiation of therapy or following a missed dose of the injectable due to its pharmacokinetic profile.
- Once-monthly dosing: Relday has demonstrated in a Phase 1 single-dose clinical trial in schizophrenic patients a pharmacokinetic profile that will allow for once-monthly dosing with dose proportionality across the therapeutic range. Risperdal Consta provides therapy for only two weeks, resulting in more frequent physician visits and a greater number of annual injections, as well as more opportunities for patients to miss or delay a dose.
- Subcutaneous delivery: All the currently available long-acting atypical antipsychotics are administered intramuscularly and, other than the lowest dosage strength of Invega Sustenna, have injection volumes greater than Relday. Intramuscular injections have been associated with inadvertent vascular injection, leading to rapid release of the drug and related adverse events, and in addition can also result in slow, painful and/or difficult injections. Utilizing the unique attributes of the Durect's SABER technology, Relday has been designed to be administered subcutaneously.
- No reconstitution: Relday is formulated as a pre-filled, single-dose product that does not require reconstitution, or the addition of a liquid dilutent, prior to administration. Risperdal Consta, Zyprexa Relprevv and Abilify Maintena all require reconstitution prior to injection, which is generally considered an inconvenience for busy healthcare practitioners.
- Preferred active ingredient: Our market research indicated that in nearly all cases, long-acting injectable antipsychotics are prescribed to patients who have experience taking the same molecule orally and have demonstrated some level of acceptable efficacy and tolerability. Oral risperidone is now the second most commonly prescribed atypical antipsychotic compound in the United States, accounting for 21% of total prescriptions in the twelve months ended December 2014 (Source® PHAST Prescription, January 2014 — December 2014).

If successfully developed and approved by the FDA, we plan to commercialize Relday in the United States by further leveraging our commercial infrastructure and sales force. We also plan to seek a development and commercialization partner or partners for Relday in territories outside of the United States such as Europe and Japan. While our current development plans are focused on schizophrenia, in the future we may consider expanding the program to address additional indications, such as bipolar disorder.

Our DosePro Technology and Pre-clinical Pipeline

Our proprietary DosePro technology is a first-in-class, easy-to-use drug delivery system designed for self-administration of a pre-filled, single dose of liquid drug, subcutaneously, without a needle. The DosePro technology has undergone more than fifteen years of design, process engineering, clinical evaluation and development work, including significant capital investment by the predecessor owners of the technology, Weston Medical Group, plc and Aradigm Corporation. We acquired the DosePro technology and related intellectual property from Aradigm in August 2006. We believe FDA approval and adoption by prescribers of SUMAVEL DosePro for the treatment of migraine in the United States validates the technology's commercial viability and readiness for other potential drug applications.

We believe that DosePro offers several benefits to patients compared to other subcutaneous delivery methods, and that it has the potential to become a preferred delivery option for patients and physicians for many injected medicines,

particularly those that are self-administered. These benefits include less anxiety or fear due to the lack of a needle, easier disposal without the need for a sharps container, no risk of needlestick injury or contamination, an easy-to-use three step process, no need to fill or manipulate the system, reliable performance, discreet use and portability. In clinical trials and market research studies, DosePro has been shown to be preferred by patients over conventional needle-based systems. For example, in a head-to-head study conducted by GlaxoSmithKline of Sumavel DosePro versus the European branded version of Imitrex STATdose, a needle-based delivery system, 61% of migraine patients preferred using Sumavel DosePro while only 18% preferred using the European branded version of Imitrex STATdose, with the remaining patients expressing no preference. In addition, in a market study conducted on our behalf by Boston Healthcare Associates, Inc. in 2007, 76% of patients indicated that they preferred the

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Sumavel DosePro delivery method over Imitrex STATdose. In addition, DosePro requires less time from physicians and other caregivers to train patients to use the system.

Physician preference for DosePro as a needle-free alternative to conventional needle-based injections has also been demonstrated in market research studies. For example, in a study conducted by Palace Healthcare Group, Inc. in 2006 on our behalf, 94% of primary care physicians and 98% of neurologists indicated they would be more willing to prescribe an injectable migraine product if it were needle-free.

Clinical studies suggest that DosePro will have significant versatility in its ability to deliver various types of therapeutic compounds, including both small molecules and biologic products where the dose volume is 0.5 mL or less. In addition to positive results using DosePro in clinical studies performed with saline and sumatriptan, there have been three positive single-dose human pilot studies conducted with a combination of a protein pharmaceutical and DosePro. These studies include pharmacokinetic bioequivalence studies comparing DosePro to a conventional needle injection for human growth hormone and erythropoietin and pharmacodynamic equivalence study using granulocyte colony-stimulating factor. Pre-clinical work with monoclonal antibodies evaluating bioavailability, pharmacokinetics and a lack of immunogenicity has also been conducted. In vitro studies with DosePro technology have demonstrated the potential to allow the subcutaneous delivery of highly viscous formulations, which can be a limiting factor for use of traditional needle-based delivery systems. At the 2013 National Biotechnology Conference of the American Association of Pharmaceutical Scientists, the results of two in vitro studies examining the integrity of three monoclonal antibody formulations after delivery by the DosePro technology were presented; these studies demonstrated that biologic integrity is not significantly different with DosePro vs. needle-based delivery controls. As a result of the versatility of DosePro to deliver various types of drug products, this technology may have significant market potential across a broad range of therapeutic areas, including those typically treated with small volume injectable products, such as hepatitis, infertility, multiple sclerosis and rheumatoid arthritis.

Since some drug formulations cannot be accommodated in a 0.5 mL dose volume, we have initiated early stage design and development of a larger volume, second generation version of our DosePro technology, which if successfully developed, would allow for a broader range of potential applications for our technology. Full development of such technology will require additional investment and we may consider entering into a third-party collaboration in order to fully develop such technology. There is no guarantee that we or any potential future third-party collaborator will successfully develop such a technology, whether for financial or technical reasons or otherwise.

We are evaluating the market potential, formulation requirements and clinical development pathway of an additional CNS compound that could be paired with DosePro to enhance its commercial attractiveness. We are also seeking to capitalize on our DosePro technology by out-licensing it to potential partners enabling them to enhance, differentiate or extend the life cycle of their proprietary injectable products. We have a co-marketing and development services agreement with Battelle Memorial Institute, or Battelle, pursuant to which we granted to Battelle the exclusive right to co-market our DosePro drug delivery technology and Battelle's DosePro development services to certain prospective pharmaceutical clients.

Sales and Marketing

We have built a highly experienced sales and marketing organization in the United States focused on marketing and selling our products to physicians, nurses and other healthcare professionals. As of December 31, 2014, our commercial organization was comprised of 149 individuals including 110 sales representatives. We continue to promote Zohydro ER to prescribers experienced with using extended-release opioids for the treatment of severe chronic pain, including pain specialists, anesthesiologists, physical medicine specialists and those additional primary care physicians who care for these patients and prescribe ER/LA opioids.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities,

including larger, well established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than us. We face competition not only in the commercialization of Zohydro ER or any product candidates for which we obtain marketing approval from the FDA or other regulatory authorities, but also for the in-licensing or acquisition of additional product candidates, and the out-licensing of our DosePro drug delivery technology.

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Zohydro ER

Zohydro ER competes against other marketed branded and generic pain therapeutics. Opioid therapeutics generally fall into two classes: immediate-release and extended-release/long acting medications. Zohydro ER is an extended-release hydrocodone, the most commonly prescribed opioid in the United States, and Zohydro ER competes with therapeutics within the extended-release/long acting class for the treatment of chronic pain. These therapeutics include controlled substance products being marketed by companies such as Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, Mallinckrodt Inc., Pfizer Inc., Purdue Pharma L.P., Teva Pharmaceutical Industries Limited, Depomed, Inc. and Actavis, Inc. Two significant market events occurred in the fourth quarter of 2014, which include the rescheduling of all immediate-release hydrocodone combination products from Schedule III to Schedule II, and the approval by the FDA of a once-daily single entity extended-release hydrocodone product with abuse deterrent properties developed by Purdue Pharma L.P. which became available on the market in February 2015.

Zohydro ER will also compete with a significant number of opioid product candidates under development, including those products with abuse deterrent and tamper resistant properties being developed by companies such as Egalet A/S, Pfizer, and Teva Pharmaceutical Industries Limited. Zohydro ER may also face competition from non-opioid product candidates including new chemical entities, as well as alternative delivery forms of NSAIDs. These new opioid and non-opioid product candidates are being developed by companies such as Acura Pharmaceuticals, Inc., Collegium Pharmaceutical, Inc., Eli Lilly and Company, Elite Pharmaceuticals, Inc., Hospira, Inc., Inspirion Delivery Technologies, LLC, Intellipharmaceutics International Inc., and Nektar Therapeutics.

ZX008

There are currently no FDA-approved treatments specifically indicated for Dravet syndrome. The standard of care usually involves a combination of the following anticonvulsant drugs: clobazam, clonazepam, leviteracetam, topirimate, valproic acid, ethosuximide or zonisamide. Stiripentol is approved in Europe for the treatment of Dravet syndrome in conjunction with clobazam and valproate. In Europe, stiripentol was granted an orphan drug designation for the treatment of Dravet syndrome in 2001. In the United States, the drug is not FDA approved and can only be obtained via the FDA's Personal Importation Policy. The FDA's PIP is meant to help people with life threatening illnesses obtain drugs when FDA approved drugs have failed. The FDA does not consider the PIP a "license" to import drugs for personal use (even for people with life threatening illnesses). In 2013, the FDA mandated that all new patients obtaining stiripentol must have a patient specific Investigational New Drug, or IND, application submitted to the FDA by the prescribing physician, who is most often an academic pediatric neurologist. It is believed that there are no plans to obtain an official FDA approval for Stiripentol.

Even though there are several other drugs in clinical development, ZX008 has a distinctive mechanism of action (serotonin activity) that is different from that of all other drugs being developed in the United States and European Union for the treatment of Dravet syndrome. The two other drugs in development for the treatment of Dravet syndrome are cannabanoids; these are not viewed as direct competitors to ZX008, since they will not block the FDA from granting orphan drug status to ZX008 even if they are approved prior to ZX008, nor will their usage in patients prevent the concurrent use of ZX008. It is believed that some patients may respond better to ZX008 as compared to a cannabanoid drug, some may do better with a cannabanoid, and some may experience a synergistic effect from being prescribed both classes of drug; this belief will need to be evaluated in future clinical trials if both classes of drugs are approved by the FDA.

GW Pharmaceutical's Epidiolex is a liquid drug formulation of purified cannabidiol, or CBD, a component of marijuana. Anecdotal evidence has suggested that patients with Dravet syndrome experience a reduction in seizures when CBD is prescribed to them. Epidiolex is currently in Phase 3 trials. Because the drug is a cannabanoid, it is believed that if the FDA approves it, it will be viewed as a controlled substance and thus will be a scheduled drug. Insys Therapeutics, or Insys, is also developing a cannabanoid for the treatment of Dravet syndrome. Insys has publicly announced that it has submitted an IND application for its CBD formulation and that it has received fast track designation from the FDA. Insys plans to begin a Phase 1 pharmacokinetic trial in the first quarter of 2015, followed

by a Phase 3 clinical trial in the second half of 2015. Because Insys' drug is also a cannabanoid, it is believed that if the drug receives FDA approval it will be viewed as a controlled substance and thus will be a scheduled drug.

Relday

If approved for the treatment of schizophrenia, we anticipate that Relday will compete against other marketed, branded and generic, typical and atypical antipsychotics, including both long-acting injectable and oral products. Currently marketed long-acting injectable atypical antipsychotic products include Risperdal Consta, and Invega Sustenna marketed by Johnson & Johnson, Zyprexa Relprevv marketed by Eli Lilly & Company, and Abilify Maintena (apripiprazole) marketed by Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S. Currently approved and marketed oral atypical antipsychotics include

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Risperdal (risperidone) and Invega (paliperidone) marketed by Johnson & Johnson, generic risperidone, Zyprexa (olanzapine) marketed by Eli Lilly and Company, Seroquel (quetiapine) marketed by AstraZeneca plc, Abilify (aripiprazole) marketed by BMS/Otsuka Pharmaceutical Co., Ltd., Geodon (ziprasidone) marketed by Pfizer, Fanapt (iloperidone) marketed by Novartis AG, Saphris (asenapine) marketed by Merck & Co., Latuda (lurasidone) marketed by Dainippon Sumitomo Pharma and generic clozapine. Finally, in addition to these currently marketed products, we may also face competition from additional long-acting injectable product candidates that could be developed by the large companies listed above, as well and by other pharmaceutical companies such as Alkermes Pharma Ireland Limited, Endo Health Solutions Inc., Laboratorios Farmaceuticos Rovi SA, Novartis AG, and Reckitt Benckiser Group plc, each of which has announced they are developing long-acting antipsychotic product candidates.

DosePro Technology

Traditional needle and syringe remain the primary method for administering subcutaneous injections. The injectable drug market is increasingly adopting new injection systems including pre-filled syringes, pen injectors and autoinjector devices. The majority of these devices, however, still employ a needle. We will compete with companies operating in the needle-based drug delivery market. These companies include, but are not limited to, Becton, Dickinson and Company, Owen Mumford Ltd. and Ypsomed AG. Additional competition may come from companies focused on out-licensing needle-free technology including Antares Pharma Inc. and Bioject Inc., which have commercialized gas- or spring-driven, multiple-use, patient-filled, needle-free injectors, primarily for injecting human growth hormone or insulin for diabetes. Other companies, such as Crossject SA and LTS Lohmann Therapie-Systeme AG, are developing single-use, pre-filled, needle-free delivery systems. We also may experience future competition from alternative delivery systems which bypass the need for an injection, including inhaled, nasal, sublingual or transdermal technologies.

Distribution

During the year ended December 31, 2014, we sold Sumavel DosePro and Zohydro ER to wholesale pharmaceutical distributors, who, in turn, sold the products to pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors, McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., individually comprised 33.0%, 32.0% and 23.0%, respectively, of our total ex-factory gross product sales for the year ended December 31, 2014.

We use a third-party logistics provider, Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services), for key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. We also rely on Inmar Inc. to process our product returns. In addition, we utilize other third parties to perform various other services for us relating to drug safety monitoring and surveillance, sample accountability and regulatory monitoring, including adverse event reporting, education regarding the safe use of our products, safety database management and other product maintenance services.

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Manufacturing

Sumavel DosePro, marketed by Endo Pharmaceuticals, and our DosePro system are manufactured by contract manufacturers, component fabricators and secondary service providers. Suppliers of components, subassemblies and other materials are located in the United Kingdom, Germany, Ireland and the United States. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the DosePro system. FDA regulations require that materials be produced under current Good Manufacturing Practice, or cGMP, or Quality System Regulations, or QSR, as required for the respective unit operation within the manufacturing process. Manufacturing equipment specific to the production of critical DosePro components and assemblies was developed and purchased by us and the prior owners of the DosePro technology and is currently owned by us.

We manage the supply chain for Sumavel DosePro, consisting of the DosePro system and the active pharmaceutical ingredient, or API, internally with experienced operations professionals, including employees residing in the United Kingdom who oversee European contract manufacturing operations. We have entered into supply agreements relating to Sumavel DosePro with our critical contract manufacturers, most component fabricators and secondary service providers to secure commercial supply for Sumavel DosePro and expect manufacturing capacity to adequately support our projected Sumavel DosePro demand through 2015. Each of these manufacturers and each other company that supplies, fabricates or manufactures any component used in our DosePro system is currently the sole qualified source of their respective components. If demand exceeds our expectation in 2016 and beyond, we may be required to expand the capacity of some of our existing contract manufacturers and suppliers or qualify new manufacturers or suppliers. DosePro systems intended for clinical trials of DosePro-based products other than Sumavel DosePro are provided by using the existing manufacturing infrastructure, supplemented with clinical scale operations as appropriate for the stage and scale of the product under clinical development.

Daravita is the exclusive manufacturer and supplier (subject to certain exceptions) for Zohydro ER under the terms of our commercial manufacturing and supply agreement described below.

The following are manufacturing and supply arrangements and agreements that we believe are material to the ongoing operation of our business.

Patheon UK Limited

In November 2008, we entered into a manufacturing services agreement with Patheon UK Limited, or Patheon, located in Swindon, United Kingdom, a specialist in the aseptic fill/finish of injectables and other sterile pharmaceutical products. Under the terms of the agreement, Patheon serves as our exclusive manufacturer for the aseptic capsule assembly, filling and inspection, final system assembly and packaging of Sumavel DosePro, as well as other manufacturing and support services. The agreement had an initial five-year term, which expired October 31, 2013. In February 2013, we entered into a new manufacturing services agreement with Patheon to replace our original manufacturing services agreement upon its expiration. The new manufacturing services agreement had a termination date of April 31, 2015. In August 2013, we entered into an amendment to the new manufacturing services agreement, or the amended services agreement, with Patheon which replaced our original manufacturing services agreement upon its expiration. The amended services agreement has similar terms to the original agreement and will expire on April 30, 2016. The parties may mutually agree in writing to renew the agreement for additional terms prior to the expiration of the then-current term.

Although we are not required to have any minimum quantity of Sumavel DosePro manufactured under the agreement, we have agreed to provide Patheon with forecasts of the required volumes of Sumavel DosePro we need, and we are required to pay Patheon a monthly manufacturing fee of £419,000, or approximately $651,000 (based on the exchange rate as of December 31, 2014) through the remaining term of the amended services agreement, aggregating to £6,704,000, or approximately $10,416,000, over the remaining amended term. Under the agreement, we are also required to pay support and service fees, with the level of service fees increasing if annual production exceeds a specified volume.

Under the amended services agreement, either party may terminate the agreement (1) upon specified written notice to the other party, (2) upon written notice if the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under the agreement within a specified period following receipt of

written notice of such breach, and (3) immediately upon written notice to the other party in the event that the other party is declared insolvent or bankrupt by a court of competent jurisdiction, a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party or the agreement is assigned by such other party for the benefit of creditors. Patheon may also terminate the agreement upon specified written notice if we assign the agreement to certain specified parties.

Nypro Limited

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Nypro Limited, located in Bray, Ireland, manufactures the actuator assemblies and injection molded components for our DosePro system pursuant to purchase orders. We are currently negotiating a commercial supply agreement with Nypro.

Nipro Glass, Germany AG (formerly MGlas AG)

In May 2009, we entered into a commercial manufacturing and supply agreement with Nipro Glass, Germany AG, or Nipro Glass, located in Munnerstadt, Germany. Under the terms of the agreement, Nipro Glass is our exclusive supplier of the glass capsule that houses the sumatriptan API in Sumavel DosePro (and will be the exclusive supplier of glass capsules for any future 0.5 mL DosePro product candidates or products). The agreement had an initial three-year term, which expired in May 2012. Although the commercial manufacturing and supply agreement with Nipro Glass expired in May 2012, we have continued to exclusively purchase glass capsules from Nipro Glass under the expired agreement terms. We are currently negotiating an extension of the commercial manufacturing and supply agreement with Nipro Glass to continue the exclusive supply of the glass capsule.

Dr. Reddy's Laboratories, Inc.

We are party to a supply agreement with Dr. Reddy's Laboratories, Inc., or Dr. Reddy's, which was originally entered into between Aradigm and Dr. Reddy's in September 2004. Under the terms of the agreement, Dr. Reddy's, a global pharmaceutical company and supplier of bulk API located in India, agreed to supply us with the sumatriptan API for Sumavel DosePro at a specified price. Dr. Reddy's has agreed to sell to us, and we agreed to purchase on a non-exclusive basis from Dr. Reddy's, not less than 50% of our quarterly requirements for sumatriptan in the United States, Canada and the European Union. The initial term of the agreement expires in 2020. The term of the agreement may be extended by us for successive one-year periods by written notice to Dr. Reddy's, unless Dr. Reddy's gives written notice to us that it does not wish to extend the term. We may terminate the agreement upon written notice if Dr. Reddy's is unable to deliver sufficient amounts of sumatriptan over a specified period of time. We may also terminate the agreement if we are negotiating an agreement with a third party to commercialize such third party's formulation of sumatriptan and such agreement would preclude us from sourcing sumatriptan from any party other than such third party. Either party may terminate the agreement upon written notice if the other party commits a material breach of its obligations and fails to remedy the breach within a specified time period, if the other party becomes insolvent or subject to bankruptcy proceedings, or where a force majeure event continues for a specified period of time.

Daravita Manufacturing and Supply Agreement

In November 2012, we entered into a commercial manufacturing and supply agreement for Zohydro ER finished commercial product with Daravita, formerly Alkermes Pharma Ireland Limited. Under the agreement, Daravita is the exclusive manufacturer and supplier to us, subject to certain exceptions, of Zohydro ER. We must purchase all of our requirements of Zohydro ER, subject to certain exceptions, from Daravita.

Under the agreement, we will provide Daravita with an 18 month forecast on a monthly basis and with a three-year forecast on an annual basis for commercial supply requirements of Zohydro ER. In each of the four months following the submission of the 18-month forecast, we are obligated to order the quantity of Zohydro ER specified in the forecast. Daravita will use commercially reasonable efforts to supply the orders of Zohydro ER subject to the availability of the DEA quota for hydrocodone. Daravita is not obligated to supply us with quantities of Zohydro ER in excess of forecasted amounts, but has agreed to use commercially reasonable efforts to do so. Further, we are obligated to purchase at least 75% of forecasted quarterly quantities of Zohydro ER from Daravita, and are required to make compensatory payments if we do not purchase 100% of our requirements from Daravita, subject to certain exceptions.

If a failure to supply occurs under the agreement, other than a force majeure event, Daravita must use commercially reasonable efforts to assist us in transferring production of Zohydro ER to either us or a third-party manufacturer, provided that such third party is not a technological competitor of Daravita. In a failure to supply circumstance, we would be able to utilize (or sublicense to a third party who is not a technological competitor of Daravita) the manufacturing license rights granted to us in the license agreement with Daravita, until such time as Daravita can resume supply of Zohydro ER.

Either party may terminate the agreement by written notice if the other party commits a material breach of its obligations which is either incapable of remedy or is not remedied within a specified period following receipt of written notice of such breach. Unless otherwise terminated due to a material breach, the agreement will continue until the expiry or termination of the license agreement with Daravita described below.

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Collaborations, Commercial and License Agreements

Daravita License Agreement

In 2007, we entered into a license agreement with Daravita, or the Daravita License Agreement, which was initially amended in 2009 and amended again on September 12, 2014. The Daravita License Agreement granted us an exclusive license in the United States and its possessions and territories, with defined sub-license rights to third parties other than certain technological competitors of Daravita, to certain Daravita intellectual property rights related to Zohydro ER and the exclusive right under certain Daravita patents and patent applications to import, use, offer for sale and sell oral controlled-release capsule or tablet formulations of hydrocodone, where hydrocodone is the sole active ingredient, for oral prescriptions in the treatment or relief of pain, pain syndromes or pain associated with medical conditions or procedures in the United States. This right enables us to exclusively develop and sell Zohydro ER in the United States. Daravita has retained the exclusive right to take action in the event of infringement or threatened infringement by a third party of Daravita's intellectual property rights under the Daravita License Agreement. We have the right to pursue an infringement claim against the alleged infringer should Daravita decline to take or continue an action.

Under the Daravita License Agreement, we paid an upfront fee and additional milestone payments and we are required to pay royalties on net sales of the product for an initial royalty term equal to the longer of the expiration of Daravita’s patents covering the product in the United States, or 15 years after commercial launch, if Daravita does not have patents covering the product in the United States. After the initial royalty term, the Daravita License Agreement will continue automatically for three-year rolling periods during which we will continue to pay royalties to Daravita on net sales of the product at a reduced rate.

We also agreed in a separate agreement that Daravita is the exclusive manufacturer and supplier to us of Zohydro ER, subject to certain exceptions. Daravita also granted us, in the event they are unwilling or unable to manufacture or supply commercial product to us, a non-exclusive license to make product under their intellectual property rights. This non-exclusive license also includes the right to sublicense product manufacturing to a third party, other than certain technological competitors of Daravita.

On September 12, 2014, we entered into a third amendment to the Daravita License Agreement, pursuant to which we may exercise our option to obtain an exclusive license to certain abuse-deterrent technology and know-how from Altus pursuant to the Development and Option Agreement that we entered into with Altus in November 2013 as described below. Following such exercise and the first commercial sale by us, our affiliates or our permitted sublicensees of any extended-release formulations of hydrocodone using Altus’ abuse-deterrent technology, Daravita will be entitled to receive a royalty from us on net sales of product using such formulations.

Either party may terminate the Daravita License Agreement upon a material, uncured default or certain insolvency events of the other party or upon 12 months' written notice prior to the end of the initial royalty term or any additional three-year rolling period. We may also terminate the Daravita License Agreement, with or without cause, at any point in time upon 12 months' prior written notice, or if the sale of Zohydro ER is prohibited by regulatory authorities.

Altus Formulation Inc. Development and Option Agreement

In November 2013, we entered into a development and option agreement with Altus. Under the agreement Altus is responsible for the development of abuse deterrent formulations of hydrocodone using Altus’ Intellitab™ drug delivery platform and will be reimbursed by us for its development efforts on the product. We are responsible for the conduct of the clinical development of the product. We paid a non-refundable upfront fee to Altus and we are obligated to pay Altus upon the achievement of various development and regulatory milestones. The term of the development agreement will end upon expiration of the earlier of (1) the date upon which an NDA or similar application for regulatory approval is submitted by us for an Altus abuse deterrent formulation of hydrocodone, or (2) November 1, 2016.

We were also granted an option to obtain an exclusive, royalty-bearing license, with the right to sublicense, certain Altus intellectual property rights to make, have made, use, sell, have sold, offer for sale and import an abuse deterrent formulation of hydrocodone for the treatment or relief of pain in the United States. If we exercise this option, Altus will be eligible to receive additional regulatory and sales milestones and a royalty based on net sales of the licensed product.

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Endo Ventures Limited Asset Purchase Agreement

In April 2014, we entered into an asset purchase agreement, or the Asset Purchase Agreement, with Endo Ventures Bermuda Limited, or Endo Ventures Bermuda, and Endo Ventures Limited, or Endo Ventures and, together with Endo Ventures Bermuda, Endo, to sell our Sumavel DosePro business to Endo. The Asset Purchase Agreement closed on May 16, 2014. We also entered into a supply agreement pursuant to which we retain the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo Ventures, subject to Endo Venture's right to qualify and maintain a back-up manufacturer. Also, Endo agreed to provide our Sumavel DosePro manufacturing operations with a working capital advance.

Mallinckrodt LLC Co-Promotion Agreement

In June 2012 we entered into a co-promotion agreement which granted Mallinckrodt LLC, or Mallinckrodt , a co-exclusive right (with us) to promote Sumavel DosePro in the United States. We remained responsible for the manufacture, supply and distribution of commercial product for sale in the United States. In January 2014, we entered into a termination and amendment to the agreement and the agreement terminated on January 31, 2014.

We paid Mallinckrodt a service fee quarterly based on a percentage of net sales generated from Mallinckrodt's efforts. Also, following completion of the co-promotion term in January 2014, we were required to pay Mallinckrodt a one-time tail payment based on net sales from the Mallinckrodt targeted prescriber audience during the 12-month period ending on January 31, 2015.

Astellas Co-Promotion Agreement

In July 2009, we entered into the co-promotion agreement, or the Astellas Co-Promotion Agreement with Astellas Pharma U.S. Inc., or Astellas, in which we granted Astellas the co-exclusive right (along with us) to market and sell Sumavel DosePro in the United States until June 30, 2013. The agreement provided that both we and Astellas were obligated to collaborate and fund the marketing of Sumavel DosePro and to provide annual minimum levels of sales effort directed at Sumavel DosePro during the term. In December 2011, we entered into an amendment to the Astellas Co-Promotion Agreement whereby the agreement terminated on March 31, 2012.

Following completion of the co-promotion term in March 2012, we were required to pay Astellas one tail payment in July 2013 and another tail payment in July 2014, calculated as percentages of net sales generated by Astellas' sales efforts during the twelve months ended March 31, 2012.

Valeant Pharmaceuticals North America LLC Co-Promotion Agreement

In June 2013, we entered into a co-promotion agreement with Valeant Pharmaceuticals North America LLC, or Valeant. The agreement granted us the exclusive right (with Valeant or any of its affiliates) to promote Migranal to a prescriber audience of physicians and other health care practitioners in the United States. The term of the agreement will run through December 31, 2015 (unless otherwise terminated), and can be extended by mutual agreement of the parties in additional 12-month increments. Valeant remains responsible for the manufacture, supply and distribution of Migranal for sale in the United States. In addition, Valeant will supply us with a specified amount of product samples every six months, and we will reimburse Valeant for the cost of additional samples and any promotional materials that we order.

As part of the agreement, Valeant pays us a co-promotion fee based on net sales generated by us. Also, upon completion of the co-promotion term, and only if the agreement is not terminated by Valeant due to a bankruptcy event (as defined in the agreement) or a material failure by us to comply with our material obligations under the agreement, Valeant will pay us an additional tail payment based on our net sales generated.

We may terminate the agreement in the event of a Valeant supply failure (as defined in the agreement) or material product recall, or if the net sales price in a fiscal quarter is less than a specified percentage of the net sales price in the immediately preceding quarter, if the reduction in such net sales price would have a material adverse effect on our financial return as a result of performance of our obligation under the agreement.

Either party may terminate the agreement with six months' notice. Either party may terminate the agreement with 30 days' prior notice if our net sales within a fiscal quarter fall below the Baseline Forecast (or Adjusted Baseline Forecast) for one or more fiscal quarters, or following the commercial introduction of a generic product to Migranal

promoted or otherwise commercialized by a third party in the United States. In addition, either party may terminate the agreement in the event of a change of control of itself or the other party (upon 90 days' prior written notice), upon any action taken or objection raised by governmental authority that prevents either party from performing its obligations under the agreement, upon the filing of an

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action alleging patent infringement, in connection with the material breach of the other party's material obligations, or if a bankruptcy event of the other party occurs.

Aradigm Corporation Asset Purchase Agreement

In August 2006, we entered into an asset purchase agreement with Aradigm whereby Aradigm assigned and transferred to us all of its right, title and interest to tangible assets and intellectual property related to the DosePro needle-free drug delivery system. Aradigm also granted to us a license under all other intellectual property of Aradigm that is necessary or useful to the DosePro delivery system. Aradigm also retained a license under all transferred intellectual property rights solely for purposes of the pulmonary field, and we granted Aradigm a license under other intellectual property rights solely for use in the pulmonary field.

Under terms of the agreement, if we or one of our future licensees, if any, commercializes a non-sumatriptan product in the DosePro delivery system, we will be required to pay Aradigm, at our election, either a royalty on net sales of each non-sumatriptan product commercialized, or a percentage of the royalty revenues received by us from the licensee, if any. Royalty revenues under this agreement include, if applicable, running royalties on the net sales of non-sumatriptan products, license or milestone fees not allocable to development or other related costs incurred by us, payments in consideration of goods or products in excess of their cost, or payments in consideration for equity in excess of the then fair market value of the equity.

Durect Corporation Development and License Agreement

In July 2011, we entered into a development and license agreement with Durect Corporation. Under the terms of the agreement, we are responsible for the clinical development and commercialization of Relday. Durect is responsible for non-clinical, formulation and chemistry, manufacturing and controls, or CMC, development responsibilities. Durect will be reimbursed by us for its research and development efforts on the product.

We paid an upfront fee to Durect and may be obligated to pay up to $103.0 million in total future milestone payments based on specified development, regulatory and sales targets. We are also required to pay a royalty on annual net sales of the product. Further, until an NDA for Relday has been filed in the United States, we are obligated to spend no less than $1.0 million in external expenses on the development of Relday in any trailing twelve-month period beginning in July 2012. We are also required to pay Durect a tiered percentage of fees received in connection with any sublicense of the licensed rights.

Durect granted to us an exclusive license to intellectual property rights related to Durect’s proprietary polymeric and non-polymeric controlled-release formulation technology to make risperidone products, where risperidone is the sole active agent, for administration by injection in the treatment of schizophrenia, bipolar disorder or other psychiatric related disorders in humans. Durect retains the right to supply our Phase 3 clinical trial and commercial product requirements on the terms set forth in the agreement.

Durect may terminate the agreement with respect to specific countries if we fail to advance the development of the product in such country within a specified time period, either directly or through a sublicensee. In addition, either party may terminate the agreement upon insolvency or bankruptcy of the other party, upon written notice of a material uncured breach or if the other party takes any act that attempts to impair such other party’s relevant intellectual property rights. We may terminate the agreement upon written notice if during the development or commercialization of the product, the product becomes subject to one or more serious adverse drug experiences or if either party receives notice from a regulatory authority, independent review committee, data safety monitory board or other similar body alleging significant concern regarding a patient safety issue and, as a result, we believe the long-term viability of the product would be seriously impacted. We may also terminate the agreement with or without cause, at any time upon prior written notice.

Intellectual Property

Our success will depend to a significant extent on our ability to obtain, expand and protect our intellectual property estate, enforce patents, maintain trade secret and trademark protection and operate without infringing the proprietary rights of other parties.

Zohydro ER

Zohydro ER with BeadTek is an extended-release oral hydrocodone pain reliever. Our in-licensed patents from Daravita relating to Zohydro ER are expected to expire in 2019. U.S. Patent Nos. 6,902,742, 6,228,398 and 6,730,325

relating to Zohydro ER cover a modified release composition containing hydrocodone and are expected to expire in November 2019. Upon the expiration of these patents, we or Daravita, as applicable, will lose the right to exclude others from practicing the claimed inventions.

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We also have filed two pending U.S. patent applications and one pending foreign application related to Zohydro ER. There is no certainty that any of these applications will issue as a patent. If issued the patents would be expected to expire in July of 2033.

Needle-free Drug Delivery Technologies

Sumavel DosePro is a drug-system combination that subcutaneously delivers sumatriptan utilizing our proprietary needle-free drug delivery system to treat migraine and cluster headache. Our patent portfolio is directed to various types and components of needle-free and other drug delivery systems. As of December 31, 2014, we have 28 issued U.S. patents, 13 pending U.S. patent applications, 54 issued foreign patents and 39 pending foreign patent applications. Of the above, we have 23 issued U.S. patents, three pending U.S. patent applications, 43 issued foreign patents and seven pending foreign patent applications relating to various aspects of Sumavel DosePro and our DosePro technology.

Our issued U.S. Patent No. 5,957,886 claims a needleless injector system using a viscous damping medium, and is expected to expire in 2016. We have corresponding patents (one each in Canada, Germany, France, United Kingdom and Japan), which are all expected to expire in 2015. Our issued U.S. Patent No. 6,135,979 covers a needleless injector with particular safety mechanisms, and is expected to expire in 2017. We have corresponding patents in Germany, France, United Kingdom and Japan, which are all expected to expire in 2016. Our issued U.S. Patents Nos. 7,776,007 and 8,287,489 each cover systems with a cap and latch mechanism, and are expected to expire in 2026 and 2024, respectively. We have a corresponding patent in Japan. Our issued U.S. Patent Nos. 7,901,385 and 8,267,903 encompass various embodiments of the casing for enclosing the injection systems, and are expected to expire in 2026 and 2023. We have corresponding patents in Australia, Canada, Germany, Spain, France, United Kingdom, Italy, and Japan. Our issued U.S. Patent Nos. 8,118,771, 8,241,243 and 8,241,244 correspond to methods of reducing breakage of glass capsules used in the system, and are expected to expire in 2023, 2025 and 2022, respectively. We have corresponding patents in Canada, Germany, France, United Kingdom and Japan. Our U.S. Patent No. 8,343,130 covers a method of reducing the propensity to create a shock wave on firing the system used in Sumavel DosePro and expires in 2022. We have corresponding patents in Canada, Germany, France and the United Kingdom, and two in Japan. Our U.S. Patent No. 8,491,524 relates to a drug capsule filled with a formulation purged with an inert gas and expires in 2022. U.S. Patents 5,957,886; 6,135,979; 7,776,007; 7,901,385; 8,267,903; 8,118,771; 8,241,243; 8,241,244; 8,287,489; and 8,343,130 are listed in the FDA Orange Book for Sumavel DosePro.

We also have three U.S. Patents Nos., 7,150,297, 6,554,818 and 6,280,410, and one each in Canada and Japan, and two each in Germany, France and the United Kingdom corresponding to methods of filling needle-free injector capsules and the filled capsules, such as those used in the manufacture of Sumavel DosePro. These U.S. patents are expected to expire in 2022, 2017 and 2017, respectively.

We also have three U.S. Patents Nos. 6,174,304, 6,681,810 and 6,251,091, and one in Japan corresponding to needle-free injector drug capsules as well as methods and adaptors for filling capsules with liquid drug, such as those used in the manufacture of Sumavel DosePro. These U.S. patents are expected to expire in 2022, 2025 and 2016, respectively.

Our remaining issued patents, pending U.S. patent applications and pending foreign patent applications are not currently used in Sumavel DosePro, but may be used with alternate versions of, or future product candidates utilizing, our DosePro technology.

We do not have patent protection for Sumavel DosePro in a significant number of countries, including large territories such as India, Russia and China, and accordingly we are not able to use the patent system to provide for market exclusivity in those countries. Additionally, the eleven U.S. patents listed in the FDA Orange Book for Sumavel DosePro expire on various dates between 2016 and 2026. Upon expiration, we will lose certain advantages that come with Orange Book listing of patents and will no longer be able to prevent others in the United States from practicing the inventions claimed by the eleven patents.

Self Priming Device

We have acquired ownership of U.S. Patent 7,814,871 which is expected to expire in October of 2022 and U.S. Patent 7,281,502 which is expected to expire in April of 2024. The patents cover a needle-free injector with a self priming piston component.

ZX008

In connection with our acquisition of Brabant, we acquired rights to three pending U.S. patent applications directed to methods of treating Dravet syndrome. There is no certainty that any of these applications will issue as patents. If the patents issue, they would be expected expire in May 2033.

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Relday

With respect to Relday, we have licensed a number of U.S. and foreign patent applications from Durect that are intended to cover the formulation of Relday and its delivery. However, as the formulation and delivery of Relday are the subject of ongoing research it remains uncertain if the Durect patents or applications, should they issue as patents, will cover the final formulation or delivery of Relday.

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, or 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 FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing which must become effective before human clinical trials may begin in the United States;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practice, or GCP, regulations, to establish the safety and efficacy of the proposed drug product for each intended use;
- submission to the FDA of an NDA; and
- FDA review and approval of the NDA.

The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The results of pre-clinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places a trial on clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage.

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- Phase 3: When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, Phase 3 "pivotal" trials are undertaken in large patient populations to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites.

In some cases, the FDA may condition approval of NDA on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval clinical trials are typically referred to as Phase 4 clinical trials.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, CMC and proposed labeling, among other things. For some drugs, the FDA may determine that a REMS is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and may require submission of a REMS as a condition of approval. The submission of an NDA is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. 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 has been accepted for filing, the FDA begins an in-depth substantive review.

During the FDA's review of an NDA the FDA may inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP, and if applicable, QSR, requirements and are adequate to assure consistent production of the product within required specifications. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements before approving an NDA. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

Once the FDA's NDA review process is substantially complete, it may issue an approval letter, or it may issue a complete response letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or a post-market REMS requirement. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct of additional pre-clinical studies and clinical trials.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug/device listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. There also are extensive U.S. Drug Enforcement Administration, or DEA, regulations applicable to marketed controlled substances. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP or QSR requirements. Changes to the manufacturing

process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP or QSR compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market, though the FDA must provide an application holder with notice and an opportunity for a hearing in order to withdraw its approval of an application. Later

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discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug and device products that are placed on the market. While physicians may prescribe drugs and devices for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. 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.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, and associated FDA regulations, which governs the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs. With the enactment of the Drug Quality and Security Act in November 2013, drug manufacturers will also be subject to new requirements for identifying and tracking prescription drugs as they are distributed in the United States. The requirements of the new law will be phased in over a ten-year period, including requirements for unique product identifiers and provision of product handling information to the FDA.

The FDA may require post-approval studies and clinical trials if the FDA finds they are appropriate based on scientific data, including information regarding related drugs. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug. For example, on September 10, 2013, the FDA announced class-wide safety labeling changes, including required new boxed warnings, and new post-market study requirements for all ER/LA opioids intended to treat pain. The FDA requires a boxed warning (sometimes referred to as a "Black Box" Warning) for products that have shown a significant risk of severe or life-threatening adverse events. Including the additional warnings the FDA added with the class-wide safety labeling changes, Zohydro ER's boxed warnings highlight the product's risk of addiction, abuse, and misuse; life-threatening respiratory depression; accidental exposure; neonatal opioid withdrawal syndrome; and interaction with alcohol. Applicable ER/LA opioid marketers, including us, are required to comply with the labeling requirements and conduct post-market studies and clinical trials to assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose and death. Zohydro ER bears the required labeling and we are currently participating with nine other NDA holders of ER/LA opioid analgesics to address the FDA's post-marketing study requirements.

The FDA also has the authority to require a REMS to ensure that the benefits of a drug outweigh its risks. 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 for a new drug, the drug sponsor must submit a proposed REMS as part of its NDA prior to approval. 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 continue to outweigh its risks. A REMS may be required to include various elements, such as a medication guide or patient

package insert, a communication plan to educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations and other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy, at a minimum, at 18 months, three years, and seven years after the strategy's approval. In February 2009, the FDA informed opioid analgesic drug manufacturers that it would require a class-wide REMS for all long-acting and sustained-release opioid drug products, and as an extended-release formulation of hydrocodone, Zohydro ER became subject to the ER/LA opioid REMS upon approval. Pursuant to the FFDCA, the manufacturers subject to this class-wide REMS must work together to implement the REMS as part of a single shared system to reduce the burden of the REMS on the healthcare system. The central component of the ER/LA opioid REMS program is an education program for prescribers

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and patients. Specifically, the REMS includes a Medication Guide available for distribution to patients who are dispensed the drug, as well as a number of elements to assure safe use. These elements include training for healthcare professionals who prescribe the drug; information provided to prescribers that they can use to educate patients in the safe use, storage, and disposal of opioids; and information provided to prescribers of the existence of the REMS and the need to successfully complete the necessary training. The prescriber training required as part of the REMS is conducted by accredited, independent continuing education providers, without cost to the healthcare professionals, under unrestricted grants funded by the opioid analgesic manufacturers. Moreover, REMS assessments must be submitted on an annual basis to assess the extent to which the elements to assure safe use are meeting the goals of the REMS and whether the goals or elements should be modified.

Concurrently with our clinical development program for ZX008, we plan to develop the appropriate elements of a REMS program to support and maintain a long-term favorable benefit-risk profile for ZX008. We expect that the FDA will require a REMS for ZX008 including elements to assure safe use, among other requirements, as a condition of approval, consistent with other drugs with known safety issues and that are approved for serious diseases with high unmet need. Because ZX008 will not initially be part of a single, shared REMS system similar to the ER/LA opioid REMS, we will be solely responsible for the costs of development of any REMS for ZX008 and will continue to be responsible for all costs associated with implementation and operation of the REMS if ZX008 is approved.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex requirements on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet and social media. The FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If the FDA approves a sponsor’s marketing application for a designated orphan drug for use in the rare disease or condition for which it was designated, the sponsor is eligible for a seven-year period of marketing exclusivity, during which the FDA may not approve another sponsor’s marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor’s orphan drug exclusivity period, competitors, however, may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for a drug with the same active moiety intended for the same indication before we do, unless we are able to demonstrate that grounds for withdrawal of the orphan drug exclusivity exist, or that our product is clinically superior. Further, if a designated orphan drug receives marketing approval for an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity.

We may seek orphan drug designation for one or more of our product candidates, but the FDA may disagree with our analysis of the prevalence of the particular disease or condition or other criteria for designation and refuse to grant orphan status. We cannot guarantee that we will obtain orphan drug designation or approval for any product candidate, or that we will be able to secure orphan drug exclusivity if we do obtain approval.

Section 505(b)(2) New Drug Applications

An applicant may submit an NDA under Section 505(b)(2) of the FFDCA to seek approval for modifications or new uses of products previously approved by the FDA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, and permits the filing of an NDA where at least

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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. The applicant may rely upon published literature and the FDA's previous findings of safety and effectiveness for an approved product based on the prior pre-clinical or clinical trials conducted for the approved product. The FDA may also require companies to perform new 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 a Section 505(b)(2) NDA relies on studies conducted for a previously approved drug product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's current list of "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patent or that such patent is invalid is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification, the Section 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) NDA application also will not be accepted or approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product, has expired.

If the 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the referenced NDA and patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge based on the Paragraph IV certification. Under the FFDCA, if a patent infringement lawsuit is filed against the 505(b)(2) NDA applicant within 45 days of receipt of the Paragraph IV certification notice, an automatic stay of approval is imposed, which prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, or until a court decision or settlement finding that the patent is invalid, unenforceable or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month stay if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the 505(b)(2) NDA applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized.

The 505(b)(2) NDA applicant may be eligible for its own regulatory exclusivity period, such as three-year new product exclusivity. The first approved 505(b)(2) applicant for a particular condition of approval, or change to a marketed product, such as a new extended-release formulation for a previously approved product, may be granted three-year Hatch-Waxman exclusivity if one or more clinical trials, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA is precluded from making effective any other application for the same condition of use or for a change to the drug product that was granted exclusivity until after that three-year exclusivity period has run. Additional exclusivities may also apply, such as an added six-month pediatric exclusivity period based on studies conducted in pediatric patients under a written request from the FDA.

Additionally, the 505(b)(2) NDA applicant may list its own relevant patents in the Orange Book, and if it does, it can initiate patent infringement litigation against subsequent applicants that challenge such patents, which could result in a thirty-month stay delaying those applicants.

DEA Regulation

One of our products, Zohydro ER, is regulated as a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Zohydro ER, our proprietary oral, extended-release version of hydrocodone, is listed by the DEA as a Schedule II controlled substance under the CSA. Consequently, its manufacture, shipment, storage, sale and use is subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example,

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separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and authorization must be obtained to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Because Zohydro ER, an oral, extended-release version of hydrocodone, is regulated as a Schedule II controlled substance, it is subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much hydrocodone 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. This limited aggregate amount of hydrocodone that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including hydrocodone for use in manufacturing Zohydro ER. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our contract manufacturers' quota of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing 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 meet its responsibilities, 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 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 proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

Individual states also regulate controlled substances, and we and our contract manufacturers will be subject to state regulation on distribution of these products.

International Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval and, if applicable, DEA classification. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is

valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we are subject to a variety of other foreign regulations governing, among other things, the conduct of clinical trials, pricing and reimbursement and commercial distribution of our products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. These laws are potentially applicable to manufacturers of products regulated by the FDA, such as us, and hospitals, physicians and other potential purchasers of such products.

In particular, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the TRICARE, Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. 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 or statutory exceptions. Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and have brought cases against numerous pharmaceutical and medical device companies, and certain sales and marketing personnel for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business or reward past purchases or recommendations.

Another development affecting the healthcare industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The civil False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price and improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug's label). In addition, various states have enacted false claim 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.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, also imposes new reporting and disclosure requirements on drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers, and any ownership or investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Manufacturers are required to report such data to the government by the 90th day of each calendar year. The government made such information publicly available on September 30, 2014.

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In addition, under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, or OIG Guidance, and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, or the PhRMA Code. The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals, entertainment and speaker programs, among others. Also, certain states have imposed restrictions on the types of interactions that pharmaceutical companies or their agents (e.g., sales representatives) may have with health care professionals, including bans or strict limitations on the provision of meals, entertainment, hospitality, travel and lodging expenses, and other financial support, including funding for continuing medical education activities.

Healthcare Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by, HIPAA, and its implementing regulations, including the final omnibus rule published on January 25, 2013, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA's privacy and security standards directly applicable to "business associates" — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Third-Party Payor Coverage and Reimbursement

The commercial success of Zohydro ER and our product candidates, if and when commercialized, will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

Changes in third-party payor coverage and reimbursement rules can impact our business. For example, the PPACA changes include increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and established a new Medicare Part D coverage gap discount program, in which manufacturers must provide 50% point-of-sale discounts on products covered under Part D. Further, the law imposes a significant annual, nondeductible fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with health care practitioners. Although it is too early to determine the full effect of PPACA, the new law appears likely to continue the pressure on pharmaceutical pricing, and may also increase our regulatory burdens and operating costs.

Moreover, other legislative changes have also been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate 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, will remain in effect through 2024 unless additional Congressional action is taken.
On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, 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 health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

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In addition, 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 health care, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as health care legislative reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care 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 Zohydro ER and our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Manufacturing Requirements

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA's cGMP regulations and, if applicable, QSR requirements. The cGMP regulations include requirements relating to, among other things, organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers are also subject to periodic unannounced inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including, among other things, warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Employees

As of December 31, 2014, we employed 201 full-time employees. Of the full-time employees, 149 were engaged in sales and marketing, 9 were engaged in manufacturing operations, 22 were engaged in product development, quality assurance and clinical and regulatory activities and 21 were engaged in general and administrative activities (including business and corporate development).

None of our employees are represented by a labor union, and we consider our employee relations to be good. We currently utilize two employer services companies to provide human resource services. These service companies are the employer of record for payroll, benefits, employee relations and other employment-related administration.

Research and Development

We invested $18.9 million, $12.8 million and $21.4 million in research and development in the years 2014, 2013 and 2012, respectively.

About Zogenix

We were formed as a Delaware corporation on May 11, 2006 as SJ2 Therapeutics, Inc. We commenced our operations on August 25, 2006 and changed our name to Zogenix, Inc. on August 28, 2006. Our principal executive offices are located at 12400 High Bluff Drive, Suite 650, San Diego, CA 92130, and our telephone number is 1-866-ZOGENIX (1-866-964-3649). We formed a wholly-owned subsidiary, Zogenix Europe Limited, in June 2010, a company organized under the laws of

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England and Wales and which is located in the United Kingdom, and whose principal operations are to support the manufacture of the DosePro technology.

Financial Information about Segments

We operate only in one business segment, which is the commercialization and development of pharmaceutical products. See Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K. For financial information regarding our business, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and those financial statements and related notes.

Available Information

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K electronically with the Securities and Exchange Commission, or SEC, pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make copies of these reports available on our website at www.zogenix.com, free of charge, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the Securities and Exchange Commission, or SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Pending Sale of the Zohydro ER Business to Pernix Therapeutics Holdings, Inc.

The announcement and pendency of the sale of our Zohydro ER business to affiliates of Pernix Therapeutics Holdings, Inc., or Pernix, could have an adverse effect on our stock price and/or our business, results of operations, financial condition and prospects.

The announcement and pendency of the sale of our Zohydro ER business to Pernix pursuant to the asset purchase agreement we entered into on March 10, 2015, or the asset purchase agreement, could disrupt our business in the following ways, among others:

- third parties may determine to delay or defer purchase decisions with regard to Zohydro ER or terminate and/or attempt to renegotiate their relationships with us as a result of the pending sale, whether pursuant to the terms of their existing agreements with us or otherwise; and
- the attention of our management may be directed toward the completion of the pending sale and related matters, and their focus may be diverted from the day-to-day business operations of our company, including from other opportunities that might otherwise be beneficial to us.

Should they occur, any of these matters could adversely affect our stock price or harm our business, results of operations, financial condition and prospects.

Obtaining required approvals necessary to satisfy the conditions to the completion of the sale of our Zohydro ER business to Pernix may delay or prevent completion of the pending sale.

The completion of the sale of our Zohydro ER business to Endo is conditioned upon the expiration or termination of the waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act. We

intend to pursue all required approvals in accordance with the terms of the asset purchase agreement. However, no assurance can be given that the required approvals will be obtained and, even if all such approvals are obtained, no assurance can be given as to the terms, conditions and timing of the approvals or that they will satisfy the terms of the asset purchase agreement.

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Inability to complete the sale of our Zohydro ER business could negatively impact our business, financial condition, results of operations or our stock price.

The completion of the sale of our Zohydro business is subject to a number of conditions, including, among others, clearance under the HSR Act, the receipt of any required third party consents and there not having been a material adverse effect with respect to such business, and there can be no assurance that the conditions to the completion of the pending sale will be satisfied. The asset purchase agreement may also be terminated by us and Pernix in certain specified circumstances, including if the sale has not been consummated by May 9, 2015 (subject to a 60-day extension in certain circumstances) due to an inability to satisfy any condition to closing. If the pending sale is not completed, we will be subject to several risks, including:

- the current trading price of our common stock may reflect a market assumption that the sale will be completed;
- we expect to incur substantial transaction costs in connection with the pending sale whether or not it is completed; and
- under the asset purchase agreement, we are subject to certain restrictions on the conduct of our business prior to the completion of the pending sale, which restrictions could adversely affect our ability to realize certain of our business strategies or take advantage of certain business opportunities.

If the pending sale is not completed, these risks may materialize and materially and adversely affect our business, financial condition, results of operations or our stock price.

Even if we complete the sale of our Zohydro ER business, we may not realize the full economic benefit from such sale.

Pursuant to the asset purchase agreement, in addition to the $30.0 million upfront cash payment, we will also receive stock consideration of $20.0 million of Pernix's common stock and a secured promissory note for $50.0 million. We will not be permitted to sell such stock payable to us under the asset purchase agreement for six months, and the value of such stock is subject to change based on fluctuations in the market value of Pernix's common stock. In addition, since $50.0 million of the transaction consideration is in the form of a secured promissory note, there is also the risk that Pernix will default under the note, including its obligation to re-pay the note by its maturity date, in which case we can exercise our remedies to have the Zohydro ER business returned to us.

We may also receive contingent payments of up to $283.5 million, based on Pernix's achievement of pre-determined milestones, including a $12.5 million payment upon approval by the FDA of an abuse-deterrent extended-release hydrocodone tablet (currently in development in collaboration with Altus) and up to $271.0 million in potential sales milestone payments. Our ability to receive these contingent payments is dependent upon Pernix successfully maintaining and increasing market demand for, and sales of, Zohydro ER in a manner in which the requisite sales of the product will be achieved and devoting the resources necessary to achieve the manufacturing milestone.

In addition, we have agreed to indemnify Pernix and its affiliates against losses suffered as a result of our material breach of representations and warranties and our other obligations in the asset purchase agreement, and $3.0 million of the upfront cash payment will be deposited into escrow to fund such potential indemnification claims for a period of 12 months following the closing of the sale. An additional $7.0 million will be placed into the escrow fund upon repayment by Pernix of the secured promissory note to be issued under the asset purchase agreement. In addition, we have agreed to indemnify Pernix for certain indemnification matters up to an aggregate amount of $5.0 million. We cannot provide any assurance that we will receive all or any portion of the $10.0 million escrow amount or any of the contingent milestone payments.

If our pending sale of Zohydro ER to Pernix is consummated, our success will depend substantially on our product candidates, ZX008 and Relday. We cannot be certain that any product candidate will receive regulatory approval or be successfully commercialized.

If our pending sale of Zohydro ER to Pernix is consummated, we will have only a limited number of product candidates in development, and our business will depend substantially on their successful development and commercialization. Following the completion of the pending sale of Zohydro ER to Pernix, we will have no drug products approved for sale, and we may not be able to develop marketable drug products in the future. All of our product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant

marketing efforts before we can generate any revenues from product sales. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country.

We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries, and we

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may never receive such regulatory approvals. Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be obtained. Any failure to obtain regulatory approval of any of our product candidates would limit our ability to generate future revenues (and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue), would potentially harm the development prospects of our product candidates and would have a material and adverse impact on our business. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, on our ability to commercialize such products as well as the size of the markets in the territories for which we gain regulatory approval. If the markets for our product candidates are not as significant as we estimate, our business and prospects will be harmed.

Risks Related to Our Business and Industry

We have a history of significant net losses and negative cash flow from operations. We cannot predict if or when we will become profitable and anticipate that our net losses and negative cash flow from operations will continue for at least the next year.

We were organized in 2006, began commercialization of Sumavel DosePro in January 2010 and launched the commercial sale of Zohydro ER in the United States in March 2014. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies commercializing new products.

We have generated substantial net losses and negative cash flow from operations since our inception in 2006. For example, for the years ended December 31, 2014, 2013 and 2012, we incurred net income (loss) of $8.6 million, $(80.9) million and $(47.4) million, respectively, our net cash used in operating activities was $(80.8) million, $(44.9) million and $(52.2) million, respectively, and, at December 31, 2014, our accumulated deficit was $(401.7) million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of the expenses incurred in connection with the commercialization of Zohydro ER, including introduction of the new formulation of Zohydro ER with BeadTek, the development for ZX007, ZX008 (previously referred to as Brabafen, our recently acquired product candidate) and Relday, required FDA post-market required studies for Zohydro ER, safe use initiatives for Zohydro ER and additional development activities with respect to Zohydro ER, including the development of ZX007, which is an additional formulation with abuse deterrent properties. Our ability to generate revenues from sales of Zohydro ER, our Sumavel DosePro contract manufacturing services, or any of our product candidates will depend on a number of factors including, in the case of Zohydro ER and Sumavel DosePro contract manufacturing services, the factors described in risk factors below and, in the case of our product candidates, including ZX007, ZX008 and Relday, our ability to successfully complete clinical trials, obtain necessary regulatory approvals and negotiate arrangements with third parties to help finance the development of, and market and distribute, any product candidates that receive regulatory approval. In addition, we are subject to the risk that the marketplace will not accept our products.

Because of the numerous risks and uncertainties associated with our commercialization and product development efforts, we are unable to predict the extent of our future losses or when or if we will become profitable and it is possible we will never become profitable. If we do not increase sales of Zohydro ER or generate significant sales from any of our product candidates that may receive regulatory approval, there would likely be a material adverse effect on our business, results of operations, financial condition and prospects which could result in our inability to continue operations.

We will require additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. To date, our operations have been primarily financed through the proceeds from the issuance of our common and preferred stock, including the proceeds from our initial public offering completed in November 2010, our follow-on public offerings completed in September 2011, July 2012 and November 2013, our controlled equity offering program, which was terminated in November 2013, and borrowings under financing agreements. In addition, we may fund our operations through the proceeds from

the sales and issuances of our common stock, if any, pursuant to the controlled equity offering program that we established on November 6, 2014 with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which we may, from time to time, sell shares of common stock up to an aggregate offering price of $25.0 million. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under our shelf registration statement on Form S-3 filed on November 6, 2014, which was declared effective on January 20, 2015. There can be no

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assurance that Cantor will be successful in consummating sales under the program based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Cantor or we are permitted to terminate the controlled equity offering sales agreement, or sales agreement, at any time upon 10 days' prior written notice, and Cantor is also permitted to terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change in our company.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of December 31, 2014, the $8.5 million of the upfront cash payment received from the sale of our Sumavel DosePro business that is included in restricted cash, availability of funds under our revolving line of credit, our projected product revenues from Zohydro ER, the $5.0 million in remaining payments due for the exclusivity waiver granted to Purdue Pharma L.P. due by July 1, 2015, and our projected manufacturing and other service revenues will be sufficient to fund our operations through the third quarter of 2015. We may need to obtain additional funds to finance our operations beyond that point, or possibly earlier, in order to:

- maintain our sales and marketing activities for Zohydro ER;
- fund our operations and fund required FDA post-market studies of Zohydro ER and additional development activities with respect to Zohydro ER, including the development of Zohydro ER with abuse deterrent properties, as well as further development of ZX008 and Relday and development of any other product candidates to support potential regulatory approval; and
- commercialize Zohydro ER with abuse deterrent properties or any of our other product candidates, or any products or product candidates that we may develop, in-license or otherwise acquire, if any such product candidates receive regulatory approval.

In addition, our estimates of the amount of cash necessary to fund our business and development and commercialization activities may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the commercial success of Zohydro ER;
- the costs of maintaining our sales and marketing infrastructure or establishing distribution capabilities;
- the rate of progress and cost of our clinical trials and other product development programs for ZX008, Relday and our other product candidates and any other product candidates that we may develop, in-license or acquire;
- the timing of regulatory approval for any of our other product candidates and the commercial success of any approved products
- the receipt of contingent payments from the sale of our Sumavel DosePro business, which are based on the achievement of pre-determined sales and gross margin milestones by Endo Health Solutions Inc., or Endo;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Zohydro ER, our DosePro technology, ZX008, Relday and any of our other product candidates;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for any product candidate;
- the effect of competing technological and market developments; and
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the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

Until we can generate a sufficient amount of product revenue and cash flow from operations and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings, receivables financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product

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candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern.

Our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern.

In its report accompanying our audited consolidated financial statements for the year ended December 31, 2014, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations and negative cash flows from operating activities raise substantial doubt as to our ability to continue as a going concern. A “going concern” opinion could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans. Our ability to continue as a going concern will depend, in large part, on our ability to generate positive cash flow from operations and obtain additional financing, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations and may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment.

We are largely dependent on the commercial success of Zohydro ER, and although we have generated revenue from sales of Zohydro ER, it is still early in the commercialization process and we may never significantly increase these sales or become profitable.

Our ability to generate revenues and become profitable will depend in large part on the commercial success of Zohydro ER. We launched the commercial sale of Zohydro ER in the United States in March 2014 and expect to launch Zohydro ER with BeadTek in the second quarter of 2015. The commercial success of Zohydro ER depends on several factors, including our ability to:

- successfully launch and educate prescribers on Zohydro ER's efficacy and safety, as well as our safe use initiatives, through our own marketing and sales activities;
- create market demand for Zohydro ER through our own marketing and sales activities, and any other arrangements to promote this product that we may later establish;
- commercialize Zohydro ER with BeadTek and successfully develop and commercialize ZX007;
- establish and maintain adequate levels of coverage for Zohydro ER from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- maintain compliance with regulatory requirements;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- maintain commercial manufacturing arrangements with third-party manufacturers as necessary to meet commercial demand for Zohydro ER and manufacture commercial quantities at acceptable cost levels; and
- successfully maintain intellectual property protection for Zohydro ER.

If we are unable to successfully commercialize Zohydro ER, we may be unable to generate sufficient revenues to grow or sustain our business and we may never become profitable, and our business, financial condition and results of

operations will be materially adversely affected.

If Zohydro ER, Zohydro ER with BeadTek, ZX007, ZX008, Relday or any other product candidate for which we receive regulatory approval does not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate will be limited.

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The commercial success of Zohydro ER, Zohydro ER with BeadTek, ZX007, ZX008, Relday or any other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our approved product by third-party payors is also necessary for commercial success. The degree of market acceptance of Zohydro ER and any product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- acceptance by physicians and patients of the product as a safe and effective treatment;
- any negative publicity or political action related to our or our competitors' products;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- limitations or warnings contained in a product's FDA-approved labeling;
- the clinical indications for which a product is approved;
- in the case of Zohydro ER and product candidates that are controlled substances, the U.S. Drug Enforcement Administration, or DEA, scheduling classification;
- availability and perceived advantages of alternative treatments;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage and reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage.

For example, as part of its own initiatives to address the safety risks associated with opioid analgesics, in September 2013, the FDA announced class-wide safety labeling changes, including required new boxed warnings and new post-market study requirements for all extended-release, or ER, and long-acting, or LA, opioid analgesics intended to treat chronic pain. Because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, the FDA determined that this class of drugs should be reserved for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In addition, the FDA required the drug companies that make these drugs to work together to design and conduct further studies and clinical trials to assess the known serious risks of misuse, abuse, addiction, overdose and death , as well as evaluate the possibility of causing an increased sensitivity to pain (hyperalgesia) with chronic administration. The scope and design of these required additional studies and clinical trials are under development and the related cost is currently unknown, which could negatively affect our business. The FDA held a public meeting in May 2014 to obtain stakeholder input on the design and conduct of the post-marketing requirements for ER/LA opioid analgesic drug products and is using this input to provide feedback to the companies on these post marketing study requirements. We cannot predict how the results of these post-marketing required studies will affect the commercialization of Zohydro ER and future formulations of Zohydro ER with abuse deterrent properties.

Controlled substances are classified by the DEA as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. Zohydro ER contains hydrocodone and is regulated as a Schedule II controlled substance, and despite the strict regulations on the marketing, prescribing and dispensing of such substances, illicit use and abuse of hydrocodone, like all other opioid medications, is well-documented. Because the United States has had an epidemic of opioid abuse, misuse, and diversion for over a decade, the FDA approval and subsequent marketing of Zohydro ER did generate public controversy that adversely affected the market acceptance of Zohydro ER in 2014. Due to the concerns regarding abuse of opioids like Zohydro ER, we are developing formulations of Zohydro ER designed to have abuse deterrent properties. We filed an sNDA on September 30, 2014 for a next-generation formulation of Zohydro ER that is designed using safe, well-known excipients and proprietary manufacturing processes to create an inactive

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ingredient that immediately forms a viscous gel when crushed or dissolved in liquids or solvents. This formulation was approved by the FDA for marketing on January 30, 2015, and we anticipate a transition from the currently marketed product to this new capsule formulation of Zohydro ER in the second quarter of 2015, at which time this new formulation (Zohydro ER with BeadTek) will be available to prescribers.

Further, we are targeting an NDA submission for a proprietary tablet formulation of a single entity extended-release hydrocodone (ZX007) during the first half of 2016 which incorporates multiple features to maintain the extended-release property of the medication when crushed or chewed, reducing one of the ways in which opioids are abused through oral ingestion, as well other features to address abuse by injection or nasal administration.

Our efforts to educate the medical community and third-party payors on the benefits of Zohydro ER and formulations of Zohydro ER with abuse deterrent properties, ZX008, Relday or any of our other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors, pharmacists, and patients, we may not generate sufficient revenue from these products to become or remain profitable.

Negative publicity and political action regarding Zohydro ER could delay or impair our ability to market this product, present significant distractions to our management and result in the incurrence of significant costs.

Products used to treat and manage pain, especially in the case of opioids like Zohydro ER, are from time to time subject to negative publicity, including political influences, illegal use, overdoses, abuse, diversion, serious injury and death. In November 2013, eight members of Congress submitted a letter to Department of Health and Human Services Secretary, Kathleen Sebelius, urging reconsideration of the FDA's approval of Zohydro ER, and in December 2013, a bipartisan coalition of attorneys general from 29 states and territories submitted a letter to FDA Commissioner Margaret Hamburg with the same request. In April 2014, Purdue Pharma, L.P., or Purdue, announced that it filed an NDA for its extended-release hydrocodone product candidate that is formulated to incorporate abuse deterrent properties, which was accepted by the FDA in July 2014 for a priority review. On October 29, 2014, we entered into a mutual exclusivity waiver agreement with Purdue, pursuant to which we granted a waiver to Purdue, of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of the Purdue Products. In addition, Teva Pharmaceutical Industries Limited announced that the FDA has accepted their NDA submission as of February 2015. Approval of these product candidates or any abuse-deterrent formulation of hydrocodone may drive further negative publicity and political action, or even result in the FDA revoking its approval of our NDA for Zohydro ER. While we do not believe that the FDA will revoke its Zohydro ER approval, and, in any event, the FDA would have to provide us with notice and opportunity for a hearing first, the related negative publicity, political influences and actions by our competitors could negatively affect our ability to market Zohydro ER and any opioid analgesic product candidates for which we may seek approval in the future. If the FDA did revoke its approval of Zohydro ER, our business, results of operations, financial condition and prospects would be materially and adversely affected.

In addition, in March 2014, the Governor of the Commonwealth of Massachusetts issued an executive order to ban Zohydro ER in Massachusetts. In response, in April 2014 we filed a lawsuit in the U.S. District Court in Massachusetts requesting that the court preliminarily enjoin implementation of Governor Patrick's executive order prohibiting the prescribing and dispensing of Zohydro ER. The lawsuit asserted that the executive order was in direct conflict with the authority of the FDA to determine on behalf of the public whether a drug is safe and effective, and to impose the measures necessary to ensure that such drug will be used safely and appropriately. After the U.S. District Court in Massachusetts entered the requested preliminary injunction preventing the implementation of the Governor's order on constitutional grounds, the Commonwealth adopted emergency regulations which restricted distribution of Zohydro ER in Massachusetts. We challenged these emergency regulations as preempted by the FDA approval for Zohydro ER, and the U.S. District Court in Massachusetts on July 8 agreed that implementation of the emergency regulations also should be preliminarily enjoined. In the interim, Massachusetts has issued final regulations also imposing certain restrictions on distribution of Zohydro ER, and we have challenged these final regulations in the court proceeding. While we believe the FDA has the authority to determine on behalf of the public whether a drug is safe and effective and to impose the measures necessary to ensure that such drug will be used safely and appropriately,

and the U.S. District Court in Massachusetts has ruled in our favor, state officials in Massachusetts or elsewhere may nevertheless seek to place additional restrictions on the prescribing and use of Zohydro ER, which could negatively affect our ability to market Zohydro ER.

This negative publicity and political action could also cause a diversion of our management's time and attention, cause us to incur additional significant costs with respect to litigation, marketing or otherwise, and could also result in an increased number of product liability claims, whether or not these claims have a valid basis.

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Our short operating history makes it difficult to evaluate our business and prospects.

We commenced our operations on August 25, 2006. Our operations to date have been limited to organizing and staffing our company, scaling up manufacturing operations with our third-party contract manufacturers, building a sales and marketing organization, conducting product development activities for our products and product candidates, in-licensing rights to Zohydro ER and Relday, acquiring rights to ZX008 and commercializing Sumavel DosePro and Zohydro ER. In January 2010, we launched Sumavel DosePro and began generating revenues. We launched Zohydro ER in March 2014 and sold our Sumavel DosePro business in April 2014. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a longer history of developing and commercializing pharmaceutical products.

We depend on wholesale pharmaceutical distributors for retail distribution of Zohydro ER, and if we lose any of our significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our sales of Zohydro ER are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors, McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., individually comprised 33.0%, 32.0% and 23.0%, respectively, of our total ex-factory gross product sales of Zohydro ER for the year ended December 31, 2014. Sales to these wholesale pharmaceutical distributors may result in substantial fluctuations in our results of operations from period to period and the loss of any of these wholesale pharmaceutical distributors' accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. In addition, at times, wholesaler purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters, which may result in substantial fluctuations in our results of operations from period to period. We cannot assure you that we can manage these pricing pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

Our sales can be greatly affected by the inventory levels our wholesalers carry. We monitor wholesaler inventory of Zohydro ER using a combination of methods. Pursuant to distribution service agreements with our three largest wholesale customers, we receive inventory level reports. For most other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive production (requiring us to hold substantial quantities of unsold inventory), inadequate supplies of products in distribution channels, insufficient product available at the retail level, and unexpected increases or decreases in orders from our wholesalers. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or the expectations of securities analysts or investors. If our financial results are below expectations for a particular period, the market price of our common stock may drop significantly.

We face intense competition, including from generic products, and if our competitors market and/or develop treatments for Dravet syndrome, pain or psychiatric disorders that are marketed more effectively, approved more quickly than our product candidates or demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, including larger, well-established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than we do.

Zohydro ER competes against other marketed branded and generic pain therapeutics. Opioid therapeutics generally fall into two classes: immediate-release and extended-release/long acting opioids. Zohydro ER is an extended-release form of hydrocodone, the most commonly prescribed opioid in the United States, and Zohydro ER competes with

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therapeutics within the extended-release/long acting class. These therapeutics are all Schedule III products (meaning that they are considered controlled substances by the DEA) being marketed by companies such as Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, Mallinckrodt, Pfizer, Purdue, Teva Pharmaceutical Industries Limited, Depomed, Inc. and Actavis. On August 22, 2014, the DEA issued a final rule to reschedule all immediate-release hydrocodone combination products from Schedule III to Schedule II. The rescheduling went into effect on October 6, 2014 and requires previously classified Schedule III immediate-release hydrocodone combination products to comply with more restrictive regulatory requirements under Schedule II classification. Zohydro ER is already a Schedule II product.

Zohydro ER may also face competition from non-opioid product candidates including new chemical entities, as well as alternative delivery forms of non-steroidal anti-inflammatory drugs. These new opioid and non-opioid product candidates are being developed by companies such as Acura Pharmaceuticals, Inc., Collegium Pharmaceutical, Inc., Eli Lilly and Company, Elite Pharmaceuticals, Inc., Hospira Inc., Inspirion Delivery Technologies, LLC, Intellipharmaceutics International, Inc., Nektar Therapeutics, Pfizer and QRxPharma Ltd.

If approved for the chronic treatment of Dravet syndrome, ZX008 may compete against other product candidates. Epidiolex, which is being developed by GW Pharmaceuticals, has received an orphan designation by the European Medicines Agency, or EMA, and fast track status by the FDA for the treatment of Dravet syndrome. In October 2014, GW Pharmaceuticals initiated a Phase 2/3 clinical trial for Epidiolex, a cannabanoid drug. Insys Therapeutics has advanced its pharmaceutical cannabinoid program, which has received orphan drug designation and fast track status by the FDA for use of cannabidiol as a potential treatment for Dravet syndrome. Sage Therapeutics is developing its lead compound SAGE-547, an allosteric modulator of GABA receptors, for the acute treatment of super-refractory status epilepticus, which are acute prolonged seizures that can be associated with Dravet syndrome, as well as other seizure conditions.

If approved for the treatment of schizophrenia, we anticipate that Relday will compete against other marketed, branded and generic, typical and atypical antipsychotics, including both long-acting injectable and oral products. Currently marketed long-acting injectable atypical antipsychotic products include Risperdal Consta and Invega Sustenna marketed by Johnson & Johnson, Zyprexa Relprevv marketed by Eli Lilly & Company, and Abilify Maintena (apripiprazole) marketed by Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S. Currently approved and marketed oral atypical antipsychotics include Risperdal (risperidone) and Invega (paliperidone) marketed by Johnson & Johnson, generic risperidone, Zyprexa (olanzapine) marketed by Eli Lilly and Company, Seroquel (quetiapine) marketed by AstraZeneca plc, Abilify (aripiprazole) marketed by BMS/Otsuka Pharmaceutical Co., Ltd., Geodon (ziprasidone) marketed by Pfizer, Fanapt (iloperidone) marketed by Novartis AG, Saphris (asenapine) marketed by Merck & Co., Latuda (lurasidone) marketed by Dainippon Sumitomo Pharma, and generic clozapine. Finally, in addition to these currently marketed products, we may also face competition from additional long-acting injectable product candidates that could be developed by the large companies listed above, as well and by other pharmaceutical companies such as Alkermes, Endo Health Solutions Inc., Laboratorios Farmaceuticos Rovi SA, Novartis AG, and Reckitt Benckiser Group plc, each of which has announced they are developing long-acting antipsychotic product candidates. In May 2014, Janssen Pharmaceuticals, Inc., announced the submission of sNDAs for once-monthly atypical long-acting antipsychotic Invega Sustenna (paliperidone palmitate) to the FDA for approval to treat schizoaffective disorder as either monotherapy or adjunctive therapy.

We expect Zohydro ER and, if approved, ZX007, ZX008, Relday and any of our other product candidates to compete on the basis of, among other things, product efficacy and safety, time to market, price, patient reimbursement by third-party payors, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop injectable products, products to address chronic pain or other products that compete with ours, obtain necessary approvals for such products from the FDA, or other agencies, if required, more rapidly than we do or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us. The competition that we will encounter with respect to any of our product candidates that receive the requisite regulatory approval and classification and are marketed will have, and the competition we are currently encountering with Zohydro ER has had and will continue to have, an effect on our product prices, market share and results of operations. We may not be able to differentiate any products that we are able to market from those

of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

In addition, competitors may seek to develop alternative formulations of our product candidates and/or alternative drug delivery technologies that address our targeted indications. On August 13 and September 20, 2014, we received separate notices of paragraph IV certifications from Actavis Laboratories FL, Inc., or Actavis, and from Alvogen Pine Brook, Inc., or Alvogen, respectively, advising us of the filing of Abbreviated New Drug Applications, or ANDAs, with

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the FDA for a generic version of Zohydro ER. These certification notices allege that the two U.S. patents listed in the FDA's Orange Book for Zohydro ER, each with an expiration date in November 2019, will not be infringed by Actavis' or Alvogen's proposed products, are invalid and/or are unenforceable. On September 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Actavis, and on November 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Alvogen. Daravita has licensed rights to Zohydro ER to us, and, under the Zohydro ER license agreement, Daravita has the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation.

The commercial opportunity for Zohydro ER and our product candidates could be significantly harmed if competitors are able to develop alternative formulations and/or drug delivery technologies outside the scope of our products.

Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop drugs that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with Zohydro ER or any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. For example, in October 2014, we completed the acquisition of Brabant, which owns worldwide development and commercialization rights to ZX008 for the treatment of Dravet syndrome. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;

- write-downs of assets or goodwill or impairment charges;

- increased amortization expenses;

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- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Although we have been granted three-year Hatch-Waxman exclusivity for Zohydro ER, we have entered into a waiver agreement with Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of the Purdue Products and can offer no assurance that such exclusivity will effectively prevent or otherwise limit further competition from other hydrocodone products, either generic or otherwise.

In addition to patent protection, we rely, in part, on Hatch-Waxman marketing exclusivity for the commercialization of Zohydro ER in the United States. Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments, newly approved drugs may benefit from certain statutory periods of non-patent marketing exclusivity in the United States. Exclusivity provides the holder of an approved application limited protection from new competition in the marketplace for the innovation represented by its approved drug product.

A three-year period of exclusivity is available for a drug product that contains an active ingredient that has been previously approved and the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the applicant that were essential to approval of the application. Changes to an approved drug product that may qualify for this exclusivity include changes that affect the product’s active ingredient(s), strength, dosage form, route of administration, or conditions of use, so long as clinical investigations were essential to approval of the application containing those changes. The exclusivity prevents FDA from approving other applications for the same change for three years from the date of the new product’s approval.

While Zohydro ER has been granted three-year Hatch-Waxman exclusivity as the first single-entity hydrocodone product approved for the treatment of chronic pain on the basis of a comprehensive Phase 3 safety and efficacy program, there can be no assurance that such exclusivity will effectively prevent or otherwise limit competition from other hydrocodone products, either generic or otherwise. On October 29, 2014, we entered into a waiver agreement with Purdue, pursuant to which we granted a waiver to Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of the Purdue Products (as defined in the waiver agreement). On November 20, 2014, Purdue announced the FDA had approved its product Hysingla ER®. Such competition by the Purdue Products and other hydrocodone products, including other 505(b)(2) applications for different conditions of use or other changes to the hydrocodone products that would not be restricted by the three-year exclusivity, could have a significantly negative impact on our future revenues from Zohydro ER.

We are dependent on numerous third parties in our supply chain, all of which are currently single source suppliers, for the commercial supply of Sumavel DosePro and Zohydro ER and for the clinical supply of ZX008 and Relday, and if we experience problems with any of these suppliers, the manufacturing of Sumavel DosePro, Zohydro ER, ZX008 and Relday could be delayed.

While we own most of the specialized equipment used to manufacture critical components of Sumavel DosePro, we do not own or operate manufacturing facilities and currently lack the in-house capability to manufacture Sumavel DosePro, Zohydro ER, ZX008, Relday or any other product candidates. Our DosePro system and Sumavel DosePro are manufactured by contract manufacturers, component fabricators and secondary service providers. Aseptic fill, finish, assembly and packaging of Sumavel DosePro are performed at Patheon UK Limited, Swindon, United Kingdom, or Patheon, a specialist in the aseptic fill/finish of injectables and other sterile pharmaceutical products. In addition to Patheon's manufacturing services, Nypro Limited, located in Bray, Ireland, manufactures the actuator

assemblies and injection molded components for our DosePro system and Nipro Glass, Germany AG (formerly MGlas AG), located in Münnerstadt, Germany, manufactures the specialized glass capsule (cartridge) that houses the sumatriptan API in our DosePro system. Each of these manufacturers and each other company that supplies, fabricates or manufactures any component used in our DosePro system is currently the only qualified source of their respective components. We currently rely on Dr. Reddy's Laboratories as the only supplier of sumatriptan API for use in Sumavel DosePro. Daravita is the

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exclusive manufacturer and supplier (subject to certain exceptions) for Zohydro ER. We also outsource all manufacturing and packaging of the clinical trial materials for ZX008 and Relday to third parties.

Although we plan to qualify additional manufacturers and suppliers of some of the components used in Sumavel DosePro, there can be no assurance that we will be able to do so and the current manufacturers and suppliers of these components will likely be single source suppliers to us for a significant period of time. Similarly, Daravita is the exclusive manufacturer of Zohydro ER and Durect is the exclusive manufacturer of the risperidone formulation using Durect's SABER™ controlled-release technology for all Relday clinical trials through Phase 2 and has the option to supply the same formulation for Phase 3 clinical trials and, if approved, commercial production. ZX008, if approved, would require a technology transfer to an alternate source to establish commercial supply capabilities, for which there can be no assurance of a successful transfer and validation. We have restrictions on establishing a second source of supply under our agreement with Daravita, and we may never be able to establish additional sources of supply for Zohydro ER, ZX008 or Relday's risperidone formulation.

Manufacturers and suppliers are subject to regulatory requirements covering, among other things, manufacturing, testing, quality control and record keeping relating to our products and product candidates, and are subject to ongoing inspections by regulatory agencies. Failure by any of our manufacturers or suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing supply, and increase our costs, while we seek to secure another supplier who meets all regulatory requirements, including obtaining regulatory approval to utilize the new manufacturer or supplier. Accordingly, the loss of any of our current third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition and prospects.

Reliance on third-party manufacturers and suppliers entails risks to which we would not be subject if we manufactured Sumavel DosePro, Zohydro ER or our product candidates ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- the possibility of termination or non-renewal of the agreements by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

Production capacity to support launch and initial forecast demand for Zohydro ER is installed and has received final packaging qualification. In order to meet future anticipated growth in demand for Zohydro ER, Daravita has initiated activities to qualify additional production lines and expand the manufacturing capacity for Zohydro ER. However, if Daravita or our other contract manufacturers or suppliers are unable to deliver the required commercial quantities of our products and their various components, the quantities of our product candidates required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our products, product candidates and components and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our product candidates, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully.

Our product candidates are subject to extensive regulation, and we cannot give any assurance that any of our product candidates will receive regulatory approval or be successfully commercialized.

We currently are developing ZX007, an abuse deterrent tablet formulation of single entity, extended-release hydrocodone, ZX008 for the treatment of Dravet syndrome, and Relday for the treatment of the symptoms of schizophrenia. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug

products, among other things, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market ZX007, ZX008, Relday or any of our other product candidates in the United States unless and until we receive regulatory approval from the FDA. We cannot provide any assurance that we will obtain regulatory

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approval for any of our product candidates, or that any such product candidates will be successfully commercialized. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, as renewed in 2012 by the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA is subject to a two-tiered system of review times for new drugs: standard review and priority review. For drugs subject to standard review that do not contain a new molecular entity, such as Relday, the FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. The review process and the PDUFA target action date may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission. The FDA's review goals are subject to change, and the duration of the FDA's review may depend on the number and type of other NDAs that are submitted to the FDA around the same time period.

The FDA may also refer applications for novel products or products which 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. Although the FDA is not bound by the recommendation of an advisory committee, the matters discussed at the advisory committee meeting, and in particular any concerns regarding safety, could limit our ability to successfully commercialize our product candidates subject to advisory committee review.

As part of its review of an NDA, the FDA may inspect the facility or facilities where the drug is manufactured. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA will issue an action letter, which will be either an approval letter, authorizing commercial marketing of the drug for a specified indication, or a Complete Response Letter containing the conditions that must be met in order to secure approval of the NDA. These conditions may include deficiencies identified in connection with the FDA's evaluation of the NDA submission or the clinical and manufacturing procedures and facilities. Until any such conditions or deficiencies have been resolved, the FDA may refuse to approve the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

• the FDA may not deem a product candidate safe and effective;
• the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval;
• the FDA may require additional pre-clinical studies or clinical trials;
• the FDA may not approve of our third-party manufacturers' processes and facilities; or
• the FDA may change its approval policies or adopt new regulations.

Product candidates such as ZX007, ZX008, and Relday and any of our other product candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a REMS, which limits the labeling, distribution or promotion of a drug product. For example, the approval of our NDA for Zohydro ER was associated with post-market study and REMS requirements due to the risks of misuse, abuse, addiction, overdose and death associated with the active ingredient hydrocodone.

ZX007, ZX008, Relday and any of our other product candidates may not achieve their specified endpoints in clinical trials. The safety and effectiveness of ZX008 has been evaluated in a continuing, long-term, open-label, study in 15 Dravet syndrome patients at a single academic medical center site in Belgium. Based upon feedback from the FDA and the EMA we expect to initiate two Phase 3 studies (of 40 to 60 Dravet syndrome patients per study) during the third quarter of 2015 in the United States and Europe, with top-line results potentially available in the first half of 2016. We initiated a Phase 1 safety and pharmacokinetic clinical trial for Relday in July 2012 and announced positive single-dose pharmacokinetic results from this trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, we

extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation and announced positive top-line results from

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the extended Phase 1 clinical trial in May 2013. The positive results from this study extension positioned us to begin a multi-dose clinical trial, which will provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. We started this multi-dose clinical trial in the first half of 2015 with top-line results potentially available in the second half of 2015.

If we are unable to obtain regulatory approval for ZX007, ZX008, Relday or any other product candidates on the timeline we anticipate, we may not be able to execute our business strategy effectively and our ability to generate additional revenues beyond Zohydro ER may be limited.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for ZX007, ZX008, Relday or any of our other product candidates, which could prevent or significantly delay their regulatory approval.

ZX007, ZX008, Relday and any of our other product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for the commercial sale of ZX008, Relday or any other product candidate, we must gather substantial evidence from well-controlled clinical trials that demonstrate to the satisfaction of the FDA that the product candidate is safe and effective, and similar regulatory approvals would be necessary to commercialize our product candidates in other countries.

In light of widely publicized events concerning the safety risk of certain drug products, particularly opioid drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval.

The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of our clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in a delay or failure in obtaining approval or approval for a more limited indication than originally sought. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If ZX007, ZX008, Relday or any of our other product candidates are not shown to be safe and effective in clinical trials, the programs could be delayed or terminated, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Delays in the commencement or completion of clinical testing for ZX007, ZX008, Relday or pre-clinical or clinical testing for any of our other product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval for, or generate revenues from, such product candidates.

Clinical trials are very expensive, time consuming and difficult to design and implement. Delays in the commencement or completion of clinical testing for ZX007, ZX008, Relday or pre-clinical or clinical testing for any of our other product candidates could significantly affect our product development costs and business plan.

The safety and effectiveness of ZX008 has been evaluated in a continuing, long-term, open-label, study in 15 Dravet syndrome patients. Based upon feedback from the FDA and the EMA, we expect to initiate two Phase 3 studies (of 40 to 60 Dravet syndrome patients per study) during the third quarter of 2015 in the United States and Europe, with top-line results potentially available in the first half of 2016. We do not know whether any of our other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all.

We initiated clinical testing for Relday in patients with schizophrenia in July 2012 and announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial in January 2013. Based on the favorable safety and pharmacokinetic profile demonstrated in the Phase 1 trial, we extended the study to include an additional dose of the same formulation and announced positive top-line results in May 2013. The results for the extended Phase 1 clinical trial showed risperidone blood concentrations in the therapeutic range were achieved on the first day of dosing and maintained throughout the one-month period. In addition, dose proportionality was demonstrated across the full dose range studied. In February 2015, we began a multi-dose clinical trial, which we believe will provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies.

The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

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- obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical investigators and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical investigators and trial sites;
- manufacturing or obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining IRB approval to initiate and conduct a clinical trial at a prospective site;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of similar indications;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues, or for any other reason they choose, or who are lost to further follow-up;
- uncertainty regarding proper dosing; and
- scheduling conflicts with participating clinicians and clinical institutions.

In addition, if a significant number of patients fail to stay enrolled in any of our current or future clinical trials of ZX008, Relday or any of our other product candidates and such failure is not adequately accounted for in our trial design and enrollment assumptions, our clinical development program could be delayed. Clinical trials may also be delayed or repeated as a result of ambiguous or negative interim results or unforeseen complications in testing. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- inability to design appropriate clinical trial protocols;
- inability by us, our employees, our CROs or their employees to conduct the clinical trial in accordance with all applicable FDA, DEA or other regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other unforeseen safety issues;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- lack of effectiveness of any product candidate during clinical trials;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
-

inability of our CROs or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;

- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unfavorable results from on-going clinical trials and pre-clinical studies.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience

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delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for ZX008, Relday and our other product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

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

We conducted prior clinical trials under agreements with third-party CROs, and we anticipate that we may enter into agreements with third-party CROs in the future regarding ZX008, Relday or any of our other product candidates. We rely heavily on these parties for the execution of our clinical and pre-clinical studies, 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 regulatory requirements. We and our CROs are required to comply with current GCP. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA and similar foreign regulators will determine that any of our clinical trials comply or complied with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and require a large number of test subjects. Our inability to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. 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 or that these delays or challenges will not have a material adverse impact on our business, results of operations, financial condition and prospects.

Our inability to successfully establish new partnerships with pharmaceutical companies or contract sales organizations to co-promote Zohydro ER and any additional product candidates that may receive regulatory approval may impair our ability to effectively market and sell such product candidates.

Major pharmaceutical companies usually employ groups of sales representatives numbering in the thousands to call on the large number of primary care physicians. Our sales and marketing organization, which as of December 31, 2014 was comprised of approximately 149 personnel, promotes Zohydro ER in the United States, primarily targeting pain specialists. We may seek a co-promotion or other partnering opportunity for Zohydro ER, or may further expand our sales force.

In addition, in order to promote any product candidates that receive regulatory approval, we may need to further expand our sales and marketing personnel and commercial infrastructure and/or establish partnerships with pharmaceutical companies or contract sales organizations to co-promote such additional products. We currently, and on an ongoing basis will have to, compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We also face competition in our search for collaborators and potential co-promoters. To the extent we rely on additional third parties to co-promote or otherwise commercialize any products and/or product candidates that may receive regulatory approval, we are likely to receive less revenue than if we commercialized these products ourselves. Further, by entering into strategic partnerships or similar arrangements, we

may rely in part on such third parties for financial and commercialization resources. Even if we are able to identify suitable partners to assist in the commercialization of our products and/or product candidates, they may be unable to devote the resources necessary to realize the full commercial potential of our products.

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Further, we may lack the financial and managerial resources to maintain and potentially increase the size of our sales and marketing organization to adequately promote and commercialize Zohydro ER and any product candidates that may be approved. Any increase in our sales force will result in an increase in our expenses, which could be significant before we generate revenues from any newly approved product candidate. Even though we were able to recently expand our sales and marketing personnel, and may be successful in establishing future partnership arrangements, such sales force and marketing teams may not be successful in commercializing our products, which would adversely affect our ability to generate revenue for such products, and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may encounter delays in the manufacturing of Sumavel DosePro or fail to generate contract manufacturing revenue if our supply of the components of our DosePro drug delivery system is interrupted .

Our DosePro drug delivery system is sourced, manufactured and assembled by multiple third parties across different geographic locations in Europe, including the United Kingdom, Germany and Ireland. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the DosePro system. The components of DosePro include the actuator subassembly, capsule subassembly and the setting mechanism. The actuator subassembly is comprised of nine individual components which are collectively supplied by six different third-party manufacturers. The capsule subassembly that houses the sterile drug formulation sumatriptan is comprised of five different components also supplied by four third-party manufacturers. Each of these third-party manufacturers is currently the single source of their respective components. If any of these manufacturers is unable to supply its respective component for any reason, including due to violations of the FDA's QSR requirements, our ability to manufacture the finished DosePro system will be adversely affected and our ability to meet the distribution requirements for any Sumavel DosePro purchase orders from Endo and the resulting contract manufacturing revenue therefrom will be negatively affected. Accordingly, there can be no assurance that any failure in any part of our supply chain will not have a material adverse effect on our ability to generate contract manufacturing revenue from Sumavel DosePro or our ability to generate revenue from any potential future DosePro products, which in turn could have a material adverse effect on our business, results of operations, financial condition and prospects.

We rely on third parties to perform many necessary services for our commercial products, including services related to the distribution, invoicing, storage and transportation of our products, as well as the performance of services to support our safe use initiatives for Zohydro ER.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which are out of our direct control. For example, we rely on Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services) to provide key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management, and, as a result, most of our inventory is stored at a single warehouse maintained by the service provider. We also rely on Inmar Inc. to process our product returns. We place substantial reliance on these providers as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers are unable to comply with applicable laws and regulations, are unable to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired.

In addition, we utilize other third parties to perform various other services for us relating to drug safety monitoring and surveillance, sample accountability and regulatory monitoring, including adverse event reporting, education regarding the safe use of our products, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

We may not realize the full economic benefit from the sale of our Sumavel DosePro business.

Pursuant to the asset purchase agreement with Endo that we entered into in April 2014, or the asset purchase agreement, in addition to the $89.6 million upfront cash payment, we may receive contingent payments, based on Endo's achievement of pre-determined sales and gross margin milestones, in an amount up to $20.0 million. Our ability to receive these contingent payments under our supply agreement with Endo is dependent upon Endo successfully maintaining and increasing market demand for, and sales of, Sumavel DosePro.

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In addition, we have agreed to indemnify Endo and its affiliates against losses suffered as a result of our material breach of representations and warranties and our other obligations in the asset purchase agreement, and $8.5 million of the upfront cash payment has been deposited into escrow to fund such potential indemnification claims for a period of 12 months following the closing of the sale, which period will end in May 2015. We cannot provide any assurance that we will receive all or any portion of the $8.5 million escrow amount or any of the contingent milestone payments.

If we are unable to attract and retain key personnel, we may not be able to manage our business effectively or develop our product candidates or commercialize our products.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and key clinical development, regulatory, sales and marketing and other personnel. As of December 31, 2014, we employed 201 full-time employees. Of the full-time employees, 149 were engaged in sales and marketing, nine were engaged in manufacturing operations, 22 were engaged in product development, quality assurance and clinical and regulatory activities and 21 were engaged in general and administrative activities (including business and corporate development). If we are not able to retain our expanded employee base, we may not be able to effectively manage our business or be successful in commercializing our products.

We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management team. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the areas in Southern and Northern California, where we currently operate. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital, our ability to implement our business strategy and our ability to maintain effective internal controls for financial reporting and disclosure controls and procedures as required by the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. The loss of the services of any members of our senior management team, especially our Chief Executive Officer, Roger L. Hawley, and President, Stephen J. Farr, Ph.D., could negatively impact the commercialization of Zohydro ER and could delay or prevent the development and commercialization of any of our product candidates, including ZX007, ZX008 and Relday. Further, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business may be harmed as a result. In addition to the competition for personnel, our locations in California in particular are characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Although we have employment agreements with each of our executive officers, these agreements are terminable by them at will at any time with or without notice and, therefore, do not provide any assurance that we will be able to retain their services. We do not maintain “key man” insurance policies on the lives of our senior management team or the lives of any of our other employees. In addition, we have clinical advisors who assist us in formulating our clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. If we are unable to attract and retain key personnel, our business, results of operations, financial condition and prospects will be adversely affected.

The implementation of a REMS for Zohydro ER has resulted in additional regulatory requirements, including the requirement for a Medication Guide and educational requirements for prescribers and patients, which could significantly impact our ability to commercialize Zohydro ER and dramatically reduce its market potential.

The Food and Drug Administration Amendments Act added Section 505-1 to the FFDCA. Section 505-1 permits FDA to require a REMS for a drug product to ensure the safe use of the drug. A REMS is a strategic safety program that the FDA requires to ensure that the benefits of a drug outweigh its risks. In determining whether a REMS is necessary, the FDA will 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 health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy minimally at 18 months, three years and seven years after the strategy's approval.

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In February 2009, the FDA informed opioid analgesic drug manufacturers that it would require a class-wide REMS for all long-acting and sustained-release opioid drug products, and as an extended-release formulation of hydrocodone, Zohydro ER became subject to the ER/LA opioid REMS upon approval. Pursuant to the FFDCA, the manufacturers subject to this class-wide REMS must work together to implement the REMS as part of a single shared system to reduce the burden of the REMS on the healthcare system. The central component of the ER/LA opioid REMS program is an education program for prescribers and patients. Specifically, the REMS for these products includes a Medication Guide available for distribution to patients who are dispensed the drug, as well as a number of elements to assure safe use. These elements include training for healthcare professionals who prescribe the drug; information provided to prescribers that they can use to educate patients in the safe use, storage, and disposal of opioids; and information provided to prescribers of the existence of the REMS and the need to successfully complete the necessary training. The prescriber training required as part of the REMS is conducted by accredited, independent continuing education providers, without cost to the healthcare professionals, under unrestricted grants funded by the opioid analgesic manufacturers. Moreover, REMS assessments must be submitted to the FDA on an annual basis to assess the extent to which the elements to assure safe use are meeting the goals of the REMS and whether the goals or elements should be modified.

In addition to the REMS, on September 10, 2013 the FDA announced post-marketing requirements for all ER/LA opioid analgesic NDA holders, which we are required to comply with. We are currently participating with eight other NDA holders to address these post-marketing requirements. These requirements and the REMS could significantly impact our ability to commercialize Zohydro ER and dramatically reduce its market potential.

Our inability to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We intend to in-license, acquire, develop and/or market additional products and product candidates in the area of CNS disorders. Because our internal research and development capabilities are limited, we may be dependent upon other pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including pre-clinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

Additionally, as part of our growth strategy, we intend to seek to expand our product pipeline by exploring acquisition or in-licensing opportunities of proven drugs that can be paired with our DosePro needle-free drug delivery system. If we are not able to identify additional drug compounds that can be delivered via the current version of our DosePro technology, or if we are unable to successfully develop higher dose versions of this technology, our ability to develop additional product candidates and grow our business would be adversely affected. We and Battelle, our technology co-marketing partner, are also seeking opportunities to out-license the DosePro technology to partners seeking to enhance, differentiate, or extend the life-cycle of their injectable products. However, there can be no assurance that our or Battelle's efforts to secure such a partnership will be successful. If we are unable to secure partnerships with companies that have compounds that can be delivered via the current version of our DosePro technology, or if we are

unable to successfully develop higher dose versions of this technology, we will not be able to generate revenues from out-licensing our DosePro technology.

If we are unable to license or acquire additional product candidates or approved products and successfully develop and commercialize them, or if we are otherwise unable to pair our DosePro delivery system with other drugs or out-license the DosePro technology to others, it may have a material adverse effect on our business, results of operations,

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financial condition and prospects.

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

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, we have in the past experienced failures in our information systems and computer servers, which may have been the result of a cyber-attack. These failures resulted in an interruption of our normal business operations and required substantial expenditure of financial and administrative resources to remedy. We cannot be sure that similar failures will not occur in the future. System failures, accidents or security breaches can cause interruptions in our operations, and can result in a material disruption of our commercialization activities, drug development programs and our business operations. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval and post-market study compliance efforts and significantly increase our costs to recover or reproduce the data. Similarly, we rely on a large number of third parties to supply components for and manufacture our products and product candidates, warehouse and distribute Zohydro ER, and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 and the commercialization of Zohydro ER and development of ZX008, Relday or any of our other product candidates could be delayed.

Fluctuations in the value of the Euro or U.K. pound sterling could negatively impact our results of operations and increase our costs.

Payments to our material suppliers and contract manufacturers are denominated in the Euro and U.K. pound sterling. Our reporting currency is the U.S. dollar and to date all of the revenues we have generated have been in U.S. dollars. For the year ended December 31, 2014, $ 20.4 million (based on exchange rates as of December 31, 2014) of our materials, contract manufacturing costs and other manufacturing-related costs were denominated in foreign currencies. As a result, we are exposed to foreign exchange risk, and our results of operations may be negatively impacted by fluctuations in the exchange rate between the U.S. dollar and the Euro or U.K. pound sterling. A significant appreciation in the Euro or U.K. pound sterling relative to the U.S. dollar will result in higher expenses and cause increases in our net losses. 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 results of operations. We currently have not entered into any foreign currency hedging contracts to reduce the effect of changes in foreign currency exchange rates, and foreign currency hedging is inherently risky and may result in unanticipated losses.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for Zohydro ER or any of our other product candidates for which we may receive regulatory approval on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. For example, in August

2014, Express Scripts added Zohydro ER to its list of excluded drugs for their National Preferred Drug formulary for 2015. Express Scripts is the largest U.S. pharmacy benefit manager, and the inclusion of Zohydro ER on its list of excluded drugs for their National Preferred Drug formulary may have a negative impact on prescriptions and sales of Zohydro ER.

In addition, regional healthcare authorities and individual hospitals are increasingly using competitive bidding

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procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for Zohydro ER or any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

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 regulated by the FDA, such as the case with Zohydro ER, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Zohydro ER or our product candidates could result in injury to a patient or even death. For example, Zohydro ER is an opioid pain reliever that contains hydrocodone, which is a regulated "controlled substance" under the Controlled Substances Act of 1970, or CSA, and could result in harm to patients relating to its potential for abuse. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury.

Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our products or product candidates;
- decreased demand for our products or, if approved, product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $20 million per occurrence and annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on sales of Zohydro ER, approval of ZX007, ZX008, or Relday, or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of Zohydro ER and our product candidates. A successful product liability claim or series of claims brought against us could cause our stock

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price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

We may never receive regulatory approval or commercialize our product candidates outside of the United States.

We intend to market certain of our product candidates outside of the United States. For example, ZX008 has recently received orphan drug designation in Europe, and we expect to initiate two Phase 3 studies during the third quarter of 2015, one in the United States and one in Europe. In order to market our products outside of the United States, we, or any potential partner, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these “Risk Factors” regarding FDA approval in the United States, as well as other risks. For example, in the European Economic Area (comprised of 27 European Union, or EU, member states plus Iceland, Liechtenstein, and Norway), we can take advantage of the hybrid application pathway of the EU Centralized Procedure, which is similar to the FDA’s 505(b)(2) pathway. Hybrid applications may rely in part on the results of pre-clinical tests and clinical trials contained in the authorization dossier of the reference product, but must be supplemented with additional data. In territories where data is not freely available, we or our partners may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. We, or any potential partner, may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety effectiveness dossiers. 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 have a negative effect on the regulatory process in others.

Inability to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed in these “Risk Factors” regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved at all or for all requested indications, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly, post-marketing studies. In addition, we, or any potential partner, may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we are unable to comply with applicable foreign regulatory requirements.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. In particular, as part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks require our most subjective and complex judgment due to the need to make estimates about matters that are

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inherently uncertain. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Changes in accounting standards and their interpretations could adversely affect our operating results.

GAAP are subject to interpretation by the Financial Accounting Standards Board, the American Institute of Certified Public Accountants, the SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

Risks Related to Our Financial Position and Capital Requirements

We have never generated net income from operations or positive cash flow from operations and are dependent upon external sources of financing to fund our business and development.

We launched our first approved product, Sumavel DosePro, in January 2010 and subsequently sold the business in April 2014. We launched our approved product, Zohydro ER, in March 2014. Given our limited sales history for Zohydro ER, we may not accurately predict future sales, and we may never be able to significantly increase sales. We have financed our operations primarily through the proceeds from the issuance of our common and preferred stock, including the proceeds from our initial public offering completed in November 2010, our follow-on public offerings completed in September 2011, July 2012 and November 2013, our controlled equity offering program, which was terminated in November 2013, and debt, and have incurred losses and negative cash flow from operations in each year since our inception. For the years ended December 31, 2014, 2013 and 2012, we incurred net income (loss) of $8.6 million, $(80.9) million and $(47.4) million, respectively, and our cash used in operating activities was $(80.8) million, $(44.9) million and $(52.2) million, respectively. As of December 31, 2014, we had an accumulated deficit of $(401.7) million. These losses and negative cash flow from operations have had a material adverse effect on our stockholders' equity and working capital.

We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of the expenses incurred in connection with the commercialization of Zohydro ER, including introduction of Zohydro ER with BeadTek to the market, the clinical development of ZX008 and Relday, required post-market testing for Zohydro ER, safe use initiatives for Zohydro ER and additional development activities with respect to Zohydro ER, including the development of ZX007, an additional formulation with abuse deterrent properties. As a result, we may remain dependent upon external sources of financing to fund our business and the development and commercialization of our approved products and product candidates. To the extent we need to raise additional capital in the future, we cannot ensure that debt or equity financing will be available to us in amounts, at times or on terms that will be acceptable to us, or at all. Any shortfall in our cash resources could require that we delay or abandon certain development and commercialization activities and could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to sell shares of our common stock under our controlled equity offering program with Cantor at times, prices or quantities that we desire, and if such sales do occur, they may result in dilution to our existing stockholders.

On November 6, 2014, we entered into the sales agreement with Cantor. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under our shelf registration statement on Form S-3 filed on November 6, 2014, which was declared effective on January 20, 2015. Under the terms of the sales agreement, Cantor will use its commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Global Market, to sell shares of our common stock designated by us. However, there can be no assurance that Cantor will be successful in consummating such sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. In addition, we will not be able to make sales of our common stock pursuant to the sales agreement unless certain conditions are met, which include accuracy of representations and warranties made to Cantor under the sales agreement; compliance with laws; and the continued listing of our stock on the Nasdaq Global Market.

In addition, Cantor is permitted to terminate the sales agreement at any time. If we are unable to access funds through sales under the sales agreement, or it is terminated by Cantor, we may be unable to access capital on favorable terms or at all.

To the extent that we sell shares pursuant to the sales agreement, it will dilute the holdings of our existing stockholders, and may result in downward pressure on the price of our common stock. If we sell shares under the sales agreement at a time when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was

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higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may need to raise additional funds through public or private equity offerings, including through our controlled equity offering program with Cantor, debt financings, receivables or royalty financings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership interest in us will be diluted. Debt financing typically contains covenants that restrict operating activities.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current product or product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the commercialization and development of our product or product candidates.

Our ability to utilize our net operating loss and research and development income tax credit carryforwards may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, substantial changes in our ownership may limit the amount of net operating loss and research and development income tax credit carryforwards (collectively, tax attributes) that could be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period as determined under the IRC, which we refer to as an ownership change. Any such annual limitation may significantly reduce the utilization of these tax attributes before they expire. Prior to our initial public offering in November 2010, we performed an IRC Section 382 and 383 analysis and determined that we had one ownership change, which occurred in August 2006 upon the issuance of convertible preferred stock. We performed an additional IRC Section 382 and 383 analysis upon the issuance of common stock in our follow-on public offering in September 2011, and together with the issuance of common stock in our initial public offering and certain other transactions involving our common stock, resulted in an additional ownership change. We had a third ownership change as defined by IRC Sections 382 and 383, which occurred in January 2014. There was no forfeiture in federal and California net operating loss carryforwards or research and development income tax credits as a result of the third ownership change. As a result of these ownership changes, our ability to use our then existing tax attributes to offset future taxable income, if any, was limited. Any future equity financing transactions, private placements and other transactions that occur within the specified three-year period may trigger additional ownership changes, which could further limit our use of such tax attributes. Any such limitations, whether as the result of prior or future offerings of our common stock or sales of common stock by our existing stockholders, could have an adverse effect on our consolidated results of operations in future years.

The terms of our credit facility place restrictions on our operating and financial flexibility.

Effective as of December 30, 2014, we entered into a loan and security agreement, or the credit facility, with Oxford as collateral agent, and the lenders party thereto from time to time, or the lenders, including Oxford and SVB, that is

secured by substantially all of our personal property other than our intellectual property. The outstanding principal balance under the credit facility was $21.5 million at the closing of the loan and security agreement on December 30, 2014.

The credit facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements

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regarding accounts receivable. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000, one or more judgments against us in an amount greater than $400,000 individually or in the aggregate and any action by the FDA that limits or prohibits our ability to sell or market Zohydro ER.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so 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.

Risks Related to Regulation of our Product and Product Candidates

Annual DEA quotas on the amount of hydrocodone allowed to be produced in the United States and our specific allocation of hydrocodone by the DEA could significantly limit the production or sale of Zohydro ER.

The DEA limits the production and availability of all Schedule II substances through a quota system which includes a national aggregate production quota and individual procurement quotas. Because hydrocodone is subject to the DEA's production and procurement quota scheme, the DEA establishes annually an aggregate production quota for how much hydrocodone 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. This limited aggregate amount of hydrocodone 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. The DEA may adjust individual procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning procurement quotas to manufacturers and research organizations. Daravita which has licensed us the right to sell Zohydro ER in the United States, has been granted sufficient procurement quota of hydrocodone by the DEA to support our current demand of Zohydro ER and expected growth through the end of 2015.

We do not know what amounts of hydrocodone other companies manufacturing or developing product candidates containing hydrocodone may request for future years. The DEA, in assessing factors such as medical need, abuse and diversion potential and other policy considerations, may choose to set the aggregate hydrocodone production quota lower than the total amount requested for procurement by the companies. Daravita is permitted to petition the DEA to increase the annual procurement quota after it is initially established, but there is no guarantee that the DEA would act favorably upon such a petition. Daravita's procurement quota of hydrocodone may not be sufficient to meet any future clinical development needs or commercial demand for Zohydro ER. Any delay or refusal by the DEA in establishing the procurement quota or a reduction in Daravita’s procurement quota for hydrocodone or the DEA's failure to increase it over time as we anticipate could delay or stop commercial sale of Zohydro ER or cause us not to achieve our expected operating results, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to maintain orphan drug designation or obtain or maintain orphan drug exclusivity for ZX008.

We have obtained orphan drug designation for ZX008 in the United States and Europe. In the United States, under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or

condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Orphan drug designation in the United States confers certain benefits, including tax incentives and waiver of the applicable application fee upon submission of the product for approval in the rare disease or condition.

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If a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is generally entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same drug to treat the same rare disease or condition for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The orphan drug exclusivity may not effectively protect the product from competition in the United States because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA and EMA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Our currently approved product Zohydro ER is, and any of our other product candidates that receive regulatory approval will be, subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after we achieve U.S. regulatory approval for a product, the FDA may still 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, or the implementation of a REMS program. The Zohydro ER approval requires us to conduct post-marketing studies and implement the ER/LA opioid class-wide REMS with respect to our product. We are also subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with cGMP for our marketed and investigational products, and with GCP and GLP requirements, 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 the case of Zohydro ER and any product candidates containing controlled substances, we and our contract manufacturers will also be subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. In addition, 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 regulations, QSR requirements for medical device components or similar requirements, if applicable. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we, our products or product candidates or the manufacturing facilities for our products or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

• impose restrictions on the marketing or manufacturing of a product, suspend or withdraw product approvals or revoke necessary licenses;

• issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;

• commence criminal investigations and prosecutions;

• impose injunctions, suspensions or revocations of necessary approvals or other licenses;

• impose fines or other civil or criminal penalties;
• suspend any ongoing clinical trials;
• deny or reduce quota allotments for the raw material for commercial production of our controlled substance

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products;
• delay or refuse to approve pending applications or supplements to approved applications filed by us;
• refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
• suspend or impose restrictions on operations, including costly new manufacturing requirements; or
• seize or detain products or require us to initiate a product recall.

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 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.

The FDA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For example, the FDASIA requires the FDA to issue new guidance describing its policy regarding internet and social media promotion of regulated medical products, and the FDA has since released several draft guidance documents enumerating new regulatory obligations and restrictions with respect to this type of promotion. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our drugs, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Zohydro ER, ZX007, ZX008, Relday and our other product candidates may cause undesirable side effects or have other unexpected properties that could result in post-approval regulatory action.

If we or others identify undesirable side effects, or other previously unknown problems, caused by our products, other products or our product candidates with the same or related active ingredients, after obtaining U.S. regulatory approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require us to recall the product;
- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- we may be required to have a REMS program;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

The incidence of adverse events was 33.7% and 28.8% in the open label titration and double blind treatment periods of our Phase 3 efficacy trial for Zohydro ER, respectively. Overall, the most commonly reported adverse events (>2%) in this trial were constipation, nausea, somnolence, vomiting, diarrhea, insomnia, fatigue, headache, dizziness and dry mouth. These are typical adverse events associated with chronic opioid therapy.

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Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates.

Our development strategy for Relday depends upon the FDA's prior findings of safety and effectiveness of risperidone based on data not developed by us, but which the FDA may rely upon in reviewing any future NDA.

The Hatch-Waxman Amendments added Section 505(b)(2) to the FFDCA. 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. Under this statutory provision, the FDA may rely, for purposes of approving an NDA, on safety and effectiveness data not developed by the filer of the NDA. Similar to Zohydro ER, we plan to submit an NDA for Relday under Section 505(b)(2), and as such, the NDA will rely, in part, on the FDA's previous findings of safety and effectiveness for risperidone. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for Relday, the FDA may require us, and did require us with respect to Zohydro ER, to perform additional studies or measurements to support approval. In addition, the FDA's interpretation and use of Section 505(b)(2) has been controversial and has previously been challenged in court, but without a definitive ruling on the propriety of the FDA's approach. Future challenges, including a direct challenge to the approval of our products and product candidates, may be possible and, if successful, could limit or eliminate our ability to rely on the Section 505(b)(2) pathway for the approval of Relday and our other product candidates. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of Relday and our other product candidates, such as ZX008.

Zohydro ER is a controlled substance subject to DEA regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may adversely affect our business.

Zohydro ER contains hydrocodone, a regulated "controlled substance" under the CSA, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Zohydro ER, because it is a hydrocodone product, is regulated by the DEA as a Schedule II controlled substance under the CSA. All Schedule II substance prescriptions, such as prescriptions for Zohydro ER, must be in writing and signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical products are subject to a high degree of regulation, including security, record-keeping and reporting obligations enforced by the DEA. Our failure to comply with these requirements could result in the loss of our ability to supply Zohydro ER, significant restrictions on Zohydro ER, civil penalties or criminal prosecution.

The DEA, and some states, also conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and

distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

The FDA, in conjunction with the DEA, required us to implement a comprehensive REMS containing the elements of the class-wide ER/LA opioid REMS to reduce the inappropriate use of Zohydro ER, including restrictions on the manner in which it is marketed and sold, so as to reduce the risk of improper patient selection and diversion or abuse of the product. The restrictions of this program could limit market acceptance of the product.

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Pursuant to the terms of our license agreement with Daravita, we entered into a commercial manufacturing and supply agreement for Zohydro ER with Daravita. Daravita has the exclusive right to manufacture and supply both clinical and commercial supplies of Zohydro ER (subject to certain exceptions). While Daravita is required to comply with applicable laws and regulations regarding controlled substances, we do not have any direct control over Daravita's compliance in these regards, and any failure by Daravita to comply with those laws and regulations could result in a reduction or cessation of production of Zohydro ER.

Healthcare reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of Zohydro ER and any of our product candidates that may be approved by the FDA.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If Zohydro ER or any of our product candidates that are approved by the FDA are not widely included on the formularies of these plans, our ability to market our products to the Medicare population could suffer.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, was signed into law, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

• an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

• an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

• a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

• a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;

• extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

• expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers’ Medicaid rebate liability;

• expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

• new requirements to report certain financial arrangements with physicians and others, including reporting any “transfer of value” made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year. Manufacturers were required to begin data collection on August 1, 2013 and report such data to the Centers for Medicare & Medicaid Services, or CMS, by the 90th day of each subsequent calendar year;

• a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

• a licensure framework for follow-on biologic products;

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• a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
• creation of the Independent Payment Advisory Board which, beginning in 2014, has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
• establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Other legislative changes have also been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate 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, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, 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 health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory guidelines.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General: U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management’s attention could be diverted and our reputation could be damaged.

If we do not comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. We could be subject to healthcare fraud and abuse and patient

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privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- federal “sunshine” requirements that require drug manufacturers to report and disclose any “transfer of value” made or distributed to physicians and teaching hospitals, and any investment or ownership interests held by such physicians and their immediate family members. Manufacturers are required to report data to the government by the 90th day of each calendar year; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws and impose restrictions on drug manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may be found out of compliance of one or more of the requirements.

To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other

governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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Import/export regulations and tariffs may change and increase our costs.

We are subject to risks associated with the regulations relating to the import and export of products and materials. We cannot predict whether the import and/or export of our products will be adversely affected by changes in, or enactment of, new quotas, duties, taxes or other charges or restrictions imposed by any country in the future. Any of these factors could adversely affect our business, results of operations, financial condition and prospects.

Risks Related to Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success depends in large part on obtaining and maintaining patent, trademark and trade secret protection of our product, Zohydro ER, our current product candidates, including ZX008 and Relday, and any future product candidates, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing Zohydro ER or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We in-license certain intellectual property for Zohydro ER from Daravita, and certain intellectual property for Relday from Durect. We rely on these licensors to file and prosecute patent applications and maintain patents and otherwise protect certain of the intellectual property we license from them. We have not had and do not have primary control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, with respect to our license agreements with Daravita and Durect, we cannot be certain that such activities by Daravita and Durect have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Daravita has retained the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of the intellectual property rights that Daravita has licensed to us, and enforcement of our licensed patents or defense of any claims asserting the non-infringement, invalidity or unenforceability of these patents would also be subject to the control or cooperation of Daravita. Similarly, Durect has retained the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of certain of the intellectual property rights that Durect has licensed to us, and enforcement of certain of our licensed patents or defense of any claims asserting the non-infringement, invalidity or unenforceability of these patents would also be subject to the control or cooperation of Durect. We are not entitled to control the manner in which Daravita or Durect may defend certain of the intellectual property that is licensed to us and it is possible that their defense activities may be less vigorous than had we conducted the defense ourselves. We also in-license certain data from a continuing, long-term, open-label study in 15 Dravet syndrome patients, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome from the Universities of Antwerp and Leuven in Belgium, or the Universities.

On August 13 and September 20, 2014, we received separate notices of paragraph IV certifications from Actavis and from Alvogen, respectively, advising us of the filing of ANDAs with the FDA for a generic version of Zohydro ER. These certification notices allege that the two U.S. patents listed in the FDA’s Orange Book for Zohydro ER, with an expiration date in November 2019, will not be infringed by Actavis' or Alvogen’s proposed products, are invalid and/or are unenforceable. On September 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Actavis, and on November 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Alvogen. Daravita has licensed rights to Zohydro ER to us, and, under the Zohydro ER license agreement, Daravita has the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation. An adverse outcome in this litigation could result in one or more generic versions of Zohydro ER being launched in the United States before the expiration of the applicable patents. Since Zohydro ER is currently our only approved product, the introduction of a generic version of Zohydro ER could have a material adverse effect on our business, results of operations, financial condition and prospects.

Most of our patents related to DosePro were acquired from Aradigm, who acquired those patents from a predecessor owner. Our patents related to Zohydro ER are licensed from Daravita, who acquired those patents from a predecessor owner. Thus, most of our patents, as well as many of our pending patent applications, were not written by us or our attorneys, or our licensor or licensors' attorneys, and neither we nor our licensors had control over the drafting and prosecution of these patents. Further, the former patent owners and our licensors might not have given the same attention to the drafting and prosecution of

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these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. In addition, the former patent owners may not have been completely familiar with U.S. patent law, possibly resulting in inadequate disclosure and/or claims. This could possibly result in findings of invalidity or unenforceability of the patents we own and in-license, patents issuing with reduced claim scope, or in pending applications not issuing as patents.

In addition, as part of the agreement wherein we acquired patents related to DosePro from Aradigm, Aradigm retained, and we granted to Aradigm, a non-exclusive, worldwide, royalty free license to the acquired patents solely for purposes of the delivery of one or more aerosolized active pharmaceutical ingredients, or APIs, directly into the bronchia or lungs. The agreement with Aradigm also includes a covenant not to compete with us regarding technologies or products for the delivery of one or more APIs via needle free injection. That covenant expired on August 26, 2010, giving Aradigm or its licensees the right to develop and sell other needle-free injection technologies and products.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the U.S. Patent and Trademark Office, or PTO, and Congress have recently made significant changes to the patent system. There have been three U.S. Supreme Court decisions that now show a trend of the Supreme Court which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the U.S. Patent and Trademark Office could make it increasingly difficult for us to obtain and maintain patents on our products. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are the same or similar to the pharmaceutical compounds used in Zohydro ER and our product candidates but that are not covered by the claims of our patents or our in-licensed patents;
- the APIs in Zohydro ER, ZX008 and Relday are, or will soon become, commercially available in generic drug products, and no patent protection will be available without regard to formulation or method of use;
- we or our licensors, as the case may be, may not be able to detect infringement against our in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents;
- we or our licensors, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;

- it is possible that our owned or in-licensed U.S. patents or patent applications are not Orange-Book eligible;

- it is possible that there are dominating patents to Zohydro ER, ZX008 or Relday of which we are not aware;

- it is possible that there are prior public disclosures that could invalidate our or our licensors' inventions, as the case may be, or parts of our or their inventions of which we or they are not aware;

- it is possible that others may circumvent our owned or in-licensed patents;

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- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- it is possible that the U.S. government may exercise any of its statutory rights to our owned or in-licensed patents or applications that were developed with government funding;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our system or products or our system or product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal administrative challenges by third parties;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, state laws in the Unites States vary, and their courts as well as courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Likewise, our patents covering certain technology used in our DosePro system are expected to expire on various dates from 2015 through 2026 and the patents and patent applications licensed to us by Daravita are expected to expire in 2019.

As of December 31, 2014, our patent portfolio included 23 issued U.S. patents, four pending U.S. patent applications, 43 issued foreign patents and seven pending foreign patent applications relating to various aspects of Sumavel DosePro and our DosePro technology. Thirteen of our U.S. patents relating to our DosePro technology, U.S. Patent Nos. 5,957,886, 6,135,979, 7,776,007, 7,901,385, 8,267,903, 8,118,771, 8,241,243, 8,241,244, 8,287,489, 8,343,130, 8,663,158 and 8,715,259 are expected to expire in 2016, 2017, 2026, 2026, 2023, 2023, 2025, 2022, 2024, 2022, 2022 and 2023, respectively. U.S. Patent No. 5,957,886 claims a needleless injector system using a viscous damping medium; U.S. Patent No. 6,135,979 covers the needleless injector with particular safety mechanisms; U.S. Patent Nos. 7,776,007 and 8,287,489 cover systems with a cap and latch mechanism; U.S. Patent Nos. 7,901,385, 8,267,903 and 8,715,259 encompass various embodiments of the casing for enclosing the injection systems; U.S. Patent Nos. 8,118,771, 8,241,243 and 8,241,244 cover a method of reducing breakage of glass capsules; 8,491,524 and 8,663,158 relates to a drug capsule filled with a formulation purged with an inert gas; and 8,343,130 covers a method of reducing the propensity to create a shock wave on firing the system as used in the Sumavel DosePro system. U.S. Patent Nos. 6,902,742 and 6,228,398 relating to Zohydro ER covers a modified release composition containing hydrocodone and are expected to expire in November 2019. Upon the expiration of these patents, we or Daravita, as applicable, will lose the right to exclude others from practicing the claimed inventions. Additionally, eleven of these thirteen patents are the only patents currently listed in the FDA Orange Book for Sumavel DosePro. Two patents are listed for Zohydro ER. The expiration of the Orange Book listed patents will mean that we lose certain advantages that come

with Orange Book listing of patents. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. Moreover, if Daravita or Durect decides not to commence or continue any action relating to the defense of the patents they have licensed to us, they are required to notify us and we have the right to initiate proceedings after receiving their notice. Such proceedings will require the assistance of Daravita or Durect, as applicable, and we have limited control over the amount or timing of resources Daravita or Durect devotes on our behalf or the priority they place on enforcing these patent rights.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

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Our existing licenses with Daravita, Durect and the Universities imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the affected products. If we lose such license rights, our business, results of operations, financial condition and prospects may be materially adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

If we or our collaborators or licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are not infringed, invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third-party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some tests regarding granting patents and assessing the validity of patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination or other post-grant proceeding before the PTO, or during litigation, under the revised criteria which make it more difficult to obtain patents. We are not entitled to control the manner in which Daravita or Durect may defend certain of the intellectual property that is licensed to us, either in a reexamination or other post-grant proceeding before the PTO, or during the litigation, and it is possible that their defense activities may be less vigorous than had we conducted the defense ourselves.

We may also not be able to detect infringement of our own or in-licensed patents, which may be especially difficult for methods of manufacturing or formulation products. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights. For example, Daravita, our licensor, is primarily responsible for the enforcement of the intellectual property rights related to Zohydro ER. Under the agreement, Daravita has the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer. If Daravita decides not to commence or continue any action, they are required to notify us and grant us step in rights to enforce the in-licensed intellectual property. Such enforcement will require the cooperation of Daravita, and we will be responsible for Daravita’s reasonable expenses and attorney's fees incurred as a result of that cooperation. We have limited control over the amount or timing of resources Daravita devotes on our behalf or the priority they place on enforcing these patent rights to our advantage. Similarly, Durect, our licensor, is primarily responsible for the enforcement of certain of the intellectual property rights it licenses to us related to Relday. Under the agreement, Durect has the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of those intellectual property rights through the use, marketing, sale or import of a product that is competitive to Relday. If Durect decides not to commence or continue any such action, we have the right, but not the duty, to do so and such enforcement will require the cooperation of Durect. We have limited control over the amount or timing of resources Durect devotes on our behalf or the priority it places on enforcing these patent rights to our advantage.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to Zohydro ER, ZX008 and Relday. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our products or product candidates infringe the patent rights of others. Moreover, it is not always clear to industry

participants, including us, which patents cover various types of medical devices, drugs, products or their methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our products, product candidates, technology or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our products, product candidate or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many

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foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such proceedings may be decided against us if the other party had independently arrived at the same or similar invention prior to our own or, if applicable, our licensor's invention, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, if another party has reason to assert a substantial new question of patentability against any of our claims in our owned and in-licensed U.S. patents, the third party can request that the PTO reexamine the patent claims, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement claims, interference and reexamination proceedings, we may become a party to patent opposition proceedings in the European Patent Office, Australian Patent Office or other jurisdictions where either our patents are challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that our efforts would be unsuccessful. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products and/or product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

If a third-party's patent was found to cover our products and/or product candidates, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize Zohydro ER or our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

There is a substantial amount of litigation involving patent and other intellectual property rights in the device, biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

• infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management’s attention from our core business;

• substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party’s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner’s attorneys’ fees;

• a court order prohibiting us from selling or licensing the product unless the third party licenses its patent rights to us, which it is not required to do;

• if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products; and

• redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to

continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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Periodic maintenance fees on our owned and in-licensed patents are due to be paid to the PTO in several stages over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents which may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our in-licensor to pay annuity fees due to foreign patent agencies on our pending foreign patent applications. The PTO 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 many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business. For the patents and patent applications related to Zohydro ER, Daravita is obligated to maintain our in-licensed patents in the United States under our license agreement. Should Daravita fail to pursue maintenance of our licensed patents and patent applications, Daravita is obligated to notify us and, at that time, we will be granted an opportunity to maintain the prosecution and avoid withdrawal, cancellation, expiration or abandonment of the licensed U.S. patents and applications. For the patents and patent applications related to Relday, Durect is obligated to maintain certain of our in-licensed patents on a worldwide basis, using commercially reasonable efforts, under our license agreement. Should Durect fail to pursue maintenance of certain of those licensed patents and patent applications, Durect is obligated to notify us and, at that time, we will be granted an opportunity to maintain the prosecution and avoid withdrawal, cancellation, expiration or abandonment of those licensed patents and applications.

We also may rely on trade secrets and confidentiality agreements to protect our technology and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully generate revenues from Zohydro ER, and, if approved by the FDA or other regulatory authorities, our product candidates could be adversely affected.

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

As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

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Risks Relating to the Securities Markets and an Investment in Our Stock

The market price of our common stock has fluctuated and is likely to continue to fluctuate substantially. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has recently experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Since the commencement of trading in connection with our initial public offering in November 2010, the publicly traded shares of our common stock have themselves experienced significant price and volume fluctuations. During the year ended December 31, 2014, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of $1.07 to a high sale price of $5.19. This market volatility is likely to continue. These and other factors could reduce the market price of our common stock, regardless of our operating performance. In addition, the trading price of our common stock could change significantly, both over short periods of time and the longer term, due to many factors, including those described elsewhere in this “Risk Factors” section and the following:

- announcements concerning our commercial progress in promoting and selling Zohydro ER, including sales and revenue trends;
- announcements concerning our additional labelling claims for the formulation of Zohydro ER with BeadTek;
- FDA or international regulatory actions and whether and when we receive regulatory approval for any of our product candidates;
- negative publicity, including political actions and, potentially, court decisions, related to Zohydro ER;
- announcements of the introduction of new products by us or our competitors, including abuse deterrent formulations of hydrocodone products;
- the development status of ZX007, ZX008, Relday or any of our other product candidates, including the results from our clinical trials;
- announcements concerning product development results or intellectual property rights of others;
- announcements relating to litigation, intellectual property or our business, and the public's response to press releases or other public announcements by us or third parties;
- variations in the level of expenses related to ZX007, ZX008, Relday or any of our other product candidates or clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- market conditions or trends in the pharmaceutical sector or the economy as a whole;
- changes in operating performance and stock market valuations of other pharmaceutical companies and price and volume fluctuations in the overall stock market;
- litigation or public concern about the safety of Zohydro ER or our product candidates;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, any changes in these projections or our inability to meet these projections;

- deviations from securities analysts' estimates or the impact of other analyst comments;

- ratings downgrades by any securities analysts who follow our common stock;

- additions or departures of key personnel;
- third-party payor coverage and reimbursement policies;

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- developments concerning current or future strategic collaborations, and the timing of payments we may make or receive under these arrangements;
- developments affecting our contract manufacturers, component fabricators and service providers;
- the development and sustainability of an active trading market for our common stock;
- future sales of our common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters, security breaches, system failures or responses to these events;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In addition, the stock markets, and in particular the Nasdaq Global Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. The realization of any of the above risks or any of a broad range of other risks, including those described in these “Risk Factors” could have a dramatic and material adverse impact on the market price of our common stock.

We may invest or spend our cash in ways with which you may not agree or in ways which may not yield a significant return.

Our management has considerable discretion in the use of our cash. Our cash may be used for purposes that do not increase our operating results or market value. Until the cash is used, it may be placed in investments that do not produce significant income or that may lose value. The failure of our management to invest or spend our cash effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

Our quarterly operating results may fluctuate significantly.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because the commercial success of, and demand for, Zohydro ER, as well as the success and costs of our ZX008, Relday and other product candidate development programs are uncertain and therefore our future prospects are uncertain. Our net loss and other operating results will be affected by numerous factors, including:

fluctuations in the quarterly revenues of Zohydro ER, including fluctuations resulting from our distributors' inventory management practices and buying patterns;

- the level of underlying demand for Zohydro ER or any of our product candidates that may receive regulatory approval;
- our ability to control production spending and underutilization of production capacity;
- variations in the level of development and/or regulatory expenses related to ZX008, Relday or other development programs;
- results of clinical trials for ZX008, Relday or any other of our product candidates;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments and legislative changes, including healthcare reform, affecting our products and product candidates or those of our competitors; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in

turn, cause the price of our stock to fluctuate substantially.

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We may become involved in securities class action litigation that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in these "Risk Factors," may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. As of December 31, 2014, we had research coverage by only five securities analysts. If these securities analysts cease coverage of our company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.

Persons who were our stockholders prior to the sale of shares in our initial public offering in November 2010 continue to hold a substantial number of shares of our common stock that they are able to sell in the public market, subject in some cases to certain legal restrictions. Significant portions of these shares are held by a small number of stockholders. If these stockholders 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. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of December 31, 2014, we had 153,361,743 shares of common stock outstanding. Of these shares, approximately 124,108,749 are freely tradeable, without restriction, in the public market.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

We have registered under the Securities Act 15,784,200 shares of our common stock issuable upon the exercise of the warrants we issued in July 2012, which warrants became exercisable on July 27, 2013 at an exercise price of $2.50 per share (subject to restrictions on exercise set forth in such warrants). As of December 31, 2014, warrants were still outstanding to exercise 15,215,450 shares of this registered common stock, which means that upon exercise of warrants, such shares will be freely tradeable without restriction under the Securities Act, except for shares held by our affiliates. Further, certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, which, if registered, would also become freely tradeable without restriction under the Securities Act, except for shares held by our affiliates. In addition, our directors and executive officers may establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, warrantholders or executive officers and directors, or the perception that those sales may occur, could have a material adverse effect on the trading price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

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• a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
• a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
• a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
• advance notice requirements for stockholder proposals and nominations for election to our board of directors;
• a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66 2/3% of all outstanding shares of our voting stock then entitled to vote in the election of directors;
• a requirement of approval of not less than 66 2/3% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
• the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any return to stockholders will therefore be limited to the appreciation in the market price of their stock, which may never occur.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market, or Nasdaq, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. The requirements of these rules and regulations have increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place considerable strain on our personnel, systems and resources. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these new

compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and

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coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. In particular, commencing in fiscal 2011, we performed system and process evaluation and testing of our internal controls over financial reporting which allowed management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our future testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm is required to deliver an attestation report on the effectiveness of our internal control over financial reporting. We currently do not have an internal audit function, and we may 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. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

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Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our facilities are located in San Diego and Emeryville, California, and Oxfordshire, United Kingdom. Our general and administrative and sales and marketing personnel are located at our San Diego facility. Our manufacturing operations, product development, quality assurance and clinical and regulatory personnel are primarily located in our Emeryville facility. Two consultants occupy our United Kingdom offices.

We occupy 17,361 square feet of office space in San Diego under a lease that we entered in August 2014, which expires in March 2020 with an option to renew the Lease for an additional five years. We previously occupied approximately 13,124 rentable square feet in the same location.

We also occupy 12,128 square feet of office and laboratory space in Emeryville under a lease which expires in 2015, and minimal office space in the United Kingdom under a month-to-month agreement.

We believe that the space in San Diego, Emeryville and the United Kingdom is currently adequate to meet our needs in those locations, and that, if necessary, additional space can be leased to accommodate any future growth.

The manufacturing equipment used to produce our DosePro technology is currently located at our contract manufacturers' and component suppliers' facilities in Europe where we occupy an aggregate of more than 20,000 square feet of space that is used to manufacture Sumavel DosePro.

Item 3. Legal Proceedings

Actavis Paragraph IV Litigation

On August 13, 2014, we received a notice from Actavis concerning its filing of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Zohydro ER. The FDA will determine whether Actavis may be eligible for the 180-day exclusivity period described in 21 U.S.C. § 355(j)(5)(B)(iv).

On September 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Actavis and certain of its affiliates. Daravita has licensed rights under certain patents covering Zohydro Extended Release Capsules, CII to us. Under the Zohydro ER license agreement, Daravita has the right to control the enforcement of these patents and the related proceedings involving Zohydro ER and any prospective generic entrant.

The lawsuit filed by Daravita alleges that Actavis has infringed U.S. Patent Nos. 6,228,398, or the '398 patent, and 6,902,742, or the '742 patent, by filing its ANDA seeking approval from the FDA to market a generic version of Zohydro ER prior to the expiration of these patents. The '398 patent and '742 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the notice letter, thereby triggering a stay of FDA approval of the Actavis ANDA until the earlier of the expiration of a 30-month period from the receipt of the notice letter, the expiration of the '398 patent and '742 patent, the entry of a settlement order or consent decree stating that the '398 patent and '742 patent are invalid or not infringed, a decision in the infringement case that is favorable to Actavis, or such shorter or longer period as the court may order.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for Zohydro ER. Specifically, the FDA has granted Zohydro ER three years of regulatory exclusivity, which expires in October 2016.

We and Daravita intend to vigorously enforce the intellectual property rights relating to Zohydro ER to prevent the marketing of infringing generic products prior to the expiration of the applicable patents. The '398 patent and the '742 patent each expire on November 1, 2019. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Alvogen Paragraph IV Litigation

On September 29, 2014, we received a notice from Alvogen concerning its filing of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of Zohydro ER. The FDA will determine whether Alvogen may be eligible for the 180-day exclusivity period described in 21 U.S.C. § 355(j)(5)(B)(iv).

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On November 3, 2014, Daravita filed suit in the United States District Court for the District of Delaware against Alvogen. Daravita has licensed rights to Zohydro ER to us. Under the license agreement with Daravita, Daravita has the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant.

The lawsuit filed by Daravita alleges that Alvogen has infringed the ’398 patent and ’742 patent, by filing its ANDA seeking approval from the FDA to market a generic version of Zohydro ER prior to the expiration of these patents. The ’398 patent and ’742 patent are listed in the FDA’s Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the notice letter, thereby triggering a stay of FDA approval of the Alvogen ANDA until the earlier of the expiration of a 30-month period, the expiration of the ’398 patent and ’742 patent, the entry of a settlement order or consent decree stating that the ’398 patent and ’742 patent are invalid or not infringed, a decision in the infringement case that is favorable to Alvogen, or such shorter or longer period as the court may order.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for Zohydro ER. Specifically, the FDA has granted Zohydro ER three years of regulatory exclusivity, which expires in October 2016.

We and Daravita intend to vigorously enforce the intellectual property rights relating to Zohydro ER to prevent the marketing of infringing generic products prior to the expiration of their patents. The ’398 patent and the ’742 patent each expire November 1, 2019. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Item 4. Mine Safety Disclosures

Not Applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been traded on the Nasdaq Global Market since November 23, 2010 under the symbol "ZGNX." Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales price of our common stock, as reported by the Nasdaq Global Market for the period indicated:

	High	Low
Year Ended December 31, 2014		
Fourth Quarter	$1.48	$1.07
Third Quarter	$2.39	$1.14
Second Quarter	$3.10	$1.63
First Quarter	$5.19	$2.66
Year Ended December 31, 2013		
Fourth Quarter	$3.50	$1.85
Third Quarter	$2.24	$1.50
Second Quarter	$2.10	$1.25
First Quarter	$2.12	$1.16

Holders of Common Stock

As of March 6, 2015, there were approximately 35 holders of record of our common stock. Certain shares are held in "street" name and, accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

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Performance Graph

The following stock performance graph illustrates a comparison of the total cumulative stockholder return on our common stock since November 23, 2010, which is the date our common stock first began trading on the NASDAQ Global Market, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on November 23, 2010, and that all dividends were reinvested. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain available cash to finance ongoing operations and the potential growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

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Equity Compensation Plan Information

The following table summarizes securities available under our equity compensation plans as of December 31, 2014 (in thousands, except per share data).

	Weighted average per share exercise price of stock options	Shares issuable upon exercise of outstanding stock options	Shares issuable upon vesting of outstanding restricted stock units	Total shares issuable under current outstanding awards	Number of securities available for future issuance
Equity compensation plans approved by security holders:					
2006 Equity Incentive Plan	$3.49	1,064	—	1,064	—
2010 Equity Incentive Plan (1)	$2.48	13,858	0	13,858	2,954
Total Equity Incentive Plans		14,922	0	14,922	2,954
2010 Employee Stock Purchase Plan		—	—	—	1,164
Total Equity compensation plans approved by security holders		14,922	0	14,922	4,118
Equity compensation plans not approved by security holders:					
Employment Inducement Equity Incentive Award Plan (2)	$3.43	1,992	—	1,992	708

(1) The material features of our 2010 Equity Incentive Plan, including the evergreen provision under the 2010 Equity Incentive Plan, are described in Note 11 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) The material features of our Employment Inducement Equity Incentive Award Plan are described in Note 11 to our consolidated financial statements included in this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

None.

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Item 6. Selected Financial Data.

The following table summarizes certain of our selected financial data. The selected financial data for the years ended December 31, 2014, 2013, 2012, 2011, and 2010 have been derived from our audited financial statements, of which the consolidated statement of operations and comprehensive income (loss) data for the three fiscal years ending December 31, 2014, 2013 and 2012 and consolidated balance sheet data as of December 31, 2014 and 2013 are included elsewhere in this Annual Report on Form 10-K. Our historical results and financial condition are not necessarily indicative of the results or financial condition that may be expected in the future. The selected financial data set forth below should be read together with our financial statements and related notes thereto and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(In Thousands, Except Per Share Amounts)				
Statement of Operations and Comprehensive Income (Loss) Data					
Revenue:					
Net product revenue	$21,715	$31,699	$35,826	$30,411	$19,069
Contract manufacturing revenue	15,392	—	—	—	—
Contract revenue	—	—	8,462	7,165	4,373
Service and other revenue	3,424	1,313	38	—	—
Total revenue	40,531	33,012	44,326	37,576	23,442
Operating expenses:					
Cost of goods sold	15,817	21,241	19,496	19,293	12,846
Cost of contract manufacturing	14,342	—	—	—	—
Royalty expense	1,718	1,242	1,353	1,205	843
Research and development	18,936	12,805	21,414	33,043	28,643
Selling, general and administrative	88,899	50,040	49,494	60,459	51,270
Restructuring costs	—	876	—	—	—
Impairment of long-lived assets	838	—	—	—	—
Net gain on sale of business	(79,980)	—	—	—	—
Total operating expenses	60,570	86,204	91,757	114,000	93,602
Loss from operations	(20,039)	(53,192)	(47,431)	(76,424)	(70,160)
Other income (expense):					
Interest income	20	18	53	37	5
Interest expense	(3,090)	(6,610)	(10,313)	(7,644)	(10,013)
Loss on extinguishment of debt	(1,254)	—	—	—	—
Change in fair value of warrant liability	25,332	(21,927)	11,811	445	6,725
Change in fair value of embedded derivatives	(14)	759	(147)	(240)	—
Other income (expense)	7,716	96	(1,354)	(86)	(111)
Total other income (expense)	28,710	(27,664)	50	(7,488)	(3,394)
Income (Loss) before income taxes	8,671	(80,856)	(47,381)	(83,912)	(73,554)
Provision for income taxes	(84)	—	(5)	9	(10)
Net income (loss)	$8,587	$(80,856)	$(47,386)	$(83,903)	$(73,564)
Net income (loss) per share, basic and diluted (1)	$0.06	$(0.74)	$(0.59)	$(1.96)	$(17.63)
Weighted-average shares outstanding, basic (1)	142,607	108,568	80,558	42,712	4,173
Weighted-average shares outstanding, diluted (1)	145,046	108,568	80,558	42,712	4,173
Comprehensive Income (loss)	$8,587	$(80,856)	$(47,386)	$(83,903)	$(73,564)

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(1) See Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K for an explanation of the method used to calculate net loss per share and the number of shares used in the computation of the net per share amounts.

	As of December 31,				
	2014	2013	2012	2011	2010
	(In Thousands)				
Balance Sheet Data:					
Cash and cash equivalents and investment securities, available for sale	$42,205	$72,021	$41,228	$56,525	$49,172
Working capital	33,741	34,099	29,071	37,057	38,626
Total assets	202,835	112,504	80,686	100,640	94,268
Long-term debt, less current portion	21,703	28,802	28,481	42,070	19,934
Accumulated deficit	(401,660)	(410,247)	(329,391)	(282,005)	(198,102)
Total stockholders' equity	55,279	18,426	14,473	9,312	28,734

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited, to those set forth under "Item 1A — Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

Background

We are a pharmaceutical company committed to developing and commercializing therapies to address specific clinical needs for people living with central nervous system, or CNS, disorders who need innovative treatment alternatives to help them return to normal daily functioning. Our current areas of focus are pain, epilepsy and schizophrenia. We received marketing approval in October 2013, from the U.S. Food and Drug Administration, or FDA, for Zohydro® ER (hydrocodone bitartrate) extended-release capsules, CII, an opioid agonist, extended-release oral formulation of hydrocodone without acetaminophen, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. We launched Zohydro ER in March 2014 with our own sales force and had double-digit quarter-over-quarter growth during the launch year. Total revenues for Zohydro ER for the first ten months of launch ending December 31, 2014 were $11.6 million. On September 30, 2014, we submitted a supplemental New Drug Application, or sNDA, for a modified formulation of Zohydro ER with BeadTek™ which was developed using safe, well-known excipients and proprietary manufacturing processes to create an inactive ingredient that immediately forms a viscous gel when crushed and dissolved in liquids or solvents. All of the beads within the medication capsule are indistinguishable in color, shape, density and size, and do not impact the drug release profile when taken as directed. The FDA approved this application on January 31, 2015. We anticipate a transition from the currently marketed product to this capsule reformulation of Zohydro ER in the second quarter of 2015. Zohydro ER has the potential to address significant unmet medical needs and become an important and widely-used addition to the treatment options available to patients and physicians in the United States' multi-billion dollar chronic pain market. On March 10, 2015, we entered into an asset purchase agreement, or the Asset Purchase Agreement, with Pernix Ireland Limited and Pernix Therapeutics Holdings, Inc., or Pernix Therapeutics, and, together with Pernix Ireland Limited, Pernix, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell our Zohydro ER business to Pernix.

We sold the SUMAVEL® DosePro® (sumatriptan injection) Needle-free Delivery System business in May 2014 to Endo International Plc, or Endo, for $85.0 million in cash and milestone payments of up to $20.0 million. In connection with the sale, we entered into a supply agreement, pursuant to which we retain the sole and exclusive right and obligation to manufacture Sumavel DosePro to Endo, subject to Endo's right to qualify and maintain a back-up manufacturer.

In October 2014, Zogenix Europe Limited, or Zogenix Europe, our wholly-owned subsidiary, acquired Brabant Pharma Limited, or Brabant, a privately-held company organized under the laws of England and Wales for $20.0 million cash and $15.2 million in stock, potential future regulatory milestone payments of up to $50.0 million plus up to $45.0 million in potential future sales milestones. With the acquisition, we obtained worldwide development and commercialization rights to a product candidate, ZX008 (previously referred to as Brabafen™), a low-dose fenfluramine for the treatment of Dravet syndrome. Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and for which current treatment options are very limited. ZX008 has received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome. As of December 31, 2014, plans are underway to support the initiation of Phase 3 clinical trials in both Europe and the United States in the third quarter of 2015.

We have an additional product candidate in development, Relday™ (risperidone once-monthly long-acting injectable) for the treatment of schizophrenia, which uses Durect Corporation's SABER™ controlled-release formulation technology through a development and license agreement with Durect. Risperidone is used to treat the symptoms of schizophrenia and bipolar disorder in adults and teenagers 13 years of age and older. If successfully developed and approved, we believe Relday may be the first subcutaneous antipsychotic product that allows for once-monthly dosing. In May 2012, we filed an investigational new drug, or IND, application with the FDA. In July 2012, we initiated our first clinical trial for Relday. This Phase 1 clinical trial was a single-center, open-label, safety and pharmacokinetic trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. We announced positive single-dose pharmacokinetic results from the Phase 1 clinical trial in January

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2013. Based on the favorable safety and pharmacokinetic profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, we extended the study to include an additional cohort of 10 patients at a 100 mg dose of the same formulation. We announced positive top-line results from the extended Phase 1 clinical trial in May 2013. The positive results from this study extension positioned us to begin a multi-dose clinical trial, which we believe will provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies. We began dosing patients in a multi-dose clinical study for Relday in February 2015. We continue to evaluate worldwide partnering opportunities for Relday.

The development of Relday will first focus on its delivery by conventional needle and syringe in order to allow the administration of different volumes of the same formulation of Relday by a healthcare professional. We anticipate that the introduction of our DosePro needle-free technology for administration of Relday can occur later in development or as part of life cycle management after further work involving formulation development, technology enhancements, and applicable regulatory approvals.

We have experienced operating net losses and negative cash flow from operating activities since inception, and as of December 31, 2014, had an accumulated deficit of $401.7 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of our efforts to commercialize Zohydro ER, the clinical development for ZX008 and Relday, required post-market testing for Zohydro ER, additional development activities with respect to Zohydro ER, including the development of the ZX007, an abuse deterrent formulation of Zohydro ER, using technology licensed from Altus Formulation Inc., or Altus, and the cost of the sales and marketing expenses associated with Zohydro ER and the cost of contract manufacturing of Sumavel DosePro. As of December 31, 2014, we had cash and cash equivalents of $42.2 million.

In November 2014, we entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co., as sales agent, under which we can issue and sell shares of our common stock having an aggregate offering price of up to $25.0 million. We did not sell any shares in 2014 in connection with this agreement.

In December 2014, we entered into a loan and security agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, consisting of term loans totaling $20.0 million, and a revolving credit facility of up to $4.0 million. We received net proceeds of $19.7 million related to the term loan and drew down $1.5 million on the revolving credit facility in 2014.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of December 31, 2014, and our projected product revenues from Zohydro ER, contract revenues from Sumavel DosePro, service fee revenue, release of restricted cash in conjunction with the sale of our Sumavel DosePro business, the receipt of second $5.0 million installment payment due from Purdue Pharma L.P., or Purdue, and funds available under our revolving line of credit will be sufficient to fund our operations through the third quarter of 2015. We will need to obtain additional funds to finance our operations beyond that point, or possibly earlier. We intend to raise additional capital, if necessary, through public or private equity offerings, debt financings, receivables financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. In its report on our consolidated financial statements for the year ended December 31, 2014, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern.

Recent Developments

On March 10, 2015, we entered into the Asset Purchase Agreement with Pernix, pursuant to which, and on the terms and subject to the conditions thereof, among other things, we agreed to sell our Zohydro ER business to Pernix, including the registered patents and trademarks, certain contracts, the NDA and other regulatory approvals, documentation and authorizations, the books and records, marketing materials and product data relating to Zohydro

ER.

Under the terms of the Asset Purchase Agreement, Pernix will pay us $30.0 million in cash upon the closing, or the Closing, of the transaction, $3.0 million of which will be deposited into escrow to fund potential indemnification claims for a period of 12 months, or the Escrow Period. At the Closing, we will also receive $50.0 million in the form of a secured promissory note, or the Note, and $20.0 million in common stock consideration from Pernix (based on the $11.89 per share closing price of Pernix Therapeutics' common stock on the trading day immediately preceding the execution date). The Note will mature four months after the Closing, which maturity date may be extended in Pernix's sole discretion by up to an

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additional two months and, in the event of certain intellectual property matters, by up to an additional four months, for an aggregate extension of the maturity date to ten months from the Closing. The Note is subject to customary events of default, including cross-defaults to certain defaults under Pernix's debt facilities, and will be secured by substantially all of the purchased assets. Upon repayment of the Note, an additional $7.0 million of the $50.0 million payable thereunder will be deposited into escrow to fund potential indemnification claims through the Escrow Period. In addition, we have agreed to indemnify Pernix for certain intellectual property matters up to an aggregate amount of $5.0 million.

In addition to the upfront cash payment, we are eligible to receive cash payments of up to $283.5 million based on the achievement of pre-determined milestones, including a $12.5 million payment upon approval by the FDA of an abuse-deterrent extended-release hydrocodone tablet (currently in development in collaboration with Altus) and up to $271.0 million in potential sales milestone payments. Pursuant to the Asset Purchase Agreement, Pernix has agreed to use commercially reasonable efforts (as defined in the Asset Purchase Agreement) to meet such milestones. Furthermore, Pernix will assume responsibility for our obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Zohydro ER business arising after the Closing date. We will retain all liabilities associated with the Zohydro ER business arising prior to the Closing date.

We are required to extinguish all encumbrances on the assets to be sold to Pernix, including the security interests previously granted to Oxford Finance LLC, or Oxford and Silicon Valley Bank, or SVB, pursuant to our loan and security agreement, dated December 30, 2014, with Oxford and SVB. We are currently in discussions with Oxford and SVB to amend the loan and security agreement to remove the security interests on the assets to be sold to Pernix. However, if we are unable to reach an agreement with Oxford and SVB, we expect to eliminate its existing debt obligation to Oxford and SVB by repaying all amounts owed under the loan and security agreement, including applicable termination fees, which as of December 31, 2014 was $23.3 million.

We expect the Closing to occur during April 2015, subject to the satisfaction of the foregoing closing conditions. Either party may terminate the Asset Purchase Agreement if the Closing has not occurred by May 9, 2015, provided that if the Closing has not occurred due to lack of governmental approval, the Closing may be extended up to 60 additional days to obtain such approval. We and Pernix may also terminate the Asset Purchase Agreement by mutual consent, for a material uncured breach by the other party, or if a final governmental order prohibiting the transaction is issued.

Daravita License Agreement (formerly Elan Pharma International Limited)

In 2007, we entered into a license agreement with Daravita Limited, which was amended in 2009 and amended again in September 2014. Under the terms of this agreement, we were granted an exclusive license in the United States and its possessions and territories, with defined sub-license rights to third parties other than certain technological competitors of Daravita, to certain Daravita intellectual property rights related to Zohydro ER. The license agreement grants us the exclusive right under certain Daravita patents and patent applications to import, use, offer for sale and sell oral controlled-release capsule or tablet formulations of hydrocodone, where hydrocodone is the sole active ingredient, for oral prescriptions in the treatment or relief of pain, pain syndromes or pain associated with medical conditions or procedures in the United States. This right enables us to exclusively develop and sell Zohydro ER in the United States. Daravita has retained the exclusive right to take action in the event of infringement or threatened infringement by a third party of Daravita' intellectual property rights under the license agreement. We have the right to pursue an infringement claim against the alleged infringer should Daravita decline to take or continue an action.

Under the terms of the license agreement, we and Daravita agreed that, subject to the negotiation of a supply agreement, Daravita, or an affiliate of Daravita, would have the sole and exclusive right to manufacture and supply finished commercial product of Zohydro ER to us under agreed upon financial terms. In November 2012, we entered into a commercial manufacturing and supply agreement for Zohydro ER finished commercial product with Daravita under which Daravita is the exclusive manufacturer and supplier to us, subject to certain exceptions, of Zohydro ER. Daravita also granted to us, in the event that Daravita is unwilling or unable to manufacture or supply commercial product to us, a non-exclusive license to make product under Daravita' intellectual property rights. This non-exclusive license also includes the right to sublicense product manufacturing to a third party, other than certain technological competitors of Daravita.

Under the license agreement, we paid an upfront fee of $0.5 million, which was recorded as research and development expense. We paid additional milestone payments in the amount of $0.8 million in August 2011 in connection with the completion of the treatment phase of our pivotal efficacy Phase 3 clinical trial, Study 801, and $1.0 million upon submission of the first Zohydro ER new drug application, or NDA, to the FDA in May 2012, which were recorded as research and development expense. Lastly, we paid a milestone payment of $2.8 million upon the FDA's approval of Zohydro ER in October

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2013, which was recorded as other assets in the consolidated balance sheet and will be amortized over the estimated life of the intellectual property, through November 2019.

In addition, we are required to pay a mid-single-digit percentage royalty on net sales of the product for an initial royalty term equal to the longer of the expiration of Daravita' patents covering the product in the United States, or 15 years after commercial launch, if Daravita does not have patents covering the product in the United States. After the initial royalty term, the license agreement will continue automatically for three-year rolling periods during which we will continue to pay royalties to Daravita on net sales of the product at a reduced low single-digit percentage rate in accordance with the terms of the agreement.

Either party may terminate the license agreement, upon a material, uncured default or certain insolvency events of the other party or upon 12 months' written notice prior to the end of the initial royalty term or any additional three-year rolling period. We may also terminate the license agreement, with or without cause, at any time upon 12 months' prior written notice, or if the sale of Zohydro ER is prohibited by regulatory authorities.

Altus Formulation Inc. Development and Option Agreement

In November 2013, we entered into a development and option agreement with Altus. Under the agreement, Altus is responsible for the development of abuse deterrent formulations of hydrocodone using Altus' Intellitab™ drug delivery platform and will be reimbursed by us for its development efforts on the product. We are responsible for the conduct of the clinical development of the product. We paid a non-refundable upfront fee to Altus of $0.8 million in 2013 and we are also obligated to pay Altus up to $3.5 million in total future milestone payments upon the achievement of various development and regulatory milestones. The term of the development agreement will end upon expiration of the earlier of (1) the date upon which an NDA or similar application for regulatory approval is submitted by us for an Altus abuse deterrent formulation of hydrocodone, or (2) November 1, 2016.

Pursuant to the agreement, we were granted an option to obtain an exclusive, royalty-bearing license, with the right to sublicense, to certain Altus intellectual property rights to make, have made, use, sell, have sold, offer for sale and import an abuse deterrent formulation of hydrocodone for the treatment or relief of pain in the United States. If we exercise this option, Altus will be eligible to receive additional regulatory and sales milestones and a royalty based on net sales of the licensed product.

Valeant Co-Promotion Agreement

In June 2013, we entered into a co-promotion agreement, or the Valeant agreement, with Valeant Pharmaceuticals North America LLC, or Valeant. Under the terms of the Valeant agreement, we were granted the exclusive right (with Valeant or any of its affiliates) to promote Migranal® (dihydroergotamine mesylate) Nasal Spray, or Migranal, to a prescriber audience of physicians and other health care practitioners in the United States. Our sales team began promoting Migranal to prescribers in August 2013. The term of the Valeant agreement will run through December 31, 2015 (unless otherwise terminated), and can be extended by mutual agreement of the parties in additional twelve-month increments. Valeant remains responsible for the manufacture, supply and distribution of Migranal for sale in the United States. In addition, Valeant will supply us with a specified amount of product samples every six months, and we will reimburse Valeant for the cost of additional samples and any promotional materials ordered by us. The cost of any additional samples and any promotional materials ordered by us will be recognized as selling, general and administrative expenses.

In partial consideration of our sales efforts, Valeant pays us a co-promotion fee on a quarterly basis that represents specified percentages of net sales generated by us over defined baseline amounts of net sales, or the Baseline Forecast and Adjusted Baseline Forecast. In addition, upon completion of the co-promotion term, and only if the Valeant agreement is not terminated by Valeant due to a bankruptcy event (as defined in the Valeant agreement) or a material failure by us to comply with our material obligations under the Valeant agreement, Valeant will be required to pay us an additional tail payment calculated as a fixed percentage of our net sales over the Baseline Forecast (or Adjusted Baseline Forecast) during the first full six months following the last day of the term. For the year ended December 31, 2014 and 2013, we recognized service revenue of $3.4 million and $1.1 million under the Valeant agreement, respectively.

Astellas Pharma US, Inc. Co-Promotion Agreement

In July 2009, we entered into a co-promotion agreement, or the Astellas co-promotion agreement, with Astellas Pharma U.S., Inc., or Astellas. Under the terms of the Astellas co-promotion agreement, we granted Astellas the co-exclusive right, with us, to market and sell Sumavel DosePro in the United States (excluding Puerto Rico and the other territories and possessions of the United States) until June 30, 2013. Under the Astellas co-promotion agreement, both Astellas and we were obligated to collaborate and fund the marketing of Sumavel DosePro and to provide annual minimum levels of sales effort directed at

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Sumavel DosePro during the term. In December 2011, we entered into an amendment to the Astellas co-promotion agreement, or the amended Astellas co-promotion agreement, whereby the agreement terminated on March 31, 2012. In connection with the execution of the Astellas co-promotion agreement, Astellas made a non-refundable up-front payment of $2.0 million and made additional payments of $18.0 million to us upon the achievement of a series of milestones. In consideration for Astellas' performance of its commercial efforts, we paid Astellas a service fee on a quarterly basis that represented a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to primary care physicians, OB/GYNs, emergency medicine physicians, and urologists in the United States, or the Astellas Segment.

In accordance with accounting guidance for revenue arrangements with multiple deliverables, we initially recorded the $20.0 million in upfront and milestone payments received from Astellas as deferred revenue. Beginning with the launch of Sumavel DosePro in January 2010, we began amortizing the upfront and milestone payments as contract revenue in the consolidated statement of operations and comprehensive income (loss) over the term of the agreement. Upon termination of the Astellas co-promotion agreement, we concluded that the remaining deferred revenue balance should be recognized ratably through the amended term of the agreement, and consequently, all deferred contract revenues were recognized through March 31, 2012. We recognized $8.5 million of contract revenue for the year ended December 31, 2012, and no revenue subsequently.

In addition, following completion of the co-promotion term in March 2012, we were required to pay Astellas one tail payment in July 2013 and another tail payment in July 2014, calculated as decreasing fixed percentages (ranging from mid-twenties down to a mid-teen percentage) of net sales in the Astellas Segment during the 12 months ended March 31, 2012. The fair value of the tail payments was accreted through interest expense through the dates of payment in July 2013 and July 2014. The final and first tail payments of $1.2 million and $2.0 million were made in July 2014 and July 2013, respectively. We recognized $0.1 million, $0.4 million and $0.6 million of related interest expense during the years ended December 31, 2014, 2013 and 2012, respectively.

In August 2012, we and Astellas completed a final reconciliation under the terms of the Astellas co-promotion agreement and agreed to adjust the service fees paid to Astellas over the term of the agreement, resulting in a service fee reduction of $1.5 million, which offsets the two annual tail payments, and a reduction to the annual tail payment liability of $0.7 million. The present value of the service fee receivable and tail payment reduction of $1.9 million was recorded as a reduction in selling, general and administrative expenses during the year ended December 31, 2012, and an offset to the tail payment liability. The fair value of the service fee receivable and tail payment reduction were accreted through interest income through the dates of the two tail payments in July 2013 and July 2014.

For the year ended December 2012, we recognized shared marketing expense of $0.3 million and service fee expenses of $1.8 million (excluding the $1.9 million service fee adjustment discussed above) under the Astellas co-promotion agreement. For the years ended December 31, 2014 and 2013, no shared marketing or service fee expenses were incurred in connection with the Astellas co-promotion agreement.

Mallinckrodt LLC Co-Promotion Agreement

In June 2012, we entered into a co-promotion agreement with Mallinckrodt LLC, or Mallinckrodt. Under the terms of the co-promotion agreement, Mallinckrodt was granted a co-exclusive right (with us) to promote Sumavel DosePro in the United States. Mallinckrodt's sales team began selling Sumavel DosePro in August 2012. The initial term of the agreement was to run through June 30, 2014. In January 2014, we entered into an amendment to the co-promotion agreement, whereby the agreement terminated on January 31, 2014. We assumed full responsibility for the commercialization of Sumavel DosePro in February 2014.

In partial consideration of Mallinckrodt's sales efforts, we paid Mallinckrodt a service fee on a quarterly basis through January 31, 2014 that represented a specified fixed percentage of net sales of prescriptions generated from Mallinckrodt's prescriber audience over a baseline amount of net sales. In addition, in connection with the termination of the co-promotion agreement, we are required to make a one-time tail payment to Mallinckrodt of approximately $129,000, calculated as a fixed percentage of net sales from the Mallinckrodt targeted prescriber audience during the 12-month period ending on January 31, 2015. For the twelve months ended December 31, 2014, 2013 and 2012, we incurred service fee expenses of $62,000, $1.0 million and $0.2 million, respectively.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and

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assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize revenue from the sale of Sumavel DosePro and Zohydro ER, and from contract manufacturing, license fees, milestones and service fees earned on collaborative arrangements. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (a) our price to the buyer is substantially fixed or determinable at the date of sale, (b) the buyer has paid us, or the buyer is obligated to pay us and the obligation is not contingent on resale of the product, (c) the buyer's obligation to us would not be changed in the event of theft or physical destruction or damage of the product, (d) the buyer acquiring the product for resale has economic substance apart from that provided by us, (e) we do not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (f) the amount of future returns can be reasonably estimated. We currently defer recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as we currently cannot reliably estimate expected returns of the product at the time of shipment given the limited sales history of Zohydro ER.

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. The application of the multiple element guidance requires subjective determinations, and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. In determining the units of accounting, we evaluate certain criteria, including whether the deliverables have stand-alone value, based on the consideration of the relevant facts and circumstances for each arrangement. In addition, we consider whether the buyer can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s), and whether there are other vendors that can provide the undelivered element(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria, as described above, are applied to each of the separate units of accounting in determining the appropriate period or pattern of recognition. We determine the estimated selling price for deliverables within each agreement using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or management's best estimate of selling price, or BESP, if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs.

Product Revenue, Net

We sell Zohydro ER, and sold Sumavel DosePro through May 2014, in the United States to wholesale pharmaceutical distributors and retail pharmacies, or collectively our customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. We recognized Sumavel DosePro product sales at the time title transferred to our customer, and we reduced product sales for estimated future product returns and sales allowances in the same period the related revenue was recognized.

Given the limited sales history of Zohydro ER, we cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on Zohydro ER product shipments until the right of return no longer exists, which occurs at the earlier of the time Zohydro ER is dispensed through patient prescriptions or expiration of the right of return. We estimate Zohydro ER patient prescriptions dispensed using an analysis of third-party syndicated data. Zohydro ER was launched in March 2014 and, accordingly, we do not have a significant history estimating the number of patient

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prescriptions dispensed. If we underestimate or overestimate patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as we will record sales deductions at the time the prescription unit is dispensed.

We will continue to recognize Zohydro ER revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in revenue related to the recognition of revenue previously deferred, net of estimated future product returns and sales allowances. In addition, the costs of Zohydro ER associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.

Product Returns.

In connection with the closing of the Asset Purchase Agreement, or APA, in May 2014, whereby Endo acquired our Sumavel DosePro business, Endo purchased our existing finished goods inventory of Sumavel DosePro at standard cost. We will be financially responsible for all returns of Sumavel DosePro product distributed by us prior to closing of the APA up to a maximum per unit amount as specified in the applicable agreements. We are also financially responsible for payment of Sumavel DosePro product sales allowances on product distributed by us prior to closing of the APA. Endo will be responsible for payment of all other Sumavel DosePro returns and sales allowances.

Our estimated product return allowances for Sumavel DosePro require a high degree of judgment and are subject to change based on our experience and certain quantitative and qualitative factors. Sumavel DosePro's shelf life is determined by the shorter expiry date of its two subassemblies, which is currently approximately 30 months from the date of manufacture. Our return policy allows for the customer to return unused product six months before and up to one year after its expiration date for a credit at the then-current wholesaler acquisition cost, or WAC, reduced by a nominal fee for processing the return.

We have monitored and analyzed actual return history since product launch. Our analysis of actual product return history considers actual product returns on an individual product lot basis since product launch, the dating of the product at the time of shipment into the distribution channel, prescription trends, trends in customer purchases and their inventory management practices, and changes in the estimated levels of inventory within the distribution channel to estimate our exposure for returned product. Because of the shelf life of Sumavel DosePro and the duration of time under which our customers may return product through our return policy, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have a significant effect on product sales and earnings in the period of adjustments. Based on our analysis of actual product return history, we increased our estimate for product returns, resulting in adjustments of $1.2 million in the first quarter of 2013 and $2.4 million in the third quarter of 2013, which led to decreases in net product revenue and earnings for the year ended December 31, 2013. Further, as a result of our third quarter 2013 product returns analysis, we began utilizing a higher product returns rate for Sumavel DosePro sales.

A 1% increase or decrease in our returns reserve as a percentage of product shipped prior to the sale in the years ended December 31, 2014 and 2013 would have a financial statement impact of approximately $0.2 million and $0.5 million for the years ended December 31, 2014 and 2013, respectively.

We permit certain wholesale pharmaceutical distributors to purchase limited quantities of product after the announcement of an increase to the WAC of our product and prior to the effectiveness of the increase. In turn, WAC price increases can result in accelerated purchases by wholesalers relative to anticipated retail and prescription demand. The timing of purchases made by wholesale distributors and retail pharmacies are subject to fluctuations for these reasons among others.

We do not record a reserve for refunds on sales of Zohydro ER due to our revenue recognition policy upon the earlier to occur of prescription units dispensed (which cannot be returned) or expiration of the right of return.

Wholesaler and Retail Pharmacy Distribution Fees. We offer distribution fees to certain wholesale distributors and retail pharmacies based on contractually determined rates. We accrue the distribution fees on shipment to the respective wholesale distributors and retail pharmacies and recognize the distribution fees as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the full amount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks. We provide discounts primarily to authorized users of the Federal Supply Schedule, or FSS, of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations

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under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the federal entity paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the period the related revenue is recognized.

Rebates. We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized.

Patient Discount Programs. We offer discount card programs to patients for Zohydro ER and Sumavel DosePro, prior to its sale in May 2014, in which patients receive discounts on their prescriptions that are reimbursed by us. We estimate the total amount that will be redeemed based on levels of inventory in the distribution and retail channels and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Our procedures for estimating amounts accrued for rebates, chargebacks and other incentive programs at the end of any period are based on available quantitative data and are supplemented by management's judgment with respect to many factors, including but not limited to, current market dynamics, changes in contract terms, impact of new contractual arrangements and changes in sales trends. Quantitatively, we use historical sales, inventory movement through commercial channels, product utilization and rebate data and apply forecasting techniques in order to estimate our liability amounts. Qualitatively, management's judgment is applied to these items to modify, if appropriate, the estimated liability amounts. There are inherent risks in this process. For example, patients may not achieve assumed utilization levels; third parties may misreport their utilization to us; and discounts determined under federal guidelines, which affect our rebate programs with U.S. federal government agencies, may differ from those estimated.

On a quarterly basis, we analyze our estimates against actual rebate, chargeback and incentive program activity and adjust our estimates as necessary. Given our limited history with the commercialization of Zohydro ER and Sumavel DosePro, we may experience variability in our provisions for these sales allowances as we continue to initiate new sales initiatives and/or managed care programs in connection with the commercialization of our product. An adjustment to our estimated liabilities for rebates, chargebacks and other incentive programs of 1% of product sales, based on operating results for the years ended December 31, 2014, 2013 and 2012, would have resulted in an increase or decrease to net product sales for each period of $0.2 million, $0.5 million and $0.5 million, respectively. The sensitivity of our estimates can vary by program and type of customer. Additionally, there is a time lag between the date we determine the estimated liability and when we actually pay the liability. Due to this time lag, we may record adjustments to our estimated liabilities over several reporting periods, which can result in a net increase to net revenues or a net decrease to net revenues in those periods. Material differences may result in the amount of revenue we recognize from product sales if the actual amount of rebates, chargebacks and incentives differ materially from the amounts estimated by management. To date, there have been no material differences between the amount recorded in a period and actual charges incurred.

Contract Manufacturing Revenue

In connection with the closing of the APA in May 2014, we and Endo Ventures Limited, or Endo Ventures, entered into a supply agreement, or the Supply Agreement, pursuant to which we retain the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo Ventures. We recognize deferred revenue related to our supply of Sumavel DosePro as contract manufacturing revenue when earned on a "proportional performance" basis, as product is delivered. We recognize revenue related to our sale of Sumavel DosePro product, equal to the cost of contract manufacturing plus a 2.5% mark-up, upon the transfer of title to Endo. We supply Sumavel DosePro product based on non-cancellable purchase orders. We initially defer revenue for any consideration received in advance of services being performed and product being delivered, and recognize revenue pursuant to the related pattern of performance, based on total product delivered relative to the total estimated product delivery over the minimum eight year term of the Supply Agreement. We continually evaluate the performance period

and will adjust the period of revenue recognition if circumstances change.

We follow the authoritative accounting guidance when reporting revenue as gross when we act as a principal versus reporting revenue as net when we act as an agent. For transactions in which we act as a principal, have discretion to choose suppliers, bear credit risk and perform a substantive part of the services, revenue is recorded at the gross amount billed to a customer and costs associated with these reimbursements are reflected as a component of cost of sales for contract

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manufacturing services. For transactions with Endo, we act as a principal and record revenue at gross.

Contract Revenue

Contract revenue consists of the amortization of license fees and milestone payments received under our co-promotion agreements, which have multiple deliverables. Revenue arrangements with multiple deliverables are divided into separate units of accounting if criteria are met, including whether the deliverable has stand-alone value to the customer and the customer has a general right of return relative to the delivered item and delivery or performance of the undelivered item is probable and substantially within the vendor's control. Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price. The selling price for each deliverable is determined using: (i) VSOE, if it exists, (ii) TPE, if VSOE does not exist, and (iii) BESP if neither VSOE nor TPE exists. For transactions entered into prior to January 1, 2011, revenue is recognized for each deliverable based upon the applicable revenue recognition criteria discussed above and upon acceptance of goods or performance of service. Effective January 1, 2011, for new or significantly modified transactions, we allocate revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables.

Service and Other Revenue

Service and other revenue primarily consists of payments received for our sales efforts under the Valeant agreement. We recognize service and other revenue at the time services have been rendered.

Inventories

Inventories are stated at the lower of cost (on a first in, first out, or FIFO, basis) or market and consist of materials used in the manufacture of Zohydro ER and Sumavel DosePro. We have significant lead times for the procurement and manufacture of our finished goods and we therefore order goods from our suppliers and manufacturers based on forecasts of future demand. Also, we generally do not sell product that is within twelve months of expiration. To the extent we procure component materials or produce finished goods in excess of actual future demand, we may be required to reduce the carrying value of inventories. We record these adjustments based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future demand.

The FDA approved Zohydro ER with BeadTek on January 30, 2015. We anticipate transitioning from the currently marketed product to this reformulation of Zohydro ER in the second quarter of 2015. In connection with this transition, we reviewed our inventory and estimated sales through the transition date and the wholesale and retail channel and recorded an adjustment to reduce the carrying value of inventory in excess of estimated sales of the current formulation of $5.8 million which was recorded as a cost of product sales for the year ended December 31, 2014. Further, we analyzed non-cancellable purchase commitments for the current formulation that will be replaced by the new formulation of Zohydro ER and recorded a liability of $2.6 million for these commitments at December 31, 2014, which was included as a cost of goods sold for the year ended December 31, 2014.

Warrants for Common Stock

We classify common stock warrants that contain covenants where compliance with such covenants may be outside of our control as short-term liabilities on the consolidated balance sheet. We record the warrant liability at fair value and adjust the carrying value of these common stock warrants to their estimated fair value at each reporting date with the increases or decreases in the fair value of such warrants recorded as change in fair value of warrant liability in the consolidated statement of operations and comprehensive income (loss). The significant unobservable inputs used in measuring the fair value of the common stock warrant liabilities is expected volatility, as well as the probability of the occurrence of an extraordinary event for the warrants associated with our July 2012 public offering. Significant increases in volatility would result in a higher fair value measurement and significant increases in the probability of an extraordinary event occurring would result in a significantly lower fair value measurement.

Business Combinations

Under the acquisition method of accounting, we allocate the fair value of the total consideration transferred to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values on the

date of acquisition. The fair values assigned, defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between willing market participants, are based on estimates and assumptions determined by management. We record the excess consideration over the aggregate fair value of tangible and intangible assets, net of

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liabilities assumed, as goodwill. These valuations require us to make significant estimates and assumptions, especially with respect to intangible assets.

In connection with some of our acquisitions, additional contingent consideration is earned by the sellers upon completion of certain future performance milestones. In these cases, a liability is recorded on the acquisition date for an estimate of the acquisition date fair value of the contingent consideration by applying the income approach utilizing variable inputs such as anticipated future cash flows, risk-free adjusted discount rates, and nonperformance risk. Any change in the fair value of the contingent consideration subsequent to the acquisition date is recognized in other income (expense) in our consolidated statements of operations and net income (loss). This method requires significant management judgment, including the probability of achieving certain future milestones and discount rates. Future changes in our estimates could result in expenses or gains.

Management typically uses the discounted cash flow method to value our acquired intangible assets. This method requires significant management judgment to forecast future operating results and establish residual growth rates and discount factors. The estimates we use to value and amortize intangible assets are consistent with the plans and estimates that we use to manage our business and are based on available historical information and industry estimates and averages. If the subsequent actual results and updated projections of the underlying business activity change compared with the assumptions and
projections used to develop these values, we could experience impairment charges.

Fair Value Measurements

GAAP requires us to estimate the fair value of certain assets and liabilities as of the date of their acquisition or incurrence, on an ongoing basis, or both. Determining the fair value of an asset or liability, such as our acquired in-process research and development, contingent purchase consideration and warrants for common stock requires the use of accounting estimates and assumptions which are judgmental in nature and could have a significant impact on the determination of the amount of the fair value ascribed to the asset or liability.

Clinical Trial Expenses

Our expense accruals for clinical trials are based on estimates of the services received from clinical trial investigational sites and contract research organizations, or CROs. Payments under some of the contracts we have with such parties depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. 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 possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on information available to our product development or administrative staff. If we underestimate or overestimate the activity associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee’s requisite service period, or vesting period, on a straight-line basis. Equity awards issued to non-employees are recorded at their fair value on the grant date and are periodically remeasured as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant.

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Results of Operations

Comparison of Years Ended December 31, 2014, 2013 and 2012

Revenue

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Net product revenue	$21,715	$31,699	$35,826	$(9,984)	(31.5)%	$(4,127)	(11.5)%
Contract manufacturing revenue	15,392	—	—	15,392	100.0 %	—	— %
Contract revenue	—	—	8,462	$—	— %	(8,462)	(100.0)%
Service and other revenue	3,424	1,313	38	2,111	160.8 %	1,275	3,355.3 %
Total revenue	$40,531	$33,012	$44,326	$7,519	22.8 %	$(11,314)	(25.5)%

We recognize product revenue for Zohydro ER based on product dispensed to patients as estimated by independent third party data providers, which amounts were recorded net of estimated wholesaler and retail pharmacy distribution fees, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs, as applicable. Until it was sold to Endo in May 2014, we recognized net product sales of Sumavel DosePro upon the shipment of product to wholesale pharmaceutical distributors and retail pharmacies.

The aggregate $10.0 million, or 31.5% decrease in net product revenue during 2014 compared to 2013 was due to the sale of the Sumavel business in May 2014, offset by sales of Zohydro ER totaling $11.6 million, which was commercialized in March 2014.

The aggregate $4.1 million, or 11.5% decrease in net product revenue during 2013 compared to 2012 was primarily due to decreases in unit volume of 7% and our average net selling price of 4%. The decrease in our average net selling price was primarily due to an increase in our estimate for Sumavel DosePro product returns. Based on our analysis of actual product return history, which considers actual product returns on an individual product lot basis since product launch, and factors such as the dating of our product at the time of shipment into the distribution channel, prescription trends, trends in customer purchases and their inventory management practices and changes in the estimated levels of inventory within the distribution channel, we increased our estimate for product returns, resulting in an adjustment of $3.6 million, which decreased our net product sales during the year ended December 31, 2013.

In 2014, contract manufacturing revenue was earned in connection with the supply agreement which was executed in conjunction with the sale of our Sumavel DosePro business to Endo in May 2014.

In 2012, contract revenue represented amortization of license fee payments and milestone payments we received in connection with our Astellas co-promotion agreement which terminated in 2012, and all previously unrecognized deferred contract revenue was recognized at that time.

Service and other revenue is primarily comprised of the co-promotion fee that is earned for our Migranal sales efforts under the Valeant agreement. The increases in 2014 and 2013 over 2012 resulted from increased volume of sales orders attributed to our sales force.

Cost of Goods Sold and Cost of Contract Manufacturing

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Cost of goods sold	$15,817	$21,241	$19,496	$(5,424)	(25.5)%	$1,745	9.0 %
Cost of contract manufacturing	14,342	—	—	14,342	100.0 %	$—	— %
Product gross margin	27 %	33 %	46 %		(6.0)%		(13.0)%
Contract manufacturing gross margin	7 %	— %	— %		100.0 %		— %

Cost of goods sold consists primarily of materials, third-party manufacturing costs, freight in and indirect personnel and other overhead costs associated with sales of Zohydro ER based on product dispensed to patients. Costs of contract manufacturing consists primarily of materials, third-party manufacturing costs, freight in and indirect personnel and other

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overhead costs associated with Sumavel DosePro based on units sold to wholesale pharmaceutical distributors and retail pharmacies, as well as the effect of changes in reserves for excess, dated or obsolete commercial inventories and production manufacturing variances. It represents the cost of units recognized as net product revenues in the period and the impact of underutilized production capacity and other manufacturing variances.

The decrease in cost of goods for the year ended December 31, 2014 as compared to the same period in 2013 was due to the sale of the Sumavel DosePro business to Endo in May 2014, after which costs were recorded in the cost of contract manufacturing category, which was offset by an increase of $10.6 million due to the commercialization of Zohydro ER in 2014. The increase in cost of goods sold for the year ended December 31, 2013 as compared to 2012 was primarily due to a non-recurring scrap charge and excess capacity charge related to Sumavel DosePro.

The decrease in product gross margin of 6.0% in 2014 compared to 2013 was primarily due to inventory charges recorded at December 31, 2014 in conjunction with the phase-in of the new formulation of Zohydro ER with BeadTek scheduled for 2015. The decline in product gross margin in 2013 compared to 2012 was primarily due to a non-recurring scrap charge and excess capacity charge.

Royalty Expense

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Royalty expense	1,718	$1,242	$1,353	$476	38.3 %	$(111)	(8.2)%

Royalty expense consists of royalties payable to Daravita based on net sales of Zohydro ER, and to Aridigm based on net sales of Sumavel DosePro by us or one of our licensees, and the amortization of our milestone payments. We are required to pay Daravita royalties on net sales of the product for an initial royalty term equal to the longer of the expiration of Daravita's patents covering the product in the United States, or 15 years after commercial launch, if Daravita does not have patents covering the product in the United States. After the initial royalty term, the license agreement will continue automatically for three-year rolling periods during which we will continue to pay royalties to Daravita on net sales of the product at a reduced low single-digit percentage rate in accordance with the terms of the agreement. The royalty obligation to Aridigm was assigned to Endo in conjunction with the sale of Sumavel DosePro in May 2014.

The increase in royalty expense for the year ended December 31, 2014 as compared to the same period in 2013 was due primarily to the commercialization of Zohydro ER in 2014. The decrease in royalty expense for the year ended December 31, 2013 as compared to the year ended December 31, 2012 was due to lower net revenues generated by Sumavel DosePro in 2013 as compared to the same period in 2012.

Research and Development Expenses

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Research and development	$18,936	$12,805	$21,414	$6,131	47.9 %	$(8,609)	(40.2)%

Research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including: license and milestone payments; payments made to third-party CROs and investigational sites, which conduct our trials on our behalf, and consultants; expenses associated with regulatory submissions, pre-clinical development and clinical trials; payments to third-party manufacturers, which produce our active pharmaceutical ingredient and finished product; personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation; and facility, maintenance, depreciation and other related expenses. We expense all research and development costs as incurred.

We utilize CROs, contract laboratories and independent contractors for the conduct of pre-clinical studies and clinical trials. We track third-party costs by type of study being conducted. We recognize the expenses associated with the services provided by CROs based on the percentage of each study completed at the end of each reporting period. We coordinate clinical

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trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

The table below sets forth information regarding our research and development costs for our major development programs. The period over period variances for our major development programs are explained in the narrative beneath the table.

	Year Ended December 31,		
	2014	2013	2012
	(In Thousands)		
Research and development expenses:			
Zohydro ER	$5,979	$4,535	$11,544
Relday	5,515	1,456	3,358
Sumavel DosePro	—	1,200	757
Other (1)	7,442	5,614	5,755
Total	$18,936	$12,805	$21,414

(1) Other research and development expenses include development costs incurred for ZX008, the DosePro technology enhancement and other product candidate development, as well as employee and infrastructure resources that are not tracked on a program-by-program basis.

Research and development costs increased by $6.1 million for the year ended December 31, 2014 compared to the year ended December 31, 2013 primarily due to activities to develop an abuse-deterrent formulation of Zohydro ER and product development costs incurred for Relday in preparation for the commencement of a clinical trial in 2015.

Research and development costs decreased by $8.6 million for the year ended December 31, 2013 compared to the year ended December 31, 2012 primarily due to a decrease in development expenses for Zohydro ER and Relday. The decrease in Zohydro ER development expenses was the result of fees paid in connection with our Zohydro ER NDA submission to the FDA in May 2012 and costs related to preparation for and participation in the December 2012 FDA advisory committee meeting for Zohydro ER. We incurred greater research and development expenses for Relday for the year ended December 31, 2012 as we filed our IND application with the FDA in July 2012 and initiated our first clinical trial in July 2012.

We use our employee and infrastructure resources across our product and product candidate development programs. Therefore, we have not tracked salaries, other personnel related expenses, facilities or other related costs to our product development activities on a program-by-program basis.

Selling, General and Administrative Expenses

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Selling, general and administrative	$88,899	$50,040	$49,494	$38,859	77.7 %	$546	1.1 %

Selling expenses, which include sales and marketing costs, consist primarily of salaries and benefits of sales and marketing management and sales representatives, marketing and advertising costs, service fees under our co-promotion agreements and sample product costs. General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development and internal support functions. In addition, general and administrative expenses include facility costs and professional fees for legal, consulting and accounting services.

Selling, general and administrative expenses increased to $88.9 million for the year ended December 31, 2014 compared to $50.0 million for the year ended December 31, 2013. Selling expenses were $57.3 million for the year ended December 31, 2014 compared to $33.5 million for the year ended December 31, 2013. Selling expenses increased by $16.6 million due to increased personnel costs and $5.3 million due to increased marketing and advertising costs as we launched Zohydro ER in 2014.

General and administrative expenses were $31.6 million for the year ended December 31, 2014 compared to $16.5 million for the year ended December 31, 2013. Of the increase, $5.6 million was related to monitoring and regulatory

requirements associated with the launch of Zohydro ER in 2014, $5.1 million of the increase was due to professional services

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costs incurred, including public relations and legal costs, and $4.3 million of additional personnel costs were incurred due to addition of a medical affairs department in 2014 and growth in other support areas.

Selling, general and administrative expenses increased slightly for the year ended December 31, 2013 as compared to the year ended December 31, 2012. The increase of $0.5 million in selling, general and administrative expenses was due to an increase of $2.9 million of general and administrative expenses, which was offset by a decrease of $2.4 million in sales and marketing expenses.

Selling expenses were $33.5 million for the year ended December 31, 2013 compared to $35.9 million for the year ended December 31, 2012. The decrease in sales and marketing expenses was primarily the result of a decrease in salaries and sales incentive compensation resulting from our restructuring in May 2013, which was partially offset by an increase in co-promotion fees paid to Mallinckrodt, as Mallinckrodt provided co-promotion services throughout all of 2013 compared to services provided in 2012 that commenced in August.

General and administrative expenses were $16.5 million for the year ended December 31, 2013 compared to $13.6 million for the year ended December 31, 2012. The increase in general and administrative expenses was primarily the result of an increase in non-cash stock-based compensation charges and professional service related costs, such as legal, accounting and consulting services.

Restructuring, Impairment of Long-lived Assets and Net Gain on Sale of Business

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Restructuring	$—	$876	$—	$(876)	(100.0)%	$876	100.0 %
Impairment of long-lived assets	$838	$—	$—	$838	100.0 %	$—	— %
Net gain on sale of business	$(79,980)	$—	$—	$(79,980)	100.0 %	$—	— %

In 2013, we commenced a restructuring of our workforce, resulting in a reduction in force of 55 employees across all of our functional areas. In 2014, we recognized a net gain on sale in conjunction with the sale of our Sumavel DosePro business. As a result of the sale, we recorded an impairment charge for the disposal of construction in progress that will no longer be placed into service.

Other income (expense)

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Interest income	$20	$18	$53	$2	11.1 %	$(35)	(66.0)%
Interest expense	$(3,090)	$(6,610)	$(10,313)	$3,520	(53.3)%	$3,703	(35.9)%
Loss on extinguishment of debt	$(1,254)	$—	$—	$(1,254)	(100.0)%	$—	— %
Change in fair value of warrant liabilities	$25,332	$(21,927)	$11,811	$47,259	(215.5)%	$(33,738)	(285.6)%
Change in fair value of embedded derivatives	$(14)	$759	$(147)	$(773)	(101.8)%	$906	(616.3)%
Other income (expense)	$7,716	$96	$(1,354)	$7,620	7,937.5 %	$1,450	(107.1)%
Total other income (expense)	$28,710	$(27,664)	$50	$56,374	(203.8)%	$(27,714)	(55,428.0)%

Interest Income The fluctuations in interest income were primarily driven by fluctuations in average cash and cash equivalent balances during the respective periods for the years ended December 31, 2014, 2013 and 2012.

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Interest Expense Interest expense was incurred in connection with our financing agreements and certain other arrangements, including the following:

- our $30.0 million financing agreement with Healthcare Royalty Partners, or the Healthcare Royalty financing agreement, which was terminated in 2014;
- imputed interest from annual tail payments to Astellas;
- the working capital advance of $7.0 million received from Endo in connection with the Supply Agreement;
- a $10.0 million revolving credit facility with Oxford and SVB, which was terminated in 2012; and
- a $25.0 million loan and security agreement with Oxford and SVB, or the amended Oxford/SVB loan agreement, which was terminated in 2012.

Interest expense decreased by $3.5 million for the year ended December 31, 2014 compared to the year ended December 31, 2013 primarily due to the termination of the Healthcare Royalty financing agreement in May 2014, as discussed in Note 9 to our consolidated financial statements, included in this Annual Report on Form 10-K. Interest expense decreased by $3.7 million for the year ended December 31, 2013 compared to the year ended December 31, 2012 primarily due to the termination of our amended Oxford/SVB loan agreement and revolving credit facility in July 2012.

We expect an increase in interest expense in 2015 compared to 2014 levels primarily due to the receipt of proceeds under the loan agreement entered into with Oxford/SVB in December 2014 and the revolving credit facility thereunder.

Loss on extinguishment of debt The loss on extinguishment of debt was incurred in 2014 as a result of the termination of the Healthcare Royalty financing agreement. See Note 9 to our consolidated financial statements included in this Annual Report on Form 10-K.

Change in Fair Value of Warrant Liabilities The change in fair value of warrant liabilities relates to a fair value adjustment recorded on the warrants to purchase common stock issued in connection with our July 2012 public offering and issued in connection with our Healthcare Royalty financing agreement. See Note 9 to our consolidated financial statements included in this Annual Report on Form 10-K.

Change in Fair Value of Embedded Derivatives The change in fair value of embedded derivatives relates to a fair value adjustment recorded on the embedded derivatives associated with the Healthcare Royalty financing agreement, which was repaid in 2014. See Note 9 to our consolidated financial statements included in this Annual Report on Form 10-K.

Other Income (Expense) Other income for the year ended December 31, 2014 was comprised of the of sale of right of reference to certain carcinogenicity data generated by us for $3.5 million, consideration received for a waiver of regulatory exclusivity rights of $5.0 million offset by fees incurred to register our Brabant stock of $0.7 million (see Note 3 to our consolidated financial statements included in this Annual Report on Form 10-K) and net foreign exchange losses of $0.1 million. Other income for the year ended December 31, 2013 was comprised primarily of foreign currency transaction gains and losses. Other expense for the year ended December 31, 2012 consists of expense incurred in July 2012 from the issuance of warrants in our public offering, slightly offset by foreign currency transaction gains.

Provision for Income Tax Expense

	Year Ended December 31,			2013 to 2014		2012 to 2013	
(Dollars in thousands)	2014	2013	2012	$ change	% change	$ change	% change
Net income (loss) before income taxes	8,671	(80,856)	(47,381)	$89,527	(110.7)%	$(33,475)	70.7%
Provision for income taxes	(84)	—	(5)	(84)	100.0%	5	(100.0)%

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Provision for income tax expense is primarily related to the taxable income generated by our wholly-owned subsidiary, Zogenix Europe Limited.

Net Operating Loss and Tax Credit Carryforwards As of December 31, 2014, we had available federal, California and foreign net operating loss carryforwards of approximately $211.2 million, $209.1 million and $2.0 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2026 for federal tax purposes and 2015 for state tax purposes. As of December 31, 2014, we had federal and state research and development tax credit carryforwards of approximately $2.2 million and $2.7 million, respectively. The federal research and development income tax credit carryforwards will begin to expire in 2026 unless previously utilized. The California research and development income tax credit carryforwards will carry forward indefinitely until utilized.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, substantial changes in our ownership may limit the amount of net operating loss and research and development income tax credit carryforwards that could be utilized annually in the future to offset taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire.

We completed an analysis under IRC Sections 382 and 383 to determine if our net operating loss carryforwards and research and development credits are limited due to a change in ownership. We determined that as of December 31, 2014 we had three ownership changes. The first ownership change occurred in August 2006 upon the issuance of our Series A-1 convertible preferred stock. As a result of this ownership change, we reduced our net operating loss carryforwards by $1.9 million and research and development income tax credits by $8,000. We determined that we had a second ownership change, as defined by IRC Section 382 and 383, which occurred in September 2011 upon the issuance of stock in our follow-on offering. As a result of this second ownership change, we reduced our federal and state net operating loss carryforwards as of December 31, 2011 by $121.1 million and $53.4 million, respectively, and research and development income tax credits as of December 31, 2011 by $3.0 million. We had a third ownership change as defined by IRC Sections 382 and 383, which occurred in January 2014. There was no forfeiture in federal and California net operating loss carryforwards or research and development income tax credits as a result of the third ownership change.

Pursuant to IRC Section 382 and 383, the use of our net operating loss and research and development income tax credit carryforwards may be limited in the event of a future cumulative change in ownership of more than 50% within a three-year period. Any such limitations, whether as the result of prior or future offerings of our common stock or sales of common stock by our existing stockholders, could have an adverse effect on our consolidated results of operations in future years. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal or state income tax benefit in our consolidated statement of operations and comprehensive income (loss).

Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of December 31, 2014, had an accumulated deficit of $401.7 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year primarily as a result of the expenses incurred in connection with the commercialization of Zohydro ER, the clinical development for ZX007, ZX008 and Relday, required post-market testing for Zohydro ER, additional activities with respect to Zohydro ER, including the development of an abuse deterrent formulation of Zohydro ER. As of December 31, 2014, we had cash and cash equivalents of $42.2 million.

We may fund our operations through the proceeds from the sales and issuances of our common stock, if any, pursuant to the controlled equity offering program that we established on November 6, 2014 with Cantor Fitzgerald & Co., or Cantor, as sales agent, under which we may, from time to time, sell shares of common stock up to an aggregate offering price of $25.0 million. Sales of our common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under our effective shelf registration statement on Form S-3. There can be no assurance that Cantor will be successful in consummating sales under the program based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Cantor or we are permitted to

terminate the controlled equity offering sales agreement, or sales agreement, at any time upon 10 days' prior written notice, and Cantor is also permitted to terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change in our Company.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of December 31, 2014, and our projected product revenues from Zohydro ER, contract revenues from Sumavel DosePro, service fee revenue, release of restricted cash in conjunction with the sale of our Sumavel DosePro business, the receipt of second $5.0 million installment payment due from Purdue and funds available under our revolving line of credit will be sufficient to fund

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our operations through the third quarter of 2015. We expect our current financial resources and the expected proceeds from the sale of the Zohydro ER business to provide a cash runway through three significant clinical milestones: the end of Phase 2 meeting for Relday, followed by the regulatory submissions in the United States and Europe for ZX008, which are anticipated to occur in the fourth quarter of 2016. We will need to obtain additional funds to finance our operations beyond that point, or possibly earlier. We intend to raise additional capital, if necessary, through public or private equity offerings, debt financings, receivables financings or through collaborations or partnerships with other companies. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available.

In its report on our consolidated financial statements for the year ended December 31, 2014, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern. A “going concern” opinion means, in general, that our independent registered public accounting firm has substantial doubt about our ability to continue our operations without continuing infusions of capital from external sources and this opinion could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans. Our ability to continue as a going concern depends, in large part, on our ability to generate positive cash flow from operations and obtain additional financing, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations and have to liquidate our assets and may receive less than the value at which those assets were carried on our financial statements, and it is likely that investors will lose all or part of their investment.

Since inception, our operations have been financed primarily through equity and debt financings, the issuance of convertible notes and payments received from Astellas under our Astellas co-promotion agreement. Through December 31, 2014, we received aggregate net cash proceeds of approximately $417.5 million from the sale of shares of our preferred and common stock, including the following financing transactions:

- in July 2012, we issued and sold a total of 35,058,300 shares of common stock and warrants to purchase 15,784,200 shares of common stock in a public offering, including the underwriters' over-allotment purchase, for aggregate net proceeds of $65.4 million;
- in 2013, we issued and sold a total of 6,753,104 shares of common stock under our controlled equity offering program, resulting in aggregate net proceeds of $10.8 million; and
- in November 2013, we issued and sold a total of 30,666,667 shares of common stock in a follow-on public offering, including shares issued upon the exercise of the underwriters' option to purchase over-allotment shares, for aggregate net proceeds of $64.5 million.

In December 2014, we entered into a loan and security agreement, or the Loan and Security Agreement, with Oxford and SVB consisting of term loans totaling $20.0 million, and a revolving credit facility of up to $4.0 million. Total outstanding advances under the revolving credit facility are limited to the lesser of $4.0 million or 85% of eligible accounts receivable as defined in the Loan and Security Agreement. We are required to make interest-only payments on the term loan through (i) January 1, 2016 or (ii) if we achieve trailing 12 month consolidated revenues of at least $50.0 million, July 1, 2016. The term loan will begin amortizing at the end of the applicable interest-only period, with equal monthly payments of principal plus interest in consecutive monthly installments following such interest-only period until the credit facility matures on December 1, 2018. We may prepay the outstanding principal balance of the term loan subject to graded prepayment fees. The credit facility also includes events of default, as defined in the Loan and Security Agreement, which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility. At December 31, 2014, we had received proceeds of $20.0 million on the term loan and drawn down $1.45 million on the revolving line of credit that are included in our cash and cash equivalents balance at year end. The loans will be used for working capital and general business purposes.

The obligations under the Loan and Security Agreement are collateralized by our personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash), and we have agreed to not encumber any of our intellectual property. We were required to establish a controlled deposit account with SVB containing at least 85% of our account balances at all financial institutions which can be utilized by the lenders to satisfy the obligations in the event of default by us. The credit facility includes affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring us to maintain legal existence and governmental approvals, deliver certain financial reports, maintain

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insurance coverage and satisfy certain requirements regarding accounts receivable. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and upon a change in control, in each case subject to certain exceptions.

Upon repayment of the term loan, we are also required to make a final payment equal to 5% of the original principal amount of the term loan funded. Upon the entry into the credit facility, we were required to pay a term loan facility fee of $200,000 and a revolving line commitment fee of $32,000. Three additional $32,000 revolving line commitment fees will be due and payable on each of the first, second, and third anniversaries of the effective date or upon termination of the revolving line.

On July 18, 2011, we closed the Healthcare Royalty financing agreement. Under the terms of the Healthcare Royalty financing agreement, we borrowed $30.0 million and we were obligated to repay such borrowed amount together with a specified return to Healthcare Royalty. Healthcare Royalty exercised its option to terminate the financing agreement in connection with our sale of our Sumavel DosePro business to Endo on May 16, 2014. Upon termination of the financing agreement, we were obligated to make a final payment of $40.0 million to Healthcare Royalty, which was an amount that generated a 17% internal rate of return on the borrowed amount as of the date of final payment, reduced by the revenue interest and principal payments received by Healthcare Royalty up to the date of final payment. Healthcare Royalty's security interest in all of our assets was extinguished upon early termination of the financing agreement.

Cash and Cash Equivalents. Cash and cash equivalents totaled $42.2 million and $72.0 million at December 31, 2014 and December 31, 2013, respectively.

The following table summarizes our cash flows from (used in) operating, investing and financing activities for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
	2014	2013	2012
	(In Thousands)		
Statement of Cash Flows Data:			
Total cash provided by (used in):			
Operating activities	$(80,816)	$(44,920)	$(52,202)
Investing activities	61,002	(810)	(293)
Financing activities	(10,002)	76,523	37,198
Net (decrease) increase in cash and cash equivalents	$(29,816)	$30,793	$(15,297)

Operating Activities. Net cash used in operating activities was $80.8 million, $44.9 million and $52.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. Use of cash in operating activities in 2014 includes non-cash adjustments of $80.0 million reflecting the gain on sale of the Sumavel DosePro business and the change in the fair value of our warrant liabilities of $25.3 million. Net cash used for the year ended December 31, 2014 primarily reflects increases in personnel, advertising and promotion, professional fees and required monitoring expenses associated with the launch of Zohydro ER.

Net cash used for the year ended December 31, 2013 primarily reflects the use of cash for operations, adjusted for non-cash charges, including a $21.9 million change in fair value of warrant liabilities and $8.2 million for stock-based compensation (which includes $0.2 million in stock-based compensation from restructuring), partially offset by a $(0.8) million change in fair value of embedded derivatives. Significant working capital uses of cash for the year ended December 31, 2013 included personnel-related costs, sales and marketing expenses for Sumavel DosePro and preparation for the launch of Zohydro ER, research and development costs (primarily for employee and infrastructure resources) and other professional services.

Net cash used for the year ended December 31, 2012 primarily reflects the use of cash for operations, adjusted for non-cash charges, including $6.2 million in stock-based compensation, offset by an $11.8 million change in fair value

of warrant liabilities and an $8.5 million reduction in deferred revenue related to the termination of the Astellas co-promotion agreement. Significant working capital uses of cash for the year ended December 31, 2012 included personnel-related costs, research and development costs (primarily for Zohydro ER and Relday), sales and marketing expenses for Sumavel DosePro, and other professional services.

Investing Activities. Net cash provided (used) in investing activities was $61.0 million, ($0.8) million and ($0.3) million for the years ended December 31, 2014, 2013 and 2012, respectively. In the year ended December 31, 2014, we received

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proceeds of $89.6 million as a result of the sale of our Sumavel DosePro business, offset by $8.5 million we were required to deposit in escrow related to the sale. We also used $20.0 million to acquire Brabant. Cash used for the years ended December 31, 2013 and 2012 was for the purchase of property and equipment primarily for use in manufacturing Sumavel DosePro.

We expect to incur capital expenditures of approximately $1.0 million in 2015. These planned capital expenditures primarily relate to further investments in our manufacturing operations for Zohydro ER and toward enhancing our existing manufacturing technology and equipment.

Financing Activities. Net cash provided (used) by financing activities was $(10.0) million, $76.5 million and $37.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. Net cash provided by financing activities for the year ended December 31, 2014 included net proceeds of our term loan and revolving line of credit with Oxford and SVB of $21.0 million, a working capital advance from Endo of $7.0 million and proceeds of $1.5 million from the exercise of warrants and stock options, offset by $40.0 million paid to Healthcare Royalty to terminate the Healthcare Royalty financing arrangement.

Net cash provided by financing activities for the year ended December 31, 2013 included net proceeds from the sale of common stock in November 2013 and under our controlled equity offering program. Net cash provided by financing activities for the year ended December 31, 2012 included net proceeds from the issuance of common stock and warrants to purchase common stock during our July 2012 public offering, and net proceeds provided by our revolving credit facility with Oxford and SVB, offset by payments on our borrowed debt.

Our sources of liquidity include our cash balances and cash receipts from the sale of Zohydro ER and contract revenue from Sumavel DosePro. Through December 31, 2014, we received aggregate net cash proceeds of approximately $417.5 million from the sale of shares of our preferred and common stock. As of December 31, 2014, we had $42.2 million in cash and cash equivalents. Other potential sources of near-term liquidity include (i) our unused balance of the revolving credit facility, (ii) the remaining $5.0 million exclusivity rights payment due from Purdue, (iii) equity, debt or other financing, (iv) entering into a commercialization agreement for Zohydro ER, or a licensing arrangement for ZX008 or Relday, or (v) further leveraging our sales force capacity to promote Migranal or another new product. Successful transition to profitability is dependent upon achieving a level of product revenues adequate to support our cost structure. We will continue to monitor and evaluate our sales progress, the level of our research, development, manufacturing, sales and marketing and general and administrative expenditures and may adjust such expenditures based upon a variety of factors, such as our available cash, our ability to obtain additional cash, the results and progress of our Zohydro ER commercialization efforts, results and progress in our clinical program, the time and costs related to clinical trials and regulatory decisions, as well as the U.S. economic environment.

If we fail to pay amounts owing under the Loan and Security Agreement when due, if we breach our other covenants or obligations under the agreement, or if other events of default under the agreement occur, Oxford and SVB would be entitled to demand immediate repayment of all borrowings and other obligations thereunder and to seize and sell the collateral pledged as security under the agreements to satisfy those obligations. If we were to breach our covenants and obligations and we were unable to obtain a waiver or amendment from the lender, we would be required to seek additional equity or debt financing to refinance our obligations under the agreement. Additional debt or equity financing may not be available to us in amounts or on terms we consider acceptable, or at all. In that regard, we have from time to time been required to obtain waivers and amendments under our debt instruments in order to avoid breaches or other defaults. For example, in each of 2012, 2011 and 2010 we were required to obtain amendments or waivers under our credit facilities.

We cannot be certain if, when and to what extent we will generate positive cash flow from operations from the commercialization of our products and, if approved, product candidates. We expect our expenses to be substantial and to increase over the next few years as we continue to grow the Zohydro ER brand and as we potentially advance ZX008 and Relday through clinical development.

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Contractual Obligations and Commitments

The following table describes our long-term contractual obligations and commitments as of December 31, 2014:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
	(In Thousands)				
Debt obligations (1)	$27,000	$—	$13,333	$6,667	$7,000
Debt interest (2)	5,302	1,604	2,382	1,316	—
Operating lease obligations (3)	7,933	1,874	3,809	1,990	260
Purchase obligations (4)	17,822	14,833	2,989	—	—
Total	$58,057	$18,311	$22,513	$9,973	$7,260

(1) Represents payments due in conjunction with our term debt and working capital advance note. See Note 9 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) Represents the estimated interest on scheduled debt payments under the term debt and revolving line of credit agreement, using the effective interest method.

(3) Represents the minimum rental payments for our San Diego, California office pursuant to a lease entered into in August 2014, which expires in March 2020 and the rental payments for a fleet vehicles pursuant to a lease entered into in August 2009. Each vehicle has a lease term of 36 months.

(4) Primarily represents non-cancellable purchase orders for the production of key components of Sumavel DosePro, a minimum manufacturing fee payable to Patheon UK Limited through the remaining term of our manufacturing services agreement, and non-cancellable orders for the purchase of Zohydro ER. These purchase obligations are based on the exchange rate at December 31, 2014.

Under our development and license agreement with Daravita we will be required to pay a mid-single-digit percentage royalty on Zohydro ER net sales for a specified period of time and continue to pay royalties on net sales of the product thereafter at a reduced low single-digit percentage rate in accordance with the terms of the license agreement.

Under our development and option agreement with Altus, we are obligated to pay Altus up to $3.5 million in total future milestone payments with respect to an abuse deterrent formulation of hydrocodone, subject to the achievement of various development and regulatory milestones. In addition, if we exercise our option to license certain Altus intellectual property, we will be required to pay additional regulatory and sales milestones and a royalty on net sales of the licensed product.

Under our asset purchase agreement with Aradigm, we are required to pay a 3% royalty on global net sales of Sumavel DosePro by us or one of our licensees and, in the event that we or one of our future licensees, if any, commercializes a non-sumatriptan product in the DosePro delivery system, we are required to pay Aradigm, at our election, either a 3% royalty on net sales of each non-sumatriptan product commercialized or a fixed low-twenties percentage of royalty revenue received by us from the licensee. This agreement was assigned to Endo in conjunction with the sale of the Sumavel DosePro business in May 2014.

Under the terms of our agreement to acquire Brabant (see Note 6 to our consolidated financial statements, included in this Annual Report on Form 10-K) we may be obligated to pay up to $95.0 million in total future milestone payments upon the achievement of specified regulatory and sales milestones.

Under our Relday license agreement with Durect we are obligated to pay Durect up to $103.0 million in total future milestone payments with respect to the product subject to and upon the achievement of various development, regulatory and sales milestones. In addition, we are required to pay Durect a mid-single-digit to low double-digit percentage patent royalty on annual net sales of the product determined on a jurisdiction-by-jurisdiction basis, and we are also required to pay to Durect a tiered percentage of fees received in connection with any sublicense of the licensed rights. Further, until an NDA for Relday has been filed in the United States, we are obligated to spend no less than $1.0 million in external expenses on the development of Relday in any trailing twelve month period beginning in July 2012.

We also maintain agreements with third parties to manufacture our product, conduct our clinical trials, and perform data collection and analysis. Our payment obligations under these agreements will likely depend upon the progress of our development programs, sales of our product and commercialization efforts. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements.

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Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board, or FASB, issued an accounting update that raises the threshold for disposals to qualify as discontinued operations and allows companies to have significant continuing involvement with and continuing cash flows from or to the discontinued operations. This accounting update also requires additional disclosures for discontinued operations and new disclosures for individually material disposal transactions that do not meet the definition of a discontinued operation. This guidance will be effective for fiscal years beginning after December 15, 2014, with early adoption permitted. We do not expect that the adoption of the guidance will have a material impact on our financial statements.

In May 2014, the FASB issued new accounting guidance related to revenue recognition. This new standard will replace all current GAAP guidance on this topic and eliminate all industry-specific guidance. The new revenue recognition standard provides a unified model to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration for which the entity expects to be entitled in exchange for those goods or services. This guidance will be effective for fiscal years beginning after December 16, 2016, including interim periods within that reporting period, and can be applied either retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is prohibited. We are evaluating the timing and impact of adopting this new accounting standard on our financial statements and related disclosures.

In June 2014, the FASB issued new accounting guidance related to stock compensation. The new standard requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015 and can be applied either prospectively or retrospectively to all awards outstanding as of the beginning of the earliest annual period presented as an adjustment to opening retained earnings. Early adoption is permitted. We do not expect that the adoption of the guidance will have a material impact on our financial statements.

In August 2014, the FASB issued new accounting guidance which requires management to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and provide related footnote disclosures. The guidance is effective for annual and interim reporting periods beginning on or after December 15, 2016. Early adoption is permitted. We do not expect that the adoption of the guidance will have a material impact on our financial statements.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of December 31, 2014 consisted of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve principal. Instruments that meet this objective include commercial paper, money market funds and government and non-government debt securities. Some of the investment securities available-for-sale that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment securities available-for-sale to fluctuate. To minimize this risk, we intend to continue to maintain our portfolio of cash and money market funds. Due to the short-term nature of our investments and our ability to hold them to maturity, we believe that there is no material exposure to interest rate risk.

Our term notes payable and revolving line of credit with Oxford and SVB contain adjustable rate interest terms. The term loan bears interest at an annual rate equal to the greater of (i) 8.75% and (ii) the sum of (a) the “prime rate” rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately

precedes the month in which the interest will accrue, plus (b) 5.25%. Each revolving advance under the credit facility bears interest at an annual rate equal to the sum of (a) the "prime rate" rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 4.75%. Based on our outstanding

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principal balances and historical interest rate volatility, we do not believe an adjustment of 100 basis points would create a material exposure.

Foreign Exchange Risk

All of the revenues we have generated to date have been paid in U.S. dollars and we expect that our revenues will continue to be generated primarily in U.S. dollars for at least the next several years. Payments to our material suppliers and contract manufacturers for Sumavel DosePro are denominated in the Euro and U.K. pounds sterling, however, terms of our contract manufacturing supply agreement are cost plus, so foreign exchange risk is borne by the customer.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and the report of our independent registered public accounting firm are included in this report on pages F-1 through F-40.

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 Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

Management's Annual Report on Internal Control Over Financial Reporting

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

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control 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 Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the

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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, 2014, the end of our most recent fiscal year. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting for the year ended December 31, 2014, which is included below.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Zogenix, Inc.

We have audited Zogenix, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Zogenix, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting 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 the assets of the company; (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 receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Zogenix, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Zogenix, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014 of Zogenix, Inc. and our report dated March 11, 2015 expressed an unqualified opinion thereon that included an explanatory paragraph regarding Zogenix, Inc.'s ability to continue as a going concern.

/s/ ERNST & YOUNG LLP

San Diego, California
March 11, 2015

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Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be contained in our Definitive Proxy Statement, or the Definitive Proxy Statement, to be filed with the Securities and Exchange Commission in connection with our 2015 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2014, under the headings “Election of Directors,” “Corporate Governance and Other Matters ,” “Executive Officers,” and “Section 16(a) Beneficial Ownership Reporting Compliance,” and is incorporated herein by reference .

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our internet website at www.zogenix.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

Information required by this item will be contained in our Definitive Proxy Statement under the heading “Executive Compensation and Other Information” and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this item will be contained in our Definitive Proxy Statement under the headings “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

Item 13. Certain Relationships, Related Transactions and Director Independence

Information required by this item will be contained in our Definitive Proxy Statement under the headings “Certain Relationships and Related Party Transactions” and “Independence of the Board of Directors” and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information required by this item will be contained in our Definitive Proxy Statement under the heading “Independent Registered Public Accounting Firm’s Fees” and is incorporated herein by reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements. The following consolidated financial statements of Zogenix, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

2. Financial Statement Schedules.

All schedules are omitted as the required information is inapplicable, or the information is presented in the consolidated financial statements or related notes.

3. Exhibits.

A list of exhibits to this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding such exhibits and is incorporated herein by reference.

(b) See Exhibit Index.

(c) See Item 15(a)(2) above.

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Zogenix, Inc.
Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Zogenix, Inc.

We have audited the accompanying consolidated balance sheets of Zogenix, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Zogenix, Inc. at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that Zogenix, Inc. will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations and negative cash flows from operating activities raise substantial doubt about its ability to continue as a going concern. Management's plans as to these matters also are described in Note 1. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Zogenix, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 11, 2015 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California

March 11, 2015

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Zogenix, Inc.
Consolidated Balance Sheets
(In Thousands, except Par Value)

	December 31, 2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$42,205	$72,021
Restricted cash	8,500	—
Trade accounts receivable, net	8,877	6,665
Inventory	13,439	9,936
Prepaid expenses	2,224	2,144
Other current assets	2,733	2,113
Total current assets	77,978	92,879
Property and equipment, net	10,618	13,011
Intangible assets	102,500	—
Goodwill	6,234	—
Other assets	5,505	6,614
Total assets	$202,835	$112,504
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$8,523	$4,622
Accrued expenses	15,486	18,865
Common stock warrant liabilities	5,093	31,341
Accrued compensation	5,090	3,952
Revolving credit facility	1,450	—
Deferred revenue	8,595	—
Total current liabilities	44,237	58,780
Long-term debt	21,703	28,802
Deferred revenue, less current portion	7,063	—
Contingent purchase consideration	53,000	—
Deferred tax liability	20,500	—
Other long-term liabilities	1,053	6,496
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized at December 31, 2014 and 2013; 153,363 and 138,927 shares issued and outstanding at December 31, 2014 and 2013, respectively.	153	139
Additional paid-in capital	456,786	428,534
Accumulated deficit	(401,660)	(410,247)
Total stockholders' equity	55,279	18,426
Total liabilities and stockholders' equity	$202,835	$112,504

See accompanying notes.

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Zogenix, Inc.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(In Thousands, except Per Share Amounts)

	Year Ended December 31,		
	2014	2013	2012
Revenue:			
Net product revenue	$21,715	$31,699	$35,826
Contract manufacturing revenue	15,392	—	—
Contract revenue	—	—	8,462
Service and other revenue	3,424	1,313	38
Total revenue	40,531	33,012	44,326
Operating expenses:			
Cost of goods sold	15,817	21,241	19,496
Cost of contract manufacturing	14,342	—	—
Royalty expense	1,718	1,242	1,353
Research and development	18,936	12,805	21,414
Selling, general and administrative	88,899	50,040	49,494
Restructuring	—	876	—
Impairment of long-lived assets	838	—	—
Net gain on sale of business	(79,980)	—	—
Total operating expenses	60,570	86,204	91,757
Loss from operations	(20,039)	(53,192)	(47,431)
Other income (expense):			
Interest income	20	18	53
Interest expense	(3,090)	(6,610)	(10,313)
Loss on extinguishment of debt	(1,254)	—	—
Change in fair value of warrant liabilities	25,332	(21,927)	11,811
Change in fair value of embedded derivatives	(14)	759	(147)
Other income (expense)	7,716	96	(1,354)
Total other income (expense)	28,710	(27,664)	50
Net income (loss) before income taxes	8,671	(80,856)	(47,381)
Provision for income taxes	(84)	—	(5)
Net income (loss)	$8,587	$(80,856)	$(47,386)
Net income (loss) per share, basic and diluted	$0.06	$(0.74)	$(0.59)
Weighted average shares outstanding, basic	142,607	108,568	80,558
Weighted average shares outstanding, diluted	145,046	108,568	$80,558
Comprehensive income (loss)	$8,587	$(80,856)	$(47,386)

See accompanying notes.

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Zogenix, Inc.
Consolidated Statements of Stockholders' Equity
In Thousands, except Per Share Amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2011	65,369	$65	$291,252	$(282,005)	$9,312
Net loss	—	—	—	(47,386)	(47,386)
Issuance of common stock from July 2012 offering, net of issuance costs of $3,328	35,058	35	45,774	—	45,809
Issuance of common stock in conjunction with exercise of stock options	18	—	33	—	33
Issuance of common stock from ESPP purchase	364	1	547	—	548
Stock-based compensation	—	—	6,157	—	6,157
Balance at December 31, 2012	100,809	101	343,763	(329,391)	14,473
Net loss	—	—	—	(80,856)	(80,856)
Issuance of common stock from November 2013 offering, net of issuance costs of $4,529	30,667	31	64,440	—	64,471
Issuance of common stock from controlled equity offering, net of issuance costs of $371	6,753	7	10,827	—	10,834
Issuance of common stock in conjunction with exercise of stock options	291	—	574	—	574
Issuance of common stock from ESPP purchase	304	—	385	—	385
Issuance of common stock in conjunction with exercise of warrants	103	—	338	—	338
Stock-based compensation	—	—	8,006	—	8,006
Stock-based compensation, restructuring	—	—	201	—	201
Balance at December 31, 2013	138,927	$139	$428,534	$(410,247)	$18,426
Net income	—	—	—	8,587	8,587
Issuance of common stock in conjunction with exercise of stock options	152	—	343	—	343
Issuance of common stock from ESPP purchase	504	1	555	—	556
Issuance of common stock in conjunction with exercise of warrants	465	—	2,079	—	2,079
Issuance of common stock in conjunction with vesting of restricted stock units	1,321	1	—	—	1
Issuance of common stock in conjunction with acquisition	11,995	12	15,225	—	15,237
Issuance of common stock warrants in conjunction with debt	—	—	558	—	558
Stock-based compensation	—	—	9,492	—	9,492
Balance at December 31, 2014	153,364	$153	$456,786	$(401,660)	$55,279

See accompanying notes.

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Zogenix, Inc.
Consolidated Statements of Cash Flows
(In Thousands)

	Year Ended December 31,		
	2014	2013	2012
Operating activities:			
Net income (loss)	$8,587	$(80,856)	$(47,386)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Stock-based compensation	9,492	8,006	6,157
Stock-based compensation, restructuring	—	201	—
Depreciation	1,625	1,806	1,599
Amortization of debt issuance costs and non-cash interest	457	569	2,017
Change in fair value of warrant liabilities	(25,332)	21,927	(11,811)
Change in fair value of embedded derivatives	14	(759)	147
Loss on disposal and impairment of property and equipment	838	—	9
Loss on debt extinguishment	1,254	—	—
Gain on sale of business	(79,980)	—	—
Changes in operating assets and liabilities:			
Trade accounts receivable	(2,212)	(1,022)	(730)
Inventory	(3,503)	2,950	3,890
Prepaid expenses and other current assets	(9,200)	(2,004)	163
Other assets	(4,367)	(1,747)	11
Accounts payable and accrued expenses	5,645	6,142	2,194
Restructuring liabilities	—	4	—
Deferred revenue	15,658	(137)	(8,462)
Deferred rent	208	—	—
Net cash used in operating activities	(80,816)	(44,920)	(52,202)
Investing activities:			
Purchases of property and equipment	(122)	(810)	(293)
Proceeds from sale of business	89,624	—	—
Restricted cash from sale of business	(8,500)	—	—
Acquisition of business, net of cash acquired	(20,000)	—	—
Net cash provided by (used in) investing activities	61,002	(810)	(293)
Financing activities:			
Proceeds from borrowings of debt and revolving credit facility, net of issuance costs	27,977	—	9,900
Payments on borrowings of debt	(40,041)	—	(25,000)
Payments on revolving credit facility	—	—	(15,051)
Proceeds from exercise of common stock options and warrants	1,506	833	33
Proceeds from issuance of common stock and common stock warrants, net of issuance costs	556	75,690	67,316
Net cash provided (used) by financing activities	(10,002)	76,523	37,198
Net (decrease) increase in cash and cash equivalents	(29,816)	30,793	(15,297)
Cash and cash equivalents at beginning of period	72,021	41,228	56,525
Cash and cash equivalents at end of period	$42,205	$72,021	$41,228
Supplemental disclosure of cash flow information:			
Cash paid for interest	$12,847	$2,463	$5,284
Noncash investing and financing activities:			

Issuance of common stock in conjunction with acquisition	$15,237	$—	$—
Purchase of property and equipment in accounts payable	$12	$446	$—
Change in common stock warrant liability associated with exercise of warrants	$(916)	$(79)	$—
Warrants issued in connection with public offering	$—	$—	$20,959
Asset retirement obligation	$—	$—	$286
Warrants issued in connection with debt	$558	$—	$—

See accompanying notes.

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Zogenix, Inc.
Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

Zogenix, Inc. (the Company) is a pharmaceutical company committed to developing and commercializing therapies that address specific clinical needs for people living with central nervous system disorders who need innovative treatment alternatives to help them return to normal daily functioning. The Company was incorporated in the state of Delaware on May 11, 2006 as SJ2 Therapeutics, Inc. and commenced operations on August 25, 2006. On August 28, 2006, the Company changed its name to Zogenix, Inc.

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through equity financings, debt financings, revenues from the sale of its product Sumavel DosePro and proceeds from business collaborations. As the Company continues to incur losses, successful transition to profitability is dependent upon achieving a level of revenues adequate to support the Company's cost structure. This may not occur and, unless and until it does, the Company will continue to need to raise additional cash. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business.

On October 25, 2013, the Company received marketing approval from the U.S. Food and Drug Administration (FDA) for Zohydro® ER (hydrocodone bitartrate) extended-release capsules, CII, an opioid agonist, extended-release oral formulation of hydrocodone without acetaminophen, 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. Zohydro ER is the first extended-release oral formulation of hydrocodone without acetaminophen. The Company launched Zohydro ER in March 2014. On September 30, 2014, the Company submitted a supplemental New Drug Application (sNDA) for a modified formulation of Zohydro ER which was has been designed to have abuse deterrent properties. The FDA approved the Company's sNDA on January 30, 2015.

The Company's first commercial product, Sumavel® DosePro® (sumatriptan injection) Needle-free Delivery System, was launched in January 2010. The Company sold its Sumavel DosePro business to Endo Ventures Bermuda Limited (Endo Ventures Bermuda) and Endo Ventures Limited (Endo Ventures and, together with Endo Ventures Bermuda, Endo) on May 16, 2014 (the Closing) and in connection with the Closing, entered into a supply agreement (the Supply Agreement), pursuant to which the Company will supply Sumavel DosePro to Endo Ventures, subject to Endo Venture's right to qualify and maintain a back-up manufacturer. Endo will support the Company's Sumavel DosePro manufacturing operations with a working capital advance. In addition to the working capital advance, Endo paid the Company $85,000,000 and $4,624,000 for finished goods inventory on hand at the Closing. The Company is eligible to receive additional cash payments of up to $20,000,000 based on the achievement of pre-determined milestones (see Note 5).

On October 24, 2014, Zogenix Europe Limited (Zogenix Europe), a wholly-owned subsidiary of the Company, acquired Brabant Pharma Limited, for consideration of $20,000,000 in cash and 11,995,202 shares of the Company's common stock. Zogenix Europe also committed to paying up to an aggregate amount of $95,000,000 in connection with the achievement of certain milestones for ZX008 (see Note 6).

On November 6, 2014, the Company entered into a controlled equity offering sales agreement with Cantor Fitzgerald & Co., (Cantor) as sales agent, under which the Company can issue and sell shares of its common stock having an aggregate offering price of up to $25,000,000 from time to time through Cantor. Sales of the Company's common stock made pursuant to the controlled equity offering program, if any, will be made on the Nasdaq Global Market under the Company's shelf registration statement on Form S-3 filed on November 6, 2014 which was declared effective by the SEC on January 20, 2015. There can be no assurance that Cantor will be successful in consummating sales under the program based on prevailing market conditions or in the quantities or at the prices that the Company deems appropriate.

Management expects operating losses and negative cash flows to continue for at least the next year as the Company continues to incur costs related to the commercialization of Zohydro ER, the introduction of Zohydro ER with abuse deterrent properties to the market, the clinical development of ZX008 and Relday, required post-market testing for Zohydro ER, safe use initiatives for Zohydro ER and additional development activities with respect to Zohydro ER, including the development of multiple formulations of extended-release hydrocodone with abuse deterrent properties. Management intends to pursue additional opportunities to raise additional capital through public or private equity offerings, including through debt financings,

receivables financings or through collaborations or partnerships with other companies to further support its planned operations. There can be no assurance that the Company will be able to obtain any source of financing on acceptable terms, or at all. If the Company is unsuccessful in raising additional required funds, it may be required to significantly delay, reduce the scope of or eliminate one or more of its development programs or its commercialization efforts, or cease operating as a going concern. The Company also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that it would otherwise seek to develop or commercialize itself on terms that are less favorable than might otherwise be available.

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Zogenix, Inc.
Notes to Consolidated Financial Statements (continued)

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ materially from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of Zogenix, Inc. and its wholly owned subsidiary Zogenix Europe, which was incorporated under the laws of England and Wales in June 2010. All intercompany transactions and investments have been eliminated in consolidation. Zogenix Europe's functional currency is the U.S. dollar, the reporting currency of its parent.

Cash and Cash Equivalents

The Company considers cash equivalents to be only those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased.

Restricted Cash

In connection with its sale of the Sumavel DosePro business in May 2014, the Company has $8,500,000 of cash in escrow as of December 31, 2014 to fund potential indemnification claims for a period of 12 months from the closing date of the sale (see Note 5). The Company classifies the cash flow from this restricted cash as an investing activity in the consolidated statement of cash flows as the source of the restricted cash is related to the sale of the Sumavel DosePro business.

Further, in December 2009 the Company issued a letter of credit for $200,000 in connection with an operating lease. The letter of credit was collateralized by a certificate of deposit in the same amount. Restricted cash of $200,000 at December 31, 2013 is included in other assets on the consolidated balance sheet. This line of credit and certificate of deposit were terminated in February 2014 in connection with a renegotiation of the operating lease.

Accounts Receivable

Trade accounts receivable are recorded at the invoice amount net of allowances for cash discounts for prompt payment and uncollectible accounts. The Company evaluates the utilization of payment discounts and collectibility of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. The Company reserves specific receivables if collectibility is no longer reasonably assured. The Company reviews the reserves on a regular basis and adjusts its reserves as needed. Once a receivable is deemed to be uncollectible, the balance is charged against the reserve.

Based upon the review of these factors, the Company recorded allowances of $102,000 and $18,000 for uncollectible accounts and $59,000 and $118,000 for payment discounts at December 31, 2014 and 2013, respectively.

Acquisitions

The Company measures all assets acquired and liabilities assumed, including contingent consideration, at fair value as of the acquisition date. Contingent purchase considerations to be settled in cash are remeasured to estimated fair value at each reporting period with the change in fair value recorded in operating expenses. In addition, the Company capitalizes in-process research and development (IPR&D) and either amortizes it over the life of the product upon commercialization, or impairs it if the carrying value exceeds the fair value or if the project is abandoned. Post-acquisition adjustments in deferred tax liabilities are recorded in current period income tax expense in the period of the adjustment.

Fair Value Measurements

The carrying amount of financial instruments consisting of cash, restricted cash, trade accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses (excluding the tail payment due to Astellas Pharmaceutical US, Inc. (Astellas)) and accrued compensation included in the Company's consolidated financial statements are reasonable estimates of fair value due to their short maturities. Based on the borrowing rates currently

available to the Company for loans with similar terms, management believes the fair value of long-term debt (including the discount on the working

capital advance from Endo) approximates its carrying value. The accrued liability for the annual tail payment due to Astellas (see Note 3) for the termination of the Company's co-promotion agreement was measured at fair value using a present value technique, which incorporated the Company's own credit risk as measured by the most recent round of debt financing with Healthcare Royalty Partners (Healthcare Royalty) (formerly Cowen Healthcare Royalty Partners II, L.P.).

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company classifies its cash equivalents within Level 1 of the fair value hierarchy because it values its cash equivalents using quoted market prices. The Company classifies its common stock warrant liabilities, contingent purchase consideration and embedded derivative liability within Level 3 of the fair value hierarchy because they are valued using valuation models with significant unobservable inputs. Assets and liabilities measured at fair value on a recurring basis at December 31, 2014 and December 31, 2013 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At December 31, 2014				
Assets				
Cash equivalents (1)	$8,021	$—	$—	$8,021
Liabilities				
Common stock warrant liabilities (2)	$—	$—	$5,093	$5,093
Contingent purchase consideration (3)	$—	$—	$53,000	$53,000
At December 31, 2013				
Assets				
Cash equivalents (1)	$69,120	$—	—	$69,120
Liabilities				
Common stock warrant liability (2)	$—	$—	$31,341	$31,341
Embedded derivative liability (4)	$—	$—	$233	$233

(1) Cash equivalents are comprised of money market fund shares and are included as a component of cash and cash equivalents on the consolidated balance sheet.

(2) Common stock warrant liabilities include liabilities associated with warrants issued in connection with the Company's July 2012 public offering of common stock and warrants (see Note 10) and warrants issued in connection with the financing agreement entered into with Healthcare Royalty (the Healthcare Royalty Financing Agreement) (see Note 9), which are measured at fair value using the Black-Scholes option pricing valuation model. The assumptions used in the Black-Scholes option pricing valuation model for both common stock warrant liabilities were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero based on

the Company’s expectation that it will not pay dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the warrants; and (d) given the Company’s lack of relevant historical data due to the Company’s limited historical experience, an expected volatility based upon the Company's historical volatility, supplemented with historical volatility of comparable companies whose share prices have been publicly available for a sufficient period of time. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities associated with the Healthcare Royalty Financing Agreement is the

expected volatility. Significant increases in volatility would result in a higher fair value measurement. The following additional assumptions were used in the Black-Scholes option pricing valuation model to measure the fair value of the warrants sold in the July 2012 public offering: (a) management's projections regarding the probability of the occurrence of an extraordinary event and the timing of such event; and for the valuation scenario in which an extraordinary event occurs that is not an all cash transaction or an event whereby a public acquirer would assume the warrants, (b) an expected volatility rate using the Company's historical volatility, supplemented with historical volatility of comparable companies, through the projected date of public announcement of an extraordinary transaction, blended with a rate equal to the lesser of 40% and the 180-day volatility rate obtained from the HVT function on Bloomberg as of the trading day immediately following the public announcement of an extraordinary transaction. The significant unobservable inputs used in measuring the fair value of the common stock warrant liabilities associated with the July 2012 public offering are the expected volatility and the probability of the occurrence of an extraordinary event. Significant increases in volatility would result in a higher fair value measurement and significant increases in the probability of an extraordinary event occurring would result in a significantly lower fair value measurement.

(3) Contingent purchase consideration was measured at fair value using the income approach based on significant unobservable inputs including management's estimates of the probabilities of achieving specific net sales levels and development milestones and appropriate risk adjusted discount rates. Significant changes of either unobservable input could have a significant effect on the calculation of fair value of the contingent purchase consideration liability.

(4) Embedded derivatives were measured at fair value using various discounted cash flow valuation models and were included as a component of other long-term liabilities on the consolidated balance sheet at December 31, 2013. The assumptions used in the discounted cash flow valuation models included: (a) management's revenue projections and a revenue sensitivity analysis based on possible future outcomes; (b) probability weighted net cash flows based on the likelihood of Healthcare Royalty receiving interest payments over the term of the Healthcare Royalty Financing Agreement; (c) probability of bankruptcy; (d) weighted average cost of capital that included the addition of a company specific risk premium to account for uncertainty associated with the Company achieving future cash flows; (e) the probability of a change in control occurring during the term of the Healthcare Royalty Financing Agreement; and (f) the probability of an exercise of the embedded derivative instruments. The significant unobservable inputs used in measuring the fair value of the embedded derivatives were management’s revenue projections. Significant decreases in these significant inputs would result in a higher fair value measurement of the liability. The embedded derivatives were derecognized in May 2014 as a result of the early extinguishment of the Healthcare Royalty Financing Agreement (see Note 9).

The following table provides a reconciliation of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) for the years ended December 31, 2014 and 2013 (in thousands):

	Contingent Purchase Consideration	Common Stock Warrant Liability	Embedded Derivative Liabilities
Balance at December 31, 2012	$—	$9,493	$992
Exercises	—	(79)	—
Changes in fair value	—	21,927	(759)
Balance at December 31, 2013	—	31,341	233
Purchases/additions	53,000	—	—
Exercises	—	(916)	—
Derecognition of liability	—	—	(247)
Changes in fair value	—	(25,332)	14

Balance at December 31, 2014	$53,000	$5,093	$—

Changes in fair value of contingent purchase consideration is reflected as operating expenses. Changes to the warrant liabilities shown in the table above are recorded through a change in fair value of warrant liabilities and change in fair value of embedded derivatives in other income (expense) in the consolidated statements of operations and comprehensive loss.

Concentration of Credit Risk, Sources of Supply and Significant Customers

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and trade accounts receivable. The Company maintains accounts in federally insured financial institutions in

excess of federally insured limits. The Company also maintains investments in money market funds that are not federally insured. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which these deposits are held and of the money market funds and other entities in which these investments are made. Additionally, the Company has established guidelines regarding the diversification of its investments and their maturities, which are designed to maintain safety and liquidity.

The Company sells its products primarily to established wholesale distributors and retailers in the pharmaceutical industry, and provides contract manufacturing services to one customer. Three wholesale pharmaceutical distributors individually comprised 33%, 32% and 23% of the Company's total ex-factory product gross sales for the year ended December 31, 2014.

Approximately 79.0% of the gross trade accounts receivable balance as of December 31, 2014 represents amounts due from three customers. Credit is extended based on an evaluation of the customer's financial condition, and collateral is not required. The Company evaluates the collectibility of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company recorded an allowance of doubtful accounts of $102,000 and $18,000 at December 31, 2014 and December 31, 2013, respectively. There were no significant write-offs of trade accounts receivable balances for the years ended December 31, 2014 and 2013.

The Company relies on a third-party manufacturer and supplier of Zohydro ER. The Company also relies on third-party manufacturers for the production of Sumavel DosePro and single source third-party suppliers to manufacture several key components of Sumavel DosePro. If the Company's third-party manufacturers are unable to continue manufacturing Zohydro ER or Sumavel DosePro, or if the Company lost one or more of its single source suppliers used in the manufacturing process, the Company may not be able to meet market demand for the products.

Inventory

Inventory is stated at the lower of cost or market. Cost includes amounts related to materials, labor and overhead, and is determined in a manner which approximates the first-in, first-out (FIFO) method. The Company adjusts the carrying value of inventory for potentially excess, dated or product within one year of expiration and obsolete products based on an analysis of inventory on hand and compared to forecasts of future sales.

The FDA approved Zohydro ER with BeadTek on January 30, 2015. The Company anticipates transitioning from the currently marketed product to this reformulation of Zohydro ER in the second quarter of 2015. In connection with this transition, the Company reviewed its inventory and estimated sales through the transition date and the wholesale and retail channel and recorded an adjustment to reduce the carrying value of inventory in excess of estimated sales of the current formulation of $5,769,000 which was recorded as a cost of product sales for the year ended December 31, 2014. Further, the Company analyzed non-cancellable purchase commitments for the current formulation that will be replaced by the new formulation of Zohydro ER and recorded a liability of $2,594,000 for these commitments at December 31, 2014, which was included as a cost of goods sold for the year ended December 31, 2014.

Property and Equipment, Net

Property and equipment is recorded at cost, net of accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the respective assets, as follows:

Computer equipment and software	3 years
Furniture and fixtures	3-7 years
Manufacturing equipment and tooling	3-15 years
Leasehold improvements	Shorter of estimated useful life or lease term

Goodwill, Intangible Assets and Other Long-Lived Assets

Goodwill, which has an indefinite useful life, represents the excess of cost over fair value of net assets acquired. The Company recorded goodwill during the year ended December 31, 2014 as a result of the acquisition of Brabant (see

Note 6). Goodwill will be reviewed for impairment at least annually or more frequently if any indicators of potential impairment are

present. In performing its goodwill impairment review, the Company may assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If, after assessing the totality of these qualitative factors, the Company determines that it is not more likely than not that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, the Company will proceed to perform a two-step test for goodwill impairment. The first step involves comparing the estimated fair value of the reporting unit with its carrying value, including goodwill. If the carrying amount of the reporting unit exceeds its fair value, the Company performs the second step of the goodwill impairment test to determine the amount of impairment, which involves comparing the implied fair value of the goodwill to the carrying value of the goodwill. The Company may also elect to bypass the qualitative assessment in a period and elect to proceed to perform the first step of the goodwill impairment test. The Company did not perform an impairment assessment for goodwill for the year ended December 31, 2014 due to the proximity of the acquisition of Brabant to year end.

Intangible assets, which consist of in-process research and development (IPR&D) purchased in conjunction with the acquisition of Brabant (see Note 6) also have an indefinite useful life. IPR&D will be reviewed for impairment at least annually, or more frequently if any indicators of potential impairment are present. The IPR&D impairment test requires the Company to assess the fair value of the asset as compared to its carrying value and record an impairment charge if the carrying value exceeds the fair value. The Company did not perform an impairment assessment for IPR&D the year ended December 31, 2014 due to the proximity of the acquisition of Brabant to year end.

The Company reviews its other long-lived assets, consisting of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. As a result of the sale of its Sumavel DosePro business in May 2014, the Company recorded an impairment charge of $838,000 in the consolidated statement of operations and comprehensive income (loss) during the year ended December 31, 2014 related to the disposal of construction in progress that will no longer be placed into service. There were immaterial charges as a result of impairment losses during the year ended December 31, 2013.

Warrants for Common Stock

In accordance with accounting guidance for warrants for shares in redeemable securities or warrants that could be settled for cash, the Company classifies warrants for common stock as current liabilities or equity on the consolidated balance sheet as appropriate. The Company adjusts the carrying value of warrants for common stock that can be settled in cash to their estimated fair value at each reporting date with the increases or decreases in the fair value of such warrants recorded as change in fair value of warrant liabilities in the consolidated statement of operations and comprehensive income (loss).

Embedded Derivatives

The Company records embedded derivatives in the consolidated balance sheet at fair value. The carrying value of the embedded derivatives are adjusted to their estimated fair value at each reporting date with the increases or decreases in the fair value of such embedded derivatives recorded as change in fair value of embedded derivatives in the consolidated statement of operations and comprehensive income (loss). The Company derecognized the balance of embedded derivatives in May 2014 as a result of the early extinguishment of the Healthcare Royalty Financing Agreement (see Note 9).

Revenue Recognition

The Company recognizes revenue from the sale of Zohydro ER and Sumavel DosePro prior to the sale of Sumavel DosePro to Endo in May 2014, and from contract manufacturing, license fees, milestones and service fees earned on collaborative arrangements. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized

at the time of sale only if (a) the Company's price to the buyer is substantially fixed or determinable at the date of sale, (b) the buyer has paid the Company, or the buyer is obligated to pay the Company and the obligation is not contingent on resale of the product, (c) the buyer's obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (d) the buyer acquiring the product for resale has economic substance apart from that provided by the Company, (e) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (f) the amount of future returns can be reasonably estimated. The Company currently defers recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists, as the Company currently cannot reliably estimate expected returns of the

product at the time of shipment given the limited sales history of Zohydro ER.

Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units. The application of the multiple element guidance requires subjective determinations, and requires the Company to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. In determining the units of accounting, the Company evaluates certain criteria, including whether the deliverables have stand-alone value, based on the consideration of the relevant facts and circumstances for each arrangement. In addition, the Company considers whether the buyer can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s), and whether there are other vendors that can provide the undelivered element(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria, as described above, are applied to each of the separate units of accounting in determining the appropriate period or pattern of recognition. The Company determines the estimated selling price for deliverables within each agreement using VSOE of selling price, if available, TPE of selling price if VSOE is not available, or management's BESP if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs.

Product Revenue, Net

The Company sells Zohydro ER, and sold Sumavel DosePro through May 2014 in the United States to wholesale pharmaceutical distributors and retail pharmacies, or collectively the Company's customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. The Company recognized Sumavel DosePro product sales at the time title transferred to its customer, and reduced product sales for estimated future product returns and sales allowances in the same period the related revenue was recognized.

Given the limited sales history of Zohydro ER, the Company cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on Zohydro ER product shipments until the right of return no longer exists, which occurs at the earlier of the time Zohydro ER is dispensed through patient prescriptions or expiration of the right of return. The Company estimates Zohydro ER patient prescriptions dispensed using an analysis of third-party syndicated data. Zohydro ER was launched in March 2014 and, accordingly, the Company does not have a significant history estimating the number of patient prescriptions dispensed. If the Company underestimates or overestimates patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods. The deferred revenue balance does not have a direct correlation with future revenue recognition as the Company will record sales deductions at the time the prescription unit is dispensed, or may be subject to future exchange or product returns.

The Company will continue to recognize Zohydro ER revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until it can reliably estimate product returns, at which time the Company will record a one-time increase in revenue related to the recognition of revenue previously deferred, net of estimated future product returns and sales allowances. In addition, the costs of Zohydro ER associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized, subject to future exchange or product returns.

Product sales allowances for Zohydro ER and Sumavel DosePro include wholesaler and retail pharmacy distribution fees, prompt pay discounts, chargebacks, rebates and patient discount programs, and 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 its customers and third-party payors and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support 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 records product sales

deductions in the statement of operations at the time product revenue is recognized.

In connection with the Closing of the Asset Purchase Agreement in May 2014, whereby Endo acquired the Company's Sumavel DosePro business, Endo purchased the Company's existing finished goods inventory of Sumavel DosePro at standard cost. The Company will be financially responsible for all returns of Sumavel DosePro product distributed by the Company prior to Closing of the Asset Purchase Agreement up to a maximum per unit amount as specified in the agreements. The Company was also financially responsible for payment of Sumavel DosePro product sales allowances on product distributed by the Company prior to Closing of the Asset Purchase Agreement. Endo will be responsible for payment of all other Sumavel DosePro returns and sales allowances.

Product Returns. Generally, the Company does not provide a reserve for product refunds for sales of Zohydro ER due to its revenue recognition policy of deferring recognition of revenue on product shipments of Zohydro ER until the right of return no longer exists.

The Company is responsible for product returns for Sumavel DosePro product distributed by the Company prior to the sale of Sumavel DosePro to Endo in May 2014 up to a maximum per unit amount, as specified in the APA. This estimate of returns requires a high degree of judgment and is subject to change based on the Company's experience and certain quantitative and qualitative factors. Sumavel DosePro's shelf life is determined by the shorter expiry date of its two subassemblies, which is currently approximately 30 months from the date of manufacture. The Company's return policy allows for customers to return unused product that is within six months before and up to one year after its expiration date for a credit at the then-current wholesaler acquisition cost (WAC) reduced by a nominal fee for processing the return.

The Company has monitored and analyzed actual return history of Sumavel DosePro since product launch. The Company's analysis of actual product return history considers actual product returns on an individual product lot basis since product launch, the dating of the product at the time of shipment into the distribution channel, prescription trends, trends in customer purchases and their inventory management practices, and changes in the estimated levels of inventory within the distribution channel to estimate its exposure for returned product. Because of the shelf life of Sumavel DosePro and the duration of time under which the Company's customers may return product through the Company's return policy, there may be a significant period of time between when the product is shipped and when the Company issues credits on returned product. Based on the Company's analysis of actual product return history, the Company increased its estimate for product returns, resulting in adjustments of $1,226,000 in the first quarter of 2013 and $2,408,000 in the third quarter of 2013, which led to decreases in net product revenue and earnings for the year ended December 31, 2013 and increased net loss by $0.03 per share for the year ended December 31, 2013. Further, as a result of the Company’s third quarter 2013 product returns analysis, the Company began to utilize a higher product returns rate for Sumavel DosePro sales.

The Company permits certain wholesale pharmaceutical distributors to purchase limited quantities of product after the announcement of an increase to the WAC of the Company’s product and prior to the effectiveness of the increase. In turn, WAC price increases can result in accelerated purchases by wholesalers relative to anticipated retail and prescription demand. The timing of purchases made by wholesale distributors and retail pharmacies are subject to fluctuations for these reasons among others.

Wholesaler and Retail Pharmacy Distribution Fees. The Company offers distribution fees to certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the distribution fees on shipment to the respective wholesale distributors and retail pharmacies and recognizes the distribution 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.

Chargebacks. The Company provides discounts primarily to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and

various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the period the related revenue is recognized.

Rebates. The Company participates in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, the Company pays a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. The Company estimates and accrues these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized.

Patient Discount Programs. The Company offers discount card programs to patients for Sumavel DosePro in which patients receive discounts on their prescriptions that are reimbursed by the Company. The Company estimates the total amount that will be redeemed based on levels of inventory in the distribution and retail channels and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Contract Manufacturing Revenue

In connection with the closing of the Asset Purchase Agreement in May 2014, the Company and Endo Ventures entered into the Supply Agreement, pursuant to which the Company retains the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo Ventures (see Note 5). The Company recognizes deferred revenue related to its supply of Sumavel DosePro as contract manufacturing revenue when earned on a "proportional performance" basis, as product is delivered. The Company recognizes revenue related to its sale of Sumavel DosePro product, equal to the cost of contract manufacturing plus a 2.5% mark-up, upon the transfer of title to Endo. The Company supplies Sumavel DosePro product based on non-cancellable purchase orders. The Company initially defers revenue for any consideration received in advance of services being performed and product being delivered, and recognizes revenue pursuant to the related pattern of performance, based on total product delivered relative to the total estimated product delivery over the minimum eight year term of the Supply Agreement. The Company continually evaluates the performance period and will adjust the period of revenue recognition if circumstances change.

In addition, the Company follows the authoritative accounting guidance when reporting revenue as gross when the Company acts as a principal versus reporting revenue as net when the Company acts as an agent. For transactions in which the Company acts as a principal, has discretion to choose suppliers, bears credit risk and performs a substantive part of the services, revenue is recorded at the gross amount billed to a customer and costs associated with these reimbursements are reflected as a component of cost of sales for contract manufacturing services.

Contract Revenue

Contract revenue consists of the amortization of license fees and milestone payments received under co-promotion agreements, which have multiple deliverables. Revenue arrangements with multiple deliverables are divided into separate units of accounting if criteria are met, including whether the deliverable has stand-alone value to the customer and the customer has a general right of return relative to the delivered item and delivery or performance of the undelivered item is probable and substantially within the vendor's control. Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price. The selling price for each deliverable is determined using: (i) VSOE, if it exists, (ii) TPE, if VSOE does not exist, and (iii) the Company's BESP if neither VSOE nor TPE exists. For transactions entered into prior to January 1, 2011, revenue was recognized for each deliverable based upon the applicable revenue recognition criteria discussed above and upon acceptance of goods or performance of service. Effective January 1, 2011, for new or significantly modified transactions, the Company allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables.

Service and Other Revenue

Service and other revenue primarily consists of payments received for the Company's sales efforts under the co-promotion agreement with Valeant Pharmaceuticals North America LLC (Valeant). The Company recognizes service and other revenue at the time services have been rendered.

Collaborative Arrangements

The Company records certain transactions between collaborators in the consolidated statement of operations and comprehensive income (loss) on either a gross or net basis within revenues or operating expenses, depending on the characteristics of the collaboration relationship, and provides for enhanced disclosure of collaborative relationships. The Company evaluates its collaborative agreements for proper classification of shared expenses, license fees, milestone payments

and any reimbursed costs within the consolidated statement of operations and comprehensive income (loss) based on the nature of the underlying activity. If payments to and from collaborative partners are not within the scope of other authoritative accounting literature, the statement of operations and comprehensive income (loss) classification for the payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. For collaborations relating to commercialized products, if the Company acts as the principal in the sale of goods or services, the Company records revenue and the corresponding operating costs in its respective line items within the consolidated statement of operations and comprehensive income (loss) based on the nature of the shared expenses. Per authoritative accounting guidance, the principal is the party who is responsible for delivering the product to the customer, has latitude with establishing price and has the risks and rewards of providing product to the customer, including inventory and credit risk.

Research and Development Expenses

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation expense, outside service providers, facilities costs, fees paid to consultants, milestone payments prior to FDA approval, license fees prior to FDA approval, professional services, travel costs, dues and subscriptions, depreciation and materials used in clinical trials and research and development. The Company expenses costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred until FDA approval is received.

The Company reviews and accrues expenses related to clinical trials based on work performed, which relies on estimates of total costs incurred based on completion of patient studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical development costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Advertising Expense

The Company records the cost of its advertising efforts when services are performed or goods are delivered. The Company incurred approximately $6,062,000, $1,330,000 and $1,333,000 in advertising costs for the years ended December 31, 2014, 2013 and 2012, respectively. There were no capitalized advertising costs at December 31, 2014 or December 31, 2013.

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates which will be in effect when the differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position.

Foreign Currency Transactions

Gains or losses resulting from transactions denominated in foreign currencies are included in other expense in the consolidated statements of operations and comprehensive loss. The Company recorded losses from foreign currency transactions in other income (expense) of $(145,000), $(95,000) and $(68,000) for the years ended December 31, 2014, 2013 and 2012, respectively.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee’s requisite service period on a straight-line basis. As of December 31, 2014, there were no outstanding equity awards with market or performance conditions. Equity awards issued to non-employees are recorded at their fair value on the measurement date and are re-measured at each reporting date as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant.

Net Income (Loss) per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding for the period reduced by weighted average shares subject to repurchase, without consideration for

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common stock equivalents. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and as-if converted method, as applicable. For purposes of this calculation, stock options, restricted stock units, warrants and common stock subject to repurchase are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per share (in thousands, except per share amounts):

	Year Ended December 31,		
	2014	2013	2012
Numerator			
Net income (loss), basic and diluted	$8,587	$(80,856)	$(47,386)
Denominator			
Weighted average common shares outstanding, basic	142,607	108,568	80,558
Effect of dilutive securities:			
Common stock warrants	2,439	—	—
Weighted average common shares outstanding, diluted	145,046	108,568	80,558
Basic and diluted net income (loss) per share	$0.06	$(0.74)	$(0.59)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in thousands, of common equivalent shares):

	Year Ended December 31,		
	2014	2013	2012
Common stock options and restricted stock units	9,953	11,027	47
Common stock warrants	—	15,681	—
	9,953	26,708	47

Segment Reporting

Management has determined that the Company operates in one business segment, which is the development and commercialization of pharmaceutical products for people living with pain-related conditions and central nervous system disorders.

Reclassifications

Prepaid expenses and other current asset balances at December 31, 2013 which were previously combined in the consolidated balance sheet have been discretely presented to conform to the December 31, 2014 presentation.

Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board (FASB) issued an accounting update that raises the threshold for disposals to qualify as discontinued operations and allows companies to have significant continuing involvement with and continuing cash flows from or to the discontinued operations. This accounting update also requires additional disclosures for discontinued operations and new disclosures for individually material disposal transactions that do not meet the definition of a discontinued operation. This guidance will be effective for fiscal years beginning after December 15, 2014, with early adoption permitted. The Company does not expect that the adoption of the guidance will have a material impact on the Company's financial statements.

In May 2014, the FASB issued new accounting guidance related to revenue recognition. This new standard will replace all current GAAP guidance on this topic and eliminate all industry-specific guidance. The new revenue recognition standard provides a unified model to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration for which the entity expects to be entitled in exchange for those goods or services. This guidance will be effective for fiscal

years beginning after December 16, 2016, including interim periods within that reporting period, and can be applied either retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. Early adoption is prohibited. The Company is evaluating the impact and method of adoption of adopting this new accounting standard on its financial statements and related disclosures.

In June 2014, the FASB issued new accounting guidance related to stock compensation. The new standard requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015 and can be applied either prospectively or retrospectively to all awards outstanding as of the beginning of the earliest annual period presented as an adjustment to opening retained earnings. Early adoption is permitted. The Company does not expect that the adoption of the guidance will have a material impact on the Company's financial statements.

In August 2014, the FASB issued new accounting guidance which requires management to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and provide related footnote disclosures. The guidance is effective for annual and interim reporting periods beginning on or after December 15, 2016. Early adoption is permitted. The Company does not expect that the adoption of the guidance will have a material impact on the Company’s financial statements.

3. Collaboration, License and Purchase Agreements

Teva Letter Agreement

On November 4, 2014, the Company entered into an agreement with Teva Pharmaceuticals USA, Inc. (Teva), under which the Company granted Teva a right of reference to certain carcinogenicity data generated by the Company for Zohydro ER for use in connection with Teva’s NDA for its extended-release hydrocodone product candidate. Teva paid the Company a one-time fee of $3,500,000 which was recorded as other income in the consolidated statement of operations.

Purdue Pharma L.P. Waiver Agreement

On October 29, 2014, the Company entered into a waiver agreement (the Waiver Agreement) with Purdue Pharma L.P. (Purdue) pursuant to which the Company granted a waiver to Purdue of the three-year Hatch-Waxman regulatory exclusivity period with respect to NDA 202880 for Zohydro ER in support of Purdue’s single-entity, extended-release hydrocodone product Hysingla ER® and any single-entity, once-daily hydrocodone successor products or NDAs filed by Purdue (the Purdue Products). In addition, Purdue granted the Company a waiver of the Hatch-Waxman regulatory exclusivity period with respect to Purdue Products in support of our single-entity, twice-a-day hydrocodone product, including Zohydro ER and any successor products with any abuse deterrent properties or labeling claims. Under the terms of the Waiver Agreement, Purdue will pay to the Company (i) $5,000,000 within fifteen (15) days of the date of the Waiver Agreement, (ii) $5,000,000 on July 1, 2015, and (iii) a percentage royalty in the low single-digits on Purdue’s net sales of Purdue Product commencing on October 1, 2015 and ending on October 25, 2016, only to the extent such royalty payment by Purdue in the aggregate would exceed $5,000,000 and then only with respect to royalties in excess of such amount. The Company recorded the $5,000,000 payment received in 2014 as other income in the consolidated statement of operations, and will record the second $5,000,000 installment when received. Future royalties, if any, will be recognized when earned in accordance with applicable generally accepted accounting principles.

Brabant Pharma Limited Sales and Purchase Agreement

On October 24, 2014, Zogenix Europe acquired Brabant, pursuant to the terms of the Sale and Purchase Agreement dated October 24, 2014, by and among Zogenix Europe, the Company, Brabant and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Reyker Nominees Limited and Aquarius Life Science Limited (collectively, the

Sellers). In connection with the consummation of the transactions on October 24, 2014 (the Brabant Closing) contemplated by the Sale and Purchase Agreement, Zogenix Europe purchased the issued share capital of Brabant from the Sellers (the Acquisition) and the Company agreed to guarantee the obligations, commitments, undertakings and warranties of Zogenix Europe. Brabant owned worldwide development and commercialization rights to Brabafen, low-dose fenfluramine, for the treatment of Dravet syndrome. Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and current

treatment options are very limited. Brabafen has recently received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome.

Under the terms of the Sale and Purchase Agreement, at the Brabant Closing Zogenix Europe paid to the Sellers consideration of (i) $20,000,000 in cash (plus $8,718,000 which represents the net cash position of Brabant at the Brabant Closing), of which $2,000,000 (the escrow amount) will be deposited into escrow to fund potential indemnification claims for a period of six months, and (ii) 11,995,202 shares (the Shares) of the Company's common stock. Zogenix Europe also committed to paying up to an aggregate amount of $95,000,000 in connection with the achievement of certain milestones for Brabafen, including $50,000,000 in regulatory milestones and $45,000,000 in sales milestones. The Company has agreed to use commercially reasonable efforts (as defined in the Sale and Purchase Agreement) to develop and commercialize Brabafen and to achieve the milestones.

In September 2012, Brabant entered into a collaboration and license agreement with the Universities of Antwerp and Leuven in Belgium (the Universities), which was amended and restated in October 2014. Under the terms of the agreement, the Universities granted Brabant an exclusive worldwide license to use the data obtained from the study, as well as certain intellectual property related to fenfluramine for the treatment of Dravet syndrome. Brabant is required to pay a mid-single-digit percentage royalty on net sales of fenfluramine for the treatment of Dravet syndrome or, in the case of a sublicense of fenfluramine for the treatment of Dravet syndrome, a percentage in the mid-twenties of the sub-licensing revenues. The agreement terminates in September 2020; however, upon the commencement of Phase 3 clinical trials of fenfluramine or marketing approval by a regulatory authority, the agreement will be extended until September 2045. The agreement may be terminated by the Universities if Brabant: (a) does not use commercially reasonable efforts to (i) develop and commercialize fenfluramine for the treatment of Dravet syndrome or related conditions stemming from infantile epilepsy, or (ii) seek approval of fenfluramine for the treatment of Dravet syndrome in the United States; or (b) if Brabant becomes insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it or if a petition for any similar relief has been filed against it. Brabant can terminate the agreement upon specified prior written notice to the Universities.

Both Zogenix Europe and the Sellers agreed to customary warranties and covenants in the Sale and Purchase Agreement. The Sellers agreed to indemnify Zogenix Europe for certain matters, including breaches of warranties and covenants included in the Sale and Purchase Agreement, up to the escrow amount, subject to limited exceptions.

Mallinckrodt LLC Co-Promotion Agreement

On June 6, 2012, the Company and Mallinckrodt LLC (Mallinckrodt) entered into a co-promotion agreement (the Co-Promotion Agreement). Under the terms of the Co-Promotion Agreement, Mallinckrodt was granted a co-exclusive right (with the Company) to promote Sumavel DosePro in the United States. Mallinckrodt's sales team began selling Sumavel DosePro to its customer base of prescribers in August 2012. Mallinckrodt committed to a minimum number of sales representatives for the initial term of the agreement, which ran through June 30, 2014.

In partial consideration of Mallinckrodt's sales efforts, the Company paid Mallinckrodt a service fee on a quarterly basis through January 31, 2014 that represented a specified fixed percentage of net sales of prescriptions generated from Mallinckrodt's prescriber audience over a baseline amount of net sales to the same prescriber audience. For the years ended December 31, 2014, 2013 and 2012, the Company incurred $62,000, $1,035,000 and $161,000 in service fee expenses under the Co-Promotion Agreement which is reflected in selling, general and administrative expense in the consolidated statements of operations and comprehensive income (loss).

In January 2014, the Company entered into an amendment to the Co-Promotion Agreement, whereby the Co-Promotion Agreement terminated on January 31, 2014. The Company assumed full responsibility for the commercialization of Sumavel DosePro in February 2014. In connection with the termination of the Co-Promotion Agreement, the Company is required to make a one-time tail payment to Mallinckrodt, calculated as a fixed percentage of net sales from the Mallinckrodt targeted prescriber audience during the 12 month period ending on January 31, 2015. An estimate for the liability for the tail payment of $129,000 is included in the balance of accrued expenses at December 31, 2014.

Altus Formulation Inc. Development and Option Agreement

On November 1, 2013, the Company entered into a Development and Option Agreement (the Development Agreement) with Altus Formulation Inc. (Altus). Under the Development Agreement, Altus is responsible for the development of abuse deterrent formulations of hydrocodone using Altus' Intellitab™ drug delivery platform and will be reimbursed by the Company for its development efforts on the product, and the Company is responsible for the conduct of the clinical development of the product. The Company paid a non-refundable upfront fee to Altus of $750,000 which was recorded as research and

development expense during the twelve months ended December 31, 2013. The Company is also obligated to pay Altus up to $3,500,000 in total future milestone payments upon the achievement of various development and regulatory milestones.

Pursuant to the Development Agreement, the Company was granted an option to obtain an exclusive, royalty-bearing license, with the right to sublicense, to certain Altus intellectual property rights to make, have made, import, use, sell, have sold and offer for sale an abuse deterrent formulation of hydrocodone for the treatment or relief of pain in the United States. If the Company exercises this option, Altus will be eligible to receive additional regulatory and sales milestones and a royalty based on net sales of the licensed product.

The term of the Development Agreement will end upon expiration of the earlier of (1) the date upon which an NDA or similar application for regulatory approval is submitted by the Company for the Altus abuse resistant formulation of hydrocodone, or (2) November 1, 2016. The Company may terminate the Development Agreement upon 30 days' written notice or upon written notice of a material uncured breach by Altus. In addition, the Company may terminate any work plan under the Development Agreement upon written notice. Altus may only terminate the Development Agreement upon the occurrence of certain bankruptcy events with respect to the Company. Altus may also terminate a work plan under the Development Agreement upon written notice of the Company's material uncured breach.

Valeant Pharmaceuticals North America LLC Co-Promotion Agreement

On June 27, 2013, the Company entered into a co-promotion agreement with Valeant (the Valeant Agreement). Under the terms of the Valeant Agreement, the Company was granted the exclusive right (with Valeant or any of its affiliates) to promote Migranal® (dihydroergotamine mesylate) Nasal Spray (Migranal) to a prescriber audience of physicians and other health care practitioners in the United States. The Company's sales team began promoting Migranal to prescribers in August 2013. The term of the Valeant Agreement will run through December 31, 2015 (unless otherwise terminated), and can be extended by mutual agreement of the parties in additional twelve month increments. Valeant remains responsible for the manufacture, supply and distribution of Migranal for sale in the United States. In addition, Valeant will supply the Company with a specified amount of product samples every six months, and the Company will reimburse Valeant for the cost of additional samples and any promotional materials ordered by the Company. The cost of any additional samples and any promotional materials ordered by the Company will be recognized as selling, general and administrative expenses.

In partial consideration of the Company's sales efforts, Valeant will pay the Company a co-promotion fee on a quarterly basis that represents specified percentages of net sales generated by the Company over defined baseline amounts of net sales (Baseline Forecast or Adjusted Baseline Forecast). In addition, upon completion of the co-promotion term, and only if the Valeant Agreement is not terminated by Valeant due to a bankruptcy event (as defined in the Valeant Agreement) or a material failure by the Company to comply with its material obligations under the Valeant Agreement, Valeant will be required to pay the Company an additional tail payment calculated as a fixed percentage of the Company's net sales over the Baseline Forecast (or Adjusted Baseline Forecast) during the first full six months following the last day of the term.

The Company may terminate the Valeant Agreement in the event of a Valeant supply failure (as defined in the Valeant Agreement) or material product recall, or if the net sales price in a fiscal quarter is less than a specified percentage of the net sales price in the immediately preceding quarter, if the reduction in such net sales price would have a material adverse effect on the Company's financial return as a result of performance of its obligation under the Valeant Agreement.

Either party may terminate the Valeant Agreement with six months' notice. Either party may terminate the Valeant Agreement with 30 days' prior notice if the Company's net sales within a fiscal quarter fall below the Baseline Forecast (or Adjusted Baseline Forecast) for one or more fiscal quarters, or following the commercial introduction of a generic product to Migranal promoted or otherwise commercialized by a third party in the United States. In addition, either party may terminate the Valeant Agreement in the event of a change of control of itself or the other party (upon 90 days' prior written notice), upon any action taken or objection raised by governmental authority that prevents either party from performing its obligations under the Valeant Agreement, upon the filing of an action alleging patent

infringement, in connection with the material breach of the other party's material obligations, or if a bankruptcy event of the other party occurs.

The Company recognizes co-promotion fees received under the Valeant Agreement as service revenue in the period in which its promotional activities generate net sales over the Baseline Forecast or Adjusted Baseline Forecast. For the years ended December 31, 2014 and 2013, the Company recognized service revenue of $3,357,000 and $1,109,000, respectively, under the Valeant Agreement.

Daravita Commercial Manufacturing and Supply Agreement

In 2007, the Company entered into a license agreement (the Daravita License Agreement) with Daravita Limited (Daravita), which was initially amended in 2009 and amended again on September 12, 2014. Under the terms of the Daravita License Agreement, Daravita granted the Company an exclusive license in the United States and its possessions and territories, with defined sub-license rights to third parties other than certain technological competitors of Daravita, to certain Daravita intellectual property rights related to Zohydro ER. The Daravita License Agreement grants the Company the exclusive right under certain Daravita patents and patent applications to import, use, offer for sale and sell oral controlled-release capsule or tablet formulations of hydrocodone, where hydrocodone is the sole active ingredient, for oral prescriptions in the treatment or relief of pain, pain syndromes or pain associated with medical conditions or procedures in the United States. This right enables the Company to exclusively develop and sell Zohydro ER in the United States. Daravita has retained the exclusive right to take action in the event of infringement or threatened infringement by a third party of Daravita's intellectual property rights under the Daravita License Agreement. The Company has the right to pursue an infringement claim against the alleged infringer should Daravita decline to take or continue an action.

Under the Daravita License Agreement, the Company paid an upfront fee of $500,000 to Daravita, which was recorded as research and development expense. The Company paid additional milestone payments in the amount of $750,000 to Daravita in August 2011 in connection with the completion of the treatment phase of the Company’s pivotal efficacy Phase 3 clinical trial, Study 801, and $1,000,000 upon submission of the first Zohydro ER NDA to the FDA in May 2012, which were recorded as research and development expense. Lastly, the Company paid a milestone payment of $2,750,000 upon the first NDA approval of Zohydro ER in October 2013, which was recorded as other assets in the consolidated balance sheet and is being amortized over the estimated life of the technology, through November 2019.

In addition, the Company is required to pay a mid-single-digit percentage royalty on net sales of the product for an initial royalty term equal to the longer of the expiration of Daravita’s patents covering the product in the United States, or 15 years after commercial launch, if Daravita does not have patents covering the product in the United States. After the initial royalty term, the Daravita License Agreement will continue automatically for three-year rolling periods during which the Company will continue to pay royalties to Daravita on net sales of the product at a reduced low single-digit percentage rate in accordance with the terms of the Daravita License Agreement.

Under the terms of the Daravita License Agreement, the Company and Daravita agreed that, subject to a separate commercial manufacturing and supply agreement entered into by the Company and Daravita in November 2012, Daravita is the exclusive manufacturer and supplier to the Company of Zohydro ER, subject to certain exceptions. Daravita also granted to the Company, in the event that Daravita is unwilling or unable to manufacture or supply commercial product to the Company, a non-exclusive license to make product under Daravita's intellectual property rights. This non-exclusive license also includes the right to sublicense product manufacturing to a third party, other than certain technological competitors of Daravita.

On September 12, 2014, the Company and Daravita entered into a third amendment (Third Amendment) to the Daravita License Agreement. Pursuant to the Third Amendment, the Company may exercise its option to obtain an exclusive license to certain abuse-deterrent technology and know-how from Altus (pursuant to the Development Agreement). Following such exercise and the first commercial sale by the Company, its affiliates or any of its permitted sublicensees of any extended-release formulations of hydrocodone using Altus’ abuse-deterrent technology (Altus Product), Daravita will be entitled to receive from the Company a royalty on net sales of Altus Product through the date that is 15 years following the first commercial sale of the Altus Product in the United States and its possessions and territories. Prior to December 31, 2019, such royalty will be (i) in the mid-single-digits if Daravita or an affiliate is the manufacturer of the Altus Product or (ii) in the low twenty-percent range if Daravita or an affiliate is not the manufacturer of the Altus Product. After December 31, 2019, such royalty will be in the high single digits, regardless of whether Daravita or an affiliate is the manufacturer. Neither the Company nor Daravita shall be obligated to have Daravita or an affiliate manufacture commercial supplies of Altus Product for the Company. No monetary value was exchanged in connection with the Third Amendment during the year ended December 31, 2014.

Either party may terminate the Daravita License Agreement upon a material, uncured default or certain insolvency events of the other party or upon 12 months written notice prior to the end of the initial royalty term or any additional three-year rolling period. The Company may also terminate the Daravita License Agreement, with or without cause, at any point in time upon 12 months' prior written notice, or if the sale of Zohydro ER is prohibited by regulatory authorities.

Astellas Pharma US, Inc. Co-Promotion Agreement

In July 2009, the Company entered into a co-promotion agreement with Astellas (Astellas Co-Promotion Agreement).

Under the terms of the agreement, the Company granted Astellas the co-exclusive right (with the Company) to market and sell Sumavel DosePro in the United States until June 30, 2013. Under the Astellas Co-Promotion Agreement, both Astellas and the Company were obligated to collaborate and fund the marketing of Sumavel DosePro and to provide annual minimum levels of sales effort directed at Sumavel DosePro during the term. In December 2011, the Company entered into an amendment to the Astellas Co-Promotion Agreement, or the amended Astellas Co-Promotion Agreement, whereby the agreement terminated on March 31, 2012.

In connection with the execution of the Astellas Co-Promotion Agreement, Astellas made a non-refundable up-front payment of $2,000,000 and made an additional $18,000,000 of payments to the Company upon the achievement of a series of milestones. In consideration for Astellas' performance of its commercial efforts, the Company paid Astellas a service fee on a quarterly basis that represented a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to primary care physicians, OB/GYNs, emergency medicine physicians, and urologists in the United States (the Astellas Segment).

In accordance with accounting guidance for revenue arrangements with multiple deliverables, the Company initially recorded the $20,000,000 in upfront and milestone payments received from Astellas as deferred revenue. Beginning with the launch of Sumavel DosePro in January 2010, the Company began amortizing the upfront and milestone payments as contract revenue in the consolidated statement of operations and comprehensive income (loss) over the term of the Astellas Co-Promotion Agreement. Upon termination of the Astellas Co-Promotion Agreement, the Company concluded that the remaining deferred revenue balance should be recognized ratably through the amended term of the agreement, and consequently, all deferred contract revenues were recognized through March 31, 2012. The Company did not recognize any revenue for contract revenue sales to Astellas for the years ended December 31, 2014 and 2013, and recognized $8,462,000 in contract revenue related to Astellas for the year ended December 31, 2012.

Following completion of the co-promotion term in March 2012, the Company was required to pay Astellas one tail payment in July 2013 and another tail payment in July 2014, calculated as decreasing fixed percentages (ranging from mid-twenties down to a mid-teen percentage) of net sales in the Astellas Segment during the 12 months ended March 31, 2012. The fair value of the tail payments was accreted through interest expense through the dates of payment in July 2013 and July 2014. The first tail payment of $2,032,000 was made in July 2013 and the final tail payment of $1,218,000 was made in July 2014. The Company recognized $87,000 and $368,000 of related interest expense during the years ended December 31, 2014 and 2013, respectively.

Further, under the terms of the amended Astellas Co-Promotion Agreement, Astellas contributed its agreed upon portion of marketing expenses through March 31, 2012, and continued to earn a service fee based on product sales to the Astellas Segment during that period. Amounts received from Astellas for shared marketing costs and sample product are reflected as a reduction of selling, general and administrative expenses, and amounts payable to Astellas for shared marketing expenses and service fees are reflected as selling, general and administrative expenses, inclusive of the estimated cost of the tail payments owed upon the termination of the agreement.

In August 2012, the Company and Astellas completed a final reconciliation under the terms of the Astellas Co-Promotion Agreement and agreed to adjust the service fees paid to Astellas over the term of the Astellas Co-Promotion Agreement, resulting in a service fee reduction of $1,500,000, which offset the two annual tail payments, and a reduction to the annual tail payment liability of $742,000. The present value of the service fee receivable and tail payment reduction of $1,924,000 was recorded as a reduction in selling, general and administrative expenses during the year ended December 31, 2012, and an offset to the tail payment liability. The fair value of the service fee receivable and tail payment reduction was accreted through interest income through the dates of the two tail payments in July 2013 and July 2014.

For the year ended December 31, 2012, the Company recognized shared marketing expense and service fee expenses of $253,000 and $1,756,000 (excluding the $1,924,000 service fee adjustment discussed above), respectively. For the years ended December 31, 2014 and 2013 the Company did not incur any shared marketing expense or service fee expenses in connection with the Astellas Co-Promotion Agreement.

Durect Development and License Agreement

On July 11, 2011, the Company entered into a development and license agreement with Durect Corporation (the License Agreement). Under the License Agreement, the Company is responsible for the clinical development and commercialization of Relday, a proprietary, long-acting injectable formulation of risperidone using Durect's SABER™ controlled-release formulation technology in combination with the Company's DosePro® needle-free, subcutaneous drug delivery system. Durect is responsible for non-clinical, formulation and chemistry, manufacturing and controls development. Durect will be reimbursed by the Company for its research and development efforts on the product.

The Company paid a non-refundable upfront fee to Durect of $2,250,000, which was recorded as research and development expenses in the consolidated statement of operations and comprehensive income (loss) during the year ended December 31, 2011. The Company is obligated to pay Durect up to $103,000,000 in total future milestone payments with respect to the product subject to and upon the achievement of various development, regulatory and sales milestones. The Company is also required to pay a mid-single-digit to low double-digit percentage patent royalty on annual net sales of the product determined on a jurisdiction-by-jurisdiction basis. Further, until an NDA for Relday has been filed in the United States, the Company is obligated to spend no less than $1,000,000 in external expenses on the development of Relday in any trailing 12 month period beginning in July 2012. The patent royalty term is equal to the later of the expiration of all Durect technology patents or joint patent rights in a particular jurisdiction, the expiration of marketing exclusivity rights in such jurisdiction, or 15 years from first commercial sale in such jurisdiction. After the patent royalty term, the Company will continue to pay royalties on annual net sales of the product at a reduced rate for so long as the Company continues to sell the product in the jurisdiction. The Company is also required to pay to Durect a tiered percentage of fees received in connection with any sublicense of the licensed rights.

Durect granted the Company an exclusive worldwide license, with sub-license rights, to Durect intellectual property rights related to Durect's proprietary polymeric and non-polymeric controlled-release formulation technology to make and have made, use, offer for sale, sell and import risperidone products, where risperidone is the sole active agent, for administration by injection in the treatment of schizophrenia, bipolar disorder or other psychiatric related disorders in humans. Durect retains the right to supply the Company's Phase 3 clinical trial and commercial product requirements on the terms set forth in the License Agreement.

Durect retains the right to terminate the License Agreement with respect to specific countries if the Company fails to advance the development of the product in such country within a specified period, either directly or through a sublicensee. In addition, either party may terminate the License Agreement upon insolvency or bankruptcy of the other party, upon written notice of a material uncured breach or if the other party takes any act impairing such other party's relevant intellectual property rights. The Company may terminate the License Agreement upon written notice if during the development or commercialization of the product, the product becomes subject to one or more serious adverse drug experiences or if either party receives notice from a regulatory authority, independent review committee, data safety monitoring board or other similar body alleging significant concern regarding a patient safety issue and, as a result, the Company believes the long-term viability of the product would be seriously impacted. The Company may also terminate the License Agreement with or without cause, at any time upon prior written notice.

Aradigm Corporation Asset Purchase Agreement

In 2006, the Company entered into an asset purchase agreement with Aradigm Corporation (Aradigm). Under the terms of the agreement, Aradigm assigned and transferred to the Company all of its right, title and interest to tangible assets and intellectual property related to the DosePro needle-free drug delivery system. Aradigm also granted to the Company a non-exclusive, fully paid, worldwide, perpetual, irrevocable, transferable, sublicensable license under all other intellectual property of Aradigm that was owned, controlled or employed by Aradigm prior to the closing of the asset purchase and that is necessary or useful to the development, manufacture or commercialization of the DosePro delivery system. Aradigm also retained a worldwide, royalty-free, non-exclusive license, with a right to sublicense, under all transferred intellectual property rights solely for purposes of the pulmonary field, and the Company granted Aradigm a license under other intellectual property rights solely for use in the pulmonary field.

The Company paid Aradigm $4,000,000 at the closing of the asset purchase and was required to make an additional $4,000,000 milestone payment to Aradigm upon the U.S. commercialization of Sumavel DosePro (which payment was made in 2010). The Company is also required to pay a 3% royalty on global net sales of Sumavel DosePro, by the Company or one of the Company's future licensees, if any, until the later of January 2020 or the expiration of the last valid claim of the transferred patents covering the manufacture, use, or sale of the product. The Company recorded the second milestone payment as other assets in the consolidated balance sheet and is amortizing the milestone over the

estimated life of the technology, through December 2023. For the years ended December 31, 2014, 2013 and 2012, the Company recorded $591,000, $1,242,000 and $1,353,000, respectively, of expense related to the amortization of the milestone and royalties from net sales of Sumavel DosePro. The Company expects to record annual amortization expense of approximately $286,000 during each year ended December 2015 through 2019, and $1,143,000 in amortization expense thereafter related to the amortization of the milestone.

In addition, in the event the Company or one of its future licensees, if any, commercializes a non-sumatriptan product in the DosePro delivery system, the Company will be required to pay Aradigm, at the Company's election, either a 3% royalty on net sales of each non-sumatriptan product commercialized, or a fixed low-twenties percentage of the royalty revenues received

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by the Company from the licensee, if any, until the later of the ten year anniversary of the first commercial sale of the product in the United States or the expiration of the last valid claim of the transferred patents covering the manufacture, use or sale of the product. Royalty revenues under this agreement include, if applicable, running royalties on the net sales of non-sumatriptan products, license or milestone fees not allocable to development or other related costs incurred by the Company, payments in consideration of goods or products in excess of their cost, or payments in consideration for equity in excess of the then fair market value of the equity.

4. Consolidated Balance Sheet Details

Inventory (in thousands)

	December 31,	
	2014	2013
Raw materials	$3,453	$2,770
Work in process	7,998	6,054
Finished goods	972	1,112
Deferred cost of goods sold	1,016	—
	$13,439	$9,936

Deferred cost of goods sold consists of the costs of Zohydro ER associated with the deferred revenue, which are included in inventory until such time the related deferred revenue is recognized.

Property and Equipment, Net (in thousands)

	December 31,	
	2014	2013
Machinery, equipment and tooling	$12,847	$12,479
Construction in progress	4,974	6,222
Computer equipment and software	1,038	951
Leasehold improvements	783	783
Furniture and fixtures	615	628
Property and equipment, at cost	20,257	21,063
Less accumulated depreciation	(9,639)	(8,052)
	$10,618	$13,011

Depreciation expense for the years ended December 31, 2014, 2013 and 2012 was $1,625,000, $1,806,000 and $1,599,000, respectively.

Other Assets (in thousands)

	December 31,	
	2014	2013
Prepaid Aradigm royalty expense	$2,286	$2,571
Prepaid Daravita royalty expense	1,846	2,318
Debt acquisition costs	241	969
Deposits	1,033	431
Restricted cash	—	200
Other assets	99	125
	$5,505	$6,614

Accrued Expenses (in thousands)

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	December 31,	
	2014	2013
Accrued product returns	$4,694	$5,445
Liability for product transition for new formulation	3,041	—
Non-cancellable inventory purchase commitments for existing formulation	2,594	—
Accrued discounts and allowances	1,274	4,239
Accrued interest expense, current portion	—	3,033
Accrued clinical trial costs	1,785	1,238
Accrued sales and marketing costs	318	1,161
Astellas tail payment, current portion	—	1,131
Other accrued expenses	1,780	2,618
	$15,486	$18,865

Other Long-Term Liabilities (in thousands)

	December 31,	
	2014	2013
Interest expense payable, less current portion	$—	$5,901
Deferred rent	664	77
Embedded derivatives	—	233
Other long-term liabilities	389	285
	$1,053	$6,496

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5. Sale of Sumavel DosePro Business

Endo Ventures Bermuda Limited and Endo Ventures Limited Asset Purchase Agreement

On May 16, 2014, the Company closed the Asset Purchase Agreement with Endo Ventures Bermuda and Endo Ventures, pursuant to which the Company sold its Sumavel DosePro business to Endo, including the registered trademarks, certain contracts, the NDA and other regulatory approvals, the books and records, marketing materials and product data relating to Sumavel DosePro. Upon closing of the Asset Purchase Agreement, Endo paid the Company $85,000,000 in cash, $8,500,000 of which was deposited into escrow to fund potential indemnification claims for a period of 12 months, and $4,624,000 in cash for the purchase of Sumavel DosePro finished goods inventory on hand at the Company's standard cost. In addition to the upfront cash payments, the Company is eligible to receive additional cash payments of up to $20,000,000 based on the achievement of pre-determined sales and gross margin milestones. Furthermore, Endo Ventures assumed responsibility for the Company’s royalty obligation to Aradigm Corporation on sales of Sumavel DosePro.

At the closing, the Company and Endo Ventures Bermuda entered into a license agreement (License Agreement), pursuant to which the Company granted Endo an exclusive, perpetual, sublicensable, irrevocable (unless terminated as set forth in the License Agreement), fully paid-up, royalty-free license to make and have made, use and research, develop and commercialize Sumavel DosePro throughout the world under a specified subset of the Company's technology patents. The Company retained all rights to the DosePro technology patents and know-how for use with other products. Either party may terminate the License Agreement in the event of the other party's uncured material breach.

At the closing, the Company and Endo Ventures entered into the Supply Agreement, pursuant to which the Company will retain the sole and exclusive right and the obligation to manufacture, have manufactured, supply or have supplied Sumavel DosePro to Endo, subject to Endo’s right to qualify and maintain a back-up manufacturer. Endo will exclusively purchase all Sumavel DosePro supplied by the Company at the cost of goods sold plus a 2.5% mark-up. The Company will grant Endo a manufacturing license under certain circumstances outlined in the Supply Agreement, if Endo requires the use of a back-up supplier. Representatives from the Company and Endo will participate on a joint supply committee for general oversight and strategic functions regarding the Supply Agreement. Further, under the Supply Agreement, Endo will support the Company’s Sumavel DosePro manufacturing operations with an interest-free working capital advance equivalent to the book value of the inventory of materials and unreleased finished goods held by the Company in connection with the manufacture of the Sumavel DosePro minus the accounts payable associated with such materials and unreleased finished goods, capped initially at $7,000,000 and subject to annual adjustment. The working capital advance is evidenced by a promissory note (the Note) and is secured by liens on materials and unreleased finished Sumavel DosePro inventory.

The Supply Agreement may be terminated by either party upon three years' prior written notice, provided that the notice cannot be given prior to the fifth anniversary of the Closing date. Either party may also terminate the Supply Agreement in the following circumstances: (i) if the other party breaches any material term of the agreement and fails to cure such breach within a specified time period following written notice; or (ii) upon the occurrence of certain financial difficulties. Endo Ventures also may terminate the Supply Agreement in the following circumstances: (i) if Sumavel DosePro has been deemed ineffective or unsafe by the applicable governmental authorities; or (ii) if the Company fails to supply to Endo Ventures a minimum quantity of Sumavel DosePro over the course of a six month period which results in Endo Ventures being unable to supply Sumavel DosePro to its trade customers.

Further upon Closing, the Company and Endo Ventures entered into other ancillary agreements associated with the Asset Purchase Agreement, pursuant to which the Company will help facilitate the transfer of the Sumavel DosePro business to Endo Ventures, which Endo Ventures assumed responsibility for as of the Closing date. The services to be provided by the Company include assistance with co-pay/voucher programs, continuation of Zogenix Product Express services, regulatory support and processing of all payment claims made under the Company's National Drug Code. Services provided by the Company will be provided over various time periods specified in the agreements.

The Company accounted for the agreement for the sale of the Sumavel DosePro business as a sale of a business and, as such, was required to estimate the fair value of the business, including the product rights under the Asset Purchase Agreement, DosePro technology license and Sumavel DosePro finished goods inventory on hand at Closing. The Company estimated the fair value of the product rights using an income approach valuation technique through a discounted cash flow method. The assumptions used in the discounted cash flow method included estimated Sumavel DosePro units to be sold in the market based on current demand forecasts, net selling price of Sumavel DosePro based on current market price, working

capital needs estimated by management and a discount rate based on a market participant weighted average cost of capital.

The Company estimated the fair value of the DosePro technology license using a relief from royalty valuation method, whereby the presumed royalty savings from owning the license was estimated. The valuation considered royalty rates involving other injection technologies in the current pharmaceutical space.

The Company estimated the fair value of the Sumavel DosePro finished goods inventory on hand at Closing (which was sold to Endo at standard cost) using a market approach reflecting the estimated costs incurred by the Company in performing monitoring and quality control services on inventory supplied to Endo.

The agreements entered into concurrently with the sale of the Sumavel DosePro business, including the License Agreement and Supply Agreement, contain various elements and, as such, are deemed to be an arrangement with multiple deliverables as defined under authoritative accounting guidance (see Note 2). Several non-contingent deliverables were identified within the agreements. The Company identified the contract manufacturing services, manufacturing license, transition services and performance on joint supply committee as separate non-contingent deliverables within the arrangement. The transition services and manufacturing license have standalone value and qualify as separate units of accounting. Performance on the joint supply committee does not have standalone value from the contract manufacturing services, and as such, these two deliverables qualify as one unit of accounting. The non-contingent consideration received from the Endo agreements was allocated to these separate units of accounting, including the sale of the Sumavel DosePro business, based on their respective fair values, using the relative selling price method.

The Company developed its BESP for each non-contingent deliverable, as VSOE and TPE was not available, in order to allocate the non-contingent arrangement consideration to the three undelivered units of accounting. The Company used a market valuation approach to develop the BESP for contract manufacturing services through the use of market rates available for comparable contract manufacturing services and consideration of internal costs of performing inventory monitoring and quality control services. Significant increases in the hours necessary to perform inventory monitoring and quality controls services would result in a significant increase in the fair value of the contract manufacturing services.

The Company developed the BESP for the manufacturing license by estimating the total number of hours required to qualify another manufacturer, the hourly rate of internal regulatory and manufacturing employees that are required to qualify another manufacturer and the market rate for estimated cost of travel required to qualify another manufacturer.

The Company developed the BESP for the transition services through use of an estimate of the total number of hours required to complete the services and the hourly rate of an internal employee that performs the services, which was compared to hourly market rates for similar consulting services. The Company developed the BESP for performance on the joint supply committee through use of an estimate of the total number of participation hours required on the committee and the hourly rate of the internal employees that participate on the joint supply committee. Significant increases in the estimated number of hours required to qualify another manufacturer, required to perform transition services, or required for performance on the joint supply committee would significantly increase the fair value of these deliverables.

The Company allocated $9,100,000 of the upfront consideration to contract manufacturing services, which includes a discount valued at $4,748,000 related to the interest free working capital advance, and an immaterial amount of the upfront consideration was allocated to the manufacturing license, transition services and performance on the joint supply committee. Revenue associated with each of the undelivered elements will be recognized when the element is delivered. At December 31, 2014, there was $8,535,000 of unrecognized revenue related to undelivered elements in connection with the agreement.

During 2014, the Company determined that the Sumavel DosePro business, which is comprised of the product rights under the Asset Purchase Agreement, DosePro technology license and Sumavel DosePro finished goods inventory purchased at Closing, had been fully delivered, and, therefore representing control of the business obtained by Endo. As such, a gain on sale of business of $79,980,000, net of $660,000 in related transaction costs, was recognized for the

sale of the Sumavel DosePro business in the consolidated statement of operations and comprehensive income (loss) for 2014.

Based on the Sumavel DosePro finished goods inventory delivered and the contract manufacturing services performed, as measured using a proportional performance method, during the year ended December 31, 2014 a total of $15,392,000 was recognized as contract manufacturing revenue in the statement of operations and comprehensive income (loss). An immaterial amount of revenue was recognized for performance of transition services and performance on the joint supply committee during the year ended December 31, 2014. As of December 31, 2014, the Company had $8,535,000

remaining in deferred revenue attributed to the Endo arrangement.

The $79,980,000 gain on sale of Sumavel DosePro business was calculated as the difference between the allocated non-contingent consideration amount for the business and the net carrying amount of the assets transferred to Endo. The following sets forth the net assets and calculation of the gain on sale as of Closing (in thousands):

Non-contingent consideration received	$89,624
Imputed interest on working capital advance	4,748
Carrying value of Sumavel DosePro inventory on hand at Closing	(4,624)
Transaction costs	(660)
Deferred revenue associated with undelivered elements	(9,108)
Net gain on sale of business	$79,980

The net gain on sale of business may be adjusted in future periods by the contingent consideration, of up to $20,000,000, based upon the achievement of pre-determined sales and gross margin milestones. Any future adjustment of the net gain on sale of business will be determined through use of the relative selling price method.

Further, as noted above, Endo Ventures provided the Company with an interest-free working capital advance upon Closing. The working capital advance of $7,000,000, which is evidenced by the Note, was recorded as a note payable on the consolidated balance sheet at Closing, net of a $4,748,000 debt discount. The fair value of the debt discount was established using a market approach, including an interest rate reflecting recent term sheets provided to the Company for offerings of debt instruments, interest rates on the Company's most recent debt instruments, and market interest rates on similar debt instruments. The debt discount will be amortized as interest expense using the effective interest method over the minimum eight year term of the Supply Agreement, as the working capital advance must be repaid upon termination of the Supply Agreement. The Company recognized $209,000 of interest expense during the year ended December 31, 2014 related to the working capital advance from Endo.

The sale of the Sumavel DosePro business does not qualify as discontinued operations as the Company will have significant continuing involvement in the business as the exclusive supplier of Sumavel DosePro over the term of the Supply Agreement.

6. Acquisition of Brabant Pharma Limited

On October 24, 2014, Zogenix Europe, a wholly-owned subsidiary of the Company, acquired all the capital stock of Brabant, a privately-held company organized under the laws of England and Wales, pursuant to the terms of the Sale and Purchase Agreement, dated October 24, 2014. Brabant owned worldwide development and commercialization rights to ZX008, low-dose fenfluramine, for the treatment of Dravet syndrome. Dravet syndrome is a rare and catastrophic form of pediatric epilepsy with life threatening consequences for patients and current treatment options are very limited. ZX008 has recently received orphan drug designation in Europe and the United States for the treatment of Dravet syndrome.

Under the terms of the Sale and Purchase Agreement, the Company paid $20,000,000 in cash (plus $8,718,000 which represents the net cash position of Brabant at the closing), of which $2,000,000 was deposited into escrow to fund potential indemnification claims for a period of six months, and 11,995,202 shares of the Company’s common stock, plus potential cash payments of up to $95,000,000 based on the achievement of certain milestones. The aggregate purchase price was determined to be $88,200,000, including the cash paid of $20,000,000, market value of the 11,995,202 shares of the Company's common stock of $15,234,000 and fair value of the contingent purchase consideration for milestones of $53,000,000. The Company has agreed to use commercially reasonable efforts (as defined in the Sale and Purchase Agreement) to develop and commercialize ZX008 and to achieve the milestones. As of December 31, 2014, transaction costs of $300,000 were expensed as incurred in selling, general and administrative expense.

An initial liability of $53,000,000 was recorded for an estimate of the acquisition date fair value of the contingent purchase consideration. Any change in the fair value of the contingent purchase consideration subsequent to the

acquisition date was and will be recognized in operating expenses within the consolidated statement of operations and comprehensive income (loss). The fair value of the milestone payments was measured by the probability-weighted discounted cash flows. Key

assumptions used in the fair value assessments included discount rates ranging from 3.1% to 7.9%, probability weighted revenue projections, and probability and timing of achieving regulatory milestones. This fair value measurement of the contingent purchase consideration is based on significant inputs not observed in the market and thus represents a Level 3 measurement. Level 3 instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect the Company's own assumptions in measuring fair value.

As of December 31, 2014, the allocation of the purchase price to the assets acquired and liabilities assumed on the acquisition date was as follows (in thousands):

Cash and cash equivalents	$74
Prepaid expenses and other current assets	34
Property and equipment	4
Intangible assets	102,500
Goodwill	6,234
Accounts payable	(112)
Deferred tax liability	(20,500)
Total purchase price	$88,234

Intangible assets represent IPR&D related to ZX008. The IPR&D currently has an indefinite life and will be tested for potential impairment at least annually or whenever indicators of potential impairment are present. When appropriate, the IPR&D will be assigned a useful life and amortized over the estimated period of future economic benefit of the IPR&D, or impaired if the technology is abandoned and is not able to be used for another purpose. The fair value of the developed technology and trade name was estimated using an income approach. Under the income approach, an intangible asset's fair value is equal to the present value of future economic benefits to be derived from ownership of the asset. The estimated fair value was developed by discounting future net cash flows to their present value at market-based rates of return.

The excess of the fair value of the total consideration over the estimated fair value of the net assets acquired was recorded as goodwill, which was primarily attributable to expected benefit derived from utilizing the Company's established research and development infrastructure and sales, marketing and distribution channels. The goodwill recognized is not deductible for income tax purposes.

Pro Forma Information (unaudited)

The following unaudited pro forma information presents the consolidated results of operations of the Company as if the acquisitions completed during the year ended December 31, 2014 had occurred at the beginning of the year, with pro forma adjustments to give effect to intercompany transactions to be eliminated and transaction costs directly associated with the acquisitions (in thousands, except per share amounts):

	Year ended December 31,	
	2014	2013
Net revenues	$40,531	$33,012
Net income (loss)	7,873	(81,882)
Net income (loss) per share, basic and diluted	$0.06	$(0.68)

These unaudited pro forma consolidated financial results have been prepared for illustrative purposes only and do not purport to be indicative of the results of operations that actually would have resulted had the acquisition occurred on the first day of the earliest period presented, or of the future results of the combined entities. The unaudited pro forma consolidated financial information does not reflect any operating efficiencies and cost savings that may be realized as a result of the integration of the acquisition.

7. Restructuring

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In 2013, the Company commenced a restructuring of its workforce, resulting in a reduction in force of 55 employees across all functional areas of the Company. Restructuring activities were completed during the year ended December 31, 2014.

8. Commitments

Operating Leases

The Company entered into an operating lease for expanded office facilities in San Diego, California, which commenced December 1, 2014 at its previously leased location. The lease term is initially 64 months with an option to renew for an additional 60 months. The base rent will increase approximately 3.25% on an annual basis throughout the initial term. The lease also requires the Company to pay additional rent consisting of a portion of common area and pass-through expenses in excess of base year amounts. This space is used for general and administrative and sales and marketing operations and personnel.

The Company received incentives of abated rent for approximately 4.5 months of the lease term totaling $221,000, additional rent abatements of $36,000 and a tenant improvement allowance of up to $382,000. The Company has capitalized assets purchased in conjunction with the tenant improvement allowance and will amortize them when placed in service through the end of the initial lease term.

The Company also leases office space for its supply chain and inventory management and research and product development operations in Emeryville, California under a non-cancelable operating lease that expires, as extended, in September 2015. The base rent is subject to a 3% increase each year for the duration of the lease. Under the terms of the lease, as amended, the Company received an option to expand into additional space. The Company also received free rent for two months and a tenant improvement allowance of $305,000.

In August 2009, the Company entered an operating lease agreement to lease vehicles for the Company's field sales force. Each vehicle has a lease term of 36 months with a fixed monthly rental payment. As security for the vehicle leases, the lessor required a letter of credit for $200,000, which was collateralized by a certificate of deposit in the same amount. The letter of credit was released was replaced by a cash deposit in 2014.

The Company recognizes rent expense on a straight-line basis over the non-cancelable term of its operating leases. Rent expense for the years ended December 31, 2014, 2013 and 2012 was $870,000, $829,000 and $828,000, respectively.

Future minimum lease payments required under operating leases that have initial or remaining noncancelable lease terms in excess of one year as of December 31, 2014 are as follows (in thousands):

2015	$1,874
2016	2,216
2017	1,593
2018	979
2019	1,011
Thereafter	260
Total	$7,933

Manufacturing and Supply Agreements

The Company has a manufacturing services agreement with Patheon UK Limited (Patheon) for the aseptic capsule assembly, filling and inspection, final system assembly and purchasing of Sumavel DosePro, as well as other manufacturing and support services. In August 2013, the Company entered into an amended manufacturing services agreement (the Amended Services Agreement), with Patheon which replaced the Company's original manufacturing services agreement upon its expiration on October 31, 2013. The Amended Services Agreement has similar terms to the original agreement and will expire on April 30, 2016. The parties may mutually agree in writing to renew the term for additional terms prior to the expiration of the then-current term.

The Company has manufacturing and supply agreements with several third-party suppliers for the production of key components of Sumavel DosePro, which expire on various dates between 2012 and 2020. As of December 31, 2014,

the Company has non-cancellable purchase orders for 2015 totaling approximately $4,028,000 (based on the exchange rate as of December 31, 2014) under these arrangements. In addition, the Company is required to pay Patheon a monthly manufacturing fee of £419,000, or approximately $651,000 (based on the exchange rate as of December 31, 2014) through the end of the term of the Amended Services Agreement. As of December 31, 2014, the Company was committed to pay Patheon a total

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manufacturing fee of £6,704,000, or approximately $10,416,000 (based on the exchange rate as of December 31, 2014), which is payable monthly over the remaining term of the Amended Services Agreement.

The Company also has a Supply Agreement for Zohydro ER finished commercial product with Daravita (see Note 5). Under the Supply Agreement, Daravita is the exclusive manufacturer and supplier to the Company (subject to certain exceptions) of Zohydro ER. The Company must purchase all of its requirements of Zohydro ER, subject to certain exceptions, from Daravita. As of December 31, 2014, the Company has non-cancellable purchase orders for 2015 for its current formulation of Zohydro ER totaling approximately $2,435,000 under the Supply Agreement. A liability has been established at December 31, 2014 for these purchase orders as the Company intends to transition to Zohydro ER with BeadTek in the second quarter of 2015.

9. Long- term Debt

Maturities of long-term debt as of December 31, 2014, are as follows (in thousands):

2015	$—
2016	6,667
2017	6,667
2018	6,666
2019	—
Thereafter	7,000
Principal balance outstanding	27,000
Less unamortized discounts	(5,297)
Net carrying value of long-term debt	21,703
Less current portion	—
Long-term portion	$21,703

Interest expense related to long-term debt for the years ended December 31, 2014, 2013 and 2012 was $2,750,000, $5,672,000 and $6,708,000, respectively.

Healthcare Royalty Financing Agreement

On July 18, 2011, the Company closed the Healthcare Royalty Financing Agreement with Healthcare Royalty. Under the terms of the Healthcare Royalty Financing Agreement, the Company borrowed $30,000,000 from Healthcare Royalty (the Borrowed Amount) and the Company agreed to repay such Borrowed Amount together with a return to Healthcare Royalty, as described below, out of the Company's direct product sales, co-promotion revenues and out-license revenues (collectively, Revenue Interest) that the Company may record or receive as a result of worldwide commercialization of the Company's products including Sumavel DosePro, Zohydro ER and other future products. The Healthcare Royalty Financing Agreement was originally scheduled to terminate on March 31, 2018, but Healthcare Royalty exercised its right to early terminate the Healthcare Royalty Financing Agreement on May 16, 2014, as discussed below.

Upon the closing of and in connection with the Healthcare Royalty Financing Agreement, the Company issued and sold to Healthcare Royalty $1,500,000 of the Company's common stock, or 388,601 shares, at a price of $3.86 per share. The Company also issued to Healthcare Royalty a warrant exercisable for up to 225,000 shares of the Company's common stock. The warrant is exercisable at $9.00 per share and has a term of 10 years. As the warrant contains covenants where compliance with such covenants may be outside the control of the Company, the warrant was recorded as a current liability and marked to market at each reporting date using the Black-Scholes option pricing valuation model (see Note 2).

Under the Healthcare Royalty Financing Agreement, the Company was obligated to pay to Healthcare Royalty:

- 5% to 5.75% of the first $75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year (initially 5% and then 5.75% after the Astellas Co-Promotion Agreement terminated on March 31, 2012);
- 2.5% of the next $75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year; and
-

0.5% of Revenue Interest over and above $150,000,000 recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year.

Net sales of Sumavel DosePro outside the United States were only included in the Revenue Interest if such net sales exceed $10,000,000. The Company was also obligated to make three fixed payments of $10,000,000 on (or before at the option of the Company) each of January 31, 2015, January 31, 2016 and January 31, 2017.

As security for the payment of the Company's obligations under the Healthcare Royalty Financing Agreement, the Company also entered into a security agreement whereby the Company granted to Healthcare Royalty a security interest in all assets of the Company, including intellectual property and other rights of the Company to the extent necessary or used to commercialize the Company products. Healthcare Royalty's security interest was extinguished upon early termination of the Healthcare Royalty Financing Agreement on May 16, 2014.

The Company had the option to terminate the Healthcare Royalty Financing Agreement at the Company's election in connection with a change of control of the Company, upon the payment of a base amount of $52,500,000, or, if higher, an amount that generates a 19% internal rate of return on the Borrowed Amount as of the date of prepayment, in each case reduced by the Revenue Interest and principal payments received by Healthcare Royalty up to the date of prepayment.

Healthcare Royalty had the option to terminate the Healthcare Royalty Financing Agreement at its election in connection with a change of control of the Company (which includes the sale, transfer, assignment or licensing of the Company's rights in the United States to either Sumavel DosePro or Zohydro ER), or an event of default (which includes the occurrence of a bankruptcy event or other material adverse change in the Company's business), as defined in the Healthcare Royalty Financing Agreement. Healthcare Royalty exercised its option to terminate the Healthcare Royalty Financing Agreement in connection with the Company's sale of the Sumavel DosePro business to Endo on May 16, 2014. Upon termination of the Healthcare Royalty Financing Agreement, the Company was obligated to make a final payment of $40,041,000 to Healthcare Royalty, which generated a 17% internal rate of return on the Borrowed Amount as of the date of prepayment, reduced by the Revenue Interest and principal payments received by Healthcare Royalty up to the date of final payment. The Company no longer has any further payment obligations under the Financing Agreement after the final payment was made.

The rights of the Company and Healthcare Royalty to terminate the Healthcare Royalty Financing Agreement early, as well the change in the Revenue Interest rate from 5% to 5.75% in connection with the early termination of the Astellas co-promotion agreement, met the definition of an embedded derivative. As a result, the Company carved out these embedded derivatives from the Healthcare Royalty Financing Agreement and determined the fair value of each derivative using various discounted cash flow valuation models taking into account the probability of these events occurring and various scenarios surrounding the potential Revenue Interest payments that would be made if these events occurred (see Note 2). The aggregate fair value of the embedded derivatives as of December 31, 2013 was $233,000 and is included in other long-term liabilities. The fair value of the embedded derivatives of $247,000 was derecognized upon termination of the Healthcare Royalty Financing Agreement on May 16, 2014 and is included in the loss on early extinguishment of debt in the statement of operations and comprehensive income (loss) for the year ended December 31, 2014.

The Company received aggregate net proceeds of $29,485,000 from the Healthcare Royalty Financing Agreement (including the purchase of common stock). The discounts, which were being amortized using the effective interest method over the term of the arrangement within interest expense, include the fair value of the common stock warrants issued to Healthcare Royalty of $790,000 upon the closing of the Healthcare Royalty Financing Agreement, fees payable to Healthcare Royalty in connection with the execution of the arrangement of $476,000 and the fair value of embedded derivatives of $605,000 upon the closing of the Healthcare Royalty Financing Agreement. The Company has recognized other income (expense) in relation to the change in the fair value of the Healthcare Royalty common stock warrant of $378,000 and $(307,000) for the years ended December 31, 2014 and 2013, respectively, in the statement of operations and comprehensive income (loss). The Company has recognized other income (expense) in relation to the change in the fair value of the embedded derivatives of $(14,000) and $759,000 for the years ended December 31, 2014 and 2013, respectively, in the statements of operations and comprehensive income (loss).

Upon early termination of the Healthcare Royalty Financing Agreement on May 16, 2014, and the Company's final payment to Healthcare Royalty, the Company determined that the early termination resulted in an extinguishment of the outstanding debt and recognized a loss on early extinguishment of debt of $1,254,000 which was recorded as non-operating expenses in the statement of operations and comprehensive income (loss). The loss on early extinguishment of debt is related to the write-off of the unamortized balances of the debt discounts (which includes derecognition of the embedded derivative liabilities, as discussed above), debt acquisition costs, and accrued interest expenses related to the Healthcare Royalty Financing Agreement.

Term Debt and Revolving Line of Credit

In December 2014, the Company entered into a loan and security agreement with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB) consisting of term loans totaling $20,000,000, and a revolving credit facility of up to $4,000,000. Total outstanding advances under the revolving credit facility are limited to the lesser of $4,000,000 or 85% of eligible accounts receivable as defined in the Loan and Security Agreement. The term loan bears interest at an annual rate equal to the greater of (i) 8.75% and (ii) the sum of (a) the “prime rate” rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 5.25%. Each revolving advance under the credit facility bears interest at an annual rate equal to the sum of (a) the “prime rate” rate reported in the Wall Street Journal on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 4.75%.

The Company is required to make interest-only payments on the term loan through (i) January 1, 2016 or (ii) if the Company achieves trailing 12 month consolidated revenues of at least $50,000,000, July 1, 2016. The term loan will begin amortizing at the end of the applicable interest-only period, with equal monthly payments of principal plus interest in consecutive monthly installments following such interest-only period until the credit facility matures on December 1, 2018. The Company may prepay the outstanding principal balance of the term loan subject to graded prepayment fees. The credit facility also includes events of default, as defined in the Loan and Security Agreement, which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility.

The obligations under the Loan and Security Agreement are collateralized by the Company's personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash), and the Company has agreed to not encumber any of its intellectual property. The Company was required to establish a controlled deposit account with SVB containing at least 85% of the Company's account balances at all financial institutions which can be utilized by the lenders to satisfy the obligations in the event of default by the Company.

The credit facility includes affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring us to maintain legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding accounts receivable. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions. The Company was in compliance with these covenants at December 31, 2014.

In addition to principal payments, the Company is also required to make a final payment equal to 5% of the original principal amount of the term loan funded. Upon the entry into the credit facility, the Company was required to pay a term loan facility fee of $200,000 and a revolving line commitment fee of $32,000. Three additional $32,000 revolving line commitment fees will be due and payable on each of the first, second, and third anniversaries of the effective date or upon termination of the revolving line. These fees have been recorded as a discount to the term loan and revolving line of credit balances and are being amortized over the term of the loans. There was no amortization recorded relative to these costs for the year ended December 31, 2014.

In connection with entering into the Loan and Security Agreement, the Company issued warrants to Oxford and SVB exercisable into an aggregate total of 508,476 shares of the Company’s common stock. The warrants are exercisable at $1.18 per share of common stock and have a term of 10 years. The value of the warrants of approximately $558,000 was recorded as debt discount and additional paid in capital in the consolidated balance sheet as of December 31, 2014.

The Company also incurred approximately $241,000 in costs related to securing the credit facility. These loan origination costs have been deferred and will be amortized over the life of the credit facility as interest expense. They are included in other assets in the consolidated balance sheet at December 31, 2014. There was no amortization recorded relative to these costs for the year ended December 31, 2014.

Note payable for working capital advance

In connection with the sale of the Sumavel DosePro business, Endo Ventures provided the Company with an interest-free working capital advance, which is secured by a note. The working capital advance of $7,000,000 was recorded on the consolidated balance sheet, net of a $4,748,000 debt discount. The discount will be amortized as interest expense using the effective interest method over the minimum eight year term of the Supply Agreement, as the advance must be repaid upon termination of the Supply Agreement.

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10. Preferred Stock and Stockholders' Equity

Preferred Stock

Under the Company's amended and restated certificate of incorporation, as of December 31, 2014 and 2013, the Company is authorized to issue 10,000,000 shares of preferred stock with a $0.001 par value. As of December 31, 2014 and 2013, there were no shares of preferred stock issued or outstanding.

Common Stock

Under the Company's amended and restated certificate of incorporation, as of December 31, 2014 and 2013, the Company was authorized to issue 200,000,000 shares of common stock with a $0.001 par value. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available, when declared by the board of directors, subject to the prior rights of holders of convertible preferred stock.

Common stock reserved for future issuance is as follows (in thousands):

	December 31,	
	2014	2013
Stock options and restricted stock units outstanding	16,913	14,859
Warrants to purchase common stock	16,232	16,189
Shares authorized for future issuance under equity and purchase plans	4,826	2,595
	37,971	33,643

Common Stock Warrants

In July 2012, in connection with a public offering of common stock and warrants, the Company sold warrants to purchase 15,784,200 shares of common stock (including over-allotment purchase). The warrants are exercisable at an exercise price of $2.50 per share and will expire on July 27, 2017, which is five years from the date of issuance. As the warrants contain a cash settlement feature upon the occurrence of certain events that may be outside of the Company's control, the warrants are recorded as a current liability and are marked to market at each reporting date (see Note 2). During the years ended December 31, 2014 and 2013, warrants to purchase 465,250 and 103,500 shares of common stock were exercised, respectively. The fair value of the warrants outstanding was approximately $4,978,000 and $30,849,000 as of December 31, 2014 and 2013, respectively.

In July 2011, upon the closing of and in connection with the Financing Agreement (see Note 9), the Company issued to Healthcare Royalty a warrant exercisable into 225,000 shares of common stock. The warrant is exercisable at $9.00 per share of common stock and has a term of 10 years. As the warrant contains covenants where compliance with such covenants may be outside of the Company's control, the warrant was recorded as a current liability and is marked to market at each reporting date (see Note 2). The fair value of the warrant was approximately $114,000 and $492,000 as of December 31, 2014 and 2013, respectively.

In June 2011, and in connection with entering into an amendment to the second amended and restated loan and security agreement with Oxford and CIT Healthcare LLC (the Oxford Agreement), the Company issued to Oxford and SVB warrants exercisable into an aggregate of 26,455 shares of common stock. The warrants are exercisable at $3.78 per share of common stock and have a term of 7 years. The value of the warrants of approximately $76,000 was recorded as debt discount and additional paid in capital in the consolidated balance sheet as of December 31, 2011.

In December 2014, and in connection with entering into the 2014 Loan and Security Agreement (see Note 9), the Company issued to Oxford and SVB warrants exercisable into an aggregate of 508,476 shares of common stock. The warrants are exercisable at $1.18 per share of common stock and have a term of 10 years. The value of the warrants of approximately $558,000 was recorded as debt discount and additional paid in capital in the consolidated balance sheet as of December 31, 2014.

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Convertible Preferred Stock Warrants

In connection with the execution of the amended Oxford Agreement in July 2010, the Company issued warrants to Oxford and SVB to purchase 1,145,455 and 445,455 shares, respectively, of Series B convertible preferred stock at an exercise price of $1.10 per share. The warrants expire in November 2015. In connection with the Company's initial public offering (IPO) in November 2010, these warrants were converted to 159,090 warrants for common stock at an exercise price of $11.00 per share.

In accordance with accounting guidance for warrants for shares in redeemable securities, the Company classified warrants for convertible preferred stock as liabilities on the consolidated balance sheet based on fair value and increases or decreases in the fair value of such warrants were recorded as other income (expense) in the consolidated statement of operations and comprehensive income (loss). Upon the closing of the Company's IPO on November 29, 2010, all preferred stock converted into common stock. The warrants were converted into warrants to purchase common stock and reclassed from a liability to equity.

11. Stock-Based Compensation

Stock Option Plans

During 2006, the Company adopted the 2006 Equity Incentive Award Plan (as amended, the 2006 Plan) under which 1,134,000 shares of common stock were reserved for issuance to employees, directors and consultants of the Company. The 2006 Plan provides for the grant of incentive stock options, non-qualified stock options and rights to purchase restricted stock to eligible recipients. Recipients of stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2006 Plan is ten years.

Options granted pursuant to the 2006 Plan generally vest over four years at a rate of 25% upon the first anniversary of the vesting commencement date and 1/48th per month thereafter. The 2006 Plan allows the option holders to exercise their options early and acquire option shares, which are then subject to repurchase by the Company at the original exercise price of such options. At December 31, 2014 and 2013 there were no unvested shares of common stock issued to employees of the Company in connection with the early exercise of stock option grants.

During 2010, the Company adopted the 2010 Equity Incentive Award Plan (the 2010 Plan), which became effective immediately prior to the completion of the IPO. An initial 2,243,668 shares were reserved for issuance to employees, directors and consultants of the Company under the 2010 plan. The number of shares initially reserved were subsequently increased by the number of shares of common stock related to awards granted under the 2006 Plan that are repurchased, forfeited, expired or are cancelled on or after the effective date of the 2010 Plan, as well as an annual increase pursuant to an evergreen provision. The 2010 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units and rights to purchase restricted stock to eligible recipients. Recipients of stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2010 Plan is ten years.

Options granted pursuant to the 2010 Plan generally vest over four years and vest at a rate of 25% upon the first anniversary of the vesting commencement date and 1/48th per month thereafter. Restricted stock units granted pursuant to the 2010 Plan vest on the first anniversary of the vesting commencement date.

In June 2012, the Company amended and restated the 2010 Plan (the Restated 2010 Plan). Pursuant to the Restated 2010 Plan, the number of shares that are reserved for issuance under the 2010 Plan was increased to 9,300,000, plus any shares related to outstanding options granted under the 2006 Plan that are repurchased, forfeited, expire or are canceled on or after the effective date of the Restated 2010 Plan. Further, the 2010 Plan's evergreen provision was amended such that, commencing on January 1, 2013, and on each January 1 thereafter during the term of the Restated 2010 Plan, the aggregate number of shares available for issuance under the Restated 2010 Plan shall be increased by that number of shares of the Company's common stock equal to the lower of:

- 4% of the Company's outstanding common stock on the applicable January 1; or
- an amount determined by the board of directors.

At December 31, 2014 and 2013, 2,953,953 and 456,854 shares of common stock were available for future issuance under the Restated 2010 Plan, respectively.

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On December 4, 2013, the Company adopted the Employment Inducement Equity Incentive Award Plan (the Inducement Plan). The terms of the Inducement Plan are substantially similar to the terms of the Company's 2010 Equity Incentive Award Plan with two principal exceptions: (1) incentive stock options may not be granted under the Inducement Plan; and (2) the annual compensation paid by the Company to specified executives will be deductible only to the extent that it does not exceed $1,000,000, as the conditions of Section 162(m) of the Internal Revenue Code will not be met. The Inducement Plan was adopted by the board of directors without stockholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules.

The Company has initially reserved 2,700,000 shares of the Company's common stock for issuance pursuant to awards granted under the Inducement Plan. In accordance with Rule 5635(c)(4) of the NASDAQ Listing Rules, awards under the Inducement Plan may only be made to an employee who has not previously been an employee or member of the board of directors of the Company or any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. At December 31, 2014 and 2013 there were 708,500 and 1,728,000 shares of common stock available for future issuance under the Inducement Plan, respectively.

The 2006 Plan, Restated 2010 Plan and Inducement Plan are intended to encourage ownership of stock by employees, consultants and non-employee directors of the Company, as applicable, and with respect to the 2006 Plan and Restated 2010 Plan, to provide additional incentives for them to promote the success of the Company's business. The board of directors is responsible for determining the individuals to receive equity grants, the number of shares subject to each grant, the exercise price per share and the exercise period of each option. The Company satisfies option exercises through the issuance of new shares.

Information with respect to the number and weighted average exercise price of stock options under the 2006 Plan, 2010 Restated Plan and Inducement Plan is summarized as follows:

	Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2013	13,529	$2.46		
Granted	5,291	$3.23		
Exercised	(150)	$2.29		
Canceled/Forfeited	(1,757)	$2.97		
Outstanding at December 31, 2014	16,913	$2.65	7.7	$48
Exercisable at December 31, 2014	8,829	$2.63	7.0	$31
Vested and unvested expected to vest at December 31, 2014	16,667	$2.65	7.7	$48

At December 31, 2014 there were no restricted stock units outstanding. There were no grants of restricted stock units, 1,321,000 restricted stock units vested and released and 10,000 restricted stock units forfeited for the year ended December 31, 2014. At December 31, 2013, 1,331,000 restricted stock units were outstanding with a weighted average remaining contractual term of 0.4 years and an aggregate intrinsic value of $4,577,000. All restricted stock units outstanding were granted during the year ended December 31, 2013. No restricted stock units were exercisable at December 31, 2013, but 1,301,000 unvested restricted stock units were expected to vest at December 31, 2013.

The intrinsic values for stock options and restricted stock units above represent the aggregate value of the total pre-tax intrinsic value based upon a common stock price of $1.37 at December 31, 2014, and the contractual exercise prices.

	Years Ended December 31,		
	2014	2013	2012
Stock Options and Restricted Stock Units			

Weighted-average grant date fair value	$2.33	$1.58	$1.35
Aggregate intrinsic value of options exercised	$297,000	$370,000	$9,000
Total fair value of shares vested	$8,231,000	$4,895,000	$3,564,000

Employee Stock Purchase Plan

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During 2010, the Company adopted the 2010 Employee Stock Purchase Plan (the Purchase Plan), which allows employees to purchase shares of the Company's common stock during a specified offering period. The purchase price is 85% of the lower of the closing price of the stock on the first day of the offering period or the closing price of the stock on the date of purchase. Eligible employees may elect to withhold up to 20% of their compensation during any offering period for the purchase of stock up to a maximum of 20,000 shares per purchase period. At December 31, 2014 and 2013, a total of 1,163,553 and 409,646 shares of common stock were reserved for issuance under the Purchase Plan, respectively. The length of the offering period is determined by the compensation committee and may be up to 27 months long. The offering periods under the Purchase Plan generally have been from June through May of the subsequent year with two purchase periods of six months each. A total of 503,897, 304,327, and 363,879 shares were purchased under the Purchase Plan during the years ended December 31, 2014, 2013 and 2012, respectively.

Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value and stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model are as follows:

	Year Ended December 31,		
	2014	2013	2012
Stock Options			
Risk free interest rate	1.6% to 2.0%	0.8% to 1.8%	0.2% to 1.2%
Expected term	5.1 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years
Expected volatility	79.7 to 84.9%	82.8 to 87.9%	80.1% to 86.8%
Expected dividend yield	—%	—%	—%
Employee Stock Purchase Plan			
Risk free interest rate	0.1%	0.1%	0.1%
Expected term	0.5 to 1.0 years	0.5 to 1.0 years	0.5 to 1.0 years
Expected volatility	65.0% to 83.2%	74.3% to 125.6%	81.5% to 85.7%
Expected dividend yield	—%	—%	—%

The risk-free interest rate assumption was based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted average expected term of options was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, when necessary, the estimated volatility was calculated based upon the Company's historical volatility, supplemented with historical volatility of comparable companies whose share prices are publicly available for a sufficient period of time.

The Company recognized stock-based compensation expense as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Cost of sales	$467	$333	$181
Research and development	1,236	1,138	921
Selling, general and administrative	7,789	6,535	5,055
Total	$9,492	$8,006	$6,157

As of December 31, 2014, there was approximately $13,194,000 of total unrecognized compensation costs related to outstanding employee and board of director options, which is expected to be recognized over a weighted average period of 2.4 years.

At December 31, 2014, there were 153,000 unvested stock options and no restricted stock units outstanding to consultants, with approximately $173,000 of related unrecognized compensation expense based on a December 31, 2014 measurement date. These unvested stock options outstanding to consultants are expected to vest over

approximately 3.5 years. In accordance with accounting guidance for stock-based compensation, the Company remeasures the fair value of stock option grants to non-employees at each reporting date and recognizes the related income or expense during their vesting period. (Income) expense recognized for stock options and restricted stock units to consultants was $(169,000) and $323,000 for the

years ended December 31, 2014 and 2013, respectively, and was immaterial for the year ended December 31, 2012. Stock option expense for awards issued to consultants is included in the consolidated statement of operations and comprehensive income (loss) within selling, general and administrative expense.

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12. Employee Benefit Plan

Effective February 1, 2007, the Company established a defined contribution 401(k) plan (the Plan) for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan beginning on the first day of the month following one month of employment. Under the terms of the Plan, employees may make voluntary contributions as a percentage of compensation. The Company's contributions to the Plan are discretionary, and no contributions have been made by the Company to date.

13. Income Taxes

The Company only recognizes tax benefits if it is more-likely-than-not to be sustained upon audit by the relevant taxing authority based upon its technical merits. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The balance of unrecognized tax benefits at December 31, 2014 of $1,019,000 are tax benefits that, if we recognize them, would not impact our effective tax rate as long as they remain subject to a full valuation allowance.

The following table summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	December 31,	
	2014	2013
Beginning balance of unrecognized tax benefits	$899	$714
Gross increases based on tax positions related to current year	120	185
Gross increases based on tax positions related to prior year	—	—
Settlements with taxing authorities	—	—
Expiration of statute of limitations	—	—
Ending balance of unrecognized tax benefits	$1,019	$899

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrued interest or penalties on the consolidated balance sheets at December 31, 2014 and 2013 and has recognized no interest and/or penalties in the consolidated statements of operations and comprehensive loss through the year ended December 31, 2014.

The Company is subject to taxation in U.S. federal, state, and foreign jurisdictions. The Company's tax years for 2008 and forward can be subject to examination by the United States and state tax authorities due to the carry forward of net operating losses.

At December 31, 2014, the Company had available federal, California, and foreign income tax net operating loss carryforwards of approximately $211,200,000 , $209,100,000 and $1,969,000, respectively. The federal tax loss carryforwards will begin expiring in 2026 unless previously utilized, and the state tax loss carryforwards will begin expiring in 2015 unless previously utilized. In addition, the Company has federal and California research and development income tax credit carryforwards of $2,200,000 and $2,700,000, respectively. The federal research and development income tax credit carryforwards will begin to expire in 2026 unless previously utilized. The California research and development income tax credit carryforwards will carry forward indefinitely until utilized.

The Company has completed an analysis under Internal Revenue Service Code (IRC) Sections 382 and 383 to determine if the Company's net operating loss carryforwards and research and development credits are limited due to a change in ownership. The Company has determined that as of December 31, 2014 the Company had three ownership changes. The first ownership change occurred in August 2006 upon the issuance of the Series A-1 convertible preferred. As a result of this ownership change, the Company has reduced its net operating loss carryforwards by $1,900,000 and research and development income tax credits by $8,000. The Company had a second ownership change as defined by IRC Sections 382 and 383, which occurred in September 2011 upon the issuance of common stock in its follow-on offering. As a result of the second ownership change, the Company has reduced its federal net operating loss carryforwards as of December 31, 2011 by $121,100,000 and research and development income tax credits as of December 31, 2011 by $3,017,000. The Company also reduced its California net operating loss carryforwards as of December 31, 2011 by $53,329,000 as a result of the second ownership change. The Company had a third ownership change as defined by IRC Sections 382 and 383, which occurred in January 2014. There was no

forfeiture in federal and California net operating loss carryforwards or research and development income tax credits as a result of the third ownership change. Pursuant to IRC Section 382 and 383, use of the Company's net operating loss and

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research and development income tax credit carryforwards may be limited in the event of a future cumulative change in ownership of more than 50% within a three-year period.

The reconciliation of income tax computed at the Federal statutory tax rate to the expense for income taxes is as follows (in thousands):

	December 31,		
	2014	2013	2012
Tax at statutory rate	$2,941	$(27,491)	$(16,109)
State taxes, net of federal benefit	(489)	(1,821)	(1,580)
Change in valuation allowance	7,013	22,602	21,990
Permanent interest disallowed	(8,608)	7,197	(4,466)
Other permanent differences	1,226	1,279	1,360
Research and development tax credits	(1,387)	(744)	(2,352)
State tax rate benefit	(503)	(822)	842
Other	(109)	(200)	320
	$84	$—	$5

Significant components of the Company's deferred tax assets as of December 31, 2014 and 2013 are listed below. A valuation allowance of $110,338,000 and $102,949,000 for the years ended December 31, 2014 and 2013, respectively, has been established to offset the deferred tax assets as realization of such assets is uncertain. The components of the deferred tax assets are as follows (in thousands):

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating losses	$82,054	$80,388
Capitalized research and development	7,176	8,172
Accrued expenses	2,030	3,263
Research and development credits	3,395	2,010
Accrued product returns	1,772	2,029
Inventory reserve and UNICAP	2,956	660
Amortization	2,556	2,861
Deferred revenue	4,446	—
Other, net	5,128	4,736
Total deferred tax assets	111,513	104,119
Less valuation allowance	(110,338)	(102,949)
Net deferred tax assets	1,175	1,170
Deferred tax liabilities:		
Depreciation	(1,175)	(1,170)
IPR&D	(20,500)	—
Total deferred tax liabilities	(21,675)	(1,170)
Net deferred tax liability	$(20,500)	$—

The Company incurred $84,000 in income tax expense for the year ended December 31, 2014 related to taxable income generated by its wholly-owned subsidiary Zogenix Europe, and did not incur any income tax expense for the year ended December 31, 2013.

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14. Summarized Quarterly Data (Unaudited)

The following financial information reflects all adjustments, which include only normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the consolidated financial results of the interim periods. Summarized quarterly data for the years ended December 31, 2014 and 2013 is as follows:

	2014 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share amounts)			
Revenue	$7,674	$9,161	$8,797	$14,899
Cost of goods sold and contract manufacturing	$3,382	$4,310	$4,692	$17,775
Gross profit (loss)[1]	$4,292	$4,851	$4,105	$(2,876)
Loss on extinguishment of debt [2]	$—	$(1,254)	$—	$—
Impairment of long-lived assets [3]	$—	$(838)	$—	$—
Gain on sale of business	$—	$79,980	$—	$—
Net income (loss)	$(20,932)	$62,865	$(12,825)	$(20,521)
Net income (loss) per share, basic	$(0.16)	$0.45	$(0.09)	$(0.14)
Net income (loss) per share, diluted	$(0.20)	$0.45	$(0.09)	$(0.14)
Weighted-average shares outstanding, basic	139,309	139,985	141,045	150,016
Weighted-average shares outstanding, diluted	145,323	139,985	141,045	150,040

	2013 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share amounts)			
Revenue	$6,981	$8,942	$7,168	$9,921
Cost of goods sold	$4,158	$4,630	$5,354	$7,099
Gross profit (1)	$2,823	$4,312	$1,814	$2,822
Net loss	$(21,055)	$(13,332)	$(10,852)	$(35,617)
Net loss per share, basic and diluted	$(0.21)	$(0.13)	$(0.10)	$(0.28)
Weighted-average shares outstanding, basic and diluted	100,809	100,876	104,682	127,869

(1) Gross profit (loss) is calculated as revenue less cost of goods sold and cost of contract manufacturing.
(2) Incurred in connection with termination of Healthcare Royalty Financing Agreement. See Note 9.
(3) Impairment of long lived assets related to abandonment in connection with sale of business. See Note 5.

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Zogenix, Inc.
Notes to Consolidated Financial Statements (continued)

15. Subsequent Event

During the first quarter of 2015 the Company initiated and reached a decision to sell the Zohydro ER business. On March 10, 2015, the Company entered into an asset purchase agreement (the Asset Purchase Agreement) with Pernix Ireland Limited and Pernix Therapeutics Holdings, Inc., (Pernix Therapeutics, and, together with Pernix Ireland Limited, Pernix), pursuant to which, and on the terms and subject to the conditions thereof, among other things, the Company agreed to sell its Zohydro ER business to Pernix, including the registered patents and trademarks, certain contracts, the NDA and other regulatory approvals, documentation and authorizations, the books and records, marketing materials and product data relating to Zohydro ER. The Company is currently in process of evaluating the carrying value of assets and liabilities, as well as the related income (loss), associated with the disposal group.

Under the terms of the Asset Purchase Agreement, Pernix will pay $30,000,000 in cash upon the closing (the Closing)of the transaction, $3,000,000 of which will be deposited into escrow to fund potential indemnification claims for a period of 12 months The Escrow Period). At the Closing, the Company will also receive $50,000,000 in the form of a secured promissory note (the Note) and $20,000,000 in common stock consideration from Pernix (based on the $11.89 per share closing price of Pernix Therapeutics' common stock on the trading day immediately preceding the execution date). The Note will mature four months after the Closing, which maturity date may be extended in Pernix's sole discretion by up to an additional two months and, in the case of certain intellectual property matters, by up to an additional four months, for an aggregate extension of the maturity date to ten months from the Closing. The Note is subject to customary events of default, including cross-defaults to certain defaults under Pernix's debt facilities, and will be secured by substantially all of the purchased assets. Upon repayment of the Note, $7,000,000 of the $50,000,000 payable thereunder will be deposited into escrow to fund potential indemnification claims through the Escrow Period. In addition, the Company has agreed to indemnify Pernix for certain intellectual property matters up to an aggregate amount of $5,000,000.

In addition to the upfront cash payment, the Company is eligible to receive cash payments of up to $283,500,000 based on the achievement of pre-determined milestones, including a $12,500,000 payment upon approval by the FDA of an abuse-deterrent extended-release hydrocodone tablet (currently in development in collaboration with Altus) and up to $271,000,000 in potential sales milestone payments. Pursuant to the Asset Purchase Agreement, Pernix has agreed to use commercially reasonable efforts (as defined in the Asset Purchase Agreement) to meet such milestones. Furthermore, Pernix will assume responsibility for the Company's obligations under the purchased contracts and regulatory approvals, as well as other liabilities associated with the Zohydro ER business arising after the Closing date. The Company will retain all liabilities associated with the Zohydro ER business arising prior to the Closing date. In connection with the stock consideration the Company will receive pursuant to the Asset Purchase Agreement, Pernix Therapeutics will use commercially reasonable efforts to file a resale shelf registration statement and to have such registration statement declared effective no later than five months after the Closing date. The Company will agree not to sell its shares in Pernix Therapeutics for a period of six months after such Closing date.

The Asset Purchase Agreement contains customary representations, warranties and covenants, including covenants to cooperate in seeking regulatory approvals, as well as the Company's covenant not to compete in the single entity, extended release hydrocodone market for five years following the Closing.

The obligation of Pernix to purchase the Zohydro ER business is subject to the satisfaction or waiver of a number of conditions set forth in the Asset Purchase Agreement, including (i) the accuracy of the representations and warranties and compliance with covenants contained in the Asset Purchase Agreement, (ii) the absence of any law or order by any governmental authority that would make illegal or otherwise prohibit the consummation of the transactions under the Asset Purchase Agreement, (iii) all required consents of, notifications to and filings with any governmental authority shall have been made and any waiting periods shall have expired, including the expiration or termination of applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (iv) the absence of any actions or proceedings challenging or seeking to restrain or prohibit any of the transactions under the

Asset Purchase Agreement, (v) there not having been a material adverse effect with respect to the Company's Zohydro ER business, (vi) the delivery to Pernix of a transition services agreement, registration rights agreement, escrow agreement and other ancillary transaction documents and receipt of third party consents, and (vii) other customary conditions. In addition, the Company is required to extinguish all encumbrances on the assets to be sold to Pernix, including the security interests previously granted to Oxford Finance LLC and Silicon Valley Bank (together, the lenders) pursuant to the Company’s loan and security agreement, dated December 30, 2014, with the lenders. The Company is currently in discussions with the lenders to amend the loan and security agreement to remove the security interests on the assets to be sold to Pernix. However, if the Company is unable to reach an agreement with the lenders,

the Company expects to eliminate its existing debt obligation to the lenders by repaying all amounts owed under the loan and security agreement, including applicable termination fees, which as of December 31, 2014 was $23,300,000. The Company expects the Closing to occur during April 2015, subject to the satisfaction of the foregoing closing conditions.

Either party may terminate the Asset Purchase Agreement if the closing has not occurred by May 9, 2015, provided that if the Closing has not occurred due to lack of governmental approval, the Closing may be extended up to an additional 60 days to obtain such approval. The Company and Pernix may also terminate the Asset Purchase Agreement by mutual consent, for a material uncured breach by the other party, or if a final governmental order prohibiting the transaction is issued.

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SIGNATURES

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

ZOGENIX, INC.

Date: March 11, 2015 By: /s/ Roger L. Hawley
Chief Executive Officer

Date: March 11, 2015 By: /s/ Ann D. Rhoads
Executive Vice President, Chief Financial Officer, Treasurer and Secretary

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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/ ROGER L. HAWLEY Roger L. Hawley	Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2015
/S/ ANN D. RHOADS Ann D. Rhoads	Executive Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 11, 2015
/S/ CAM L. GARNER Cam L. Garner	Chairman of the Board	March 11, 2015
/S/ LOUIS C. BOCK Louis C. Bock	Director	March 11, 2015
/S/ JAMES B. BREITMEYER, M.D., Ph.D. James B. Breitmeyer, M.D., Ph.D	Director	March 11, 2015
/S/ STEPHEN J. FARR, PH.D. Stephen J. Farr, Ph.D.	President and Director	March 11, 2015
/S/ ERLE T. MAST Erle T. Mast	Director	March 11, 2015
/S/ RENEE TANNENBAUM, Pharm.D. Renee Tannenbaum, Pharm.D.	Director	March 11, 2015
/S/ MARK WIGGINS Mark Wiggins	Director	March 11, 2015

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EXHIBIT INDEX

Exhibit Number	Description
2.1†(18)	Asset Purchase Agreement dated April 23, 2014 by and among the Registrant, Endo Ventures Bermuda Limited and Endo Ventures Limited
2.2†(21)	Sale and Purchase Agreement dated October 24, 2014 by and among the Registrant, Zogenix Europe Limited, Brabant Pharma Limited and Anthony Clarke, Richard Stewart, Ann Soenen-Darcis, Jennifer Watson, Rekyer Securities plc and Aquarius Life Science Limited, as sellers
3.1(2)	Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.2(6)	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Registrant
3.3(2)	Amended and Restated Bylaws of the Registrant
4.1(3)	Form of the Registrant's Common Stock Certificate
4.2(1)	Third Amended and Restated Investors' Rights Agreement dated December 2, 2009
4.3(1)	Amendment to Third Amended and Restated Investors' Rights Agreement dated July 1, 2010
4.4(4)	Second Amendment to Third Amended and Restated Investors' Rights Agreement dated June 30, 2011
4.5(1)	Warrant dated June 30, 2008 issued by the Registrant to CIT Healthcare LLC (subsequently transferred to The CIT Group/Equity Investments, Inc.)
4.6(1)	Transfer of Warrant dated March 24, 2009 from CIT Healthcare LLC to The CIT Group/Equity Investments, Inc.
4.7(4)	Warrant dated July 18, 2011 issued by the Registrant to Cowen Healthcare Royalty Partners II, L.P.
4.8(22)	Warrant dated December 30, 2014 issued to Oxford Finance LLC
4.9(22)	Warrant dated December 30, 2014 issued to Silicon Valley Bank
10.1(2)	Form of Director and Executive Officer Indemnification Agreement
10.2#(1)	Form of Executive Officer Employment Agreement
10.3#(1)	2006 Equity Incentive Plan, as amended, and forms of option agreements thereunder
10.4#(2)	2010 Equity Incentive Award Plan and forms of option and restricted stock agreements thereunder
10.5#(2)	2010 Employee Stock Purchase Plan and form of Offering document thereunder
10.6#(1)	Executive Officer Employment Agreement dated March 1, 2010 by and between the Registrant and Ann D. Rhoads

10.7†(1)	Supply Agreement dated September 29, 2004 by and between the Registrant and Dr. Reddy's Laboratories, Inc.
10.8†(1)	Asset Purchase Agreement dated August 25, 2006 by and between the Registrant and Aradigm Corporation
10.9(1)	Lease dated October 31, 2006 by and between the Registrant and Emery Station Joint Venture, LLC
10.10(1)	First Amendment to Lease dated July 10, 2007 by and between the Registrant and Emery Station Joint Venture, LLC
10.11(1)	Second Amendment to Lease dated October 20, 2009 by and between the Registrant and Emery Station Joint Venture, LLC
10.12†(1)	License Agreement dated November 27, 2007 by and between the Registrant and Elan Pharma International Limited
10.13†(1)	First Amendment to License Agreement dated September 28, 2009 by and between the Registrant and Elan Pharma International Limited
10.14†(2)	Manufacturing Services Agreement dated November 1, 2008 by and between the Registrant and Patheon U.K. Ltd.

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10.15†(1)	Commercial Manufacturing and Supply Agreement dated April 1, 2009 by and between the Registrant and MGlas AG
10.16†(4)	Development and License Agreement dated July 11, 2011 by and between the Registrant and Durect Corporation
10.17#(4)	2011 Annual Incentive Plan
10.18(7)††	Amendment to Co-Promotion Agreement dated December 20, 2011 by and between the Registrant and Astellas Pharma US, Inc.
10.19(8)†	Co-Marketing and Option Agreement dated March 29, 2012 by and between the Registrant and Battelle Memorial Institute
10.20(9)†	Co-Promotion Agreement dated June 6, 2012 by and between the Registrant and Mallinckrodt, LLC
10.21(10)†	Commercial Manufacturing and Supply Agreement dated November 2, 2012 by and between the Registrant and Alkermes Pharma Ireland Ltd.
10.22(11)†	Manufacturing Services Agreement dated February 28, 2013 by and between the Registrant and Patheon UK Limited
10.23(11)†	Second Amendment to the License Agreement dated March 12, 2013 by and between the Registrant and Alkermes Pharma Ireland Limited
10.24(11)	Independent Director Compensation Policy as amended and restated effective March 15, 2013
10.25(11)	Annual Incentive Plan as amended and restated effective March 15, 2013
10.26(11)†	Amendment No. 1 to the Development and License Agreement dated March 18, 2013 and made retroactive to January 1, 2013 by and between the Registrant and Durect Corporation
10.27(11)†	First Amendment to the Co-marketing and Option Agreement dated March 29, 2012 entered into as of March 21, 2013 by and between the Registrant and Battelle Memorial Institute
10.28(12)	Form of Restricted Stock Unit Award Agreement under the 2010 Equity Incentive Award Plan
10.29(13)†	Co-promotion Agreement dated June 27, 2013, by and between the Registrant and Valeant Pharmaceuticals North America LLC
10.30(12)	Agreement on Termination of Agreements dated August 5, 2013, by and between the Registrant and Desitin Arzneimittel GmbH
10.31(15)†	Amendment #1 to the Manufacturing Services Agreement, dated February 28, 2013 with an effective date of November 1, 2013, by and between the Registrant and Patheon UK Limited
10.32†(15)	Co-Marketing and Development Services Agreement dated November 26, 2013, by and between the Registrant and Battelle Memorial Institute

10.33#(14)	Employment Inducement Equity Incentive Award Plan and form of stock option agreement thereunder
10.34#(15)	Annual Incentive Plan as amended and restated effective, December 4, 2013
10.35(15)	Employment Agreement dated December 17, 2013 by and between the Registrant and Bradley S. Galer, M.D.
10.36†(15)	Development and Option Agreement dated November 1, 2013 by and between the Registrant and Altus Formulation, Inc.
10.37(15)	Employment Transition Agreement dated November 1, 2013 by and between the Registrant and Cynthia Y. Robinson, Ph.D.
10.38†(16)	Termination and Amendment Agreement effective as of January 31, 2014 by and between the Registrant and Mallinckrodt LLC
10.39†(16)	Amendment No. 1 - Development and Option Agreement dated March 10, 2014 by and between the Registrant and Altus Formulation Inc.
10.40(16)	Independent Director Compensation Policy as amended and restated effective March 21, 2014

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10.41#(17)	Annual Incentive Plan as amended and restated effective July 22, 2014
10.42†(18)	Manufacturing and Supply Agreement dated May 16, 2014 by and between the Registrant and Endo Ventures Limited
10.43†(19)	License Agreement dated May 16, 2014 by and between the Registrant and Endo Ventures Bermuda Limited
10.44†(19)	Third Amendment to License Agreement dated September 12, 2014 by and between the Registrant and Daravita Limited
10.45†(19)	First Amendment to Commercial Manufacturing and Supply Agreement dated September 12, 2014 by and between the Registrant and Daravita Limited
10.46†(19)	Amendment No. 2 - Development & Option Agreement dated September 15, 2014 by and between the Registrant and Altus Formulation, Inc.
10.47†(19)	Waiver Agreement between the Registrant and Purdue Pharma L.P. dated October 29, 2014
10.48†(19)	Collaboration and License Agreement dated as of October 23, 2014 by and among The Katholieke Universiteit Leuven, University Hospital Antwerp and Brabant Pharma Limited
10.49(19)	Office Lease dated August 5, 2014 by and between the Registrant and Kilroy Realty, L.P.
10.50(20)	Controlled Equity Offering^{SM} Sales Agreement between the Registrant and Cantor Fitzgerald & Co.
10.51(22)	Loan and Security Agreement dated December 30, 2014 by and among the Registrant, Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC and Silicon Valley Bank
10.52†	Amendment No. 3 - Development & Option Agreement dated October 30, 2014 by and between the Registrant and Altus Formulation, Inc.
10.53	Right of Reference Letter Agreement dated November 5, 2014 by and between the Registrant and Teva Pharmaceuticals USA, Inc.
21.1(5)	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)

32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. §1350, as adopted)
101	The following financial statements from Zogenix, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2014, filed on March 10, 2015, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) the Notes to Consolidated Financial Statements.

(1) Filed with the Registrant's Registration Statement on Form S-1 on September 3, 2010 (Registration No. 333-169210).
(2) Filed with Amendment No. 2 to Registrant's Registration Statement on Form S-1 on October 27, 2010 (Registration No. 333-169210).
(3) Filed with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 on November 4, 2010 (Registration No. 333-169210).
(4) Filed with the Registrant's Quarterly Report on Form 10-Q on August 11, 2011.
(5) Filed with the Registrant's Annual Report on Form 10-K on March 4, 2011.
(6) Filed with the Registrant's Quarterly Report on Form 10-Q on November 8, 2012.
(7) Filed with the Registrant's Quarterly Report on Form 10-K on March 12, 2012.
(8) Filed with the Registrant's Quarterly Report on Form 10-Q on May 15, 2012.

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(9) Filed with the Registrant's Quarterly Report on Form 10-Q on August 9, 2012.
(10) Filed with the Registrant's Annual report on Form 10-K on March 15, 2013
(11) Filed with the Registrant's Quarterly Report on Form 10-Q on May 9, 2013
(12) Filed with the Registrant's Quarterly Report on Form 10-Q on August 8, 2013
(13) Filed with the Registrant's amendment to its Quarterly Report on Form 10-Q on January 14, 2014
(14) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K on December 5, 2013
(15) Filed with the Registrant’s Annual Report on Form 10-K on March 7, 2014.
(16) Filed with the Registrant’s Quarterly Report on Form 10-Q on May 8, 2014.
(17) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K on July 24, 2014.
(18) Filed with the Registrant’s Quarterly Report on Form 10-Q on August 6, 2014.
(19) Filed with the Registrant’s Quarterly Report on Form 10-Q on November 6, 2014.
(20) Filed with the Registrant’s Registration Statement on Form S-3 on November 6, 2014 (Registration No. 333-199957).
(21) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A on December 23, 2014.
(22) Filed with the Registrant’s Current Report on Form 8-K on December 31, 2014.

† Confidential treatment has been granted or requested, as applicable, for portions of this exhibit. These portions have been omitted from the Registration Statement and filed separately with the Securities and Exchange Commission
# Indicates management contract or compensatory plan.