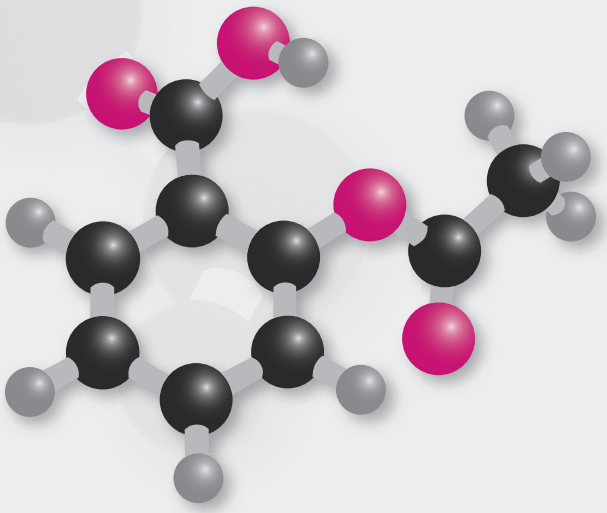
POZEN®
Transforming medicine. Transforming lives.

> ANNUAL REPORT 2014

>> BOLDPARTNERSHIPS

Creative collaboration brings out the best in everyone



> Transforming medicine. Transforming lives.

POZEN Inc. is a small pharmaceutical company that specializes in developing novel therapeutics for unmet medical needs and licensing those products to other pharmaceutical companies for commercialization. By utilizing a unique in-source model and focusing on integrated therapies, POZEN has successfully developed and obtained FDA approval of two self-invented products. Funded by these milestones/royalty streams, POZEN has created a portfolio of cost-effective, evidence-based integrated aspirin therapies designed to enable the full power of aspirin by reducing its GI damage.

POZEN is currently seeking strategic partners to help maximize the opportunities for its portfolio assets.

POZEN®
Transforming medicine. Transforming lives.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **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 000-31719

POZEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**62-1657552**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1414 Raleigh Rd, Suite 400, Chapel Hill, NC 27517
(Address of principal executive offices including zip code)

(919) 913-1030
(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, $0.001 par value	NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
Preferred Share Purchase Right

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition 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 ☒
Non-accelerated filer ☐	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in 12b-2 of the Act). Yes ☐ No ☒.

The aggregate market value of the common stock held by non-affiliates computed by reference to the last reported sale price on June 30, 2014 was approximately $204,875,000. As of February 24, 2015, there were outstanding 32,246,397 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the POZEN Inc. definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year are incorporated by reference into Part III of this Form 10-K and certain documents are incorporated by reference into Part IV.

POZEN INC.
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

Forward-Looking Information

This report includes "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as "may," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The forward-looking statements are subject to a number of risks and uncertainties which are discussed below in the section entitled "Item 1A --Risk Factors." We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements, other than as is required under the federal securities laws.

PART I

Item 1. Business

Overview

We are a pharmaceutical company focused on transforming medicines that can transform lives. We have operated a business model that has focused on the following:

- developing innovative products that address unmet medical needs in the marketplace;
- obtaining patents for those innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas by working with strategic outsource partners;
- developing a regulatory pathway with the appropriate agency; and
- determining how best to commercialize our products.

We hire experts with strong project management skills in the specific disciplines we believe are important to maintain within our company. We contract with and manage strong outsource partners as we complete the necessary development work, permitting us to avoid incurring the cost of buying or building laboratories, manufacturing facilities or clinical research operation sites. This allows us to control our annual expenses, but to utilize "best in class" resources as required. We decided to retain ownership of our PA product candidates for cardiovascular indications which contain a combination of a proton pump inhibitor and enteric coated aspirin in a single tablet through the clinical development and pre-commercialization stage and our chief commercial officer was responsible for developing the commercialization strategy for these products and conducting all the required pre-commercialization activities.

On September 3, 2013 we entered into an exclusive license agreement with Sanofi US, for the commercialization of PA8140 and PA32540, now known as YOSPRALA™ 81/40 and 325/40 (aspirin / omeprazole delayed release tablets). Under the terms of the agreement, Sanofi US had exclusive rights to commercialize all PA combinations that contain 325 mg or less of enteric-coated aspirin in the United States.

On April 25, 2014, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA in its then-current form. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. Satisfactory resolution of these deficiencies is required before the NDA may be approved. There were no clinical or safety deficiencies noted with respect to either PA8140 or PA32540 and no other deficiencies were noted in CRL. On June 30, 2014, we resubmitted the NDA for PA32540 and PA8140 to the FDA and the FDA notified us that the new action fee date is December 30, 2014. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The termination agreement further provides for the transfer of specified commercial know-how developed by Sanofi US relating to the PA products to us and allows us, and any future collaborators, to use this know-how to commercialize the products. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products.

On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. We continue to assist the FDA compliance division with their review.

FDA regulations allow us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting, which was held in late January 2015. At the meeting, representatives from the FDA's Office of Compliance stated that the active ingredient supplier's responses to the 483 inspectional observations submitted in May 2014 were still under review and the Office of Compliance would be communicating with the supplier in the coming weeks. The active ingredient supplier has informed POZEN that they received a warning letter relating to the Form 483 inspection deficiencies. They are evaluating what additional corrective actions may be required to address the matters raised in the warning letter. We will continue to provide assistance to our active ingredient supplier in taking corrective actions to address the inspectional observations at its facility

In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

Our commercialization strategy for PA outside the United States is to secure relationships with one or more strong commercial partners with relevant expertise to commercialize our future products globally. With respect to future products we may develop, we have decided that we will no longer commit substantial resources to further drug development without a partner who agrees to pay the full cost of that development. Consistent with this model, we have reduced our R&D staff and other costs and expenses as our PA development program activities wind down. Our board of directors and management team continue to explore potential ways to return value to our stockholders. On November 21, 2013, our Board of Directors declared a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with a payment date of December 30, 2013. This distribution represented a surplus of corporate cash and is accounted for as a return of capital to stockholders. We may consider other cash distributions in the future if prudent to do so.

The success of our business is highly dependent on the marketplace value of our ideas and the related patents we obtain, our ability to obtain from the required regulatory agencies approval to sell the developed products and our ability to find strong commercial or outsource partners to successfully commercialize the products.

Treximet

We have previously developed Treximet® in collaboration with GlaxoSmithKline, or GSK. Treximet is the brand name for the product combining sumatriptan 85 mg, formulated with RT Technology™ and naproxen sodium 500 mg in a single tablet designed for the acute treatment of migraine. On April 15, 2008, the U.S. Food and Drug Administration, or FDA, approved Treximet for the acute treatment of migraine attacks with or without aura in adults. Upon receipt of FDA approval, GSK notified us of its intention to launch the product and Treximet was available in pharmacies in May 2008.

On November 23, 2011, we entered into a purchase and sale agreement, or the Purchase Agreement, with CPPIB Credit Investments Inc. or CII, pursuant to which we sold, and CII purchased, our right to receive future royalty payments arising from U.S. sales of MT 400, including Treximet. Under the Purchase Agreement, we received $75 million and will receive a twenty percent (20%) interest in any royalties received by CII relating to the period commencing on April 1, 2018.

On May 13, 2014, we, Glaxo Group Limited, d/b/a GlaxoSmithKline, or GSK, CII and Pernix Therapeutics Holdings, Inc., or Pernix, entered into certain agreements in connection with GSK's divestiture of all of its rights, title and interest to develop, commercialize and sell Treximet® in the U.S. to Pernix. Upon the closing of the divestiture on August 20, 2014, GSK assigned the Product Development and Commercialization Agreement executed as of June 11, 2003 between us and GSK, the Treximet Agreement, to Pernix. Immediately following the closing of the divestiture, Amendment No. 1 to the Treximet Agreement, or Amendment No.1, between us and Pernix became effective. Amendment No. 1, among other things, amends the royalty provisions of the Agreement to provide for a guaranteed quarterly minimum royalty payable to CII of $4 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018 and requires that Pernix continue certain of GSK's ongoing development activities and to undertake certain new activities, for which we will provide reasonable assistance.

Amendment No. 1 also eliminates restrictions in the Agreement on our right to develop and commercialize certain dosage forms of sumatriptan/naproxen combinations outside of the United States and permits POZEN to seek approval for these combinations on the basis of the approved NDA for Treximet. Pernix has also issued us a warrant to purchase 500,000 shares of Pernix common stock at an exercise price equal to $4.28, the closing price of Pernix common stock as listed on the NASDAQ Global Market on May 13, 2014. The common stock underlying the warrants will be registered by Pernix with the Securities and Exchange Commission and the warrant is exercisable from August 20, 2014, the closing date of the Divestiture, until February 28, 2018. Because the warrant has not been registered by Pernix with the Securities and Exchange Commission, the Company cannot sell or transfer the warrant in reliance upon Rule 144 until after November 13, 2014 when the Company meets certain holding requirements. The warrant is valued using the Black-Scholes valuation model. Under the terms of the warrant, the Company may elect to receive the number of shares equal to the value of the Pernix shares less $4.28 divided by the fair market value of one share. At December 31, 2014 this would have been 272,098 shares valued at $2.6 million. Lastly, we, GSK, Pernix and CII executed a letter agreement whereby we expressly consented to the assignment by GSK and the assumption by Pernix of the Treximet Agreement. On July 30, the parties entered into Amendment No. 2 to the Treximet Agreement which will permit Pernix's Irish affiliate to which Pernix will assigns its rights to further assign the Agreement without our prior written consent as collateral security for the benefit of the lenders which financed the acquisition. Amendment No. 2 became effective upon the closing of the divestiture on August 20, 2014.

VIMOVO

We have developed VIMOVO® with AstraZeneca AB, or AstraZeneca. VIMOVO (formerly referred to as PN 400) is the brand name for a proprietary fixed dose combination of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of osteoarthritis, or OA, rheumatoid arthritis, or RA, and ankylosing spondylitis, or AS, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca to co-develop and commercialize VIMOVO, which agreement was amended in September 2007 and October 2008. We began the Phase 3 program in September 2007. As part of the program, we conducted two Phase 3 pivotal trials of VIMOVO in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which was the reduction in endoscopic gastric ulcers.

The NDA for VIMOVO was submitted on June 30, 2009 and was accepted for filing by FDA in August 2009. POZEN received a $10.0 million milestone payment from AstraZeneca in September 2009 for the achievement of such milestone. Earlier, in May 2010, we had received a $20.0 million milestone payment when we received FDA approval of VIMOVO. In October 2009, AstraZeneca submitted a Marketing Authorization Application, or MAA, for VIMOVO in the European Union, or EU, via the Decentralized Procedure, or DCP, and has filed for approval in a number of other countries which are not covered by the DCP. On October 11, 2010, we announced with AstraZeneca that VIMOVO had received positive agreement for approval in 23 countries across the EU following all 22 Concerned Member States agreeing with the assessment of the Netherlands Health Authority (MEB), acting as the Reference Member State for the DCP. We received a $25.0 million milestone payment when pricing and reimbursement for VIMOVO was granted in the United Kingdom.

On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understand that AstraZeneca will instead now focus on those countries where the product has shown growth and which AstraZeneca believes have the greatest potential for future growth.

On November 18, 2013, AstraZeneca and Horizon Pharma Inc., or "Horizon," entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. As required by the terms of our agreement with AstraZeneca, we gave our consent to AstraZeneca's divestiture of such rights to Horizon because we believed that Horizon's expertise in commercializing products for pain and inflammatory disease, including a similar combination product containing a NSAID and a gastroprotective agent, make it an excellent partner to maximize the potential of VIMOVO in the United States. We were also able to negotiate a guaranteed annual minimum royalty in the United States in the amount of $5 million in calendar year 2014, and a guaranteed annual minimum royalty amount of $7.5 million each calendar year thereafter, provided that the patents owned by us which cover VIMOVO are in effect and no generic forms of VIMOVO are in the marketplace.

On July 28, 2014, Horizon announced that it had been verbally notified by CVS Caremark and Express Scripts, Inc. that VIMOVO would no longer be on their formularies and will be placed on their exclusion lists effective January 1, 2015. We have been informed that Horizon estimates that approximately 20-30% of VIMOVO prescriptions could be impacted by these decisions. While Horizon believes it has a strategy to mitigate the effect on VIMOVO sales, POZEN's royalty revenue from Net Sales of VIMOVO beginning in 2015 may be negatively affected, although we will continue to receive a guaranteed annual minimum royalty of $7.5 million as described above.

Our Principal Product Candidates

Our PA product candidates, containing a PPI and aspirin, have completed clinical development testing in the United States. Our PA product candidates, now known as YOSPRALA™ 81/40 and 325/40 (aspirin / omeprazole delayed release tablets), are excluded from our agreement with AstraZeneca. We met with the FDA to discuss the overall development program requirements for PA32540 for the secondary prevention of cardiovascular and cerebrovascular disease in patients at risk for gastric ulcers. An investigational new drug application, or IND, was filed in the fourth quarter of 2007. We completed a study which demonstrated that the (SA) component of PA32540 was bioequivalent to the reference drug, EC aspirin. We filed a Special Protocol Assessment, or SPA, with the FDA for the design of the Phase 3 studies for the product, the primary endpoint for which is the reduction in the cumulative incidence of endoscopic gastric ulcers.

Based upon the FDA's earlier confirmation that endoscopic gastric ulcers were an acceptable primary endpoint, in October 2009, we began two pivotal Phase 3 and one long-term safety study for PA32540 for the cardiovascular indication. The primary endpoint of the pivotal studies, which included approximately 500 subjects per study, was a significant reduction in the cumulative incidence of gastric ulcers following administration of PA32540 vs. 325 mg enteric-coated aspirin over the six-month treatment period. The primary endpoint was met in both studies. Additionally, the studies met their key secondary endpoints, including a reduction in gastroduodenal ulceration as well as a reduction in discontinuation due to upper gastrointestinal adverse events in subjects taking PA32540 compared to 325 mg enteric-coated aspirin.

In February 2012, the FDA requested an additional Phase 1 study to assess the bioequivalence of PA32540 to EC aspirin 325 mg with respect to acetylsalicylic acid, or ASA. After the Company completed the requested bioequivalence study, the FDA made a preliminary review of the study results and the Company's summary analyses and, based on its preliminary assessment of the information available to it at the time, the FDA did not agree that bioequivalence of PA32540 to EC aspirin 325 mg was demonstrated. The Company then submitted to the FDA additional information and analyses from the requested bioequivalence study, as well as other relevant pharmacokinetic, clinical pharmacology, and in vitro dissolution data as a Briefing Document in support of a request for a Type A meeting with the FDA. At the Type A meeting held in August 2012, the FDA confirmed that, although it believes bioequivalence of PA32540 to EC aspirin 325 mg, was not strictly established in our bioequivalence study according to the predetermined criteria, the results from this study, together with additional information that will be submitted by the Company in the NDA, constitutes sufficient data to support the establishment of a clinical and pharmacological bridge between the product and EC aspirin 325 mg. The FDA indicated that it would make a final determination during the NDA review. The FDA also indicated that a similar strategy to bridge to the reference listed drug, inclusive of a new, single pharmacokinetic study, could be utilized for a low dose version of PA32540 (currently PA8140). The Company conducted this study with the low dose version against the EC aspirin 81mg. Based on the predetermined criteria acceptable to the FDA, the study demonstrated that PA8140 is bioequivalent to EC aspirin 81mg using criteria for highly variable drugs and had comparable bioavailability.

During a pre-submission meeting with respect to its NDA for PA32540 in April 2012, the FDA suggested that the Company also seek approval for a lower dose formulation of the product containing 81 mg of enteric coated aspirin as part of its NDA for PA32540. Absent the availability of such a lower dose formulation in the market if PA32540 is approved, the FDA indicated that it may limit the indication for PA32540 to use in post coronary artery bypass graft surgery (CABG) with treatment duration not to exceed one year. During the Type A meeting held in August 2012, the FDA confirmed its preference to have both PA32540 and a lower dose version available in the market so that physicians can have both a low and high dose option available, and agreed that, if both dosage strengths were included in the NDA and subsequently approved, the indications for both will be consistent with the full range of indications described in the current aspirin monograph.

We had generated some clinical pharmacology data and chemical, manufacturing and controls (CMC) data for a product which contains 81 mg of enteric coated aspirin and 40 mg of omeprazole in a single tablet known as PA8140. The Company filed this existing data, together with additional CMC data to be generated and evidence from the scientific literature relating to the ulcerogenic risk of 81 mg of aspirin with the FDA. At this time, we do not intend to conduct Phase 3 clinical trials for PA8140. The data package submitted for PA8140 was similar to that used to gain approval for a lower dosage form of VIMOVO containing 375 mg of naproxen. We have no assurance such data will be sufficient for the FDA to approve PA8140

or to allow a broader indication for PA32540. The FDA will make a final determination with respect to the approvability of and indications for PA32540 and PA8140.

Generation of additional data with respect to PA8140 and incorporation of data into the NDA for PA32540 delayed submission of the NDA from the original planned submission date in the third quarter of 2012. The NDA was filed for both products in March 2013 and in May 2013 the FDA accepted the NDA for review. The FDA assigned a user fee date of January 24, 2014. As part of our continuing discussions with the FDA concerning the NDA for PA32540 and PA8140 tablets, we decided to conduct an additional comparative Phase 1 pharmacokinetic study to determine the pharmacokinetic profile of the omeprazole component of PA 8140 tablets and compare it to that of PA32540 tablets. We submitted study information and data to the FDA as it became available during the conduct of the study and FDA reviewed such information and data from the study when submitted. The final study report for the study was submitted to the FDA in accordance with our agreed timeline. FDA informed us that the Company's user fee date was April 25, 2014. On April 25, 2014, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA in its current form. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. Satisfactory resolution of these deficiencies is required before the NDA may be approved. There were no clinical or safety deficiencies noted with respect to either PA8140 or PA32540 and no other deficiencies were noted in CRL. On June 30, 2014, we resubmitted the NDA for PA32540 and PA8140 to the FDA and the FDA notified us that the new action fee date is December 30, 2014. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. We continue to assist the FDA compliance division with their review. FDA regulations allow us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting which was held in late January 2015. At the meeting, representatives from the FDA's Office of Compliance stated that the active ingredient supplier's responses to the 483 inspectional observations submitted in May 2014 were still under review and the Office of Compliance would be communicating with the supplier in the coming weeks. The active ingredient supplier has informed POZEN that they received a warning letter relating to the Form 483 inspection deficiencies. They are evaluating what additional corrective actions may be required to address the matters raised in the warning letter. We will continue to provide assistance to our active ingredient supplier in taking corrective actions to address the inspectional observations at its facility.

To assess whether a similar interaction occurs between clopidogrel and PA32540, which contains immediate release omeprazole, we completed two Phase 1 drug-drug interaction studies to evaluate the ex-vivo platelet aggregation effects of PA32540 plus clopidogrel. In the first study, we evaluated ex-vivo platelet aggregation of PA32540 plus clopidogrel when dosed at the same time or dosed 10 hours apart compared to aspirin 325 mg plus clopidogrel dosed together. When PA32540 and clopidogrel were dosed together, data from the study showed a mean 36.7% platelet inhibition compared to a mean 44.0% platelet inhibition when aspirin and clopidogrel were dosed together suggesting a drug-drug interaction based on the study's pre-specified primary analysis. When PA32540 and clopidogrel were dosed 10 hours apart, data from the study indicate no ex-vivo drug-drug interaction based on the study's pre-specified primary analysis. In the second Phase 1 study, we evaluated ex-vivo platelet aggregation of PA32540 plus clopidogrel dosed 10 hour apart compared to a current standard of care of Plavix + Prilosec 40 mg + EC ASA 81 mg dosed together. Subjects on PA32450 demonstrated significantly greater inhibition of platelet aggregation than subjects on standard of care. The clinical relevance of these ex vivo platelet data on cardiovascular events is not known. No further Phase 1 studies on the clopidogrel-PPI interaction are planned. FDA assessment of available data on the drug-drug interaction may result in the inclusion of a warning, similar to that in the current Prilosec label, against the concomitant use of PA32540 and Plavix.

We are also continuing to evaluate how best to commercialize the PA product candidates and programs. We are evaluating the regulatory requirements to obtain an indication for PA for the secondary prevention of colorectal neoplasia. In January 2010, we received input from the FDA with respect to the development requirements for a possible indication in colorectal neoplasia. Further discussions are being considered. We are also evaluating the possibility of developing another dosage strength of PA containing 650 mg of enteric coated aspirin and 20 mg of omeprazole (PA65020) for the treatment of osteoarthritis and similar conditions and we met with the FDA in December 2010 to obtain input with respect to the regulatory requirements to obtain such an indication. The FDA advised us that we will need to demonstrate a reduction in gastric ulcers compared to aspirin alone in a replicate Phase 3 program similar to that we performed for VIMOVO, in addition to a study to establish efficacy of the product in the treatment of osteoarthritis.

We met with a European country that served as the reference member state for approval of VIMOVO in Europe to obtain guidance on a clinical development program for approval of PA65020 in the Europe. We were advised that Phase 3 endoscopic trials demonstrating a reduction in gastric ulcers would not be required in addition to an osteoarthritis efficacy study since omeprazole's actions on gastric ulcers has been well characterized. Instead, Phase 1 studies assessing pharmacokinetics and gastric acid suppression could be used to support the benefit of omeprazole as a component of PA65020.

We have also received Scientific Advice from the Medicines Evaluation Board, or MEB in the Netherlands, which has agreed to be the Reference Member State in a decentralized filing procedure, regarding the development program required for the approval in the European Union, or EU, of PA tablets, including a lower dosage form containing 100 mg of aspirin and 40 mg of omeprazole (PA10040) for the secondary prevention of cardiovascular disease. The MEB agreed that a full Phase 3 clinical development program for PA10040, to demonstrate the reduction of endoscopic gastric ulcers vs. EC aspirin, would not be necessary. Instead, a Phase 1 pharmacodynamic study comparing gastric pH control for PA10040 vs.EC omeprazole 20 mg, along with a study to demonstrate bioequivalence of PA10040 to a currently marketed EC aspirin product using ASA as the analyte would be sufficient. Study PA10040-101 demonstrated that PA10040 had comparable bioavailability and is bioequivalent to a European Union reference listed enteric coated aspirin 100 mg. Study PA10040-102 demonstrated that PA10040 provides gastric pH greater than 4 control for a percent time over 24 hours of 47%. Furthermore, compared to Losec 20 mg (EC omeprazole 20 mg), PA10040 produced a similar level of 24-hour pH control ((p=0.02).

A pre-submission follow up meeting with the MEB was held in July 2014. We proposed seeking approval of PA10040 only since the ASA component in that dosage form matches the clinical practice for use of ASA in the EU. Approval of PA10040 would be based on specific studies conducted with the product, as well as data from the entire PA program conducted in the United States. Based on discussions at the meeting, the MEB agreed that the MAA filing can proceed without any further clinical studies and that the Netherlands would be the lead country for the decentralized review process. The MEB also requested that a complete risk-benefit analysis of PA10040 for the intended cardiovascular patient population and proposed indication should be included as part of the MAA submission.

We have incurred significant losses since our inception and have not yet generated significant revenue from product sales. As of December 31, 2014, our accumulated deficit was approximately $96.9 million. We record revenue under the following categories: royalty revenues and licensing revenues. Our licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, while the royalty payments are based on product sales. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and sales, general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented approximately 64% of our total operating expenses. For the fiscal year ended December 31, 2014, our research and development expenses represented approximately 36% of our total operating expenses.

Operating losses may be incurred over the next several years as we complete the development and seek regulatory approval for our product candidates, develop other product candidates, conduct pre-commercialization activities, and acquire and/or develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of our PA product candidates and our other product candidates in the clinical and regulatory process;

- The ability of Horizon and AstraZeneca to successfully commercialize VIMOVO in the United States and outside the United States, respectively, and our ability to successfully commercialize our PA product candidates in the United States;

- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates;

- Our ability to successfully defend our regulatory market exclusivity and patent rights against generic challenges and to succeed in obtaining extensions of such exclusivity for which we may be eligible;

- Our ability to commercialize our products with commercial partners in a highly regulated and extremely competitive marketplace; and

- The possible acquisition and/or in-licensing, and development of our therapeutic product candidates.

We do not currently have internal commercialization or manufacturing capabilities. We have entered into collaborations and may continue to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. We decided to retain control of our PA product candidates for cardiovascular indications through the clinical development and pre-commercialization stage. To that end, our chief commercial officer evaluated the commercial opportunities for these product candidates and developed a worldwide commercial strategy, which enabled us to conduct pre-commercialization activities prior to licensing these products to commercial partners. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products. In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

Our ability to generate revenue in the near term is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, to successfully develop product candidates, to obtain regulatory approvals and to successfully manufacture and commercialize our future products. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 6, 2014, as amended by Amendment No. 1 to our Annual Report on Form 10-K/A, filed with the Securities and Exchange Commission on September 22, 2014, and incorporated by reference herein. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

Our principal executive office is located at 1414 Raleigh Road, Suite 400, Chapel Hill, North Carolina 27517, and our telephone number is (919) 913-1030. Our website address is ***www.POZEN.com***. The information on our website is not incorporated into this prospectus and should not be considered to be a part of this prospectus. We have included our website address as an inactive textual reference only.

Overview of Our Results of Operations

We have incurred significant losses since our inception and have not yet generated significant revenue from product sales. As of December 31, 2014, our accumulated deficit was approximately $96.9 million. We record revenue under the following categories: royalty revenues and licensing revenues. Our licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, while the royalty payments are based on product sales. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and sales, general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented approximately 64% of our total operating expenses. For the fiscal year ended December 31, 2014, our research and development expenses represented approximately 36% of our total operating expenses.

Operating losses may be incurred over the next several years as we complete the development and seek regulatory approval for our product candidates, develop other product candidates, conduct pre-commercialization activities, and acquire and/or develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of our PA product candidates and our other product candidates in the clinical and regulatory process;
- The ability of Horizon and AstraZeneca to successfully commercialize VIMOVO in the United States and outside the United States, respectively, and the ability of Sanofi US to successfully commercialize our PA product candidates in the United States;
- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates;
- Our ability to successfully defend our regulatory market exclusivity and patent rights against generic challenges and to succeed in obtaining extensions of such exclusivity for which we may be eligible;
- Our ability to commercialize our products with commercial partners in a highly regulated and extremely competitive marketplace; and
- The possible acquisition and/or in-licensing, and development of our therapeutic product candidates.

Our ability to generate revenue in the near term is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, to successfully develop product candidates, to obtain regulatory approvals and to successfully manufacture and commercialize our future products. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included elsewhere in this Annual Report on Form 10-K. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

Our Business Strategy

Our goal had been to develop medicines that can transform lives. The principal elements of our business strategy had been to:

- ***Utilize expected cash flow from licensed products to fund new product ideas that meet our internal criteria.*** We expect to utilize the cash and cash flows from VIMOVO and from the monetization of our royalties from *Treximet* to complete development for our PA franchise of product candidates, as well as other new product concepts should we choose to move these product concepts into exploratory stage.

- ***Develop and perform pre-commercialization activities for our portfolio of product candidates.*** We filed a NDA for our PA32540 and PA8140 product candidates with the FDA in March 2013. We expect to focus on obtaining approval to market the products in the United States and are currently evaluating all strategic options available to us now that we have full ownership of the PA products in the United States. We expect to enter into partner relationships for the continued development and commercialization of these product candidates and other unlicensed assets outside of the United States, and to control expenses consistent with the achievement of these goals.

- ***Leverage development and commercialization efforts through strategic outsourcing.*** While maintaining overall control of the planning, development and regulatory processes, we seek to enter into strategic outsourcing relationships to develop and manufacture our product candidates in as cost-effective a manner as possible. We have contracted with third parties for product candidate testing, development, manufacturing and commercialization activities and plan to continue to do so for any future development and commercialization efforts.

Our business strategy has evolved over the past several years and may continue to evolve as we evaluate all strategic options available to us now that we have full ownership of the PA products in the United States. We previously announced that we were returning to our historical business model in which the Company funded development activities for pipeline products through proof of concept and then licensed the product prior to initiating Phase 3 clinical trials. The Company has developed and funded all or a major portion of the development costs for three products, *Treximet*, VIMOVO, and our PA product candidates, since 2003. We have now decided that we will no longer commit substantial resources to further drug development without a partner who agrees to pay the full cost of that development.

Arthritis Market Overview

Arthritis means joint inflammation and the term is used to describe the pain, stiffness and/or swelling in the joints of the body where one or more bones are joined by tendons and muscles. An arthritic joint is one that may have varying degrees of inflammation and possibly destruction of the joint cartilage, which normally provides a smooth surface enabling adjacent bones to move and glide on each other during normal motion.

The most common type of arthritis is called osteoarthritis and is more common with advancing age. Osteoarthritis is one of the most frequent causes of physical disability among adults. It is estimated that by 2030, 20% of Americans who are over the age of 65 years, or approximately 70 million people, will be at risk for osteoarthritis. People with osteoarthritis usually have joint pain and limited movement. Unlike some other forms of arthritis, osteoarthritis affects only the joints. This condition is also sometimes called degenerative joint disease. Osteoarthritis primarily affects the joint cartilage. Healthy cartilage allows bones to glide over one another and absorbs energy from the shock of physical movement. However, with osteoarthritis, the surface layer of cartilage breaks down and wears away. This allows the bony surface under the cartilage to rub together, causing, pain, swelling, and loss of motion of the joint. Over time, affected joints may lose their normal shape. Also, bone spurs, small growths called osteophytes, may grow on the edges of the joint. Thus bits of bone or cartilage can break off and float inside the joint space, causing more pain and possible damage.

The second most common form of arthritis, rheumatoid arthritis, may affect not only the joints, but organs of the body as well. Rheumatoid arthritis is recognized as a systemic disease that involves responses of the immune system that play a role in the inflammation that affects joints and other organs. Rheumatoid arthritis may begin at a younger age than does osteoarthritis. Often patients with rheumatoid arthritis will require medications not only to treat the pain of arthritis, but drugs which modulate the immune system to control inflammation in other parts of the body.

Non-steroidal anti-inflammatory drugs, or NSAIDs, both over-the-counter and prescription, are commonly taken to manage the pain of backache, osteoarthritis, rheumatoid arthritis, headache and other painful conditions. In 2012, approximately 100 million prescriptions were dispensed for oral anti-arthritis NSAIDs for the management of pain. Prescription sales of oral anti-arthritis NSAIDs in the U.S. in 2011 were approximately $3.0 billion. In spite of their widespread use and apparent safety, according to the Agency for Healthcare Research and Quality Statistical Brief released in December 2008, in 2006, there were approximately 16,300 deaths and 500,000 hospitalizations with a primary diagnosis of upper gastrointestinal, or GI, bleeding costing approximately $2 billion. The most common underlying conditions of GI bleeding were gastric, duodenal, peptic, or gastroduodenal ulcers or perforations, conditions frequently associated with NSAID use. We are responding to this unmet medical need to provide a "safer NSAID" through development of our PN product candidates for the treatment of conditions such as osteoarthritis in patients who are at risk for developing NSAID-associated gastric ulcers.

PN Program

Under our PN program, we completed formulation development and clinical studies for several combinations of a PPI and a NSAID in a single tablet intended to provide effective management of pain and inflammation associated with chronic conditions such as osteoarthritis, and intended to have fewer gastrointestinal complications compared to a NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. We entered into an exclusive ,worldwide (except for Japan) collaboration agreement with AstraZeneca on August 1, 2006 and which was amended in September 2007 and October 2008 relating to the development and commercialization of our PN products. Our agreement with AstraZeneca covered the development and commercialization of proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. The initial product developed under the agreement, VIMOVO (formerly PN 400), was approved by the FDA on April 30, 2010 for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

The NDA for VIMOVO was submitted on June 30, 2009 and was accepted for filing in August 2009. We received a $10.0 million milestone payment from AstraZeneca in September 2009 for the achievement of such milestone. On April 30, 2010, VIMOVO was approved by FDA for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. We received a $20.0 million milestone payment from AstraZeneca in May 2010 in connection with such approval. As required by the terms of our agreement with AstraZeneca, we transferred ownership of the NDA and other regulatory filings for VIMOVO to AstraZeneca on June 1, 2010, and AstraZeneca now has responsibility for all ongoing regulatory obligations for the product in the U.S., including post marketing clinical trial requirements, in addition to responsibility for all regulatory obligations outside the U.S.

Under our agreement with AstraZeneca, AstraZeneca had responsibility for the development program for PN products outside the U.S., including interactions with regulatory agencies. In October 2009, AstraZeneca submitted a MAA for VIMOVO in the EU via the DCP and has filed for approval in a number of other countries which are not covered by the DCP. On October 11, 2010, we announced with AstraZeneca that VIMOVO had received positive agreement for approval in 39 countries across the EU following all 22 Concerned Member States agreeing with the assessment of the Netherlands Health Authority, acting as the Reference Member State for the DCP. We received a $25.0 million milestone payment when pricing and reimbursement for VIMOVO was granted in the United Kingdom. Other Member States are now pursuing pricing and reimbursement and national approvals. Earlier, in May 2010, we had received a $20.0 million milestone payment when we received FDA approval of VIMOVO. As of the end of December 31, 2013, VIMOVO has been filed for regulatory approval in 81 countries and approved in 71 countries.

On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understand that AstraZeneca will instead now focus on those countries where the product has shown growth and which AstraZeneca believes have the greatest potential for future growth. We continue to assess the financial impact this decision will have on our royalty revenue. On November 18, 2013, AstraZeneca and Horizon entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. As

required by the terms of our agreement with AstraZeneca, we gave our consent to AstraZeneca's divestiture of such rights to Horizon because we believed that Horizon's expertise in commercializing products for pain and inflammatory disease, including a similar combination product containing a NSAID and a gastroprotective agent, make it an excellent partner to maximize the potential of VIMOVO in the United States. We were also able to negotiate a guaranteed annual minimum royalty in the United States in the amount of $5.0 million in calendar year 2014, and a guaranteed annual minimum royalty amount of $7.5 million each calendar year thereafter, provided that the patents owned by us which cover VIMOVO are in effect and no generic forms of VIMOVO are in the marketplace. On July 28, 2014, Horizon announced that it had been verbally notified by CVS Caremark and Express Scripts, Inc. that VIMOVO would no longer be on their formularies and will be placed on their exclusion lists effective January 1, 2015. We have been informed that Horizon estimates that approximately 20-30% of VIMOVO prescriptions could be impacted by these decisions. While Horizon believes it has a strategy to mitigate the effect on VIMOVO sales, POZEN's royalty revenue from Net Sales of VIMOVO beginning in 2015 may be negatively affected, although we will continue to receive a guaranteed annual minimum royalty of $7.5 million as described above.

Since inception we have incurred total direct development cost of $96.2 million associated with the development of our PN program of which $57.1 million was funded by development revenue from AstraZeneca. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expense.

Cardiovascular Market Overview

Cardiovascular disease, or CVD, is a broad term used to describe a range of common diseases that affect the heart or blood vessels. Many common conditions fall under the definition of CVD, including coronary artery disease, heart attack, heart failure, high blood pressure and stroke. In fact, the term "cardiovascular disease" is often used interchangeably with heart disease because both terms refer to diseases of the heart of arteries. Despite recent advances in medical research, cardiovascular disease, including heart attack and stroke is still the leading killer of men and women in the United States. It is also the most costly cause of death in men and women in the United States, according to the American Heart Association, or AHA.

An estimated 80 million American adults, or one in three, have one or more types of CVD, and 24 million have been identified as secondary prevention patients (post-event patients who have suffered one or more cardiovascular or cerebrovascular events). It is estimated that CVD causes one in every three deaths in the United States. Approximately every 25 seconds, someone in the United States suffers a coronary event with one related to death each minute.

Coronary artery disease is caused by atherosclerosis and often develops into angina pectoris and myocardial infarction (MI). The condition caused about 375,000 deaths in 2011 and remains the leading single cause of death in America today. Roughly 15.4 million have a history of MI and/or angina.

This year, approximately 620,000 American will have a new coronary attack, and approximately 295,000 will have a recurrent attack. It is estimated that an additional 150,000 silent myocardial incidents occur each year. Each year, approximately 795,000 people experience a new or recurrent stroke. Approximately 610,000 of these are first heart attacks, and 185,000 are recurrent attacks. On average, every 40 seconds, someone in the United States has a stroke. Direct and indirect costs related to the condition are projected to exceed $163 billion annually.

Aspirin therapy has become the standard of care for reducing an individual's risk of a second heart attack or stroke. Studies have found that a daily aspirin regimen for people who have experienced a previous heart attack reduces the risk of a second heart attack by about one-third. Aspirin has been incorporated into the American Heart Association's clinical guidelines for the secondary prevention of cardiovascular events. In accordance with these guidelines, approximately 24 million Americans should be taking aspirin for secondary prevention of cardiovascular events.

Although the CVD benefits of aspirin are well established, the use of aspirin is associated with the risk of upper gastrointestinal bleeding, or, UGIB. The use of aspirin is associated with a 2- to 4- fold increased risk of UGIB. In addition, aspirin use for CVD is an important cause of gastrointestinal bleeding-related death. The use of the proton pump inhibitors, or PPIs, such as omeprazole can significantly reduce the risk of upper gastrointestinal bleeding. The American College of Cardiology with the AHA issued a Clinical Expert Consensus in 2008 recommending PPIs as preferred agents for the therapy and prophylaxis of aspirin-associated gastrointestinal injury.

PA Program

As part of our PA program, we are developing a PPI and aspirin in a single tablet. Similar to the PN program, our PA product candidate is intended to induce fewer gastrointestinal complications compared to an aspirin taken alone in patients at risk for developing aspirin associated gastric ulcers. Our PA product candidates are covered under the same patent as PN, but we have retained all rights to this program through the clinical development and pre-commercialization stage. On September 3,

2013 we entered into a License and Collaboration Agreement with Sanofi US to commercialize our PA product candidates containing an immediate release proton pump inhibitor and 325 mg or less of delayed release or enteric coated aspirin in the United States. On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The termination agreement further provides for the transfer of specified commercial know-how developed by Sanofi US relating to the PA products to us and allows us, and any future collaborators, to use this know-how to commercialize the products. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products. In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

Our PA product candidates, PA32540 and PA8140, have completed clinical development testing in the United States. Based upon the FDA's earlier confirmation that endoscopic gastric ulcers were an acceptable primary endpoint, in October 2009, we began two pivotal Phase 3 and one long-term safety study for PA32540 for the cardiovascular indication. The primary endpoint was met in both studies. Additionally, the studies met their key secondary endpoints, including a reduction in gastroduodenal ulceration as well as a reduction in discontinuation due to upper gastrointestinal adverse events in subjects taking PA32540 compared to 325 mg enteric-coated aspirin.

In February 2012, the FDA requested an additional Phase 1 study to assess the bioequivalence of PA32540 to EC aspirin 325 mg with respect to acetylsalicylic acid, or ASA. After the Company completed the requested bioequivalence study, the FDA has made a preliminary review of the study results and the Company's summary analyses and, based on its preliminary assessment of the information available to it at the time, the FDA did not agree that bioequivalence of PA32540 to EC aspirin 325 mg was demonstrated. We then submitted to the FDA additional information and analyses from the requested bioequivalence study, as well as other relevant pharmacokinetic, clinical pharmacology, and in vitro dissolution data as a Briefing Document in support of a request for a Type A meeting with the FDA. At the Type A meeting held in August 2012, the FDA confirmed that, although it believes bioequivalence of PA32540 to EC aspirin 325 mg, was not strictly established in our bioequivalence study according to the predetermined criteria, the results from this study, together with additional information that will be submitted by us in the NDA, constitutes sufficient data to support the establishment of a clinical and pharmacological bridge between the product and EC aspirin 325 mg. The FDA indicated that it would make a final determination during the NDA review. FDA also indicated that a similar strategy to bridge to the reference listed drug, inclusive of a new, single pharmacokinetic study, could be utilized for a low dose version of PA32540 (PA8140). We have conducted this study with the low dose version against the EC aspirin 81 mg. Based on the predetermined criteria acceptable to the FDA, the study demonstrated that PA8140 is bioequivalent to EC aspirin using criteria for highly variable drugs and had comparable bioavailability.

During a pre-submission meeting with respect to its NDA for PA32540 in April 2012, the FDA suggested that the Company also seek approval for a lower dose formulation of the product containing 81 mg of enteric coated aspirin as part of its NDA for PA32540. We intended to seek an indication for the secondary prevention of cardiovascular disease in patients at risk for gastric ulcers. During the Type A meeting held in August 2012, the FDA has confirmed its preference to have both PA32540 and a lower dose version available in the market so that physicians can have both a low and high dose option available, and agreed that, if both dosage strengths were included in the NDA and subsequently approved, the indications for both will be consistent with the full range of indications described in the current aspirin monograph.

We had generated some clinical pharmacology data and chemical, manufacturing and controls, or CMC, data for a product which contains 81 mg of enteric coated aspirin and 40 mg of omeprazole in a single tablet known as PA8140. We filed this existing data, together with additional CMC data to be generated and evidence from the scientific literature relating to the ulcerogenic risk of 81 mg of aspirin with the FDA. At this time, the Company does not intend to conduct Phase 3 clinical trials for PA8140. The data package submitted for PA8140 was similar to that used to gain approval for a lower dosage form of VIMOVO containing 375 mg of naproxen. We have no assurance such data will be sufficient for the FDA to approve PA8140 or to allow a broader indication for PA32540. The FDA will make a final determination with respect to the approvability of and indications for PA32540 and PA8140.

Generation of additional data with respect to PA8140 and incorporation of data into the NDA for PA32540 delayed submission of the NDA from the original planned submission date in the third quarter of 2012. The NDA was filed for both products in March 2013 and in May 2013 the FDA accepted the NDA for review. The FDA assigned a user fee date of January 24, 2014. As part of our continuing discussions with the FDA concerning the NDA for PA32540 and PA8140 tablets, we decided to conduct an additional comparative Phase 1 pharmacokinetic study to determine the pharmacokinetic profile of the omeprazole component of PA8140 tablets and compare it to that of PA32540 tablets. We submitted study information and data to the FDA as it became available during the conduct of the study and FDA agreed to review such information and data from the study when submitted. The final study report for the study was submitted to the FDA in accordance with our agreed

timeline. FDA has informed us that the Company's user fee date was April 25, 2014. On April 25, 2014, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA in its current form. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. Satisfactory resolution of these deficiencies is required before the NDA may be approved. There were no clinical or safety deficiencies noted with respect to either PA8140 or PA32540 and no other deficiencies were noted in CRL. On June 30, 2014, we resubmitted the NDA for PA32540 and PA8140 to the FDA and the FDA notified us that the new action fee date was December 30, 2014. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. FDA regulations allow us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting, which was held in late January 2015. At the meeting, representatives from the FDA's Office of Compliance stated that the active ingredient supplier's responses to the 483 inspectional observations submitted in May 2014 were still under review, but that the review had been placed on a fast track and the Office of Compliance would be communicating with the supplier in the coming weeks. The active ingredient supplier has informed POZEN that they received a warning letter relating to the Form 483 inspection deficiencies. They are evaluating what additional corrective actions may be required to address the matters raised in the warning letter. We will continue to provide assistance to our active ingredient supplier in taking corrective actions to address the inspectional observations at its facility.

We are also continuing to evaluate how best to commercialize the PA product candidates and programs. We are evaluating the regulatory requirements to obtain an indication for PA for the secondary prevention of colorectal neoplasia. In January 2010, we received input from the FDA with respect to the development requirements for a possible indication in colorectal neoplasia. Further discussions are being considered. We are also evaluating the possibility of developing another dosage strength of PA containing 650 mg of enteric coated aspirin and 20 mg of omeprazole (PA65020) for the treatment of osteoarthritis and similar conditions and we met with the FDA in December 2010 to obtain input with respect to the regulatory requirements to obtain such an indication. The FDA advised us that we will need to demonstrate a reduction in gastric ulcers compared to aspirin alone in a replicate Phase 3 program similar to that we performed for VIMOVO, in addition to a study to establish efficacy of the product in the treatment of osteoarthritis.

We also met with a European country that served as the reference member state for approval of VIMOVO in Europe to obtain guidance on a clinical development program for approval of PA65020 in the Europe. We were advised that Phase 3 endoscopic trials demonstrating a reduction in gastric ulcers would not be required in addition to an osteoarthritis efficacy study since omeprazole's actions on gastric ulcers has been well characterized. Instead, Phase 1 studies assessing pharmacokinetics and gastric acid suppression could be used to support the benefit of omeprazole as a component of PA65020.

We have also received Scientific Advice from the Medicines Evaluation Board, or MEB in the Netherlands, which has agreed to be the Reference Member State in a decentralized filing procedure, regarding the development program required for the approval in the European Union, or EU, of PA tablets, including a lower dosage form containing 100 mg of aspirin and 40 mg of omeprazole (PA10040) for the secondary prevention of cardiovascular disease. The MEB agreed that a full Phase 3 clinical development program for PA10040, to demonstrate the reduction of endoscopic gastric ulcers vs. EC aspirin, would not be necessary. Instead, a Phase 1 pharmacodynamic study comparing gastric pH control for PA10040 vs.EC omeprazole 20 mg, along with a study to demonstrate bioequivalence of PA10040 to a currently marketed EC aspirin product using ASA as the analyte would be sufficient. Study PA10040-101 demonstrated that PA10040 had comparable bioavailability and is bioequivalent to a European Union reference listed enteric coated aspirin 100 mg. Study PA10040-102 demonstrated that PA10040 provides gastric pH greater than 4 control for a percent time over 24 hours of 47%. Furthermore, compared to Losec 20 mg (EC omeprazole 20 mg), PA10040 produced a similar level of 24-hour pH control ((p=0.02).

A pre-submission follow up meeting with the MEB was held in July 2014. We proposed seeking approval of PA10040 only since the ASA component in that dosage form matches the clinical practice for use of ASA in the EU. Approval of PA10040 would be based on specific studies conducted with the product, as well as data from the entire PA program conducted in the United States. Based on discussions at the meeting, the MEB agreed that the MAA filing can proceed without any further clinical studies and that the Netherlands would be the lead country for the decentralized review process. The MEB also requested that a complete risk-benefit analysis of PA10040 for the intended cardiovascular patient population and proposed indication should be included as part of the MAA submission.

We cannot reasonably estimate or know the amount or timing of the costs necessary to continue development and/or complete the development of any PA product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PA products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals. We have refined our strategy and decided to retain control of our PA product candidates for cardiovascular indications through the clinical development and pre-commercialization stage and then seek strong commercial partners to maximize the potential of these product candidates. On September 3, 2013 we entered into a License and Collaboration Agreement with Sanofi US to commercialize our PA product candidates containing an immediate release proton pump inhibitor and 325 mg or less of delayed release or enteric coated aspirin in the United States. Even though the License and Collaboration Agreement was terminated on November 29, 2014, we believe we were able to negotiate more favorable terms with Sanofi U.S. for rights to commercialize the products in the United States than we had licensed the product candidates at an earlier stage in development and will be able to achieve more favorable terms with other partners outside the United States if we are successful in licensing PA products in other territories in the future.

We have incurred direct development costs associated with the development of our PA program of $3.2 million during the fiscal year ended December 31, 2014. Since inception we incurred total direct development cost of $74.7 million associated with the development of our PA program. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Migraine Market Overview

Migraine is characterized by recurring attacks of throbbing headache pain, often associated with visual, auditory or gastrointestinal disturbances. Attacks range from mild to severe and can last from 4 hours to 72 hours. In the most severe attacks, migraine sufferers are unable to pursue basic daily activities. According to the American Council for Headache Education, migraines afflict 25 million to 30 million people in the U.S. alone. As many as 6% of all men and up to 18% of all women experience a migraine headache at some time in their life. While the precise mechanism of migraine is unknown, researchers believe migraine attacks are caused by acute inflammation surrounding selected blood vessels in the head. The average migraine sufferer experiences the first attack during the early teen years, and the attacks generally continue throughout adulthood.

Not all migraine attacks are of the same severity. Consequently, a variety of oral, injectable, and intranasal therapies are used to treat different types of migraine attacks. Many patients use a personal, individually developed, step-care approach to treat their attacks. Attacks are often treated initially with simple over-the-counter analgesics, particularly if the patient is unable to determine if the attack is a migraine or some other type of headache. If over-the-counter remedies are unsuccessful, patients often turn to more potent prescription drugs, including narcotics, analgesic/narcotic drug combinations and triptans.

Triptans are the family of drugs most commonly prescribed for the treatment of migraine attacks. Triptans have demonstrated the ability to treat migraines by constricting blood vessels in the brain. Although triptans can be effective in treating migraine symptoms, they are often associated with significant side effects and other disadvantages that include:

- the occurrence of cardiovascular related events, including chest pain/discomfort, throat discomfort and warm/cold sensations;
- the potential for other serious cardiovascular events, including death;
- difficulty in producing sustained benefits with a single dose in a majority of patients;
- the occurrence of nausea and dizziness during treatment; and
- the need for cardiovascular evaluations from physicians before initially prescribing triptans to patients with cardiovascular disease risk factors.

Despite these shortcomings, according to IMS Health's IMS National Sales Perspective™, or IMS, in 2011 total triptan sales in the U.S. were approximately $1.7 billion. Sumatriptan is the leading triptan product. There are currently three types of sumatriptan formulations commercially available: oral, intranasal and injectable. An oral triptan is often the physician's first choice as a prescription treatment for migraine pain. Intranasal triptans are often prescribed for patients requiring faster relief than oral drugs can provide or who cannot take oral medications. For the most severe attacks, patients sometimes use an injectable form of a triptan.

MT 400/*Treximet*

On April 15, 2008, the FDA approved *Treximet* for the acute treatment of migraine attacks with or without aura in adults. GSK notified us of its intention to launch the product and *Treximet* was available in pharmacies in May 2008. As part of our NDA program for *Treximet*, we conducted five Phase 1 trials, two Phase 3 pivotal trials, and one 12-month open label

safety trial using a formulation of *Treximet* developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate *Treximet*, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of *Treximet* (the "combination drug rule" that the FDA requires of all combination products). The efficacy endpoint for the combination was sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine. Further, GSK has conducted market support studies for *Treximet*, including evaluations in a pediatric population. As required by the terms of our agreement with GSK, we transferred ownership of the NDA and other regulatory filings for *Treximet* to GSK on May 14, 2008, and GSK took responsibility for all ongoing regulatory obligations for the product, including post marketing clinical trial requirements.

Since inception we have incurred total direct development costs of $26.5 million associated with the development of our MT 400 and *Treximet* programs. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

On November 23, 2011, we entered into the Purchase Agreement with CII, pursuant to which we sold, and CII purchased, our right to receive future royalty payments arising from U.S. sales of MT 400, including *Treximet*.

On March 21, 2011, we entered into a license agreement with Cilag GmbH International, or Cilag, a division of Johnson & Johnson, for the exclusive development and commercialization of MT 400 in Brazil, Colombia, Ecuador and Peru. On December 22, 2014, we entered into a mutual termination letter with Cilag. In accordance with the terms of the termination letter the agreement terminated on January 21, 2015. There was no dispute between the parties regarding the license agreement. At our request, for a period of two years after termination, Cilag has agreed to negotiate in good faith commercially reasonable terms of a supply agreement whereby Cilag would supply us or our licensees, with MT400 for a period equal to the shorter of (i) two (2) years; or (ii) until we establish an alternative supplier. We recognized approximately $257,300 in licensing revenue in the fourth quarter of as a result of this termination.

On May 13, 2014, we, GSK, CII and Pernix, entered into certain agreements in connection with GSK's divestiture of all of its rights, title and interest to develop, commercialize and sell *Treximet*® in the U.S. to Pernix. Upon the closing of the divestiture on August 20, 2014, GSK assigned the Treximet Agreement to Pernix. Immediately following the closing of the divestiture, Amendment No. 1 between us and Pernix became effective. Amendment No. 1, among other things, amends the royalty provisions of the Agreement to provide for a guaranteed quarterly minimum royalty of $4 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018 and requires that Pernix continue certain of GSK's ongoing development activities and to undertake certain new activities, for which we will provide reasonable assistance. Amendment No. 1 also eliminates restrictions in the Agreement on our right to develop and commercialize certain dosage forms of sumatriptan/naproxen combinations outside of the United States and permits POZEN to seek approval for these combinations on the basis of the approved NDA for Treximet. Pernix has also granted us a warrant to purchase 500,000 shares of Pernix common stock at an exercise price of $4.28, the closing price of Pernix common stock as reported on the NASDAQ Global Market on May 13, 2014. The common stock underlying the warrants will be registered by Pernix with the Securities and Exchange Commission and will be exercisable from August 20, 2014, the closing date of the divestiture until February 28, 2018. Lastly, we, GSK, Pernix and CII executed a letter agreement whereby we expressly consented to the assignment by GSK and the assumption by Pernix of the Treximet Agreement. On July 30, the parties entered into Amendment No. 2 to the Treximet Agreement which will permit Pernix's Irish affiliate to which Pernix will assign its rights to further assign the Agreement without our prior written consent as collateral security for the benefit of the lenders which financed the acquisition. Amendment No. 2 became effective upon closing of the divestiture on August 20, 2014.

Collaborative Arrangements

We have entered into and may continue to enter into collaborations with established pharmaceutical or pharmaceutical services companies to develop, commercialize and/or manufacture our product candidates. Our existing collaborations are described below.

GlaxoSmithKline (GSK)

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. We were responsible for development of the first combination product, while GSK provided formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25.0 million in

initial payments from GSK following termination of the waiting period under the Hart-Scott-Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. In October 2005, we received a $20.0 million milestone payment upon the FDA's acceptance for review of the NDA for *Treximet*, the trade name for the product. On April 26, 2008, we received, from GSK, $20.0 million in milestone payments which were associated with the approval of, and GSK's intent to commercialize, *Treximet*. In addition, GSK will pay us two sales performance milestones totaling $80.0 million if certain sales thresholds are achieved. Up to an additional $10.0 million per product is payable upon achievement of milestones relating to other products. GSK will pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (October 2, 2025) based upon the scheduled expiration of currently issued patents. GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre-determined share of the market for the combination product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop or to launch the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

On November 23, 2011, we entered into the Purchase Agreement, with CII, pursuant to which we sold, and CII purchased, our right to receive future royalty payments arising from U.S. sales of MT 400, including *Treximet*.

On May 13, 2014, we, GSK, CII and Pernix, entered into certain agreements in connection with GSK's divestiture of all of its rights, title and interest to develop, commercialize and sell *Treximet*® in the U.S. to Pernix. Upon the closing of the divestiture on August 20, 2014, GSK assigned the Treximet Agreement to Pernix. Immediately following the closing of the divestiture, Amendment No. 1 between us and Pernix became effective. Amendment No. 1, among other things, amends the royalty provisions of the Agreement to provide for a guaranteed quarterly minimum royalty of $4 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018 and requires that Pernix continue certain of GSK's ongoing development activities and to undertake certain new activities, for which we will provide reasonable assistance. Amendment No. 1 also eliminates restrictions in the Agreement on our right to develop and commercialize certain dosage forms of sumatriptan/naproxen combinations outside of the United States and permits POZEN to seek approval for these combinations on the basis of the approved NDA for Treximet. Pernix has also granted us a warrant to purchase 500,000 shares of Pernix common stock at an exercise price equal to$4.28 per share, the closing price of Pernix common stock as reported on the NASDAQ Global Market on May 13, 2014. The common stock underlying the warrants have been registered by Pernix with the Securities and Exchange Commission and was exercisable from the August 20, 2014, the closing date of the divestiture until February 28, 2018. If the Divestiture had not been consummated, the warrants would have been null and void. Because the warrant has not been registered by Pernix with the Securities and Exchange Commission, the Company cannot sell or transfer the warrant in reliance upon Rule 144 until after November 13, 2014 when the Company meets certain holding requirements. Lastly, we, GSK, Pernix and CII executed a letter agreement whereby we expressly consented to the assignment by GSK and the assumption by Pernix of the Treximet Agreement. On July 30, the parties entered into Amendment No. 2 to the Treximet Agreement which will permit Pernix's Irish affiliate to which Pernix assigned its rights to further assign the Agreement without our prior written consent as collateral security for the benefit of the lenders which financed the acquisition. Amendment No. 2 became effective upon the closing of the divestiture on August 20, 2014.

AstraZeneca AB (AstraZeneca)/Horizon Pharma Inc. (Horizon)

In August 2006, we entered into a collaboration and license agreement dated as of August 1, 2006 and effective September 7, 2006 with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers, as amended, the "Original Agreement". Under the terms of the Original Agreement, we granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under our patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). Pursuant to the terms of the agreement, we received an upfront license fee of $40.0 million from AstraZeneca following termination of the waiting period under the Hart-Scott-Rodino notification program.

We retained responsibility for the development and filing of the NDA for the product in the U.S. AstraZeneca is responsible for all development activities outside the U.S., as well as for all manufacturing, marketing, sales and distribution activities worldwide. We agreed to bear all expenses related to certain specified U.S. development activities. All other development expenses, including all manufacturing-related expenses, will be paid by AstraZeneca. The agreement established joint committees with representation of both us and AstraZeneca to manage the development and commercialization of the product. The committees operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

In September 2007, we agreed with AstraZeneca to amend the Original Agreement effective as of September 6, 2007. Under the terms of the amendment, AstraZeneca has agreed to pay us up to $345.0 million, in the aggregate, in milestone payments upon the achievement of certain development, regulatory and sales events. In September 2007 we received a $10.0 million payment upon execution of the amendment and a $20.0 million payment in recognition of the achievement of the primary endpoints for the PN400-104 study, a study which compared acid suppression of different doses of VIMOVO (formerly PN 400), and achievement of the interim results of the PN200-301 study, a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy, meeting mutually agreed success criteria. In May 2010, we received a $20.0 million payment for the NDA approval of VIMOVO. We also received an additional $25.0 million milestone in December 2010 when VIMOVO received approval (including pricing and reimbursement approval) in a major ex-U.S. market and up to $260.0 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved.

The amendment also revised the royalty rates we were to have received under the Original Agreement. Prior to the effective date of the amendment, under the terms of the Original Agreement, we were to receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees during the royalty term. The royalty rate varied based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, ranging from the mid-single digits to the mid-teens. Under the amendment, we receive a flat, low double digit royalty rate during the royalty term on annual net sales of products made by AstraZeneca, its affiliates and sublicensees, in the U.S. and royalties ranging from the mid-single digits to the high-teens on annual net sales of products made by AstraZeneca, its affiliates and sublicensees outside of the U.S. The amendment also revised the rate of reduction to the royalty rate based upon loss of market share due to generic competition inside and outside of the U.S. to account for the new royalty structure. Our right to receive royalties from AstraZeneca for the sale of such products under the collaboration and license agreement, as amended, expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights relating to such products in that country, and (b) ten years after the first commercial sale of such products in such country.

We further amended the Original Agreement effective October 1, 2008 to shorten the timing of AstraZeneca's reimbursement obligation for certain development expenses incurred by us under the agreement and to update the description of the target product profile studies (as defined in the agreement) for VIMOVO.

On December 31, 2014 we have receivables of $5.6 million related to VIMOVO royalty revenue, $4.3 million related to U.S. sales and $1.3 million related to ROW sales. The agreement, unless earlier terminated, will expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement, at any time, at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us.

On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understand that AstraZeneca will instead now focus on those countries where the product has shown growth and which AstraZeneca believes have the greatest potential for future growth.

On September 16, 2013, we and AstraZeneca entered into another amendment to the Original Agreement which made clarifications to certain intellectual property provisions of the Original Agreement to clarify that AstraZeneca's rights under those provisions do not extend to products which contain acetyl salicylic acid. On September 16, 2013, we and AstraZeneca also executed a letter agreement whereby we agreed that in the event that AstraZeneca divested its rights and obligations to market VIMOVO in the United States to a third party, AstraZeneca would be relieved of its obligations under the Original

Agreement with respect to the United States as of the effective date of such divestiture, including its obligation under the Original Agreement to guarantee the performance of such assignee and/or sublicensee.

On November 18, 2013, AstraZeneca and Horizon entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. In connection with this divestiture, on November 18, 2013 we and AstraZeneca entered into an Amended and Restated Collaboration and License Agreement for the United States, the "U.S. Agreement," and an Amended and Restated License and Collaboration Agreement for Outside the United States, the "ROW Agreement," which agreements collectively amend and restate the Original Agreement. AstraZeneca has assigned the U.S. Agreement to Horizon in connection with the Divestiture with our consent.

We and Horizon also entered into Amendment No. 1 to the U.S. Agreement which, among other things, amends the royalty provisions of the U.S. Agreement to provide for a guaranteed annual minimum royalty amount of $5 million in calendar year 2014, and a guaranteed annual minimum royalty amount of $7.5 million each calendar year thereafter, provided that the patents owned by us which cover VIMOVO are in effect and no generic forms of VIMOVO are in the marketplace. Amendment No. 1 also provides that Horizon has assumed AstraZeneca's right to lead the on-going Paragraph IV litigation relating to VIMIVO currently pending in the United States District Court for the District of New Jersey and will assume all patent-related defense costs relating to such litigation, including reimbursement up to specified amounts of the cost of any counsel retained by us, amends certain time periods for Horizon's delivery of quarterly sales reports to POZEN, and provides for quarterly update calls between the parties to discuss VIMOVO's performance and Horizon's commercialization efforts.

Further, the Company, AstraZeneca and Horizon executed a letter agreement whereby POZEN expressly consented to the assignment by AstraZeneca and the assumption by Horizon of the U.S. Agreement. In addition, the letter agreement establishes a process for AstraZeneca and Horizon to determine if sales milestones set forth in the Original Agreement are achieved on a global basis and other clarifications and modifications required as a result of incorporating the provisions of the Original Agreement into the U.S. Agreement and the ROW Agreement or as otherwise agreed by the parties.

On June 13, 2011, we and AstraZeneca received a Paragraph IV Notice Letter from Lupin informing us that Lupin had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the POZEN and the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent and, each of which are assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Lupin's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Lupin and, accordingly, we and AstraZeneca filed suit against Lupin on July 25, 2011 in the United States District Court for the District of New Jersey. On November 19, 2014, an amended complaint was filed in which the 504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent, all assigned to AstraZeneca or its affiliates, were not asserted against Lupin. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On September 19, 2011, we and AstraZeneca AB received Paragraph IV Notice Letter from Anchen informing us that Anchen had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, the '085 patent, the '070 patent, and the '466 patent. The patents are among those listed with respect to VIMOVO in the Orange Book and expire at various times between 2018 and 2023. Anchen's Paragraph IV Notice Letter asserts that its generic product will not infringe those patents or that those patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Anchen and, accordingly, we and AstraZeneca filed suit against Anchen on October 28, 2011 in the United States District Court for the District of New Jersey. On October 4, 2013, Anchen filed an amendment to its ANDA seeking to change its Paragraph IV certification to a Paragraph III. It is unclear when or if the FDA will enter Anchen's amendment. On October 25, 2013, Anchen filed a Motion to Dismiss the case against it, based on its proposed re-certification. On November 18, 2013, we and AstraZeneca filed an Opposition to Anchen's Motion to Dismiss. On June 11, 2014, the Court granted Anchen's Motion and dismissed the case against them.

On November 20, 2012 we and AstraZeneca AB received a Paragraph IV Notice Letter from Dr. Reddy's, informing us that Dr. Reddy's had filed a second ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the POZEN and the 504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent and, each of which are assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Dr. Reddy's second Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Dr. Reddy's on its second ANDA filing and, accordingly, we and AstraZeneca filed suit against Dr. Reddy's on

January 4, 2013, in the United States District Court for the District of New Jersey. On April 15, 2013 a Stipulation of Partial Dismissal was filed which sought dismissal of all infringement claims relating to the '504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent (which are each assigned to AstraZeneca), as well as Dr. Reddy's defenses and counterclaims relating to those patents. On April 18, 2013, the District Court issued the Stipulation and Order dismissing with prejudice those claims and defenses. On June 28, 2013 we and AstraZeneca filed a Motion for Summary Judgment relating to the second ANDA filing asserting that U.S. Patent No. 6,926,907 is not invalid. On August 12, 2013, DRL filed an opposition to the Motion for Summary Judgment. On March 28, 2014, the District Court denied the Motion. On October 11, 2013, DRL filed a Motion for Summary Judgment asserting that the product which is the subject matter of its second ANDA does not infringe the '907 patent. On November 4, 2013, POZEN and AstraZeneca filed a Motion for an Order Denying DRL's Motion for Summary Judgment Pursuant to Rule 56(d) and an Opposition to DRL's Motion. On May 29, 2014, the Court issued an order denying DRL's Motion. This case was consolidated with the originally filed Dr. Reddy's case and is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On March 29, 2013, we and AstraZeneca received a Paragraph IV Notice Letter from Watson, now Actavis, informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the Company and the '504 patent, the '085 patent, the '424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Watson's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Watson. On May 10, 2013, we and AstraZeneca filed a patent infringement lawsuit against Watson in the U.S. District Court of New Jersey. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On May 16, 2013, POZEN and AstraZeneca AB received a Paragraph IV Notice Letter from Mylan informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the Company and the '504 patent, the '085 patent, the '424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Mylan's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Mylan. On June 28, 2013, we and AstraZeneca filed a patent infringement lawsuit against Mylan in the U.S. District Court of New Jersey. On February 13, 2015, the Court entered a joint stipulation of dismissal of counts related to certain patents, dismissing claims related to the '504 patent, the '085 patent, the '424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On October 15, 2013, the United States Patent Office issued the '285 patent. The '285 patent, entitled "Pharmaceutical compositions for the coordinated delivery of NSAIDs" and assigned to POZEN, is related to the '907 patent. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement of the '285 patent and, accordingly, on October 23, 2013, we, and AstraZeneca filed patent infringement lawsuits against DRL, Lupin, Watson and Mylan in the U.S. District Court of New Jersey alleging that their ANDA products infringe the '285 patent. On November 8, 2013, we, and AstraZeneca filed a Motion to Amend the Complaint in the actions against DRL, Lupin, Watson and Mylan or, in the alternative, to consolidate the actions involving the '285 patent with the existing consolidated action. DRL, Lupin, Watson and Mylan have each filed answers to the respective amended complaints, thus adding claims relating to the '285 patent against each of the Defendants to the consolidated case.

As part of Horizon's purchase of all of AstraZeneca's rights, title and interest to develop, commercialize and sell VIMOVO in the United States, Horizon has assumed AstraZeneca's right to lead the above-described Paragraph IV litigation relating to VIMIVO currently pending in the United States District Court for the District of New Jersey and has assumed patent-related defense costs relating to such litigation, including reimbursement up to specified amounts of the cost of any counsel retained by us. On December 12, 2013, Horizon filed Motions to Join under Fed.R.Civ.Proc. 25(c) as a co-plaintiff in each of the above referenced actions and the consolidated action. On January 31, 2014 and February 2, 2014, the Court granted Horizon's motions.

sanof-aventis U.S. LLC

On September 3, 2013, we entered into a license and collaboration agreement with Sanofi US. On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The termination agreement further provides for the transfer of specified commercial know-how developed by

Sanofi US relating to the PA products to us and allows us, and any future collaborators, to use this know-how to commercialize the products. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products in the United States. In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

Under the license agreement, we had the responsibility for obtaining regulatory approval and Sanofi US had responsibility for the commercialization of products containing a combination of immediate release omeprazole and 325 mg or less of delayed release aspirin, including PA32540 and PA8140, which are expected to be indicated for use for the secondary prevention of cardiovascular disease in patients at risk for aspirin-associated gastric ulcers. Under the license agreement, Sanofi US had the exclusive right to commercialize licensed products in the United States, with the Company retaining the right to commercialize licensed products outside the United States. Sanofi US had responsibility for all sales, marketing and future development for the licensed products. In addition, following approval of the NDA and completion of certain manufacturing milestones, Sanofi US would have had responsibility for manufacturing the licensed products for commercialization in the United States. We retained responsibility for obtaining approval of the NDA, after which time we would have transfer the NDA to Sanofi US. The parties would have shared costs up to certain limits with respect to certain additional development activities required in order to obtain or maintain regulatory approval in the United States. During the term of the license agreement, we would not have been able to commercialize in the United States, or license any third party to commercialize in the United States, any product combining any product indicated for treatment of gastric ulcers or gastric bleeding, or both, and 325 mg or less of aspirin.

In consideration for the rights granted to Sanofi US under the license agreement, Sanofi US paid us an upfront payment of $15 million. The upfront payment was amortized and recognized as revenue, $4 million during the year ended December 31, 2013 and the remaining $11 million during the year ended December 31, 2014. We were eligible to receive pre-commercial milestone payments of $20 million and additional payments upon the achievement of specified sales milestones. We were also to receive tiered royalties ranging from 12.5% to 22.5% on sales of licensed products by Sanofi US, its affiliates and its sublicensees in the United States, subject to certain adjustments specified in the license agreement. Sanofi US was obligated to use commercially reasonable efforts to commercialize the licensed products and agreed to specified advertising and promotional expense levels and sales details for the first two years after launch. In the event net sales for licensed products were less than a specified amount during the third full year of commercialization, we could have notify Sanofi US that we wished to purchase back from Sanofi US all rights to the licensed products in the United States. In the event we wished to exercise our option, Sanofi US would have had the first right to buy out our remaining interest. The license agreement would have terminated upon the expiration of Sanofi US's royalty payment obligations, which would have occurred, on a licensed product-by-licensed product basis, upon the latest of (i) expiration of the last-to-expire patent covering a licensed product and (ii) a specified number of years following first commercial sale of such licensed product. Sanofi US could have terminated the license agreement at will in its entirety any time after the third anniversary of the effective date of the License Agreement. The license agreement could also have been terminated by either party if the other party failed to cure certain material breaches under the license agreement. In addition, Sanofi US could have terminated the license agreement under certain other specified circumstances, including in the event the licensed products did not receive approval for the expected indications or if we failed to deliver launch quantities of the product by a certain date.

Cilag GmbH International (Cilag)

On March 21, 2011, we entered into a license agreement with Cilag, a division of Johnson & Johnson, for the exclusive development and commercialization of MT 400 in Brazil, Colombia, Ecuador and Peru. On December 22, 2014, we entered into a mutual termination letter with Cilag. In accordance with the terms of the termination letter the agreement terminated on January 21, 2015. There was no dispute between the parties regarding the license agreement and, at our request, for a period of two years after termination, Cilag has agreed to negotiate in good faith commercially reasonable terms of a supply agreement whereby Cilag would supply us or our licensees, with MT400 for a period equal to the shorter of (i) two (2) years; or (ii) until we establish an alternative supplier. We recognized approximately $257,300 in licensing revenue in the fourth quarter of as a result of this termination.

Patheon Pharmaceuticals Inc. (Patheon)

On December 19, 2011, we entered into a Manufacturing Services Agreement, or the Supply Agreement, and a related Capital Expenditure and Equipment Agreement, or the Capital Agreement, relating to the manufacture of PA32450. Under the terms of the Supply Agreement, Patheon has agreed to manufacture, and we have agreed to purchase, a specified percentage of the Company's requirements of the PA32540 for sale in the United States. The term of the Supply Agreement extends until December 31st of the fourth year after the we notify Patheon to begin manufacturing services under the Supply Agreement, or the Initial Term, and will automatically renew thereafter for periods of two years, unless terminated by either party upon

eighteen months' written notice prior to the expiration of the Initial Term or twelve months' written notice prior to the expiration of any renewal term. In addition to usual and customary termination rights which allow each party to terminate the Supply Agreement for material, uncured breaches by the other party, we can terminate the Agreement upon thirty (30) days' prior written notice if a governmental or regulatory authority takes any action or raises any objection that prevents us from importing, exporting, purchasing or selling PA32540 or if it is determined that the formulation or sale of PA32540 infringes any patent rights or other intellectual property rights of a third party. We can also terminate the Supply Agreement upon twenty-four (24) months' prior written notice if we license, sell, assign or otherwise transfer any rights to commercialize PA32540 in the Territory to a third party. The Supply Agreement contains general and customary commercial supply terms and conditions, as well as establishing pricing for bulk product and different configurations of packaged product, which pricing will be adjusted annually as set forth in the Supply Agreement. Under the terms of the Capital Agreement, we will be responsible for the cost of purchasing certain equipment specific to the manufacture of PA32540, the cost of which, based on current volume projections, is expected to be less than $150,000. If additional equipment and facility modifications are required to meet our volume demands for PA32540, we may be required to contribute to the cost of such additional equipment and facility modifications, up to a maximum of approximately $2.5 million in the aggregate.

The Supply Agreement and Capital Agreement were amended on July 10, 2013. The First Amendment to the Manufacturing and Services Agreement (the "Amendment to the Supply Agreement") expressly incorporates the Company's PA8140 product candidate into the Supply Agreement. The Amendment to the Supply Agreement also clarifies that the manufacturing services contemplated by the Supply Agreement include the manufacture of validation batches, but the placing of an order for such validation batches will not trigger the Commencement Date of the Initial Term (each as defined in the Supply Agreement), updates pricing for the Company's PA32540 product candidate and a incorporates a new pricing schedule for PA8140, as well as other conforming changes to the Supply Agreement. The First Amendment to the Capital Expenditure and Equipment Agreement (the "Amendment to the Capital Agreement"), replaces the existing Schedule A of the Capital Agreement, which lists dedicated and non-dedicated capital equipment and facility modifications to be funded in whole or in part by the Company, with a new updated schedule which reflects the parties' current assumptions regarding the need for and timing of capital equipment expenditures based upon Patheon's current and anticipated production capacity and current volume projections for thePA32540 and PA8140. Under the terms of the Capital Agreement, the Company was previously required to contribute to the cost of such additional capital equipment and facility modifications, up to a maximum of approximately $2.5 million in the aggregate. Pursuant to the terms of the Amendment to the Capital Agreement, the parties have agreed to reduce the amount of such maximum expenditure to approximately $1.2 million dollars in light of the revised capacity and volume assumptions.

Manufacturing

We currently have no manufacturing capability and we do not intend to establish internal manufacturing capabilities.

To date, we have entered into arrangements with third-party manufacturers for the supply of formulated and packaged clinical trial materials. We have also entered into a Supply Agreement and a related Capital Agreement with Patheon for the manufacture of PA32450 and PA8140 for sale in the United States. We believe our current supplier agreements should be sufficient to meet our commercial supply needs for PA32540 and PA8140 in the United States. Under our agreements with GSK, AstraZeneca and Horizon, it is the obligation of our partners to obtain commercial supplies of products developed under those agreements. Use of third-party manufacturers enables us to focus on our clinical development activities, minimize fixed costs and capital expenditures and gain access to advanced manufacturing process capabilities and expertise.

Competition

Competition for VIMOVO

The competition for VIMOVO comes from the oral anti-arthritic market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC™) and the only remaining COX-2 inhibitor, Celebrex®. The U.S. prescription market for oral solid NSAIDs was approximately $2.9 billion in 2011, of which 62% was accounted for by Celebrex, according to IMS. This market is continuing to undergo significant change, due to the voluntary withdrawal of Vioxx® by Merck & Co. in September 2004, the FDA-ordered withdrawal of Bextra® by Pfizer in April 2005 and the issuance of a Public Health Advisory by the FDA in April 2005 stating that it would require that manufacturers of all prescription products containing NSAIDs provide warnings regarding the potential for adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to the FDA advisory committee meeting in February 2005 that addressed the safety of NSAIDs, and, in particular, the cardiovascular risks of COX-2 selective NSAIDs, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required for approval

of new NSAID products that may be used on an intermittent or chronic basis. However, based on a meeting with the FDA in September 2005, we believe, although we cannot guarantee, that long-term cardiovascular safety studies may not be required at this time for FDA approval of our PN product candidates containing naproxen.

Competition for PA Products

The pharmaceutical and biopharmaceutical industries are intensely competitive and are characterized by rapid technological progress. Certain pharmaceutical and biopharmaceutical companies and academic and research organizations currently engage in, or have engaged in, efforts related to the discovery and development of new medicines for the treatment of migraine symptoms. Significant levels of research in chemistry and biotechnology occur in universities and other nonprofit research institutions. These entities have become increasingly active in seeking patent protection and licensing revenues for their research results. They also compete with us in recruiting skilled scientific talent.

Our ability to compete successfully will be based on our ability to create and maintain scientifically advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products either alone or through outside parties. Some of our competitors have substantially greater financial, research and development, manufacturing, marketing and human resources and greater experience than we do in product discovery, development, clinical trial management, FDA regulatory review, manufacturing and marketing, which may enable them to compete more effectively than we can.

Treatment for the secondary prevention of cardiovascular and cerebrovascular disease typically consists of multiple prescription and over-the-counter drugs, including statins, anti-hypertensives and anti-platelet agents. Competition for PA will come from the prescription anti-platelet market as well as over-the-counter aspirin and gastro-protective agents. An estimated 24 million Americans fall within the guidelines for chronic anti-platelet therapy as set forth by the American Heart Association. Prescription anti-platelet therapies include PLAVIX (clopidogrel) and generics, EFFIENT (prasugrel) and BRILINTA (ticagrelor). In 2011, prior to loss of market exclusivity, PLAVIX sales exceeded $9 billion worldwide. Because over-the-counter aspirin is used to treat many conditions, including pain and inflammation, identifying the portion of sales attributable to anti-platelet therapy is difficult.

Patents and Proprietary Information

We have obtained and intend to actively seek to obtain, when appropriate, protection for our products and proprietary technology by means of U.S. and foreign patents, trademarks and contractual arrangements. In addition, we rely upon trade secrets and contractual agreements to protect certain of our proprietary technology and products.

We have issued U.S. patents and pending U.S. patent applications, as well as pending foreign patent applications or issued foreign patents, relating to our marketed products and product candidates. We also have U.S. and foreign patent applications pending relating to novel product concepts. There can be no assurance that our patent applications will issue as patents or, with respect to our issued patents, that they will provide us with significant protection. The following provides a general description of our patent portfolio and is not intended to represent an assessment of claim limitations or claim scope.

MT 400/Treximet

We have four issued U.S. patents with claims relating to methods, compositions and therapeutic packages involving the use of certain NSAIDs and 5-HT receptor agonists in treating patients with migraine. Outside of the U.S., we have issued patents in Australia, Canada, Europe, Hong Kong and Japan. The expected expiration date of the issued patents relating to MT 400 is August 14, 2017. We expect that patents issued from pending patents related to MT 400 will also expire in August 2017.

Oppositions were filed against the issued European patent in October 2005 by Merck & Co., Inc. and Almirall Prodesfarma asserting that the European patent should not have been granted. We filed a response to these oppositions and the Opposition Division of the European Patent Office called for oral proceedings. During the oral proceedings and in the written opinion subsequently provided, the European Patent Office found that claims relating to combinations of sumatriptan and naproxen for the treatment of migraine were valid. However, broader claims relating to certain other 5-$HT_{1B/1D}$ agonists and long-acting NSAIDs were held to be insufficiently supported by the presently available technical evidence.

We also have an issued U.S. patent with claims relating to formulations of MT 400 which, we expect to expire in October 2025. We have additional pending U.S. and foreign patent applications with claims directed to formulations of MT 400 which, if issued, we expect to expire in 2027.

PN/PA

We have issued patents in the U.S., Australia, Canada, Europe, Mexico and Eurasia, with claims directed to certain compositions containing a combination of acid inhibitors, including PPIs, and NSAIDs. The issued patents also have claims to treatment methods involving the use of such compositions. We have pending U.S. and foreign patent applications that also have claims to compositions containing acid inhibitors and NSAIDS and to various treatment methods involving such compositions. The issued U.S. patents and related U.S. patent applications are expected to expire on February 28, 2023.

Oppositions were filed against the issued European patent in April 2011 by Chatfield Pharmaceuticals and Strawman Ltd. asserting that the European patent should not have been granted. We filed for a response to these oppositions and the Opposition Division of the European Patent Office called for oral proceedings. Strawman Ltd. Subsequently withdrew from the opposition proceedings. During the proceedings in December 2012, the European Patent Office found that claims relating to combination of PPIs and NSAIDS were valid. Chatfield may appeal the decision by giving notice within sixty days of the date on which the Opposition Division issues its written decisions. The European patent will expire in May 2022, but we have obtained supplement protection certificates (SPCs) for VIMOVO which extend to October 25, 2025, and we expect to apply for SPCs for PA upon approval. We expect that patents outside of the U.S. and Europe, as well as additional patents which issue from the pending foreign patent applications, to expire on May 31, 2022.

We, together with AstraZeneca, have filed joint patent applications relating to VIMOVO. We expect any patents which issue from these applications to expire in 2029 and 2030. We have filed additional patent applications related to PA. We expect any patents which issue from these applications to expire between 2030 and 2032.

We, AstraZeneca and Horizon are engaged in Paragraph IV litigation with several generic pharmaceutical companies with respect to patents listed in the Orange Book with respect to VIMOVO currently pending in the United States District Court for the District of New Jersey which is described on page 17 of this Form 10-K.

Government Regulation

The FDA and comparable regulatory agencies in foreign countries impose substantial requirements on the clinical development, manufacture and marketing of pharmaceutical product candidates. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record-keeping, approval and promotion of our product candidates. All of our product candidates will require regulatory approval before commercialization. In particular, therapeutic product candidates for human use are subject to rigorous preclinical and clinical testing and other requirements of the Federal Food, Drug and Cosmetic Act, or FFDCA, implemented by the FDA, as well as similar statutory and regulatory requirements of foreign countries. Obtaining these marketing approvals and subsequently complying with ongoing statutory and regulatory requirements is costly and time-consuming. Any failure by us or our collaborators, licensors or licensees to obtain, or any delay in obtaining, regulatory approvals or in complying with other regulatory requirements could adversely affect the commercialization of product candidates then being developed by us and our ability to receive product or royalty revenues.

The steps required before a new drug product candidate may be distributed commercially in the U.S. generally include:

- conducting appropriate preclinical laboratory evaluations of the product candidate's chemistry, formulation and stability and preclinical studies in animals to assess the potential safety and efficacy of the product candidate;
- submitting the results of these evaluations and tests to the FDA, along with manufacturing information and analytical data, in an IND;
- initiating clinical trials under the IND and addressing any safety or regulatory concerns of the FDA;
- obtaining approval of Institutional Review Boards, or IRBs, to introduce the drug into humans in clinical studies;
- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the product candidate for the intended use, typically in the following three sequential, or slightly overlapping stages:
  Phase 1: The product is initially introduced into human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion;
  Phase 2: The product candidate is studied in patients to identify possible adverse effects and safety risks, to determine dosage tolerance and the optimal dosage, and to collect some efficacy data;
  Phase 3: The product candidate is studied in an expanded patient population at multiple clinical study sites, to confirm efficacy and safety at the optimized dose, by measuring primary and secondary endpoints established at the outset of the study;

- submitting the results of preclinical studies, and clinical trials as well as chemistry, manufacturing and control information on the product candidate to the FDA in a NDA; and
- obtaining FDA approval of the NDA prior to any commercial sale or shipment of the product candidate.

This process can take a number of years and require substantial financial resources. Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, and its amendments. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective on October 1, 2013 for the fiscal year 2014, the user fee for an application requiring clinical data, such as an NDA, is $2,169,100. PDUFA also imposes an annual product fee for each marketed prescription drug ($104,060), and an annual establishment fee ($554,600) on facilities used to manufacture prescription drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. However, there are no waivers for product or establishment fees.

The results of preclinical studies and initial clinical trials are not necessarily predictive of the results from large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including the difficulty in obtaining enough patients, clinical investigators, product candidate supply and financial support.

Even after FDA approval has been obtained, further studies, including post-marketing studies, may be required. Results of post-marketing studies may limit or expand the further marketing of the products. If we propose any modifications to a product, including changes in indication, manufacturing process, manufacturing facility or labeling, a supplement to our NDA may be required to be submitted to the FDA and approved.

The FDA may also require testing and surveillance programs to monitor the effect of approved product candidates that have been commercialized, and the agency has the power to prevent or limit further marketing of a product candidate based on the results of these post-marketing programs. Upon approval, a product candidate may be marketed only in those dosage forms and for those indications approved in the NDA.

The status of the NDAs we have submitted to the FDA for *Treximet*, VIMOVO and our PA product candidates is discussed above in "MT400/*Treximet*," "PN/VIMOVO Program," and "Status of Our Product Candidates and Exploratory Programs" – PA Program"

In addition to obtaining FDA approval for each indication to be treated with each product candidate, each domestic product candidate manufacturing establishment must register with the FDA, list its product with the FDA, comply with the applicable FDA current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation, and permit and pass manufacturing plant inspections by the FDA. Moreover, the submission of applications for approval may require additional time to complete manufacturing stability studies. Foreign establishments manufacturing product for distribution in the U.S. also must list their product candidates with the FDA and comply with cGMP regulations. They are also subject to periodic inspection by the FDA or by local authorities under agreement with the FDA.

Any product candidates manufactured or distributed by us pursuant to FDA approvals are subject to extensive continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the product candidate. In addition to continued compliance with standard regulatory requirements, the FDA may also require post-marketing testing and surveillance to monitor the safety and efficacy of the marketed product. Adverse experiences with the product candidate must be reported to the FDA. Product approvals may be affected and even withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product are discovered following approval.

The FFDCA also mandates that products be manufactured consistent with cGMP regulations. In complying with the cGMP regulations, manufacturers must continue to spend time, money and effort in production, record keeping, quality control, and auditing to ensure that the marketed product meets applicable specifications and other requirements. The FDA periodically inspects manufacturing facilities to ensure compliance with cGMP regulations. Failure to comply subjects the manufacturer to possible FDA action, such as warning letters, suspension of manufacturing, seizure of the product, voluntary recall of a product or injunctive action, as well as possible civil penalties. We currently rely on, and intend to continue to rely on, third parties to manufacture our compounds and product candidates. These third parties will be required to comply with cGMP regulations.

Products manufactured in the U.S. for distribution abroad will be subject to FDA regulations regarding export, as well as to the requirements of the country to which they are shipped. These latter requirements are likely to cover the conduct of

clinical trials, the submission of marketing applications, and all aspects of manufacturing and marketing. Such requirements can vary significantly from country to country.

We and our contractors are also subject to various federal, state and local laws, rules, regulations and policies relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances used in connection with our research work. Although we believe that safety procedures employed for handling and disposing of such materials comply with current federal, state and local laws, rules, regulations and policies, the risk of accidental injury or contamination from these materials cannot be entirely eliminated.

Before a medicinal product can be supplied in the European Union, or EU, it must first be granted a marketing authorization. There are three routes by which this may be achieved: the centralized procedure whereby a single European license is granted by the European Commission permits the supply of the product in question throughout the EU or the decentralized, or DC, or mutual recognition procedures, or MRP, through which the views of one national authority (Reference Member State, or RMS) are "recognized" by other authorities (Concerned Member States, or CMS) when conducting their reviews; the DC applies if the medicinal product in question has not yet received a marketing authorization in any member state at the time of the application whereas the MRP applies to a currently approved medicinal product. These latter two processes lead to individual licenses in each member state for the supply of products in that country only. The centralized route is compulsory for biotechnology products and is optional for certain so-called "high technology" products and products containing entirely new active substances. All products which are not authorized by the centralized route must be authorized by the DC or MRP unless the product is designed for use in a single country in which case a National Application can be made.

In making an application for a new medicinal product not governed compulsorily by the centralized procedure, typically use will be made of the DC although the MRP would be used if a marketing authorization were first secured in an RMS. The procedural steps for the DC and the MRP are governed by Directive 2001/83/EC, as amended, and are described in the Notice to Applicants, Volume 2A Chapter 2 - Mutual Recognition (updated version - November 2005). The procedures provide for set time periods for each process (DC - 120 days; MRP – 90 days) but if consensus is not reached between all the CMS and the RMS in that time, the application is referred to arbitration through the Co-ordination Group for Mutual Recognition and Decentralized Procedures, or CMD, with referral to the Committee for Human Medicinal Products, or CHMP. If a referral is made, the procedure is suspended; marketing of the product would only be possible in the RMS in the case of an MRP. The opinion of the CMD/CHMP, which is binding, could support or reject the objections or alternatively reach a compromise position acceptable to all EU countries concerned. The arbitration procedure may require the delivery of additional data. Once granted, any MAA remains subject to pharmacovigilance and all competent authorities have the power to vary, suspend or revoke an MAA on grounds of safety.

The extent of U.S. and foreign government regulation which might result from future legislation or administrative action cannot be accurately predicted. For example, in the U.S., although the Food and Drug Administration Modernization Act of 1997, or FDAMA, modified and created requirements and standards under the FFDCA with the intent of facilitating product development and marketing, the FDA is still in the process of developing regulations implementing FDAMA and the more recent Food and Drug Administration Amendments Act of 2007, or FDAAA. FDA has been actively implementing drug safety plans called Risk Evaluation and Mitigation Strategies, or REMS, as authorized by FDAAA, as a condition of drug approval, or after initial marketing, if FDA becomes aware of new safety data about the drug. These and other legislative initiatives may impose additional regulatory requirements on us, and may impact approval of our drugs or our marketing plans. The actual effect of these and other developments on our own business is uncertain and unpredictable.

Corporate Information

We were incorporated in Delaware on September 25, 1996. Our principal offices are located in the Exchange Office Building at 1414 Raleigh Road, Suite 400, Chapel Hill, NC 27517. Our telephone number is (919) 913-1030. We maintain a website at www.POZEN.com and make available free of charge through this website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also similarly make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. We are not including the information contained at www.POZEN.com, or at any other Internet address as part of, or incorporating it by reference into, this Annual Report on Form 10-K.

In addition, we make available on our website (i) the charters for the committees of our Board of Directors, including the Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee, and (ii) our Code of Business Conduct and Ethics governing our directors, officers and employees. We intend to disclose on our website any

amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and the NASDAQ Global Market.

Employees

As of February 24, 2015, we had a total of 12 full-time employees. All of our current employees are based at our headquarters in Chapel Hill, North Carolina**.** Of our 12 employees, six hold advanced degrees, including three with an M.D., Pharm.D. or Ph.D. degree.

Officers and Key Employees

Our current officers and key employees, and their ages as of February 24, 2015, are as follows:

Name	Age	Position
John R. Plachetka, Pharm.D.	61	Chairman, President and Chief Executive Officer
William L. Hodges, CPA	60	Senior Vice President, Finance and Administration, Chief Financial Officer
Dennis McNamara	49	Senior Vice President, Chief Business Officer
Gilda M. Thomas, JD	60	Senior Vice President, General Counsel
John E. Barnhardt, CPA	65	Vice President, Finance & Administration
John G. Fort, MD, MBA	60	Chief Medical Officer

John R. Plachetka, Pharm.D. is Chairman of the Board of Directors, a co-founder, President and Chief Executive Officer of POZEN and has held such positions since our inception in 1996. Prior to founding POZEN, Dr. Plachetka was Vice President of Development at Texas Biotechnology Corporation from 1993 to 1995 and was President and Chief Executive Officer of Clinical Research Foundation-America, a leading clinical research organization, from 1990 to 1992. From 1981 to 1990, he was employed at Glaxo Inc. Dr. Plachetka received his B.S. in Pharmacy from the University of Illinois College of Pharmacy and his Doctor of Pharmacy from the University of Missouri-Kansas City.

William L. Hodges joined POZEN in August 2004 as Senior Vice President of Finance and Administration and Chief Financial Officer. Mr. Hodges began his career in the pharmaceutical industry with Burroughs Wellcome Co. in 1985. In 1991, he moved to London and worked in Group Finance for the Wellcome Foundation, Ltd. Mr. Hodges worked on mergers and acquisitions and was Regional Controller for Northern Europe and Japan. In 1993, he returned to Burroughs Wellcome in North Carolina as Director of Procurement. Mr. Hodges was Vice President, Corporate Planning and Business Support at GlaxoWellcome before being appointed acting Senior Vice President and CFO for the fifteen months leading up to the merger between GlaxoWellcome plc and SmithKline Beecham plc which was completed in December of 2000. Prior to joining POZEN, Mr. Hodges was Senior Vice President and CFO of Pergo, Inc. located in Raleigh, North Carolina. Mr. Hodges received his B.S. from the University of North Carolina at Chapel Hill and is a Certified Public Accountant.

Dennis L. McNamara has been Senior Vice President and Chief Business Officer since January 2014. Mr. McNamara joined POZEN in December 1998 as Vice President of Business Development. Prior to joining POZEN, Mr. McNamara held positions in business development with private and publicly-traded development stage biotechnology companies including AlphaVax, Sequana Therapeutics and Apex Bioscience, and in pharmaceutical sales with Abbott Laboratories. Before joining the pharmaceutical industry Mr. McNamara conducted receptor pharmacology research at the University of North Carolina. Mr. McNamara earned his M.B.A. from the University of Michigan and an A.B. degree from Duke University.

Gilda M. Thomas joined POZEN in January 2007 as Senior Vice President and General Counsel. Prior to joining POZEN, Ms. Thomas was Vice President, General Counsel and company secretary at EMD Pharmaceuticals, Inc., an affiliate of Merck KGaA, Darmstadt, Germany from July 2001 to December 2006. Prior to joining EMD, she spent 14 years at Burroughs Wellcome Co., which merged into Glaxo Welcome, Inc. At Glaxo Wellcome Ms. Thomas was Associate General Counsel responsible for the 13 member corporate section of the legal department. Ms. Thomas received her J.D. from Harvard Law School, a M.S. from Simmons College and a B.A. degree from Wellesley College.

John E. Barnhardt joined POZEN in 1997 as Vice President, Finance and Administration and Principal Accounting Officer. Prior to joining POZEN, Mr. Barnhardt held finance and accounting positions with publicly traded companies

beginning in 1988. These positions included Chief Financial Officer of Medco Research, Inc., engaged in the research and development of pharmaceutical products primarily for the diagnosis and treatment of cardiovascular disease, and Principal Accounting Officer of Microwave Laboratories, Inc., a defense contractor developing and manufacturing traveling wave tubes for electronic countermeasure systems. Mr. Barnhardt received his B.S. in Zoology from North Carolina State University, and while employed at Ernst & Young, became a Certified Public Accountant.

John G. Fort, M.D. joined POZEN in July 2007 as Chief Medical Officer. Prior to joining POZEN, Dr. Fort was Vice President, Medical Affairs at Adolor Corporation from 2004 until 2007. Dr. Fort held positions with Pfizer Inc., including Vice President, Medical Affairs, and was Vice President, Arthritis and Pain at G.D. Searle & Co., Monsanto Corporation from September 1994 to December 2003. Prior to joining the pharmaceutical industry, he was an Associate Professor of Medicine at Thomas Jefferson University, Division of Rheumatology. Dr. Fort received his M.D. from the University of Valencia Faculty of Medicine and is board certified in internal medicine with a subspecialty certification in rheumatology.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Business

We have incurred losses since inception and we may continue to incur losses for the foreseeable future. Product revenue for products which we license out is dependent upon the commercialization efforts of our partners, including the sales and marketing efforts of AstraZeneca and Horizon relating to VIMOVO.

We have incurred significant losses since our inception. As of December 31, 2014, we had an accumulated deficit of approximately $96.9 million. Our ability to receive product revenue from the sale of products is dependent on a number of factors, principally the development, regulatory approval and successful commercialization of our product candidates. We expect that the amount of our operating losses will fluctuate significantly from quarter to quarter principally as a result of increases and decreases in our development efforts and the timing and amount of payments that we may receive from others. We expect to continue to incur significant operating losses associated with our research and development efforts and do not know the amount or timing of product revenue we will receive as a result of sales of VIMOVO by AstraZeneca and Horizon or our other product candidates, including PA, by other commercial partners, if any. If our licensed products do not perform well in the marketplace our royalty revenue will impacted and our business could be materially harmed.

Our primary current source of revenue is the royalty payments that we may receive pursuant to our collaboration agreement with AstraZeneca. We have received all regulatory milestone payments under our collaboration agreement with AstraZeneca and Horizon. On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understand that AstraZeneca will instead now focus on those countries where the product has shown growth and which AstraZeneca believes have the greatest potential for future growth. We will continue to assess the financial impact this decision will have on our royalty revenue. On November 18, 2013, AstraZeneca and Horizon entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. As a result, royalty revenues for sales of VIMOVO in the United States will be received from Horizon. On July 28, 2014, Horizon announced that it had been verbally notified by CVS Caremark and Express Scripts, Inc. that VIMOVO would no longer be on their formularies and will be placed on their exclusion lists effective January 1, 2015. Horizon estimates that approximately 20-30% of VIMOVO prescriptions could be impacted by these decisions. While Horizon believes it has a strategy to mitigate the effect on VIMOVO sales, POZEN's royalty revenue from Net Sales of VIMOVO beginning in 2015 may be negatively affected.

We depend heavily on the success of our product candidates, which may never be approved for commercial use. If we are unable to develop, gain approval of or commercialize those product candidates, we will never receive revenues from the sale of our product candidates.

We anticipate that for the foreseeable future our ability to achieve profitability will be dependent on the successful commercialization of VIMOVO, and. if approved, sales of our PA product candidates. If we fail to gain timely approval to

commercialize our products from the FDA and other foreign regulatory bodies, we will be unable to generate the revenue we will need to build our business. These approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all of the indications for which we seek approval. For example, absent the availability of such a lower dose formulation in the market if PA32540 is approved, the FDA indicated that it may limit the indication for PA32540 to use in post coronary artery bypass graft surgery (CABG) with a treatment duration not to exceed one year. On April 25, 2014, we received a CRL products because of deficiencies noted during an inspection of a supplier of an active ingredient used in the manufacture of the PA products, which has delayed approval of our NDA. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. There can be no assurance that our PA products will be approved by the FDA and, if so approved, for the expected indication.

Many factors could negatively affect our ability to obtain regulatory approval for our product candidates. For example, in October 2008, the FDA informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. Reduction of endoscopic gastric ulcers was the primary endpoint in our Phase 3 trials for VIMOVO and the primary endpoint in the ongoing Phase 3 trials for our PA32540 product. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. The FDA decided to obtain further advice on this issue and held an Advisory Board meeting on November 4, 2010 to discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. The Advisory Board voted in favor (8-4) that endoscopically-documented gastric/duodenal ulcers are an adequate primary efficacy endpoint for evaluating products intended to prevent NSAID-associated upper gastrointestinal (UGI) toxicity, which vote supports the clinical design of the pivotal Phase 3 trials conducted for VIMOVO and PA32540. However, there can be no assurance that FDA will continue to accept the recommendation of the Advisory Board or will not decide to reassess the acceptability of this endpoint in the future.

In addition to the inability to obtain regulatory approval, many other factors could negatively affect the success of our efforts to develop and commercialize our product candidates, including those discussed in the risk factors that follow as well as negative, inconclusive or otherwise unfavorable results from any studies or clinical trials, such as those that we obtained with respect to MT 500, which led to our decision to discontinue development of that product candidate in 2002.

Changes in regulatory approval policy or statutory or regulatory requirements, or in the regulatory environment, during the development period of any of our product candidates may result in delays in the approval, or rejection, of the application for approval of one or more of our product candidates. If we fail to obtain approval, or are delayed in obtaining approval, of our product candidates, our ability to generate revenue will be severely impaired.

The process of drug development and regulatory approval for product candidates takes many years, during which time the FDA's interpretations of the standards against which drugs are judged for approval may evolve or change. The FDA can also change its approval policies based upon changes in laws and regulations. In addition, the FDA can decide, based on its then current approval policies, any changes in those policies and its broad discretion in the approval process, to weigh the benefits and the risks of every drug candidate. As a result of any of the foregoing, the FDA may decide that the data we submit in support of an application for approval of a drug candidate are insufficient for approval. For example, in October 2008, the FDA has informed us that it was conducting an internal review of the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical trials. Reduction of endoscopic gastric ulcers was the primary endpoint in our Phase 3 trials for VIMOVO (formerly referred to as PN 400) and the primary endpoint in our on-going Phase 3 trials for PA32540. In late January 2009, the FDA informed us that it had completed its internal discussions and that there was no change to previous agreements that gastric ulcer incidence was an acceptable primary endpoint for our clinical programs. The FDA decided to obtain further advice on this issue and held an Advisory Board meeting on November 4, 2010 to discuss the adequacy of endoscopically documented gastric ulcers as an outcome measure to evaluate drugs intended to prevent gastrointestinal complications of non-steroidal anti-inflammatory drugs, including aspirin. The Advisory Board voted in favor (8-4) that endoscopically-documented gastric/duodenal ulcers are an adequate primary efficacy endpoint for evaluating products intended to prevent NSAID-associated UGI toxicity, which vote supports the clinical design of the pivotal Phase 3 trials conducted for VIMOVO and PA32540. However, there can be no assurance that FDA will accept the recommendation of the Advisory Board or will not decide to reassess the acceptability of this endpoint in the future.

Changes in policy or interpretation may not be the subject of published guidelines and may therefore be difficult to evaluate. For example, in February 2012, the FDA requested we demonstrate the bioequivalence of PA32540 to EC aspirin 325 mg, with respect to acetylsalicylic acid in an additional Phase 1 study. Enteric coated products such as PA32540 and EC aspirin

325 mg have highly variable pharmacokinetics. Based on our analyses, we believed that the results demonstrated bioequivalence, but the FDA did not agree. However, the FDA did agree that the results from this Phase 1 study, together with additional information that was submitted by us in the NDA for the product, constitutes sufficient data to support the establishment of a clinical and pharmacological bridge between the product and EC aspirin 325 mg. There can be no assurance that our PA products will be approved by the FDA and, if so approved, for the expected indications.

As another example, the FDA has not recently published guidelines for the approval of new migraine therapies, and we have had to rely on periodic guidance from the FDA obtained (in conversations) informally and in other meetings, the content of which may be subject to significant modification over the period of a drug's development program. There is also the risk that we and the FDA may interpret such guidance differently. The FDA has recently made several changes to the omeprazole label that relate, in part, to the agency's concern regarding certain reported adverse events in patients taking long term PPI such as omeprazole. For example, with VIMOVO, in Dosage and Administration, the label states to use the lowest effective dose for the shortest duration consistent with individual patient treatment goals. There is a risk that further omeprazole safety issue may arise in the future that could impact FDA's benefit/risk assessment of the dose or duration of PPI in subjects requiring long-term PPI use.

Further, additional information about the potential risks of marketed drugs may affect the regulatory approval environment, or the FDA's approval policies, for new product candidates. For example, in February 2005 an advisory committee convened by the FDA met to address the potential cardiovascular risks of COX-2 selective NSAIDs and related drugs in response to disclosures made about possible adverse effects from the use of some of these drugs. On April 7, 2005, the FDA issued a Public Health Advisory, or the Advisory, based, in part, upon the recommendations of the advisory committee. The Advisory stated that it would require that manufacturers of all prescription products containing NSAIDs provide warnings regarding the potential for adverse cardiovascular events as well as life-threatening gastrointestinal events associated with the use of NSAIDs. Moreover, subsequent to the FDA advisory committee meeting in February 2005, the FDA has indicated that long-term studies evaluating cardiovascular risk will be required for approval of new NSAID products that may be used on an intermittent or chronic basis. Long-term cardiovascular safety studies were not required at for FDA approval of our VIMOVO. However, we cannot guarantee that such studies will not be required in the future if new information about naproxen safety concerns becomes available. We will continue to evaluate and review with the FDA its expectations and recommendations regarding the efficacy and safety requirements and study design necessary to support approval of NDAs for product candidates we may develop that contain NSAIDs.

If we, or our current or future collaborators, do not obtain and maintain required regulatory approvals for one or more of our product candidates, we will be unable to commercialize those product candidates. Further, if we are delayed in obtaining or unable to obtain, any required approvals, or our contract manufacturers are unable to manufacture and supply product for sale, our collaborators may terminate, or be entitled to terminate, their agreements with us or reduce or eliminate their payments to us under these agreements or we may be required to pay termination payments under these agreements.

Our product candidates under development are subject to extensive domestic and foreign regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertisement, promotion, sale and distribution of pharmaceutical products in the U.S. In order to market our products abroad, we must comply with extensive regulation by foreign governments. If we are unable to obtain and maintain FDA and foreign government approvals for our product candidates, we, alone or through our collaborators, will not be permitted to sell them. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing that product candidate. Except for Treximet, which was approved for commercial sale in the U.S. on April 15, 2008, and VIMOVO, which was approved for commercial sale in the U.S. on April 30, 2010 and has been approved in a number of additional countries in the rest of the world, none of our other product candidates are approved for sale in the U.S. or any foreign market and they may never be approved. For example, we received two approvable letters relating to our NDA for Treximet which communicated the FDA's concerns that delayed marketing approval. An approvable letter, now called a Complete Response Letter, or CRL, is an official notification from the FDA that contains conditions that must be satisfied prior to obtaining final U.S. marketing approval. In June 2006, we received the first approvable letter in which the FDA requested additional safety information on Treximet, and in August 2007, we received a second approvable letter in which the FDA requested that we address their concern about the potential implications from one preclinical in vitro chromosomal aberration study in which a signal for genotoxicity was seen for the combination of naproxen sodium and sumatriptan. We have also previously received not-approvable letters from the FDA relating to our NDAs for MT 100 and MT 300. On April 25, 2014, we received a CRL advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA for our PA32540 and PA8140 product candidates. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. On December 17, 2014, we received a second CRL from the

FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. Satisfactory resolution of these deficiencies is required before this application may be approved.

In the U.S., an NDA or supplement must be filed with respect to each indication for which marketing approval of a product is sought. Each NDA, in turn, requires the successful completion of preclinical, toxicology, genotoxicity and carcinogenicity studies, as well as clinical trials demonstrating the safety and efficacy of the product for that particular indication. We may not receive regulatory approval of any of the NDAs that we file with the FDA or of any approval applications we may seek in the future outside the U.S.

Further, our current or future collaboration agreements may terminate, or require us to make certain payments to our collaborators, or our collaborators may have the right to terminate their agreements with us or reduce or eliminate their payments to us under these agreements, based on our inability to obtain, or delays in obtaining, regulatory approval for our product candidates or our contract manufacturers' inability to manufacture our products or to supply the sufficient quantities of our products to meet market demand. For example, under our PN collaboration agreement with AstraZeneca, AstraZeneca had the right to terminate the agreement if certain delays occurred or specified development and regulatory objectives were not met. For example, this termination right could have been triggered by AstraZeneca if the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint and we had been required to conduct additional trials which would have delayed NDA approval for VIMOVO. Both AstraZeneca, Horizon and Pernix have the right to terminate their respective agreements with us upon a 90 day notice for any reason. Further, if we or our contract manufacturers do not maintain required regulatory approvals, or our contract manufacturers are unable to manufacture our product or to supply sufficient quantities of our products to meet market demand, we may not be able to commercialize our products.

Approval of a product candidate may be conditioned upon certain limitations and restrictions as to the drug's use, such as possible a warning which the FDA may require in the PA32540 label regarding the concomitant use of PA32540 and Plavix, or upon the conduct of further studies, and is subject to continuous review. The FDA has indicated that, absent the availability of such a lower dose formulation in the market if PA32540 is approved, that it may limit the indication for PA32540 to use in post coronary artery bypass graft surgery (CABG) with a treatment duration not to exceed one year. We believe that the FDA is concerned that without a formulation containing a lower dose of aspirin, physicians will not have a full range of dosing options available to prescribe in accordance with current cardiovascular treatment guidelines, which recommend doses of 81 mgs or 162 mgs of aspirin for most indications and we followed the FDA's suggestion to seek approval for a lower dose formulation of the product containing 81 mg of enteric coated aspirin as part of our NDA for PA32540. However, there can be no assurance that the FDA will approve a lower dose formulation of the product or will allow a broader indication for PA32540. There can be no assurance that our PA products will be approved by the FDA and, if so approved, for the expected indications. The FDA may also require us to conduct additional post-approval studies. These post-approval studies may include carcinogenicity studies in animals or further human clinical trials. The later discovery of previously unknown problems with the product, manufacturer or manufacturing facility may result in criminal prosecution, civil penalties, recall or seizure of products, or total or partial suspension of production, as well as other regulatory action against our product candidates or us. If approvals are withdrawn for a product, or if a product is seized or recalled, we would be unable to sell that product and therefore would not receive any revenues from that product.

We and our contract manufacturers are required to comply with the applicable FDA current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, manufacturing facilities must be approved by the FDA before they can be used to manufacture our product candidates, and are subject to additional FDA inspection. On April 25, 2014, we announced that we had received a CRL from the FDA with respect to the NDA for our PA32540 and PA8140 product candidates. In the CRL, the FDA noted that, during an inspection of the manufacturing facility of an active ingredient supplier, inspection deficiencies were found. Satisfactory resolution of deficiencies noted by the field investigator is required before the NDA may be approved. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. We cannot guarantee that the FDA will consider any future actions taken by the active ingredient supplier to be sufficient to address the inspection deficiencies.

Manufacturing facilities may also be subject to state regulations. We, or our third-party manufacturers, may not be able to comply with cGMP regulations or other FDA regulatory requirements, or applicable state regulations, or may not be able to successfully manufacture our products which could result in a delay or an inability to manufacture the products. If we or our partners wish or need to identify an alternative manufacturer, delays in obtaining FDA approval of the alternative manufacturing facility could cause an interruption in the supply of our products.

Labeling and promotional activities are subject to scrutiny by the FDA and state regulatory agencies and, in some circumstances, the Federal Trade Commission. FDA enforcement policy prohibits the marketing of unapproved products as well as the marketing of approved products for unapproved, or off-label, uses. These regulations and the FDA's interpretation of them may limit our or our partners' ability to market products for which we gain approval. Failure to comply with these requirements can result in federal and state regulatory enforcement action. Further, we may not obtain the labeling claims we or our partners believe are necessary or desirable for the promotion of our product candidate. As part of the CRLs received in connection with our PA32540 and PA8140 products, FDA indicated that the final agreement on draft product labeling remains pending.

If third parties challenge the validity of the patents or proprietary rights of our marketed products or assert that we have infringed their patents or proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly and time consuming and could negatively impact the commercialization of our products that we develop or acquire. We have received a Paragraph IV Notice Letters notifying us of the filing of ANDAs with the FDA for approval to market a generic version of VIMOVO. We previously received Paragraph IV Letters notifying us of the filing of ANDAs with the FDA for approval to market a generic version of *Treximet* and those cases have been concluded. We filed patent infringement lawsuits in response to these ANDAs that has led and will continue to lead to costly and time consuming patent litigation.

The intellectual property rights of pharmaceutical companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. Our success in developing and commercializing pharmaceutical products may depend, in part, on our ability to operate without infringing on the intellectual property rights of others and to prevent others from infringing on our intellectual property rights. There has been substantial litigation regarding patents and other intellectual property rights in the pharmaceutical industry. For example, third parties seeking to market generic versions of branded pharmaceutical products often file ANDAs with the FDA, containing a certification stating that the ANDA applicant believes that the patents protecting the branded pharmaceutical product are invalid, unenforceable and/or not infringed. Such certifications are commonly referred to as paragraph IV certifications.

We, AstraZeneca and Horizon are engaged in Paragraph IV litigation with several generic pharmaceutical companies with respect to patents listed in the Orange Book with respect to VIMOVO currently pending in the United States District Court for the District of New Jersey which is described on page 17 of this Form 10-K.

Litigation can be time consuming and costly and we cannot predict with certainty the outcome. If we are unsuccessful in any of the above-described proceedings and the FDA approves a generic version of one of our marketed products, such an outcome would have a material adverse effect on sales of such product, our business and our results of operations.

Our reliance on collaborations with third parties to develop and commercialize our products is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize our products and adversely affecting our profitability.

With respect to the products we have licensed, we depend upon collaborations with third parties to develop these product candidates and we depend substantially upon third parties to commercialize these products. As a result, our ability to develop, obtain regulatory approval of, manufacture and commercialize our existing and possibly future product candidates depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and may in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, although not a primary component of our current strategy, the identification of new compounds or product candidates for development has led us in the past, and may continue to require us, to enter into license or other collaborative agreements with others, including pharmaceutical companies and research institutions. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed our product candidates ourselves and in our loss of control over the development of our product candidates.

Contractors or collaborators may have the right to terminate their agreements with us after a specified notice period for any reason or upon a default by us or reduce their payments to us under those agreements on limited or no notice and for no reason or reasons outside of our control. For example, For example, we had a collaboration agreement with Desitin Arzneimittel GmbH, or "Desitin," for the development and commercialization of MT 400 for the 27 countries of the European Union, as well as Switzerland and Norway, but on February 27, 2013, we received written notice from Desitin that it was terminating the license agreement due to reimbursement uncertainty for MT 400 in Germany, a major market for Desitin in the territory. We can also mutually agree with our collaborators to terminate the agreements. For example, on November 29, 2014,

we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. In December 2014, we received a mutual termination letter from Cilag GmbH International ("Cilag"), a division of Johnson & Johnson, terminating our then-current License Agreement with Cilag, for the exclusive development and commercialization of MT 400 in Brazil, Colombia, Ecuador and Peru.

Collaborators may also decide not to continue marketing our products in certain countries of the territory or to assign their rights under our agreement to third parties. For example, we had a collaboration with GSK for the development and commercialization of certain triptan combinations using our MT 400 technology, including Treximet, in the U.S. and GSK entered into an agreement to divest of all of its rights, title and interest to develop, commercialize and sell the licensed products in the U.S. to Pernix upon closing. In addition, on May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understood that AstraZeneca would instead focus on those countries where the product has shown growth and which AstraZeneca believed had the greatest potential for future growth. On November 18, 2013, AstraZeneca and Horizon entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon.

Contractors or collaborators may have the right to reduce their payments to us under those agreements. For example, a Pernix and AstraZeneca and Horizon have the right to reduce the royalties on net sales of products payable to us under their respective agreements if generic competitors enter the market and attain a pre-determined share of the market for products marketed under the agreements, or if they must pay a royalty to one or more third parties for rights it licenses from those third parties to commercialize products marketed under the agreements. AstraZeneca was also entitled to terminate its agreement with us if certain delays occur or specified development or regulatory objectives were not met. This termination could have been triggered by AstraZeneca if in January 2009, the FDA had determined that endoscopic gastric ulcers were no longer an acceptable endpoint and we had been required to conduct additional trials which would have delayed NDA approval for VIMOVO.

If our current or future licensees exercise termination rights they may have, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us. A further risk we face with our collaborations is that business combinations and changes in the collaborator or their business strategy may adversely affect their willingness or ability to complete their obligations to us.

Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various regulatory, commercialization and other activities or with respect to the timing of the development, such as our agreement with GSK, which was assigned to Pernix, under which GSK determined, among other things, the exact formulation and composition of the product candidates using our MT 400 technology for use in the Treximet clinical trials. Similarly, under our agreement with AstraZeneca, AstraZeneca had the right to manufacture clinical trial material itself or through a third party.

If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the pre-clinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated. Any delay or termination of clinical development or commercialization, such as the delay in FDA approval we experienced as a result of approvable letters we received from the FDA in June 2006 and August 2007 related to our Treximet NDA, or a delay in FDA approval of VIMOVO which could have occurred if the FDA determined in January 2009 that endoscopic gastric ulcers were no longer an acceptable primary endpoint in clinical trials and we were required to conduct additional clinical trials for the product, would delay or possibly eliminate our potential product revenues. Further, our collaborators may be able to exercise control, under certain circumstances, over our ability to protect our patent rights under patents covered by the applicable collaboration agreement. For example, under our collaboration agreements with GSK, now assigned to Pernix, Horizon and AstraZeneca, GSK, Horizon and AstraZeneca each has the first right to enforce our patents under their respective agreements and would have exclusive control over such enforcement litigation. GSK elected not to exercise its first right to prosecute infringement suits against Par, Alphapharm, Teva, Dr. Reddy's , and Sun, each of which submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets and we filed suit against these companies in the United States District Court for the Eastern District of Texas. On the other hand, AstraZeneca has elected to its first right to prosecute infringement suits against Dr. Reddy's, Lupin, Anchen, Watson and Mylan, each of which submitted an ANDA to the FDA for approval to market a generic version of VIMOVO. We and AstraZeneca filed suit against Dr. Reddy's, Lupin, Anchen, Watson and Mylan in the United States District Court for the District of New Jersey. As part of Horizon's purchase of all of AstraZeneca's rights, title and interest to develop,

commercialize and sell VIMOVO in the United States, Horizon has assumed AstraZeneca's right to lead the above-described Paragraph IV litigation relating to VIMIVO.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day-to-day control over the activities of our contractors or collaborators;
- our collaborators may fail to defend or enforce patents they own on compounds or technologies that are incorporated into the products we develop with them;
- third parties may not fulfill their regulatory or other obligations;
- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and
- disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development of our product candidates and/or the commercialization of our products or reduction in the milestone payments we receive from our collaborators, or could result in our not being able to commercialize our products. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time-consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development of our product candidates and/or the commercialization of our products will be delayed or may never be realized.

A collaborator may withdraw support or cease to perform work on our product candidates if the collaborator determines to develop its own competing product candidate or other product candidates instead.

We have entered into collaboration and license agreements, and may continue to enter into such agreements, with companies that have products and are developing new product candidates that compete or may compete with our product candidates or which have greater commercial potential. If one of our collaborators should decide that the product or a product candidate that the collaborator is developing would be more profitable for the collaborator than our product candidate covered by the collaboration or license agreement, the collaborator may withdraw support for our product candidate or may cease to perform under our agreement. On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understood that AstraZeneca would instead focus on those countries where the product had shown growth and which AstraZeneca believed had the greatest potential for future growth. On November 18, 2013, AstraZeneca and Horizon entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. In addition, GSK divested of all of its rights, title and interest to develop, commercialize and sell MT 400 products, including Treximet, in the U.S. to Pernix on August 20, 2014.

In the event of a termination of the collaborator's agreement upon such cessation of performance, we would need to negotiate an agreement with another collaborator in order to continue the development and commercialization efforts for the product candidate. If we were unsuccessful in negotiating another agreement, we might have to cease development activities of the particular product candidate. For example, our development and commercialization agreements with Horizon and AstraZeneca are subject to this risk. Under the terms of our agreement with AstraZeneca and Horizon, either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement, at any time, at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us. However, under the circumstance above, or similar circumstance, we may need to enter into a new development and commercialization agreement and may need to start the development process all over again. If we were able to negotiate a new development and commercialization agreement to develop our technology, which is not certain, or if we decide to commercialize the products previously partnered by ourselves, we would face delays and redundant expenses in that development.

We need to maintain current agreements and enter into additional agreements with third parties that possess sales, marketing and distribution capabilities, or establish internally the capability to perform these functions, in order to successfully market and sell our future drug products.

We have no sales or distribution personnel or capabilities at the present time. If we are unable to maintain current collaborations or enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to provide those capabilities, we will not be able to successfully commercialize our products. To the extent that we enter into marketing and sales agreements with third parties, such as our agreement with Horizon to sell VIMOVO in the United States and AstraZeneca to sell VIMOVO outside the United States, our revenues, if any, will be affected by the sales and marketing efforts of those third parties. If our licensed products do not perform well in the marketplace our royalty revenue will impacted and our business could be materially harmed. For example, on July 28, 2014, Horizon announced that it had been verbally notified by CVS Caremark and Express Scripts, Inc. that VIMOVO would no longer be on their formularies and will be placed on their exclusion lists effective January 1, 2015. We have been notified that Horizon estimates that approximately 20-30% of VIMOVO prescriptions could be impacted by these decisions. While Horizon believes it has a strategy to mitigate the effect on VIMOVO sales, POZEN's royalty revenue from Net Sales of VIMOVO beginning in 2015 may be negatively affected.

We refined our strategy and decided to retain control of our PA product candidates for cardiovascular indications through the clinical development and pre-commercialization stage. To that end, our chief commercial officer evaluated the commercial opportunities for these product candidates and developed a worldwide commercial strategy, which included developing certain internal commercialization capabilities to enable us to conduct pre-commercialization activities prior to licensing our PA product candidates to commercial partners. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products. In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

We need to conduct preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, and clinical trials for our product candidates. Any negative or unanticipated results, unforeseen costs or delays in the conduct of these studies or trials, or the need to conduct additional studies or trials or to seek to persuade the FDA to evaluate the results of a study or trial in a different manner, could cause us to discontinue development of a product candidate or reduce, delay or eliminate our receipt of potential revenues for one or more of our product candidates and adversely affect our ability to achieve profitability.

Generally, we must demonstrate the efficacy and safety of our product candidates before approval to market can be obtained from the FDA or the regulatory authorities in other countries. Our existing and future product candidates are and will be in various stages of clinical development. Depending upon the type of product candidate and the stage of the development process of a product candidate, we will need to complete preclinical, toxicology, genotoxicity and carcinogenicity and other safety studies, as well as clinical trials, on these product candidates before we submit marketing applications in the United States and abroad. These studies and trials can be very costly and time-consuming. For example, long-term cardiovascular safety studies, such as those the FDA has indicated will be required for approval of certain product candidates containing NSAIDs, typically take approximately three years. In addition, we rely on third parties to perform significant aspects of our studies and clinical trials, introducing additional sources of risk into our development programs.

It should be noted that the results of any of our preclinical and clinical trial testing are not necessarily predictive of results we will obtain in subsequent or more extensive clinical trials or testing. This may occur for many reasons, including, among others, differences in study design, including inclusion/exclusion criteria, the variability of patient characteristics, including patient symptoms at the time of study treatment, the larger scale testing of patients in later trials, or differences in formulation or doses of the product candidate used in later trials. For example, our results from the first of our two Phase 3 pivotal clinical trials of *Treximet* differed from the results of our second Phase 3 clinical trial and from the Phase 2 proof-of-concept trial of MT 400 that we conducted prior to entering into our collaboration with GSK. Whereas in the Phase 2 trial statistical significance was reached at two hours over placebo in the relief of all associated symptoms of migraine (nausea, photophobia and phonophobia), in the first Phase 3 study *Treximet* failed to achieve statistical significance at two hours compared to placebo in the relief of nausea. In the second Phase 3 pivotal clinical trial, *Treximet* demonstrated superiority over the individual components measured by sustained pain-free response ($p<0.001$ vs. naproxen; $p=0.009$ vs. sumatriptan) and met all other regulatory endpoints versus placebo.

The successful completion of any of our clinical trials depends upon many factors, including the rate of enrollment of patients. If we are unable to recruit sufficient clinical patients during the appropriate period, we may need to delay our clinical trials and incur significant additional costs. We also rely on the compliance of our clinical trial investigators with FDA regulatory requirements and noncompliance can result in disqualification of a clinical trial investigator and data that are unusable. In addition, the FDA or Institutional Review Boards may require us to conduct additional trials or delay, restrict or

discontinue our clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Further, even though we may have completed all clinical trials for a product candidate that were planned for submission in support of an application, we may be required to conduct additional clinical trials, studies or investigations or to submit additional data to support our marketing applications. For example, in February, 2012, the FDA requested an additional Phase 1 study to assess the bioequivalence of PA32540 to EC aspirin 325 mg with respect to ASA. Enteric coated products such as PA32540 and EC aspirin 325 mg have highly variable pharmacokinetics, making bioequivalence difficult to demonstrate using traditional methods and standards. The FDA made a preliminary review of the study results and the Company's summary analyses and, based on its preliminary assessment of the information available to it at the time, the FDA did not agree that bioequivalence of PA32540 to EC aspirin 325 mg was demonstrated.

In addition, we and/or our marketing or development partners may determine that pre-approval marketing support studies should be conducted. Unanticipated adverse outcomes of such studies, including recognition of certain risks to human subjects, could a have material impact on the approval of filed or planned market applications or could result in limits placed on the marketing of the product. We may also determine from time to time that it would be necessary to seek to provide justification to the FDA or other regulatory agency that would result in evaluation of the results of a study or clinical trial in a manner that differs from the way the regulatory agency initially or customarily evaluated the results, as was the case with the Phase 1 study to assess the bioequivalence of PA32540 to EC aspirin 325 mg described in the preceding paragraph. In addition, we may have unexpected results in our preclinical or clinical trials or other studies that require us to reconsider the need for certain studies or trials or cause us to discontinue development of a product candidate. For example, in reviewing our NDA for *Treximet*, the FDA expressed concern about the potential implications from one preclinical in-vitro chromosomal aberration study, one of four standard genotoxicity assays, in which a possible genotoxicity signal was seen for the combination of naproxen sodium and sumatriptan. Further, additional information about potential drug-drug interactions may restrict the patient population for our products, thus limiting the potential market and our potential revenue. For example, recent scientific publications contain conflicting data regarding a possible interaction between clopidogrel (Plavix®), a widely prescribed anti-platelet agent, and proton pump inhibitor products, and its impact on cardiovascular outcomes. If the clinical relevance of the possible interaction is unresolved by the time PA32540 enters the marketplace, even if the interaction is later proven definitively to have no clinical impact on cardiovascular outcomes, the market potential of the product may be reduced.

Once submitted, an NDA requires FDA approval before the product described in the application can be distributed or commercialized. Even if we determine that data from our clinical trials, toxicology, genotoxicity and carcinogenicity studies are positive, we cannot assure you that the FDA, after completing its analysis, will not determine that the trials or studies should have been conducted or analyzed differently, and thus reach a different conclusion from that reached by us, or request that further trials, studies or analyses be conducted. For example, the FDA requested additional safety information on *Treximet* in the approvable letter we received in June 2006 relating to our NDA for *Treximet*, which required conduct of additional studies, and in August 2007, we received a second approvable letter in which the FDA raised an additional concern about the potential implications from one preclinical in vitro chromosomal aberration study, one of four standard genotoxicity assays, in which a genotoxicity signal was seen for the combination of naproxen sodium and sumatriptan.

The FDA may also require data in certain subpopulations, such as pediatric use, or, if such studies were not previously completed, may require long-term carcinogenicity studies, prior to NDA approval, unless we can obtain a waiver of such a requirement. We face similar regulatory hurdles in other countries to those that we face in the U.S.

Our costs associated with our human clinical trials vary based on a number of factors, including:

- the order and timing of clinical indications pursued;
- the extent of development and financial support from collaborative parties, if any;
- the need to conduct additional clinical trials or studies;
- the number of patients required for enrollment;
- the difficulty of obtaining sufficient patient populations and clinicians;
- the difficulty of obtaining clinical supplies of our product candidates; and
- governmental and regulatory delays.

We currently depend and will in the future depend on third parties to manufacture our product candidates. If these manufacturers fail to meet our requirements or any regulatory requirements, the product development and commercialization of our product candidates will be delayed.

We do not have, and have no plans to develop, the internal capability to manufacture either clinical trial or commercial quantities of products that we may develop or have under development. We rely upon third-party manufacturers and our partners to supply us with our product candidates. We also need supply contracts to sell our products commercially. On December 19, 2011, we entered into a Supply Agreement and a related Capital Agreement with Patheon pursuant to which Patheon has agreed to manufacture, and we have agreed to purchase, a specified percentage of the Company's requirements of PA32540 for sale in the United States. The Supply Agreement and Capital Agreement were amended on July 10, 2013 to, among other things, expressly incorporate the Company's PA8140 product candidate into the Supply Agreement and to replace the schedule of the Capital Agreement which lists dedicated and non-dedicated capital equipment and facility modifications to be funded in whole or in part by the Company, with a new updated schedule reflecting the parties' current assumptions regarding the need for and timing of capital equipment expenditures. We also rely on third parties to supply the active ingredients and other ingredients used in the manufacture of our products. Failure of such ingredient suppliers to comply with regulatory requirements can impact our ability to obtain approval of our products or our ability to supply the market with our products after approval. For example, On April 25, 2014, we announced that we had received a CRL from the FDA with respect to the NDA for our PA32540 and PA8140 products. In the CRL, the FDA noted that, during an inspection of the manufacturing facility of an active ingredient supplier, inspection deficiencies were found. Satisfactory resolution of deficiencies noted by the field investigator is required before the NDA may be approved. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. We cannot guarantee that the FDA will consider any actions taken by the active ingredient supplier to be sufficient to address the inspection deficiencies.

There is no guarantee that manufacturers that enter into commercial supply contracts with us will be financially viable entities going forward, or will not otherwise breach or terminate their agreements with us. If we do not have the necessary commercial supply contracts, or if Patheon is, or any of our future manufacturers are, unable to satisfy our requirements or meet any regulatory requirements, and we are required to find alternative sources of supply, there may be additional costs and delays in product development and commercialization of our product candidates or we may be required to comply with additional regulatory requirements.

If our competitors develop and commercialize products faster than we do or if their products are superior to ours, our commercial opportunities will be reduced or eliminated.

Our product candidates will have to compete with existing and any newly developed migraine therapies or therapies for any newly developed product candidates for the treatment of other diseases. There are also likely to be numerous competitors developing new products to treat migraine and the other diseases and conditions for which we may seek to develop products in the future, which could render our product candidates or technologies obsolete or non-competitive. For example, our primary competitors will likely include large pharmaceutical companies, biotechnology companies, universities and public and private research institutions. The competition for VIMOVO and any other PN products that may be developed and receive regulatory approval will come from the oral NSAID market, or more specifically the traditional non-selective NSAIDs (such as naproxen and diclofenac), traditional NSAID/gastroprotective agent combination products or combination product packages (such as Arthrotec® and Prevacid® NapraPAC™), combinations of NSAIDs and PPIs taken as separate pills and the only remaining COX-2 inhibitor, Celebrex®. The competition for our PA product candidates for which we have conducted studies for secondary prevention of cardiovascular events will come from aspirin itself as well as other products used for secondary prevention. AstraZeneca, with whom we collaborated in the development of VIMOVO, has publicly announced that it has obtained regulatory approval for a combination product containing aspirin and esomeprazole in Europe and has also filed a NDA with the FDA for such product, and for which the FDA issued a CRL declining approval. AstraZeneca has stated that it is currently evaluating the CRL and will continue discussions with the FDA to determine next steps. This product has entered the European market and, if it enters the U.S. market, will compete with our PA cardiovascular product candidates.

Based upon their drug product and pipeline portfolios and the overall competitiveness of our industry, we believe that we face, and will continue to face, intense competition from other companies for securing collaborations with pharmaceutical companies, establishing relationships with academic and research institutions, and acquiring licenses to proprietary technology. Our competitors, either alone or with collaborative parties, may also succeed with technologies or products that are more effective than any of our current or future technologies or products. Many of our actual or potential competitors, either alone or together with collaborative parties, have substantially greater financial resources, and almost all of our competitors have larger numbers of scientific and administrative personnel than we do.

Many of these competitors, either alone or together with their collaborative parties, also have significantly greater resources to or experience in:

- developing product candidates;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates; and
- manufacturing and marketing products.

Accordingly, our actual or potential competitors may succeed in obtaining patent protection, receiving FDA or other regulatory approval or commercializing products where we cannot or before we do. Any delays we encounter in obtaining regulatory approvals for our product candidates, such as we experienced as a result of the approvable letters we received from the FDA in June 2006 and August 2007 relating to the NDA for *Treximet*, as a result of the not-approvable letters we received from the FDA on MT 100 and MT 300, and as a result of the CRLs we received from the FDA relating to the NDA for PA32540 and PA8140 on April 25, 2014 and December 16, 2014, increase this risk. Our competitors may also develop products or technologies that are superior to those that we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever receive any revenues from sales of products or may not receive sufficient revenues to achieve profitability.

If we are unable to protect our patents or proprietary rights, or if we are unable to operate our business without infringing the patents and proprietary rights of others, we may be unable to develop our product candidates or compete effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our ability, and the ability of our licensors, to obtain and to keep protection for our products and technologies under the patent laws of the United States and other countries, so that we can stop others from using our inventions. Our success also will depend on our ability to prevent others from using our trade secrets. In addition, we must operate in a way that does not infringe, or violate, the patent, trade secret and other intellectual property rights of other parties.

We cannot know how much protection, if any, our patents will provide or whether our patent applications will issue as patents. The breadth of claims that will be allowed in patent applications cannot be predicted and neither the validity nor enforceability of claims in issued patents can be assured. If, for any reason, we are unable to obtain and enforce valid claims covering our products and technology, we may be unable to prevent competitors from using the same or similar technology or to prevent competitors from marketing identical products. For example, if we are unsuccessful in protecting our patents in the litigation against Dr. Reddy's, Lupin, Anchen, Watson and Mylan or other companies who may file ANDAs for VIMOVO, such companies could market a generic version of the product prior to the expiration of our and AstraZeneca's patents.

In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our products, any patents that protect our product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us.

In certain territories outside the U.S., our issued patents may be subject to opposition by competitors within a certain time after the patent is issued. Such opposition proceedings and related appeals may not be resolved for several years, and may result in the partial or total revocation of the issued patent. For example, in October 2005 oppositions were filed against our issued European patent for MT 400 by Merck & Co., Inc. and Almirall Prodesfarma asserting that the European patent should not have been granted. As a result of these oppositions and subsequent proceedings, the European Patent Office found that claims relating to combinations of sumatriptan and naproxen for the treatment of migraine were valid. However, broader claims relating to certain other 5-HT 1B/1D agonists and long-acting NSAIDs were held to be insufficiently supported by the presently available technical evidence. In addition, in April 2011, oppositions were also filed against our issued European patent for VIMOVO and our PA Products by Chatfield Laboratories and Strawman Limited asserting that the European patent should not have been granted. Strawman Limited subsequently withdrew from the opposition. Following oral proceedings, the Opposition Division of the European Patent Office found that claims relating to the combination of PPIs and NSAIDs are valid. Chatfield Laboratories did not appeal this decision.

We may need to submit our issued patents for amendment or reissue if we determine that any claims within our patents should not have been issued. While such a submission may be based on our view that only specified claims should not have been granted to us, there can be no assurance that a patent examiner will not determine that additional claims should not have been granted to us. Such was the case with one of our patents covering MT 100, which we submitted for reissue after

determining that certain specified claims that are not central to our protection of MT 100 should not have been issued. In April 2006, we received an office action on the reissue application and, consistent with our decision not to devote further resources to the development of this product in the U.S., the reissue application was abandoned in January 2007.

We may need to license rights to third party patents and intellectual property to continue the development and marketing of our product candidates. If we are unable to acquire such rights on acceptable terms, our development activities may be blocked and we may be unable to bring our product candidates to market.

We may enter into litigation to defend ourselves against claims of infringement, assert claims that a third party is infringing one or more of our patents, protect our trade secrets or know-how, or determine the scope and validity of others' patent or proprietary rights. For example, we filed patent infringement lawsuits against Par, Alphapharm, Teva, Dr. Reddy's and Sun in the federal court in the Eastern District of Texas in connection with their respective ANDA submissions to the FDA containing Paragraph IV certifications for approval to market sumatriptan 85 mg/naproxen sodium 500 mg tablets, a generic version of Treximet tablets, before the expiration of our patents. Further, we and AstraZeneca filed a patent infringement lawsuit against Dr. Reddy's, Lupin, Anchen, Watson and Mylan in the federal court in the District of New Jersey in connection with their respective ANDA submissions to the FDA containing a paragraph IV certification for approval to market (a generic version of VIMOVO tablets, before the expiration of our and AstraZeneca's patents. With respect to some of our product candidates, under certain circumstances, our development or commercialization collaborators have the first right to enforce our patents and would have exclusive control over such enforcement litigation. For example, under our collaboration agreements with GSK and AstraZeneca, GSK and AstraZeneca each has the first right to enforce our patents under their respective agreements. GSK advised us that it elected not to exercise its first right to bring an infringement suit against Par, Alphapharm, Teva, and Dr. Reddy's, and Sun each of which submitted ANDAs to the FDA for approval to market a generic version of Treximet tablets, while AstraZeneca has exercised its first right to bring an infringement suit against Dr. Reddy's Lupin, Anchen, Watson and Mylan, each of which submitted an ANDA to the FDA for approval to market a generic version of VIMOVO tablets. As part of Horizon's purchase of all of AstraZeneca's rights, title and interest to develop, commercialize and sell VIMOVO in the United States, Horizon has assumed AstraZeneca's right to lead the above-described Paragraph IV litigation relating to VIMIVO.

If we are found to infringe the patent rights of others, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and marketing activities. Additionally, if we or our development or commercialization collaborator seek to enforce our patents and are unsuccessful, we may be subject to claims for bringing a failed enforcement action, including claims alleging various forms of antitrust violations (both state and federal) and unfair competition. If we are found to be liable for such claims, then we may be forced to pay damages in an amount that might irreparably harm our business and/or be prevented from continuing our product development and commercialization activities. Even if we are successful in defending any such claims of infringement or in asserting claims against third parties, such litigation is expensive, may have a material effect on our operations, and may distract management from our business operations. Regardless of its eventual outcome, any lawsuit that we enter into may consume time and resources that would impair our ability to develop and market our product candidates.

We have entered into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and, as a result, we may not be able to protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how. Also, many of our scientific and management personnel were previously employed by competing companies. As a result, such companies may allege trade secret violations and similar claims against us.

None of our products may be accepted by the market.

The commercial success of our product candidates depends upon the acceptance of these products in the marketplace. Even if a product displays a favorable efficacy and safety profile in clinical trials, market acceptance of a product will not be known until after it is launched and a product may not generate the revenues that we anticipate. The degree of market acceptance will depend upon a number of factors, including:

- the acceptance by physicians and third-party payors of VIMOVO as an alternative to other therapies;
- the receipt and timing of regulatory approvals;
- the availability of third-party reimbursement;
- the indications for which the product is approved;
- the rate of adoption by healthcare providers;
- the rate of product acceptance by target patient populations;

- the price of the product relative to alternative therapies;
- the availability of alternative therapies;
- the extent and effectiveness of marketing efforts by our collaborators, and third-party distributors and agents;
- the existence of adverse publicity regarding our products or similar products; and
- the extent and severity of side effects as compared to alternative therapies.

If we or our commercialization partners do not receive adequate third-party reimbursements for our future products, our revenues and profitability will be reduced.

Our ability to commercialize our product candidates successfully will depend, in part, on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the U.S., private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of a newly approved healthcare product. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payors for use of our products, our products may fail to achieve market acceptance. For example, on July 28, 2014, Horizon announced that it had been verbally notified by CVS Caremark and Express Scripts, Inc. that VIMOVO would no longer be on their formularies and will be placed on their exclusion lists effective January 1, 2015. Horizon estimates that approximately 20-30% of VIMOVO prescriptions could be impacted by these decisions. While Horizon believes it has a strategy to mitigate the effect on VIMOVO sales, POZEN's royalty revenue from Net Sales of VIMOVO beginning in 2015 may be negatively affected.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payors to contain or reduce the costs of healthcare through various means. We expect that a number of federal, state and foreign proposals will seek to control the cost of drugs through governmental regulation. We are unsure of the form that any healthcare reform legislation may take or what actions federal, state, foreign and private payors may take in response to any proposed reforms. Therefore, we cannot predict the effect of any implemented reform on our business.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA, which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. PPACA increased the minimum Medicaid drug rebates for pharmaceutical companies, expands the 340B drug discount program, and makes changes to affect the Medicare Part D coverage gap, or "donut hole." The law also revises the definition of "average manufacturer price" for reporting purposes which could increase the amount of the Company's Medicaid drug rebates to states. The law also imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are fully implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products, and we could be adversely affected by current and future health care reforms.

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

The testing and marketing of pharmaceutical products entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have product liability insurance that covers our commercialized product and human clinical trials in an amount equal to up to $10 million annual aggregate limit with a $0.1 million deductible per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We will explore, on an on-going basis, expanding our insurance coverage related to the sale of our future marketed products when we obtain marketing approval for such products and commercial sales of such products begin. However, we may not be able to obtain

commercially reasonable product liability insurance for any products approved for marketing. If a plaintiff brings a successful product liability claim against us in excess of our insurance coverage, if any, we may incur substantial liabilities and our business may be harmed or fail.

We may need additional funding and may not have access to capital. If we are unable to raise capital when needed, we may need to delay, reduce or eliminate our product development or commercialization efforts.

In the future, we may need to raise additional funds to execute our business strategy. We have incurred losses from operations since inception and we may continue to incur additional operating losses. Our actual capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the progress of preclinical studies, clinical and other testing or the need conduct additional trials, studies or other testing;
- the time and cost involved in obtaining any regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the timing of our receipt, if any, of milestone payments and royalties under collaborative agreements;
- the effect of changes and developments in, or termination of, our collaborative, license and other relationships;
- the terms and timing of any additional collaborative, license and other arrangements that we may establish; and
- our ability to commercialize or arrange for the commercialization of our product candidates.

Our operating expenses for the fiscal year ended December 31, 2014 totaled $15.8 million, including non-cash compensation expense of $1.9 million related to stock options and other stock-based awards. For fiscal years 2012 through 2014, our average annual operating expenses (including average non-cash deferred compensation of $2.9 million) were $24.6 million. As of December 31, 2014, we had an aggregate of $40.6 million in cash and cash equivalents. Our operating expenses for 2015 and 2016 may exceed the net level of our operating expenses in 2014. However, with respect to future products we may develop, we have decided that we will no longer commit substantial resources to further drug development without a partner who agrees to pay the full cost of that development. Consistent with this model, we have reduced our R&D staff and other costs and expenses as our PA development program activities wind down and intend to continue to reduce staff that is no longer required to support our then current business activities. Our board of directors and management team continue to explore potential ways to return value to our stockholders. On November 21, 2013, our Board of Directors declared a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with a payment date of December 30, 2013. This distribution represented a surplus of corporate cash and was treated as a return of capital to stockholders. We may consider other cash distributions in the future as is prudent. We believe that we will have sufficient cash reserves and cash flow to maintain our planned level of business activities, through 2015. However, our anticipated cash flow includes continued receipt of royalty revenue from Horizon and AstraZeneca's sale of VIMOVO but does not include any additional milestone or royalty payments. In addition, our expenses might increase during that period beyond currently expected levels if we decide to, or any regulatory agency requires us to, conduct additional clinical trials, studies or investigations for any of our product candidates, including in connection with the agency's consideration, or reconsideration, of our regulatory filings for our product candidates or if we decide to commercialize our PA product candidates in the United States without a commercial partner. If our projected revenues decrease, we may need to raise additional capital.

If our projected expenses increase for our product candidates currently in development, or if we expand our studies for additional indications for our PA product candidates or new product candidates, then, as a result of these or other factors, we may need to raise additional capital. While we retained ownership of our PA product candidates for cardiovascular indications through the clinical development and pre-commercialization stage, with respect to future products we may develop, we have decided that we will no longer commit substantial resources to further drug development without a partner who agrees to pay the full cost of that development.

We may be unable to raise additional equity funds when we desire to do so due to unfavorable market conditions in our industry or generally, or due to other unforeseen developments in our business. Further, we may not be able to find sufficient debt or equity funding, if at all, on acceptable terms. If we cannot, we may need to delay, reduce or eliminate research and development programs and therefore may not be able to execute our business strategy. Further, to the extent that we obtain additional funding through collaboration and licensing arrangements, it may be necessary for us to give up valuable rights to our development programs or technologies or grant licenses on terms that may not be favorable to us.

The sale by us of additional equity securities or the expectation that we will sell additional equity securities may have an adverse effect on the price of our common stock.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our research and development efforts.

We are highly dependent on the efforts of our key management and scientific personnel, especially John R. Plachetka, Pharm.D., our Chairman, President and Chief Executive Officer. Dr. Plachetka signed an amended and restated employment agreement with us on March 14, 2006, which was amended on September 28, 2007, for a three-year term with automatic one-year renewal terms. We have also entered into employment agreements with certain of our other key management personnel, which provide for one or two-year terms with automatic one-year renewal terms which were amended on September 28, 2007. If we should lose the services of Dr. Plachetka, or are unable to replace the services of our other key personnel who may leave the Company, including John G. Fort, M.D., Chief Medical Officer, or William L. Hodges, Senior Vice President Finance and Administration and Chief Financial Officer, or if we fail to recruit other key scientific and commercial personnel, we may be unable to achieve our business objectives. There is intense competition for qualified scientific and commercial personnel. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business. Furthermore, our future success may also depend in part on the continued service of our other key management personnel and our ability to recruit and retain additional personnel, as required by our business.

New and changing corporate governance and public disclosure requirements add uncertainty to our compliance policies and increase our costs of compliance.

Changing laws, regulations and standards relating to accounting, corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, other SEC regulations, and the NASDAQ Global Market rules, are creating uncertainty for companies like ours. These laws, regulations and standards may lack specificity and are subject to varying interpretations. Their application in practice may evolve over time, as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs of compliance as a result of ongoing revisions to such corporate governance standards.

In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' audit of that assessment requires the commitment of significant financial and managerial resources. We consistently assess the adequacy of our internal controls over financial reporting, remediate any control deficiencies that may be identified, and validate through testing that our controls are functioning as documented. While we do not anticipate any material weaknesses, the inability of management to assess our internal controls over financial reporting as effective could result in adverse consequences to us, including, but not limited to, a loss of investor confidence in the reliability of our financial statements, which could cause the market price of our stock to decline. The existence of this or one or more other material weaknesses or significant deficiencies in our internal control over financial reporting could result in errors in our financial statements, and substantial costs and resources may be required to rectify any internal control deficiencies. Although we continually review and evaluate internal control systems to allow management to report on the sufficiency of our internal controls, we cannot assure you that we will not discover weaknesses in our internal control over financial reporting. Any such weakness or failure to remediate any existing material weakness could materially adversely affect our ability to comply with applicable financial reporting requirements and the requirements of our various agreements.

We are committed to maintaining high standards of corporate governance and public disclosure, and our efforts to comply with evolving laws, regulations and standards in this regard have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, the laws, regulations and standards regarding corporate governance may make it more difficult for us to obtain director and officer liability insurance. Further, our board members, chief executive officer and chief financial officer could face an increased risk of personal liability in connection with their performance of duties. As a result, we may face difficulties attracting and retaining qualified board members and executive officers, which could harm our business. If we fail to comply with new or changed laws, regulations or standards of corporate governance, our business and reputation may be harmed.

Risks Related to Potential Commercialization of our Product Candidates

We continue to evaluate the commercial opportunities for our current product candidates in connection with our development of a worldwide commercialization strategy. If we decide to pursue the commercial opportunities for our future products ourselves or co-promote and/or retain a significant role in the commercialization of our future products with strategic partners and we are unable to develop sales and marketing capabilities on our own, or through partner acquisition, we will not be able to fully exploit the commercial potential of our future products and the costs of pursuing such a strategy may have a material adverse impact on our results of operations.

Although we do not have sales and marketing experience, we continue to evaluate the commercial opportunities for our product candidates in connection with our development of a worldwide commercialization strategy. We decided to retain ownership of our PA product candidates through the clinical development and pre-commercialization stage and our chief commercial officer developed the commercialization strategy for these products and conducted all the required pre-commercialization activities in the United States. On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The termination agreement further provides for the transfer of specified commercial know-how developed by Sanofi US relating to the PA products to us and allows us, and any future collaborators, to use this know-how to commercialize the products We are currently evaluating all strategic options available to us now that we have full ownership of the PA products in the United States. Outside the United States, we intend to secure relationships with one or more strong commercial partners with relevant expertise to commercialize our future products globally. If we change our strategy in the future and decide to pursue commercialization opportunities for our future products ourselves, or if we co-promote and/or retain a significant role in the commercialization of our future products with strategic partners, we may make significant expenditures to secure commercial resources to sell such products and expand our marketing capabilities to support such growth. Any failure or extended delay in the expansion of our sales and marketing capabilities or inability to effectively operate in the marketplace alone or together with our partners could adversely impact our business. There can be no assurance that if we decide to pursue commercialization opportunities ourselves or participate in the commercialization of our products with partners that our sales and marketing efforts will generate significant revenues and costs of pursuing such a strategy may have a material adverse impact on our results of operations. Events or factors that may inhibit or hinder our commercialization efforts include:

- developing our own commercial team or playing a role in the commercialization with a partner will be expensive and time-consuming and could result in high cash burn or reduced profitability;
- failure to acquire sufficient or suitable personnel to establish, oversee, or implement our commercialization strategy;
- failure to recruit, train, oversee and retain adequate numbers of effective sales and marketing personnel;
- failure to develop a commercial strategy ourselves or together with partners that can effectively reach and persuade adequate numbers of physicians to prescribe our products;
- our or our partners' inability to secure reimbursement at a reasonable price;
- unforeseen costs and expenses associated with creating or acquiring and sustaining an independent commercial organization;
- incurrence of costs in advance of anticipated revenues and subsequent failure to generate sufficient revenue to offset additional costs; and
- our ability to fund our commercialization efforts alone or together with our partners on terms acceptable to us, if at all.

If we decide to pursue commercialization opportunities for our future products ourselves or if we co-promote and/or retain a significant role in the commercialization of our future products with strategic partners, failure to comply with the laws governing the marketing and sale of such future products may result in regulatory agencies taking action against us and/or our partners, which could significantly harm our business.

We retained ownership of our PA product candidates through the clinical development and pre-commercialization stage and our chief commercial officer developed the commercialization strategy for these products and conducted pre-commercialization activities in the United States. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products. Outside the United States, we intend to secure relationships with one or more strong commercial partners with relevant expertise to commercialize our future products globally. If we decide to pursue commercial opportunities for our PA product candidates or our future products ourselves, or if we co-promote and/or retain a significant role in the commercialization of our future products with strategic partners, we will be subject to a large body of legal and regulatory requirements. In particular, there are many federal, state and local laws that we will need to comply with if we become engaged in the marketing, promoting, distribution and sale of pharmaceutical products. The FDA extensively regulates, among other things, promotions and advertising of prescription drugs. In addition, the marketing and sale of prescription drugs must comply with the Federal fraud and abuse laws, which are enforced by the Office of the Inspector General of the Division, or OIG, of the Department of Health and Human Services. These laws make it illegal for anyone to give or receive anything of value in exchange for a referral for a product or service that is paid for, in whole or in part, by any federal health program. The federal government can pursue fines and penalties under the Federal False Claims Act which makes it illegal to file, or induce or assist another person in filing, a fraudulent claim for payment to any governmental agency. Because, as part of our and/or our partners commercialization efforts, we or our partners may provide physicians with samples we will be required to comply with the Prescription Drug Marketing Act, or PDMA, which governs the distribution of prescription drug samples to healthcare practitioners. Among other things, the PDMA prohibits the sale, purchase or trade of prescription drug samples. It also sets out record keeping and other requirements for distributing samples to licensed healthcare providers.

In addition, depending upon the terms of our agreements with our partners, we may need to comply with the body of laws comprised of the Medicaid Rebate Program, the Veterans' Health Care Act of 1992 and the Deficit Reduction Act of 2005. This body of law governs product pricing for government reimbursement and sets forth detailed formulas for how we must calculate and report the pricing of our products so as to ensure that the federally funded programs will get the best price. Moreover, many states have enacted laws dealing with fraud and abuse, false claims, the distribution of prescription drug samples and gifts and the calculation of best price. These laws typically mirror the federal laws but in some cases, the state laws are more stringent than the federal laws and often differ from state to state, making compliance more difficult. We expect more states to enact similar laws, thus increasing the number and complexity of requirements with which we would need to comply.

Compliance with this body of laws is complicated, time consuming and expensive. Because we do not have experience in developing, managing and training our employees regarding, a comprehensive healthcare compliance program, we cannot assure you that we will be in compliance with all potentially applicable laws and regulations. Even minor, inadvertent irregularities can potentially give rise to claims that the law has been violated. Failure to comply with all potentially applicable laws and regulations could lead to penalties such as the imposition of significant fines, debarment from participating in drug development and marketing and the exclusion from government-funded healthcare programs. The imposition of one or more of these penalties could adversely affect our revenues and our ability to conduct our business as planned.

In addition, the Federal False Claims Act, which allows any person to bring suit alleging the false or fraudulent submission of claims for payment under federal programs and other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that companies like us may have to defend a false claim action. We could also become subject to similar false claims litigation under state statutes. If we are unsuccessful in defending any such action, such action may have a material adverse effect on our business, financial condition and results of operations.

Factors That May Affect Our Stockholders

Our stock price is volatile, which may result in significant losses to stockholders.

There has been significant volatility in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include:

- fluctuations in our operating results;
- announcements of technological innovations, acquisitions or licensing of therapeutic products or product candidates by us or our competitors;
- published reports by securities analysts;
- positive or negative progress with our clinical trials or with regulatory approvals of our product candidates;
- commercial success of VIMOVO and our other product candidates in the marketplace once approved;

- governmental regulation, including reimbursement policies;
- developments in patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- announcements by our collaborative partners regarding our products or product candidates;
- developments in new or pending litigation;
- public concern as to the safety and efficacy of our products; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these factors, including the sale or attempted sale of a large amount of our common stock into the market. From October 16, 2000, when our common stock began trading on The NASDAQ National Market (now known as The NASDAQ Global Market), through February 24, 2015, the high and low sales prices of our common stock ranged from $2.25 to $21.88. Broad market fluctuations may also adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock in the public market by us or our largest stockholders could depress our stock price.

We have not sold shares of common stock in a public offering since our initial public offering in October 2000. Accordingly, we have a relatively small number of shares that are traded in the market. Approximately 9% of our outstanding shares are beneficially held by John Plachetka, our President and Chief Executive Officer. Additionally, we believe, based upon our review of public filings by certain stockholders and other publicly available information, an aggregate of approximately 25% of our outstanding shares are held by three other stockholders, with one stockholder beneficially owning greater than 10% of our outstanding shares. Any sales of substantial amounts of our common stock in the public market, including sales or distributions of shares by our large stockholders, or the perception that such sales or distributions might occur, could harm the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, our executive officers may sell shares pursuant to Rule 10b5-1 trading plans. Further, stockholders' ownership will be diluted if we raise additional capital by issuing equity securities. We have filed with the Securities and Exchange Commission, and are seeking effectiveness of a shelf registration statement on Form S-3 under which we may offer up to and aggregate of 8,000,000 shares of our common stock for sale to the public in one or more public offerings. These shares will not be registered until this registration statement is declared effective by the Securities and Exchange Commission. The selling stockholder named in the prospectus for this registration statement may offer up to 500,000 shares of common stock, and we would not receive any of the proceeds from sales of those shares.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that our stockholders may favor and may prevent stockholders from changing the direction of our business or our management.

Provisions of our charter and bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares, and may also frustrate or prevent any attempt by stockholders to change the direction or management of POZEN. For example, these provisions:

- authorize the issuance of "blank check" preferred stock without any need for action by stockholders;
- provide for a classified board of directors with staggered three-year terms;
- require supermajority stockholder approval to effect various amendments to our charter and bylaws;
- eliminate the ability of stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Since March 2002, our corporate facilities have been located in 17,000 square feet in the Exchange Office Building in Chapel Hill, North Carolina under a lease commencing in March 2002 and expiring in 2010. We have exercised our option to renew this lease for an additional five year and seven month term, terminating on September 30, 2015, and we have an additional option to renew the extended term for one additional three year period. We believe that the Exchange Office Building facility is adequate for our current needs and that suitable additional or alternative space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

On March 14, 2011, we and AstraZeneca received a Paragraph IV Notice Letter from Dr. Reddy's informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent in 2023. The '907 patent is assigned to POZEN and listed with respect to VIMOVO in the Orange Book. On September 19, 2011, Dr. Reddy's amended its ANDA to include a Paragraph IV certification against the '504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent, which are assigned to AstraZeneca or its affiliates and listed in in the Orange Book, with respect to VIMOVO. The patents listed in the Orange Book which are owned by AstraZeneca or its affiliates expire at various times between 2014 and 2018. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Dr. Reddy's. Accordingly, we and AstraZeneca filed suit against Dr. Reddy's on April 21, 2011 in the United States District Court for the District of New Jersey, asserting only the '907 patent against Dr. Reddy's. An amended complaint was filed on October 28, 2011 to include the AstraZeneca patents. On December 19, 2012, the District Court conducted a pre-trial "Markman" hearing to determine claim construction. On May 1, 2012, the Court issued a Markman Order construing the claim terms disputed by the parties. On April 15, 2013 a Stipulation of Partial Dismissal was filed which sought dismissal of all infringement claims relating to the '504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent (which are each assigned to AstraZeneca), as well as Dr. Reddy's defenses and counterclaims relating to those patents. On April 18, 2013, the District Court issued a Stipulation and Order dismissing with prejudice those claims and defenses. The first Dr. Reddy's case is considered the lead case and has been consolidated with the actions described below for the purpose of pre-trial and discovery. A scheduling order for this case, and all of the consolidated cases, was issued by the Court on June 27, 2014. Fact discovery closed in the consolidated case on November 20, 2015. Expert discovery is ongoing and set to close May 21, 2015. In view of the upcoming retirement of presiding Judge Pisano, on February 9, 2015, the consolidated cases were reassigned to Judge Mary L. Cooper.

On June 13, 2011, we and AstraZeneca received a Paragraph IV Notice Letter from Lupin informing us that Lupin had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the POZEN and the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent and, each of which are assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Lupin's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Lupin and, accordingly, we and AstraZeneca filed suit against Lupin on July 25, 2011 in the United States District Court for the District of New Jersey. On November 19, 2014, an amended complaint was filed in which the 504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent, all assigned to AstraZeneca or its affiliates, were not asserted against Lupin. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On September 19, 2011, we and AstraZeneca AB received Paragraph IV Notice Letter from Anchen informing us that Anchen had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, the '085 patent, the '070 patent, and the '466 patent. The patents are among those listed with respect to VIMOVO in the Orange Book and expire at various times between 2018 and 2023. Anchen's Paragraph IV Notice Letter asserts that its generic product will not infringe those patents or that those patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Anchen and, accordingly, we and AstraZeneca filed suit against Anchen on October 28, 2011 in the United States District Court for the District of New Jersey. On October 4, 2013, Anchen filed an amendment to its ANDA seeking to change its Paragraph IV certification to a Paragraph III. It is unclear when or if the FDA will enter Anchen's amendment. On October 25, 2013, Anchen filed a Motion to Dismiss the case against it, based on its proposed re-certification. On November 18, 2013, we and AstraZeneca filed an Opposition to Anchen's Motion to Dismiss. On June 11, 2014, the Court granted Anchen's Motion and dismissed the case against them.

On November 20, 2012 we and AstraZeneca AB received a Paragraph IV Notice Letter from Dr. Reddy's, informing us that Dr. Reddy's had filed a second ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the POZEN and the 504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent and, each of which are assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Dr. Reddy's second

Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Dr. Reddy's on its second ANDA filing and, accordingly, we and AstraZeneca filed suit against Dr. Reddy's on January 4, 2013, in the United States District Court for the District of New Jersey. On April 15, 2013 a Stipulation of Partial Dismissal was filed which sought dismissal of all infringement claims relating to the '504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent (which are each assigned to AstraZeneca), as well as Dr. Reddy's defenses and counterclaims relating to those patents. On April 18, 2013, the District Court issued the Stipulation and Order dismissing with prejudice those claims and defenses. On June 28, 2013 we and AstraZeneca filed a Motion for Summary Judgment relating to the second ANDA filing asserting that U.S. Patent No. 6,926,907 is not invalid. On August 12, 2013, DRL filed an opposition to the Motion for Summary Judgment. On March 28, 2014, the District Court denied the Motion. On October 11, 2013, DRL filed a Motion for Summary Judgment asserting that the product which is the subject matter of its second ANDA does not infringe the '907 patent. On November 4, 2013, POZEN and AstraZeneca filed a Motion for an Order Denying DRL's Motion for Summary Judgment Pursuant to Rule 56(d) and an Opposition to DRL's Motion. On May 29, 2014, the Court issued an order denying DRL's Motion. This case was consolidated with the originally filed Dr. Reddy's case and is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On March 29, 2013, we and AstraZeneca received a Paragraph IV Notice Letter from Watson, now Actavis, informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the Company and the '504 patent, the '085 patent, the '424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Watson's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Watson. On May 10, 2013, we and AstraZeneca filed a patent infringement lawsuit against Watson in the U.S. District Court of New Jersey. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On May 16, 2013, POZEN and AstraZeneca AB received a Paragraph IV Notice Letter from Mylan informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the Company and the '504 patent, the '085 patent, the '424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Mylan's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Mylan. On June 28, 2013, we and AstraZeneca filed a patent infringement lawsuit against Mylan in the U.S. District Court of New Jersey. On February 13, 2015, the Court entered a joint stipulation of dismissal of counts related to certain patents, dismissing claims related to the '504 patent, the '085 patent, the '424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On October 15, 2013, the United States Patent Office issued the '285 patent. The '285 patent, entitled "Pharmaceutical compositions for the coordinated delivery of NSAIDs" and assigned to POZEN, is related to the '907 patent. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement of the '285 patent and, accordingly, on October 23, 2013, we, and AstraZeneca filed patent infringement lawsuits against DRL, Lupin, Watson and Mylan in the U.S. District Court of New Jersey alleging that their ANDA products infringe the '285 patent. On November 8, 2013, we, and AstraZeneca filed a Motion to Amend the Complaint in the actions against DRL, Lupin, Watson and Mylan or, in the alternative, to consolidate the actions involving the '285 patent with the existing consolidated action. DRL, Lupin, Watson and Mylan have each filed answers to the respective amended complaints, thus adding claims relating to the '285 patent against each of the Defendants to the consolidated case.

As part of Horizon's purchase of all of AstraZeneca's rights, title and interest to develop, commercialize and sell VIMOVO in the United States, Horizon has assumed AstraZeneca's right to lead the above-described Paragraph IV litigation relating to VIMIVO currently pending in the United States District Court for the District of New Jersey and has assumed patent-related defense costs relating to such litigation, including reimbursement up to specified amounts of the cost of any counsel retained by us. On December 12, 2013, Horizon filed Motions to Join under Fed.R.Civ.Proc. 25(c) as a co-plaintiff in each of the above referenced actions and the consolidated action. On January 31, 2014 and February 2, 2014, the Court granted Horizon's motions.

The filing of these patent infringement lawsuit within forty-five days of receipt of the Notice Letter from Dr. Reddy's, Lupin, Anchen, Watson and Mylan resulted in the FDA automatically instituting a stay, or bar, of approval of their respective ANDAs for up to 30 months or until a final court decision is entered in the infringement suit in favor of the defendants,

whichever occurs first. VIMOVO may be eligible for an additional six months of exclusivity upon the completion of certain pediatric studies.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Price of and Dividends on the Registrant's Common Equity

Our common stock began trading on the NASDAQ National Market (now known as the NASDAQ Global Market) under the symbol "POZN" on October 11, 2000. As of February 24, 2015, we estimate that we had approximately 71 stockholders of record and approximately 9,067 beneficial holders of the common stock.

The following table details the high and low sales prices for the common stock as reported by The NASDAQ Global Market for the periods indicated.

	Price Range	
2014 Fiscal Year	High	Low
First Quarter	$ 8.99	$ 7.37
Second Quarter	$ 9.73	$ 7.56
Third Quarter	$ 9.59	$ 5.96
Fourth Quarter	$ 9.71	$ 7.07

	Price Range	
2013 Fiscal Year	High	Low
First Quarter	$ 6.49	$ 5.02
Second Quarter	$ 5.56	$ 4.26
Third Quarter	$ 5.99	$ 4.92
Fourth Quarter	$ 9.90	$ 5.35

On February 24, 2015, the closing price for our common stock as reported by the NASDAQ Global Market was $7.23. In November 2013, we declared a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with a payment date of December 30, 2013. This distribution represented a surplus of corporate cash and was expected to be treated as a return of capital to stockholders. We paid no cash dividends in 2014 or 2012. Although we have no specific plans to pay cash dividends, we are committed to return as much cash to our stockholders as is prudent.

Equity Compensation Plans

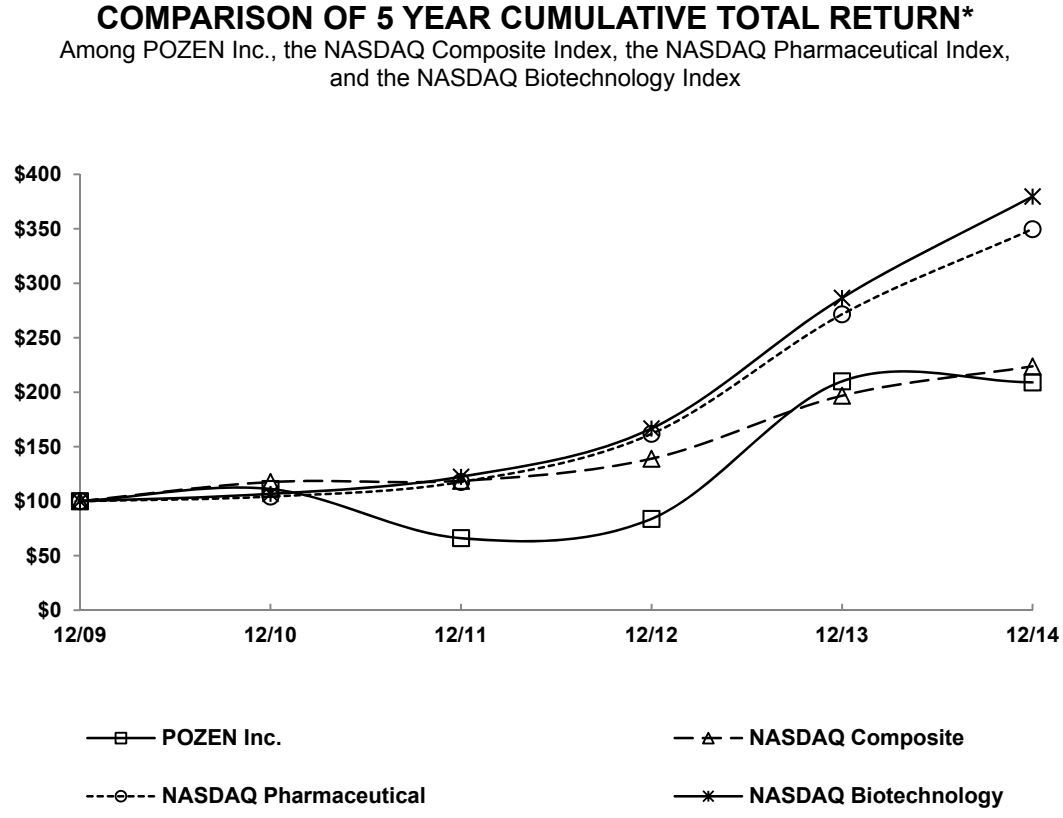
The following table provides information with respect to our compensation plans under which equity compensation is authorized as of December 31, 2014.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders[1]	2,709,162	$ 7.49	2,474,430
Equity compensation plans not approved by security holders	—	—	—
Total	2,709,162	$ 7.49	2,474,130

(1) Excludes 1,108,758 restricted stock units issued under our Equity Compensation Plans, as amended and restated.

Stock Performance Graph

The following graph compares the cumulative 5-Year total return to shareholders on POZEN Inc.'s common stock relative to the cumulative total returns of the NASDAQ Composite index, the NASDAQ Biotechnology index, and the NASDAQ Pharmaceutical index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from 12/31/2009 to 12/31/2014.



*$100 invested on 12/31/09 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

		12/09	12/10	12/11	12/12	12/13	12/14
POZEN Inc.		100.00	111.20	66.05	83.78	210.07	209.02
NASDAQ Composite		100.00	117.61	118.70	139.00	196.83	223.74
NASDAQ Pharmaceutical		100.00	104.24	117.69	161.80	271.53	349.75
NASDAQ Biotechnology		100.00	106.73	122.40	166.72	286.55	379.71

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Item 6. Selected Financial Data

The following selected financial data are derived from the financial statements of POZEN Inc., which have been audited by Ernst & Young LLP, independent registered public accounting firm. The data should be read in conjunction with the financial statements, related notes and other financial information included (and incorporated by reference) herein.

	For the Year Ended December 31,				
	2010	2011	2012	2013	2014
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue:					
Sale of royalty rights, net of costs	$ —	$ 71,870	$ —	$ —	$ —
Licensing revenue	68,417	15,081	5,349	10,322	32,394
Development revenue	132	—	—	—	—
Total revenue	68,549	86,951	5,349	10,322	32,394
Operating expenses:					
Sales, general and administrative	23,755	21,752	19,024	17,161	10,079
Research and development	22,651	23,020	11,867	9,945	5,740
Total operating expenses	46,406	44,772	30,891	27,106	15,819
Interest and other income	929	161	259	76	3,099
Net income (loss) attributable to common stockholders	$ 23,072	$ 42,340	$ (25,283)	$ (16,708)	$ 19,675
Basic net income (loss) per common share	$ 0.77	$ 1.41	$ (0.84)	$ (0.55)	$ 0.63
Shares used in computing basic net income (loss) per common share	29,880	29,925	30,092	30,450	31,360
Diluted net income per common share	$ 0.76	$ 1.40	$ (0.84)	$ (0.55)	$ 0.60
Shares used in computing diluted net income per common share	30,246	30,296	30,092	30,450	32,811

	December 31,				
	2010	2011	2012	2013	2014
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 64,091	$ 119,620	$ 87,314	$ 32,828	$ 40,582
Total assets	69,698	121,553	89,597	35,334	50,454
Total liabilities	9,070	16,055	5,519	17,546	3,713
Accumulated deficit	(116,927)	(74,588)	(99,871)	(116,579)	(96,904)
Total stockholders' equity	60,628	105,498	84,077	17,789	46,741

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

Overview

We are a pharmaceutical company focused on transforming medicines that can transform lives. We have operated a business model that has focused on the following:

- developing innovative products that address unmet medical needs in the marketplace;
- obtaining patents for those innovative ideas which we believe have value in the marketplace;
- utilizing a small group of talented employees to develop those ideas by working with strategic outsource partners;
- developing a regulatory pathway with the appropriate agency; and
- determining how best to commercialize our products.

We hire experts with strong project management skills in the specific disciplines we believe are important to maintain within our company. We contract with and manage strong outsource partners as we complete the necessary development work, permitting us to avoid incurring the cost of buying or building laboratories, manufacturing facilities or clinical research operation sites. This allows us to control our annual expenses, but to utilize "best in class" resources as required. We decided to retain ownership of our PA product candidates for cardiovascular indications which contain a combination of a proton pump inhibitor and enteric coated aspirin in a single tablet through the clinical development and pre-commercialization stage and our

chief commercial officer was responsible for developing the commercialization strategy for these products and conducting all the required pre-commercialization activities. On September 3, 2013 we entered into an exclusive license agreement with Sanofi US, for the commercialization of PA8140 and PA32540, now known as YOSPRALA™ 81/40 AND 325/40 (aspirin/omeprazole delayed release tablets). Under the terms of the agreement, Sanofi US will have exclusive rights to commercialize all PA combinations that contain 325 mg or less of enteric-coated aspirin in the United States. On April 25, 2014, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA in its current form. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. Satisfactory resolution of these deficiencies is required before the NDA may be approved. There were no clinical or safety deficiencies noted with respect to either PA8140 or PA32540 and no other deficiencies were noted in CRL. On June 30, 2014, we resubmitted the NDA for PA32540 and PA8140 to the FDA and the FDA notified us that the new action fee date is December 30, 2014. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. We continue to assist the FDA compliance division with their review. FDA regulations allow us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting, which was held in late January 2015. At the meeting, representatives from the FDA's Office of Compliance stated that the active ingredient supplier's responses to the 483 inspectional observations submitted in May 2014 were still under review, but that the review had been placed on a fast track and the Office of Compliance would be communicating with the supplier in the coming weeks. The active ingredient supplier has informed POZEN that they received a warning letter relating to the Form 483 inspection deficiencies. They are evaluating what additional corrective actions may be required to address the matters raised in the warning letter. We will continue to provide assistance to our active ingredient supplier in taking corrective actions to address the inspectional observations at its facility.

On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The termination agreement further provides for the transfer of specified commercial know-how developed by Sanofi US relating to the PA products to us and allows us, and any future collaborators, to use this know-how to commercialize the products. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products in the United States. In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

Our commercialization strategy for PA outside the United States is to secure relationships with one or more strong commercial partners with relevant expertise to commercialize our future products globally. With respect to future products we may develop, we have decided that we will no longer commit substantial resources to further drug development without a partner who agrees to pay the full cost of that development. Consistent with this model, we have reduced our R&D staff and other costs and expenses as our PA development program activities wind down and intend to continue to reduce staff that is no longer required to support our then current business activities. Our board of directors and management team continue to explore potential ways to return value to our stockholders. On November 21, 2013, our Board of Directors declared a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with a payment date of December 30, 2013. This distribution represented a surplus of corporate cash and is accounted for as a return of capital to stockholders. We are committed to return as much cash to our stockholders as is prudent and may consider other cash distributions in the future.

The success of our business is highly dependent on the marketplace value of our ideas and the related patents we obtain, our ability to obtain from the required regulatory agencies approval to sell the developed products and our ability to find strong commercial partners to successfully commercialize the products.

We have previously developed *Treximet*® in collaboration with GlaxoSmithKline, or GSK. *Treximet* is the brand name for the product combining sumatriptan 85 mg, formulated with RT Technology™ and naproxen sodium 500 mg in a single tablet designed for the acute treatment of migraine. On April 15, 2008, the U.S. Food and Drug Administration, or FDA, approved *Treximet* for the acute treatment of migraine attacks with or without aura in adults. Upon receipt of FDA approval, GSK notified us of its intention to launch the product and *Treximet* was available in pharmacies in May 2008.

On November 23, 2011, we entered into a purchase and sale agreement, or the Purchase Agreement, with CPPIB Credit Investments Inc. or CII, pursuant to which we sold, and CII purchased, our right to receive future royalty payments arising from U.S. sales of MT 400, including *Treximet*. Under the Purchase Agreement, we received $75 million and will receive a twenty percent (20%) interest in any royalties received by CII relating to the period commencing on April 1, 2018.

On May 13, 2014, we, Glaxo Group Limited, d/b/a GlaxoSmithKline, or GSK, CII and Pernix Therapeutics Holdings, Inc., or Pernix, entered into certain agreements in connection with GSK's divestiture of all of its rights, title and interest to develop, commercialize and sell *Treximet*® in the U.S. to Pernix. Upon the closing of the divestiture on August 20, 2014, GSK assigned the Product Development and Commercialization Agreement executed as of June 11, 2003 between us and GSK, the Treximet Agreement, to Pernix. Immediately following the closing of the divestiture, Amendment No. 1 to the Treximet Agreement, or Amendment No.1, between us and Pernix became effective. Amendment No. 1, among other things, amends the royalty provisions of the Agreement to provide for a guaranteed quarterly minimum royalty of $4 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018 and requires that Pernix continue certain of GSK's ongoing development activities and to undertake certain new activities, for which we will provide reasonable assistance. Amendment No. 1 also eliminates restrictions in the Agreement on our right to develop and commercialize certain dosage forms of sumatriptan/naproxen combinations outside of the United States and permits POZEN to seek approval for these combinations on the basis of the approved NDA for Treximet. Pernix has also issued us a warrant to purchase 500,000 shares of Pernix common stock at an exercise price equal to $4.28, the closing price of Pernix common stock as listed on the NASDAQ Global Market on May 13, 2014. The common stock underlying the warrants will be registered by Pernix with the Securities and Exchange Commission and the warrant is exercisable from August 20, 2014, the closing date of the Divestiture, until February 28, 2018. Because the warrant has not been registered by Pernix with the Securities and Exchange Commission, the Company cannot sell or transfer the warrant in reliance upon Rule 144 until after November 13, 2014 when the Company meets certain holding requirements. The warrant is valued using the Black-Scholes valuation model. Under the terms of the warrant, the Company may elect to receive the number of shares equal to the value of the Pernix shares less $4.28 divided by the fair market value of one share. At December 31, 2014, this would have been 272,098 shares valued at $2.6 million. Lastly, we, GSK, Pernix and CII executed a letter agreement whereby we expressly consented to the assignment by GSK and the assumption by Pernix of the Treximet Agreement. On July 30, the parties entered into Amendment No. 2 to the Treximet Agreement which will permit Pernix's Irish affiliate to which Pernix will assigns its rights to further assign the Agreement without our prior written consent as collateral security for the benefit of the lenders which financed the acquisition. Amendment No. 2 became effective upon the closing of the divestiture on August 20, 2014.

We have developed VIMOVO® with AstraZeneca AB, or AstraZeneca. VIMOVO (formerly referred to as PN 400) is the brand name for a proprietary fixed dose combination of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of osteoarthritis, or OA, rheumatoid arthritis, or RA, and ankylosing spondylitis, or AS, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

In August 2006, we entered into an exclusive global collaboration and license agreement with AstraZeneca to co-develop and commercialize VIMOVO, which agreement was amended in September 2007 and October 2008. We began the Phase 3 program in September 2007. As part of the program, we conducted two Phase 3 pivotal trials of VIMOVO in patients who are at risk for developing NSAID-associated gastric ulcers, the primary endpoint for which was the reduction in endoscopic gastric ulcers.

The NDA for VIMOVO was submitted on June 30, 2009 and was accepted for filing by FDA in August 2009. POZEN received a $10.0 million milestone payment from AstraZeneca in September 2009 for the achievement of such milestone. Earlier, in May 2010, we had received a $20.0 million milestone payment when we received FDA approval of VIMOVO. In October 2009, AstraZeneca submitted a Marketing Authorization Application, or MAA, for VIMOVO in the European Union, or EU, via the Decentralized Procedure, or DCP, and has filed for approval in a number of other countries which are not covered by the DCP. On October 11, 2010, we announced with AstraZeneca that VIMOVO had received positive agreement for approval in 23 countries across the EU following all 22 Concerned Member States agreeing with the assessment of the Netherlands Health Authority (MEB), acting as the Reference Member State for the DCP. We received a $25.0 million milestone payment when pricing and reimbursement for VIMOVO was granted in the United Kingdom. Other Member States and countries worldwide are now pursuing pricing and reimbursement and national approvals. As of December 2013, VIMOVO has been filed for regulatory approval in 81 countries, approved in 71 countries.

On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understand that

AstraZeneca will instead now focus on those countries where the product has shown growth and which AstraZeneca believes have the greatest potential for future growth.

On November 18, 2013, AstraZeneca and Horizon Pharma Inc., or "Horizon," entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. As required by the terms of our agreement with AstraZeneca, we gave our consent to AstraZeneca's divestiture of such rights to Horizon because we believed that Horizon's expertise in commercializing products for pain and inflammatory disease, including a similar combination product containing a NSAID and a gastroprotective agent, make it an excellent partner to maximize the potential of VIMOVO in the United States. We were also able to negotiate a guaranteed annual minimum royalty in the United States in the amount of $5 million in calendar year 2014, and a guaranteed annual minimum royalty amount of $7.5 million each calendar year thereafter, provided that the patents owned by us which cover VIMOVO are in effect and no generic forms of VIMOVO are in the marketplace.

On July 28, 2014, Horizon announced that it had been verbally notified by CVS Caremark and Express Scripts, Inc. that VIMOVO would no longer be on their formularies and will be placed on their exclusion lists effective January 1, 2015. We have been informed that Horizon estimates that approximately 20-30% of VIMOVO prescriptions could be impacted by these decisions. While Horizon believes it has a strategy to mitigate the effect on VIMOVO sales, POZEN's royalty revenue from Net Sales of VIMOVO beginning in 2015 may be negatively affected, although we will continue to receive a guaranteed annual minimum royalty of $7.5 million as described above.

Our PA product candidates, containing a PPI and aspirin, have completed clinical development testing in the United States. Our PA product candidates are excluded from our agreement with AstraZeneca. On September 3, 2013 we entered into a License and Collaboration Agreement with Sanofi US to commercialize our PA product candidates containing an immediate release proton pump inhibitor and 325 mg or less of delayed release or enteric coated aspirin in the United States.

We met with the FDA to discuss the overall development program requirements for PA32540 for the secondary prevention of cardiovascular and cerebrovascular disease in patients at risk for gastric ulcers. An investigational new drug application, or IND, was filed in the fourth quarter of 2007. We completed a study which demonstrated that the (SA) component of PA32540 was bioequivalent to the reference drug, EC aspirin. We filed a Special Protocol Assessment, or SPA, with the FDA for the design of the Phase 3 studies for the product, the primary endpoint for which is the reduction in the cumulative incidence of endoscopic gastric ulcers.

Based upon the FDA's earlier confirmation that endoscopic gastric ulcers were an acceptable primary endpoint, in October 2009, we began two pivotal Phase 3 and one long-term safety study for PA32540 for the cardiovascular indication. The primary endpoint of the pivotal studies, which included approximately 500 subjects per study, was a significant reduction in the cumulative incidence of gastric ulcers following administration of PA32540 vs. 325 mg enteric-coated aspirin over the six-month treatment period. The primary endpoint was met in both studies. Additionally, the studies met their key secondary endpoints, including a reduction in gastroduodenal ulceration as well as a reduction in discontinuation due to upper gastrointestinal adverse events in subjects taking PA32540 compared to 325 mg enteric-coated aspirin.

In February 2012, the FDA requested an additional Phase 1 study to assess the bioequivalence of PA32540 to EC aspirin 325 mg with respect to acetylsalicylic acid, or ASA. After the Company completed the requested bioequivalence study, the FDA made a preliminary review of the study results and the Company's summary analyses and, based on its preliminary assessment of the information available to it at the time, the FDA did not agree that bioequivalence of PA32540 to EC aspirin 325 mg was demonstrated. The Company then submitted to the FDA additional information and analyses from the requested bioequivalence study, as well as other relevant pharmacokinetic, clinical pharmacology, and in vitro dissolution data as a Briefing Document in support of a request for a Type A meeting with the FDA. At the Type A meeting held in August 2012, the FDA confirmed that, although it believes bioequivalence of PA32540 to EC aspirin 325 mg, was not strictly established in our bioequivalence study according to the predetermined criteria, the results from this study, together with additional information that will be submitted by the Company in the NDA, constitutes sufficient data to support the establishment of a clinical and pharmacological bridge between the product and EC aspirin 325 mg. The FDA indicated that it would make a final determination during the NDA review. The FDA also indicated that a similar strategy to bridge to the reference listed drug, inclusive of a new, single pharmacokinetic study, could be utilized for a low dose version of PA32540 (currently PA8140). The Company conducted this study with the low dose version against the EC aspirin 81mg. Based on the predetermined criteria acceptable to the FDA, the study demonstrated that PA8140 is bioequivalent to EC aspirin 81mg using criteria for highly variable drugs and had comparable bioavailability.

During a pre-submission meeting with respect to its NDA for PA32540 in April 2012, the FDA suggested that the Company also seek approval for a lower dose formulation of the product containing 81 mg of enteric coated aspirin as part of its NDA for PA32540. Absent the availability of such a lower dose formulation in the market if PA32540 is approved, the FDA

indicated that it may limit the indication for PA32540 to use in post coronary artery bypass graft surgery (CABG) with treatment duration not to exceed one year. During the Type A meeting held in August 2012, the FDA confirmed its preference to have both PA32540 and a lower dose version available in the market so that physicians can have both a low and high dose option available, and agreed that, if both dosage strengths were included in the NDA and subsequently approved, the indications for both will be consistent with the full range of indications described in the current aspirin monograph.

We had generated some clinical pharmacology data and chemical, manufacturing and controls (CMC) data for a product which contains 81 mg of enteric coated aspirin and 40 mg of omeprazole in a single tablet known as PA8140. The Company filed this existing data, together with additional CMC data to be generated and evidence from the scientific literature relating to the ulcerogenic risk of 81 mg of aspirin with the FDA. At this time, we do not intend to conduct Phase 3 clinical trials for PA8140. The data package submitted for PA8140 was similar to that used to gain approval for a lower dosage form of VIMOVO containing 375 mg of naproxen. We have no assurance such data will be sufficient for the FDA to approve PA8140 or to allow a broader indication for PA32540. The FDA will make a final determination with respect to the approvability of and indications for PA32540 and PA8140.

Generation of additional data with respect to PA8140 and incorporation of data into the NDA for PA32540 delayed submission of the NDA from the original planned submission date in the third quarter of 2012. The NDA was filed for both products in March 2013 and in May 2013 the FDA accepted the NDA for review. The FDA assigned a user fee date of January 24, 2014. As part of our continuing discussions with the FDA concerning the NDA for PA32540 and PA8140 tablets, we decided to conduct an additional comparative Phase 1 pharmacokinetic study to determine the pharmacokinetic profile of the omeprazole component of PA 8140 tablets and compare it to that of PA32540 tablets. We submitted study information and data to the FDA as it became available during the conduct of the study and FDA reviewed such information and data from the study when submitted. The final study report for the study was submitted to the FDA in accordance with our agreed timeline. FDA informed us that the Company's user fee date was April 25, 2014. On April 25, 2014, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA in its current form. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. Satisfactory resolution of these deficiencies is required before the NDA may be approved. There were no clinical or safety deficiencies noted with respect to either PA8140 or PA32540 and no other deficiencies were noted in CRL. On June 30, 2014, we resubmitted the NDA for PA32540 and PA8140 to the FDA and the FDA notified us that the new action fee date is December 30, 2014. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. We continue to assist the FDA compliance division with their review. FDA regulations allow us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting, which was held in late January 2015. At the meeting, representatives from the FDA's Office of Compliance stated that the active ingredient supplier's responses to the 483 inspectional observations submitted in May 2014 were still under review, but that the review had been placed on a fast track and the Office of Compliance would be communicating with the supplier in the coming weeks. The active ingredient supplier has informed POZEN that they received a warning letter relating to the Form 483 inspection deficiencies. They are evaluating what additional corrective actions may be required to address the matters raised in the warning letter. We will continue to provide assistance to our active ingredient supplier in taking corrective actions to address the inspectional observations at its facility.

To assess whether a similar interaction occurs between clopidogrel and PA32540, which contains immediate release omeprazole, we completed two Phase 1 drug-drug interaction studies to evaluate the ex-vivo platelet aggregation effects of PA32540 plus clopidogrel. In the first study, we evaluated ex-vivo platelet aggregation of PA32540 plus clopidogrel when dosed at the same time or dosed 10 hours apart compared to aspirin 325 mg plus clopidogrel dosed together. When PA32540 and clopidogrel were dosed together, data from the study showed a mean 36.7% platelet inhibition compared to a mean 44.0% platelet inhibition when aspirin and clopidogrel were dosed together suggesting a drug-drug interaction based on the study's pre-specified primary analysis. When PA32540 and clopidogrel were dosed 10 hours apart, data from the study indicate no ex-vivo drug-drug interaction based on the study's pre-specified primary analysis. In the second Phase 1 study, we evaluated ex-vivo platelet aggregation of PA32540 plus clopidogrel dosed 10 hour apart compared to a current standard of care of Plavix + Prilosec 40 mg + EC ASA 81 mg dosed together. Subjects on PA32450 demonstrated significantly greater inhibition of platelet aggregation than subjects on standard of care. The clinical relevance of these ex vivo platelet data on cardiovascular events is not known. No further Phase 1 studies on the clopidogrel-PPI interaction are planned. FDA assessment of available data on the drug-drug interaction may result in the inclusion of a warning, similar to that in the current Prilosec label, against the

concomitant use of PA32540 and Plavix. As part of the CRL, the FDA indicated that final agreement on the draft product labeling remains pending.

We are also continuing to evaluate how best to commercialize the PA product candidates and programs. We are evaluating the regulatory requirements to obtain an indication for PA for the secondary prevention of colorectal neoplasia. In January 2010, we received input from the FDA with respect to the development requirements for a possible indication in colorectal neoplasia. Further discussions are being considered. We are also evaluating the possibility of developing another dosage strength of PA containing 650 mg of enteric coated aspirin and 20 mg of omeprazole (PA65020) for the treatment of osteoarthritis and similar conditions and we met with the FDA in December 2010 to obtain input with respect to the regulatory requirements to obtain such an indication. The FDA advised us that we will need to demonstrate a reduction in gastric ulcers compared to aspirin alone in a replicate Phase 3 program similar to that we performed for VIMOVO, in addition to a study to establish efficacy of the product in the treatment of osteoarthritis.

We met with a European country that served as the reference member state for approval of VIMOVO in Europe to obtain guidance on a clinical development program for approval of PA65020 in the Europe. We were advised that Phase 3 endoscopic trials demonstrating a reduction in gastric ulcers would not be required in addition to an osteoarthritis efficacy study since omeprazole's actions on gastric ulcers has been well characterized. Instead, Phase 1 studies assessing pharmacokinetics and gastric acid suppression could be used to support the benefit of omeprazole as a component of PA65020.

We have also received Scientific Advice from the Medicines Evaluation Board, or MEB in the Netherlands, which has agreed to be the Reference Member State in a decentralized filing procedure, regarding the development program required for the approval in the European Union, or EU, of PA tablets, including a lower dosage form containing 100 mg of aspirin and 40 mg of omeprazole (PA10040) for the secondary prevention of cardiovascular disease. The MEB agreed that a full Phase 3 clinical development program for PA10040, to demonstrate the reduction of endoscopic gastric ulcers vs. EC aspirin, would not be necessary. Instead, a Phase 1 pharmacodynamic study comparing gastric pH control for PA10040 vs.EC omeprazole 20 mg, along with a study to demonstrate bioequivalence of PA10040 to a currently marketed EC aspirin product using ASA as the analyte would be sufficient. Study PA10040-101 demonstrated that PA10040 had comparable bioavailability and is bioequivalent to a European Union reference listed enteric coated aspirin 100 mg. Study PA10040-102 demonstrated that PA10040 provides gastric pH greater than 4 control for a percent time over 24 hours of 47%. Furthermore, compared to Losec 20 mg (EC omeprazole 20 mg), PA10040 produced a similar level of 24-hour pH control ((p=0.02).

A pre-submission follow up meeting with the MEB was held in July 2014. We proposed seeking approval of PA10040 only since the ASA component in that dosage form matches the clinical practice for use of ASA in the EU. Approval of PA10040 would be based on specific studies conducted with the product, as well as data from the entire PA program conducted in the United States. Based on discussions at the meeting, the MEB agreed that the MAA filing can proceed without any further clinical studies and that the Netherlands would be the lead country for the decentralized review process. The MEB also requested that a complete risk-benefit analysis of PA10040 for the intended cardiovascular patient population and proposed indication should be included as part of the MAA submission.

We have incurred significant losses since our inception and have not yet generated significant revenue from product sales. As of December 31, 2014, our accumulated deficit was approximately $96.9 million. We record revenue under the following categories: royalty revenues and licensing revenues. Our licensing revenues include upfront payments upon contract signing, additional payments if and when certain milestones in the product's development or commercialization are reached, while the royalty payments are based on product sales. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates and sales, general and administrative expenses. Research and development expenses include salaries and benefits for personnel involved in our research and development activities and direct development costs, which include costs relating to the formulation and manufacturing of our product candidates, costs relating to preclinical studies, including toxicology studies, and clinical trials, and costs relating to compliance with regulatory requirements applicable to the development of our product candidates. Since inception, our research and development expenses have represented approximately 64% of our total operating expenses. For the fiscal year ended December 31, 2014, our research and development expenses represented approximately 36% of our total operating expenses.

Operating losses may be incurred over the next several years as we complete the development and seek regulatory approval for our product candidates, develop other product candidates, conduct pre-commercialization activities, and acquire and/or develop product portfolios in other therapeutic areas. Our results may vary depending on many factors, including:

- The progress of our PA product candidates and our other product candidates in the clinical and regulatory process;

- The ability of Horizon and AstraZeneca to successfully commercialize VIMOVO in the United States and outside the United States, respectively, and our ability to successfully commercialize our PA product candidates in the United States;
- The establishment of new collaborations and progress and/or maintenance of our existing collaborations for the development and commercialization of any of our product candidates;
- Our ability to successfully defend our regulatory market exclusivity and patent rights against generic challenges and to succeed in obtaining extensions of such exclusivity for which we may be eligible;
- Our ability to commercialize our products with commercial partners in a highly regulated and extremely competitive marketplace; and
- The possible acquisition and/or in-licensing, and development of our therapeutic product candidates.

We do not currently have internal commercialization or manufacturing capabilities. We have entered into collaborations and may continue to enter into additional collaborations with established pharmaceutical or pharmaceutical services companies to commercialize and manufacture our product candidates once approved. We decided to retain control of our PA product candidates for cardiovascular indications through the clinical development and pre-commercialization stage. To that end, our chief commercial officer evaluated the commercial opportunities for these product candidates and developed a worldwide commercial strategy, which enabled us to conduct pre-commercialization activities prior to licensing these products to commercial partners. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products in the United States. In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

Our ability to generate revenue in the near term is dependent upon our ability, alone or with collaborators, to achieve the milestones set forth in our collaboration agreements, to enter into additional collaboration agreements, to successfully develop product candidates, to obtain regulatory approvals and to successfully manufacture and commercialize our future products. These milestones are earned when we have satisfied the criteria set out in our revenue recognition footnote accompanying the financial statements included elsewhere in this Annual Report on Form 10-K. These payments generate large non-recurring revenue that will cause large fluctuations in quarterly and annual profit and loss.

Status and Expenses Related to Our Approved Products and Product Candidates

There follows a brief discussion of the status of the development of our approved products and our product candidates, as well as the costs relating to our development activities. Our direct research and development expenses were $3.3 million for the fiscal year ended December 31, 2014, $6.6 million for the fiscal year ended December 31, 2013, and $7.5 million for the fiscal year ended December 31, 2012. Our research and development expenses that are not direct development costs consist of personnel and other research and development departmental costs and are not allocated by product candidate. We generally do not maintain records that allocate our employees' time by the projects on which they work and, therefore, are unable to identify costs related to the time that employees spend on research and development by product candidate. Total compensation and benefit costs for our personnel involved in research and development were $2.3 million for the fiscal year ended December 31, 2014, $3.1 million for the fiscal year ended December 31, 2013, and $3.9 million for the fiscal year ended December 31, 2012. Total compensation included $0.3 million, $0.8 million, and $0.5 million charge for non-cash compensation for stock option expense for the fiscal years ended December 31, 2014, December 31, 2013, and December 31, 2012, respectively. Other research and development department costs were $0.1 million, $0.2 million, and $0.5 million for the fiscal years ended December 31, 2014, December 31, 2013, and December 31, 2012, respectively.

Treximet. On April 15, 2008, the FDA approved *Treximet* for the acute treatment of migraine attacks with or without aura in adults. GSK notified us of its intention to launch the product and *Treximet* was available in pharmacies in May 2008. As part of our NDA program for *Treximet*, we conducted five Phase 1 trials, two Phase 3 pivotal trials, and one 12-month open label safety trial using a formulation of *Treximet* developed by GSK. The Phase 3 pivotal trials, including the endpoints required to evaluate *Treximet*, were designed to demonstrate superiority to placebo for relief of pain and the associated symptoms of migraine (nausea, photophobia and phonophobia) at two hours. Additionally, the program was designed to demonstrate that each component makes a contribution to the efficacy of *Treximet* (the "combination drug rule" that the FDA requires of all combination products). The efficacy endpoint for the combination was sustained pain free, which is defined as improvement from moderate or severe pain to no pain at two hours and remaining at no pain through twenty four hours without the use of rescue medicine. Further, GSK has conducted market support studies for *Treximet*, including evaluations in a pediatric population. As required by the terms of our agreement with GSK, we transferred ownership of the NDA and other regulatory filings for *Treximet* to GSK on May 14, 2008, and GSK took responsibility for all ongoing regulatory obligations for the product, including post marketing clinical trial requirements.

Since inception we have incurred total direct development costs of $26.5 million associated with the development of our MT 400 and *Treximet* programs. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

On November 23, 2011, we entered into the Purchase Agreement with CII, pursuant to which we sold, and CII purchased, our right to receive future royalty payments arising from U.S. sales of MT 400, including *Treximet*.

On March 21, 2011, we entered into a license agreement with Cilag GmbH International, or Cilag, a division of Johnson & Johnson, for the exclusive development and commercialization of MT 400 in Brazil, Colombia, Ecuador and Peru. On December 22, 2014, we entered into a mutual termination letter with Cilag. In accordance with the terms of the termination letter the agreement terminated on January 21, 2015. There was no dispute between the parties regarding the license agreement. At our request, for a period of two years after termination, Cilag has agreed to negotiate in good faith commercially reasonable terms of a supply agreement whereby Cilag would supply us or our licensees, with MT400 for a period equal to the shorter of (i) two (2) years; or (ii) until we establish an alternative supplier. We recognized approximately $257,300 in licensing revenue in the fourth quarter of as a result of this termination.

On May 13, 2014, we, GSK, CII and Pernix, entered into certain agreements in connection with GSK's divestiture of all of its rights, title and interest to develop, commercialize and sell *Treximet*® in the U.S. to Pernix. Upon the closing of the divestiture on August 20, 2014, GSK assigned the Treximet Agreement to Pernix. Immediately following the closing of the divestiture, Amendment No. 1 between us and Pernix became effective. Amendment No. 1, among other things, amends the royalty provisions of the Agreement to provide for a guaranteed quarterly minimum royalty of $4 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018 and requires that Pernix continue certain of GSK's ongoing development activities and to undertake certain new activities, for which we will provide reasonable assistance. Amendment No. 1 also eliminates restrictions in the Agreement on our right to develop and commercialize certain dosage forms of sumatriptan/naproxen combinations outside of the United States and permits POZEN to seek approval for these combinations on the basis of the approved NDA for Treximet. Pernix has also granted us a warrant to purchase 500,000 shares of Pernix common stock at an exercise price of $4.28, the closing price of Pernix common stock as reported on the NASDAQ Global Market on May 13, 2014. The common stock underlying the warrants will be registered by Pernix with the Securities and Exchange Commission and will be exercisable from August 20, 2014, the closing date of the divestiture until February 28, 2018. Lastly, we, GSK, Pernix and CII executed a letter agreement whereby we expressly consented to the assignment by GSK and the assumption by Pernix of the Treximet Agreement. On July 30, the parties entered into Amendment No. 2 to the Treximet Agreement which will permit Pernix's Irish affiliate to which Pernix will assign its rights to further assign the Agreement without our prior written consent as collateral security for the benefit of the lenders which financed the acquisition. Amendment No. 2 became effective upon closing of the divestiture on August 20, 2014.

PN/VIMOVO Program. Under our PN program, we completed formulation development and clinical studies for several combinations of a PPI and a NSAID in a single tablet intended to provide effective management of pain and inflammation associated with chronic conditions such as osteoarthritis, and intended to have fewer gastrointestinal complications compared to a NSAID taken alone in patients at risk for developing NSAID associated gastric ulcers. We entered into an exclusive ,worldwide (except for Japan) collaboration agreement with AstraZeneca on August 1, 2006 and which was amended in September 2007 and October 2008 relating to the development and commercialization of our PN products. Our agreement with AstraZeneca covered the development and commercialization of proprietary fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen in a single tablet. The initial product developed under the agreement, VIMOVO (formerly PN 400), was approved by the FDA on April 30, 2010 for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

The NDA for VIMOVO was submitted on June 30, 2009 and was accepted for filing in August 2009. We received a $10.0 million milestone payment from AstraZeneca in September 2009 for the achievement of such milestone. On April 30, 2010, VIMOVO was approved by FDA for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. We received a $20.0 million milestone payment from AstraZeneca in May 2010 in connection with such approval. As required by the terms of our agreement with AstraZeneca, we transferred ownership of the NDA and other regulatory filings for VIMOVO to AstraZeneca on June 1, 2010, and AstraZeneca now has responsibility for all ongoing regulatory obligations for the product in the U.S., including post marketing clinical trial requirements, in addition to responsibility for all regulatory obligations outside the U.S.

Under our agreement with AstraZeneca, AstraZeneca had responsibility for the development program for PN products outside the U.S., including interactions with regulatory agencies. In October 2009, AstraZeneca submitted a MAA for VIMOVO in the EU via the DCP and has filed for approval in a number of other countries which are not covered by the DCP.

On October 11, 2010, we announced with AstraZeneca that VIMOVO had received positive agreement for approval in 39 countries across the EU following all 22 Concerned Member States agreeing with the assessment of the Netherlands Health Authority, acting as the Reference Member State for the DCP. We received a $25.0 million milestone payment when pricing and reimbursement for VIMOVO was granted in the United Kingdom. Other Member States are now pursuing pricing and reimbursement and national approvals. Earlier, in May 2010, we had received a $20.0 million milestone payment when we received FDA approval of VIMOVO. As of the end of December 31, 2013, VIMOVO has been filed for regulatory approval in 81 countries and approved in 71 countries.

On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understand that AstraZeneca will instead now focus on those countries where the product has shown growth and which AstraZeneca believes have the greatest potential for future growth. We continue to assess the financial impact this decision will have on our royalty revenue. On November 18, 2013, AstraZeneca and Horizon entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. As required by the terms of our agreement with AstraZeneca, we gave our consent to AstraZeneca's divestiture of such rights to Horizon because we believed that Horizon's expertise in commercializing products for pain and inflammatory disease, including a similar combination product containing a NSAID and a gastroprotective agent, make it an excellent partner to maximize the potential of VIMOVO in the United States. We were also able to negotiate a guaranteed annual minimum royalty in the United States in the amount of $5.0 million in calendar year 2014, and a guaranteed annual minimum royalty amount of $7.5 million each calendar year thereafter, provided that the patents owned by us which cover VIMOVO are in effect and no generic forms of VIMOVO are in the marketplace. On July 28, 2014, Horizon announced that it had been verbally notified by CVS Caremark and Express Scripts, Inc. that VIMOVO would no longer be on their formularies and will be placed on their exclusion lists effective January 1, 2015. We have been informed that Horizon estimates that approximately 20-30% of VIMOVO prescriptions could be impacted by these decisions. While Horizon believes it has a strategy to mitigate the effect on VIMOVO sales, POZEN's royalty revenue from Net Sales of VIMOVO beginning in 2015 may be negatively affected, although we will continue to receive a guaranteed annual minimum royalty of $7.5 million as described above.

Since inception we have incurred total direct development cost of $96.2 million associated with the development of our PN program of which $57.1 million was funded by development revenue from AstraZeneca. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expense.

PA Program. As part of our PA program, we are developing a PPI and aspirin in a single tablet. Similar to the PN program, our PA product candidate is intended to induce fewer gastrointestinal complications compared to an aspirin taken alone in patients at risk for developing aspirin associated gastric ulcers. Our PA product candidates are covered under the same patent as PN, but we have retained all rights to this program through the clinical development and pre-commercialization stage. On September 3, 2013 we entered into a License and Collaboration Agreement with Sanofi US to commercialize our PA product candidates containing an immediate release proton pump inhibitor and 325 mg or less of delayed release or enteric coated aspirin in the United States. On April 25, 2014, we received a complete response letter, or CRL, from the FDA advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA in its current form. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. Satisfactory resolution of these deficiencies is required before the NDA may be approved. We believe that these manufacturing facility items can be addressed and will be working with the manufacturer to respond to the FDA as soon as possible. There were no clinical or safety deficiencies noted with respect to either PA8140 or PA32540 and no other deficiencies were noted in CRL. On June 30, 2014, we resubmitted the NDA for PA32540 and PA8140 to the FDA and the FDA notified us that the new action fee date is December 30, 2014. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. We continue to assist the FDA compliance division with their review. FDA regulations allow us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting, which was held in late January 2015. At the meeting, representatives from the FDA's Office of Compliance stated that the active ingredient supplier's responses to the 483 inspectional observations submitted in May 2014 were still under review, but that the review had been placed on a fast track and the Office of Compliance would be communicating with the supplier in the coming weeks. The active ingredient supplier has informed POZEN that they received a warning letter relating to the Form 483 inspection deficiencies. They are evaluating what additional corrective actions may be required to address the matters raised in the warning letter. We will continue to provide assistance to our active ingredient supplier in taking corrective actions to address the inspectional observations at its facility.

Our PA product candidates, PA32540 and PA8140, have completed clinical development testing in the United States. Based upon the FDA's earlier confirmation that endoscopic gastric ulcers were an acceptable primary endpoint, in October 2009, we began two pivotal Phase 3 and one long-term safety study for PA32540 for the cardiovascular indication. The primary endpoint was met in both studies. Additionally, the studies met their key secondary endpoints, including a reduction in gastroduodenal ulceration as well as a reduction in discontinuation due to upper gastrointestinal adverse events in subjects taking PA32540 compared to 325 mg enteric-coated aspirin.

In February 2012, the FDA requested an additional Phase 1 study to assess the bioequivalence of PA32540 to EC aspirin 325 mg with respect to acetylsalicylic acid, or ASA. After the Company completed the requested bioequivalence study, the FDA has made a preliminary review of the study results and the Company's summary analyses and, based on its preliminary assessment of the information available to it at the time, the FDA did not agree that bioequivalence of PA32540 to EC aspirin 325 mg was demonstrated. We then submitted to the FDA additional information and analyses from the requested bioequivalence study, as well as other relevant pharmacokinetic, clinical pharmacology, and in vitro dissolution data as a Briefing Document in support of a request for a Type A meeting with the FDA. At the Type A meeting held in August 2012, the FDA confirmed that, although it believes bioequivalence of PA32540 to EC aspirin 325 mg, was not strictly established in our bioequivalence study according to the predetermined criteria, the results from this study, together with additional information that will be submitted by us in the NDA, constitutes sufficient data to support the establishment of a clinical and pharmacological bridge between the product and EC aspirin 325 mg. The FDA indicated that it would make a final determination during the NDA review. FDA also indicated that a similar strategy to bridge to the reference listed drug, inclusive of a new, single pharmacokinetic study, could be utilized for a low dose version of PA32540 (PA8140). We have conducted this study with the low dose version against the EC aspirin 81 mg. Based on the predetermined criteria acceptable to the FDA, the study demonstrated that PA8140 is bioequivalent to EC aspirin using criteria for highly variable drugs and had comparable bioavailability.

During a pre-submission meeting with respect to its NDA for PA32540 in April 2012, the FDA suggested that the Company also seek approval for a lower dose formulation of the product containing 81 mg of enteric coated aspirin as part of its NDA for PA32540. We intended to seek an indication for the secondary prevention of cardiovascular disease in patients at risk for gastric ulcers. During the Type A meeting held in August 2012, the FDA has confirmed its preference to have both PA32540 and a lower dose version available in the market so that physicians can have both a low and high dose option available, and agreed that, if both dosage strengths were included in the NDA and subsequently approved, the indications for both will be consistent with the full range of indications described in the current aspirin monograph.

We had generated some clinical pharmacology data and chemical, manufacturing and controls, or CMC, data for a product which contains 81 mg of enteric coated aspirin and 40 mg of omeprazole in a single tablet known as PA8140. We filed this existing data, together with additional CMC data to be generated and evidence from the scientific literature relating to the ulcerogenic risk of 81 mg of aspirin with the FDA. At this time, the Company does not intend to conduct Phase 3 clinical trials for PA8140. The data package submitted for PA8140 was similar to that used to gain approval for a lower dosage form of VIMOVO containing 375 mg of naproxen. We have no assurance such data will be sufficient for the FDA to approve PA8140 or to allow a broader indication for PA32540. The FDA will make a final determination with respect to the approvability of and indications for PA32540 and PA8140.

Generation of additional data with respect to PA8140 and incorporation of data into the NDA for PA32540 delayed submission of the NDA from the original planned submission date in the third quarter of 2012. The NDA was filed for both products in March 2013 and in May 2013 the FDA accepted the NDA for review. The FDA assigned a user fee date of January 24, 2014. As part of our continuing discussions with the FDA concerning the NDA for PA32540 and PA8140 tablets, we decided to conduct an additional comparative Phase 1 pharmacokinetic study to determine the pharmacokinetic profile of the omeprazole component of PA8140 tablets and compare it to that of PA32540 tablets. We submitted study information and data to the FDA as it became available during the conduct of the study and FDA agreed to review such information and data from the study when submitted. The final study report for the study was submitted to the FDA in accordance with our agreed timeline. FDA has informed us that the Company's user fee date was April 25, 2014. On April 25, 2014, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, advising that the review of our NDA is completed and questions remain that preclude the approval of the NDA in its current form. Specifically, an inspection of the manufacturing facility of an active ingredient supplier of ours concluded with certain inspection deficiencies. Satisfactory resolution of these deficiencies is required before the NDA may be approved. There were no clinical or safety deficiencies noted with respect to either PA8140 or PA32540 and no other deficiencies were noted in CRL. On June 30, 2014, we resubmitted the NDA for PA32540 and PA8140 to the FDA and the FDA notified us that the new action fee date is December 30, 2014. On May 9, 2014, our active ingredient supplier submitted a response to the FDA addressing the inspection deficiencies and subsequently submitted an update to its initial response. On December 17, 2014, we received a second CRL from the FDA advising that the review of our NDA is completed and questions remain that preclude approval of the NDA in its

current form. In this CRL, the FDA used identical wording to that of the first CRL. Satisfactory resolution of these deficiencies is required before this application may be approved. There were no clinical or safety deficiencies noted with respect to either PA32540 and PA8140 and no other deficiencies were noted in the CRL. Final agreement on the draft product labeling is also pending. We continue to assist the FDA compliance division with their review. FDA regulations allow us to request a Type A meeting with the FDA to discuss the next steps required to gain approval of our NDA. The FDA granted the Type A meeting, which was held in late January 2015. At the meeting, representatives from the FDA's Office of Compliance stated that the active ingredient supplier's responses to the 483 inspectional observations submitted in May 2014 were still under review, but that the review had been placed on a fast track and the Office of Compliance would be communicating with the supplier in the coming weeks. The active ingredient supplier has informed POZEN that they received a warning letter relating to the Form 483 inspection deficiencies. They are evaluating what additional corrective actions may be required to address the matters raised in the warning letter. We will continue to provide assistance to our active ingredient supplier in taking corrective actions to address the inspectional observations at its facility.

We are also continuing to evaluate how best to commercialize the PA product candidates and programs. We are evaluating the regulatory requirements to obtain an indication for PA for the secondary prevention of colorectal neoplasia. In January 2010, we received input from the FDA with respect to the development requirements for a possible indication in colorectal neoplasia. Further discussions are being considered. We are also evaluating the possibility of developing another dosage strength of PA containing 650 mg of enteric coated aspirin and 20 mg of omeprazole (PA65020) for the treatment of osteoarthritis and similar conditions and we met with the FDA in December 2010 to obtain input with respect to the regulatory requirements to obtain such an indication. The FDA advised us that we will need to demonstrate a reduction in gastric ulcers compared to aspirin alone in a replicate Phase 3 program similar to that we performed for VIMOVO, in addition to a study to establish efficacy of the product in the treatment of osteoarthritis.

We recently met with a European country that served as the reference member state for approval of VIMOVO in Europe to obtain guidance on a clinical development program for approval of PA65020 in the Europe. We were advised that Phase 3 endoscopic trials demonstrating a reduction in gastric ulcers would not be required in addition to an osteoarthritis efficacy study since omeprazole's actions on gastric ulcers has been well characterized. Instead, Phase 1 studies assessing pharmacokinetics and gastric acid suppression could be used to support the benefit of omeprazole as a component of PA65020.

We have also received Scientific Advice from the Medicines Evaluation Board, or MEB in the Netherlands, which has agreed to be the Reference Member State in a decentralized filing procedure, regarding the development program required for the approval in the European Union, or EU, of PA tablets, including a lower dosage form containing 100 mg of aspirin and 40 mg of omeprazole (PA10040) for the secondary prevention of cardiovascular disease. The MEB agreed that a full Phase 3 clinical development program for PA10040, to demonstrate the reduction of endoscopic gastric ulcers vs. EC aspirin, would not be necessary. Instead, a Phase 1 pharmacodynamic study comparing gastric pH control for PA10040 vs.EC omeprazole 20 mg, along with a study to demonstrate bioequivalence of PA10040 to a currently marketed EC aspirin product using ASA as the analyte would be sufficient. Study PA10040-101 demonstrated that PA10040 had comparable bioavailability and is bioequivalent to a European Union reference listed enteric coated aspirin 100 mg. Study PA10040-102 demonstrated that PA10040 provides gastric pH greater than 4 control for a percent time over 24 hours of 47%. Furthermore, compared to Losec 20 mg (EC omeprazole 20 mg), PA10040 produced a similar level of 24-hour pH control ((p=0.02).

A pre-submission follow up meeting with the MEB was held in July 2014. We proposed seeking approval of PA10040 only since the ASA component in that dosage form matches the clinical practice for use of ASA in the EU. Approval of PA10040 would be based on specific studies conducted with the product, as well as data from the entire PA program conducted in the United States. Based on discussions at the meeting, the MEB agreed that the MAA filing can proceed without any further clinical studies and that the Netherlands would be the lead country for the decentralized review process. The MEB also requested that a complete risk-benefit analysis of PA10040 for the intended cardiovascular patient population and proposed indication should be included as part of the MAA submission.

We cannot reasonably estimate or know the amount or timing of the costs necessary to continue development and/or complete the development of any PA product candidates we may seek to develop or when, if and to what extent we will receive cash inflows from any PA products. The additional costs that may be incurred include expenses relating to clinical trials and other research and development activities and activities necessary to obtain regulatory approvals. We have refined our strategy and decided to retain control of our PA product candidates for cardiovascular indications through the clinical development and pre-commercialization stage and then seek strong commercial partners to maximize the potential of these product candidates. On September 3, 2013 we entered into a License and Collaboration Agreement with Sanofi US to commercialize our PA product candidates containing an immediate release proton pump inhibitor and 325 mg or less of delayed release or enteric coated aspirin in the United States. Even though the License and Collaboration Agreement was terminated on November 29, 2014, we believe we were able to negotiate more favorable terms with Sanofi U.S. for rights to commercialize the products in the United States than we had licensed the product candidates at an earlier stage in development and will be able to achieve

more favorable terms with other partners outside the United States if we are successful in licensing PA products in other territories in the future.

We have incurred direct development costs associated with the development of our PA program of $3.2 million during the fiscal year ended December 31, 2014. Since inception we incurred total direct development cost of $74.7 million associated with the development of our PA program. Our direct development costs do not include the cost of research and development personnel or any allocation of our overhead expenses.

Critical Accounting Policies and Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the U.S. in the preparation of our financial statements. The development and selection of the critical accounting policies, and the related disclosure about these policies, have been reviewed by the audit committee of our board of directors. We evaluate our estimates and judgments on an ongoing basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We have critical accounting estimates in the following policy areas: revenue recognition, accrued expenses, stock-based compensation, fair value measurements and income taxes.

Revenue Recognition

Revenue for the fiscal years ended December 31, 2014, 2013, and 2012 consisted of the following:

	For the year ended December 31,		
	2014	2013	2012
Royalty revenue	21,136,932	6,322,000	4,849,000
Other licensing revenue	11,257,300	4,000,000	500,000
Total licensing revenue	$ 32,394,232	$ 10,322,000	$ 5,349,000

With regard to royalty revenues, royalty revenue from VIMOVO (naproxen / esomeprazole magnesium) delayed release tablets is recognized when earned, as will any other future royalty revenues with respect to the manufacture, sale or use of the Company's products or technology. For VIMOVO or those future arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and reflects in future revenue any differences between the estimated and actual royalties. These estimates are based upon information reported to us by our collaboration partners. During the fiscal years ended December 31, 2014, 2013 and 2012, the Company recognized $21.1 million, $6.3 million, and $4.8 million for VIMOVO royalty revenue, respectively.

With regard to the licensing revenues, the Company's licensing agreements have terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product's development or commercialization are reached. When evaluating license agreements with multiple element deliverables, the Company considers whether the deliverables under the arrangement represent separate units of accounting. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The consideration received is allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria are applied to each of the separate units.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. If the milestones are deemed substantive and the milestone payments are nonrefundable, such milestone payments are recognized upon successful accomplishment of the milestones.

Accrued expenses, including contracted costs

Significant management judgments and estimates must be made and used in connection with accrued expenses, including those related to contract costs, such as costs associated with clinical trials. Specifically, the Company must make estimates of costs incurred to date but not yet paid for or not yet invoiced in relation to contracted, external costs. The

Company analyzes the progress of product development, clinical trial and related activities, invoices received, amounts paid, and budgeted costs when evaluating the adequacy of the accrued liability for these related costs.

The Company believes that its current assumptions and other considerations used to estimate accrued expenses for the period are appropriate. However, determining the date on which certain contract services commence, the extent of services performed on or before a given date and the cost of such, paid and unpaid, involves subjective judgments and estimates and often must be based upon information provided by third parties. In the event that management does not identify certain contract costs which have begun to be incurred or under- or over-estimates the extent of services performed or the costs of such services, management adjusts costs during the period in which the information becomes available.

Accrued costs related to product development and operating activities, including clinical trials, based upon the progress of these activities covered by the related contracts, invoices received and estimated costs totaled $0.3 million at December 31, 2014 and $1.7 million at December 31, 2013. The variance, at each of these ending periods, between the actual expenses incurred and the estimated expenses accrued was not material or significant.

Stock-based compensation

Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. We use the Black-Scholes model to value service condition and performance condition option awards. For awards with only service conditions and graded-vesting features, we recognize compensation cost on a straight-line basis over the requisite service period. For awards with performance conditions granted we recognize compensation cost over the expected period to achieve the performance conditions, provided achievement of the performance conditions are deemed probable.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates, and expected terms. Our expected volatility rate was estimated based on an equal weighting of the historical volatility of our common stock over a six year period. The expected term we use was estimated based on average historical terms to exercise. The risk-free interest rate is based on seven year U.S. Treasury securities.

Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

Fair Value Measurement

Financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable and accounts payable. The carrying values of these amounts, other than the investment in warrants, approximate the fair value due to their short-term nature.

A part of its acquisition of Treximet® (sumatriptan / naproxen sodium) from GlaxoSmithKline (GSK), Pernix Therapeutics Holdings, Inc. (Pernix) granted POZEN a warrant to purchase 500,000 shares of Pernix common stock at an exercise price of $4.28. The common stock underlying the warrants was registered by Pernix with the Securities and Exchange Commission and is exercisable from August 20, 2014, the closing date of the acquisition, until February 28, 2018. The warrant is valued at $2,678,773 using Black-Sholes valuation model discounted for the warrant's lack of marketability and liquidity.

Short-term investments gains consisted of the investment in warrants valuation of $2,740,800 on August 20, 2014, with a mark to market adjustment of ($62,027) at December 31, 2014 and a net December 31, 2014 short-term gain of $2,678,773.

The Company defines fair value ("FV") as the price that would be received to sell an asset or paid to transfer a liability ("the exit price") in an orderly transaction between market participants at the measurement date. The FV hierarchy for inputs maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. The Company uses the following hierarchy of inputs to measure FV:

- Level 1 - quoted prices in active markets for identical assets and liabilities.

- Level 2 - observable inputs other than quoted prices in active markets for identical assets and liabilities, including quoted prices in active markets for instruments that are similar or quoted prices in markets that are not active for identical or similar instruments and model-derived valuations in which all significant inputs and value drivers are observable in active markets.

- Level 3 - unobservable inputs that are significant to the overall valuation, for which there is little or no market data available and which require the Company to develop its own assumptions.

The Company values investments using the most observable inputs available that are current as of the measurement date and classifies them according to the lowest level of inputs used. Observable inputs are inputs that market participants would use in pricing the asset or liability developed from market data obtained from independent sources. Unobservable inputs are inputs that reflect the Company's judgment concerning the assumptions that market participants would use in pricing the asset or liability developed from the best information available under the circumstances.

The financial assets for which we perform recurring measurements are cash equivalents and investments in warrants. As of December 31, 2014, financial assets utilizing Level 1 inputs included cash equivalents. Financial assets utilizing Level 2 inputs included investments in warrants.

Fair value is a market-based measure considered from the perspective of a market participant who holds the asset or owes the liability rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date.

Our Level 1 valuations are based on the market approach and consist primarily of quoted prices for identical items on active securities exchanges. Our Level 2 valuations may also use the market approach and are based on significant other observable inputs such as quoted prices for financial instruments not traded on a daily basis. We did not rely on Level 3 input for valuation of our securities at December 31, 2014.

The following table sets forth our financial instruments carried at fair value within the fair value hierarchy and using the lowest level of input as of December 31, 2014:

	Financial Instruments Carried at Fair Value			
	Quoted prices in active Markets for identical items (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Cash and cash equivalents	$ 40,582,415	$ —	$ —	$ 40,582,415
Investment in warrants	—	2,678,773	—	2,678,773
Total cash and investments in warrants	$ 40,582,415	$ 2,678,773	$ —	$ 43,261,188

Income Taxes

We estimated an annual effective tax rate of 0% for the year ended December 31, 2014, and our effective tax rate was 0% for the fiscal year ended December 31, 2014. However, the actual effective rate may vary in the future depending upon actual licensing fees and milestone payments received, specifically the pre-tax book income for the year, and other factors. Income taxes have been accounted for using the liability method in accordance with FASB ASC 740. Since our inception, we have incurred substantial cumulative losses and may incur substantial and recurring losses in future periods. The utilization of these loss carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the loss carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership.

We currently file income tax returns in the U.S. federal jurisdiction, and the state of North Carolina. We are no longer subject to federal or North Carolina income tax examinations by tax authorities for years before 2010. However, the loss carryforwards generated prior to 2010 may still be subject to change, if we subsequently begin utilizing these losses in a year that is open under statute and subject to federal or North Carolina income tax examinations by tax authorities.

We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense. During the fiscal year ended December 31, 2014 and 2013, there were no such interest and penalties.

Historical Results of Operations

Year ended December 31, 2014 compared to the year ended December 31, 2013

Net income (loss) per share: Net income attributable to common stockholders for the fiscal year ended December 31, 2014 was $19.7 million, or $0.60 per share, on a diluted basis, as compared to a net loss of $(16.7) million, or $(0.55) per share, on a diluted basis, for the fiscal year ended December 31, 2013. The net income for the fiscal year ended December 31, 2014 included a $(1.9) million, or $(0.06) per share charge for non-cash stock-based compensation expense as compared to $(4.0) million, or $(0.13) per share for the same period of 2013.

Revenue: We recognized total revenue of $32.4 million for the fiscal year ended December 31, 2014 as compared to total revenue of $10.3 million for the fiscal year ended December 31, 2013. The increase in revenue was primarily due to an increase of $7.0 million in amortization of PA licensing revenue from receipt of $15.0 million upfront fee for the PA agreement with Sanofi US and the increase of $14.8 million in VIMOVO royalty. Revenue for the fiscal year ended December 31, 2014 consisted of $21.1 million of royalty revenue and $11.3 million of other licensing revenue compared to $6.3 million of royalty revenue and $4.0 million of other licensing revenue for 2013.

Research and development: Research and development expenses decreased by $4.2 million to $5.7 million for the fiscal year ended December 31, 2014, as compared to the same period of 2013. The decrease was due primarily to a decrease in direct development costs for our PA program including a $1.9 million FDA filing fee and departmental costs, as compared to the same period of 2013. Direct development costs for the PA program decreased by $3.3 million to $3.2 million, primarily due to the completion of the clinical trial activities and other product development activities during the fiscal year ended December 31, 2013. Other direct departmental costs and departmental expenses decreased by $0.9 million primarily due to decreased personnel costs, as compared to the same period of 2013. We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities and regulatory matters.

Sales, general and administrative: Sales, general and administrative expenses decreased by $7.1 million to $10.1 million for the fiscal year ended December 31, 2014, as compared to the same period of 2013. The decrease was due primarily to lower legal costs due to partial reimbursement by Horizon, decreased personnel costs, and lower market research and medical affairs costs as compared to the same period of 2013. Sales, general and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses, and public company activities.

Other income: Interest and bond amortization income was $43,100 and $138,900 for the fiscal years ended December 31, 2014 and 2013, respectively. Other income also included short-term investments gains consisting of the investment in warrants with an initial valuation of $2,740,800 on August 20, 2014, with a mark to market adjustment of ($62,027) at December 31, 2014 and a net of $377,269 related to the disgorgement of short-swing profits arising from trades by a POZEN shareholder under Section 16(b) of the Securities and Exchange Act of 1934.

Year ended December 31, 2013 compared to the year ended December 31, 2012

Net loss per share: Net loss attributable to common stockholders for the fiscal year ended December 31, 2013 was $(16.7) million, or $(0.55) per share, on a diluted basis, as compared to a net loss of $(25.3) million, or $(0.84) per share, on a diluted basis, for the fiscal year ended December 31, 2012. The net loss for the fiscal year ended December 31, 2013 included a $(4.0) million, or $(0.13) per share charge for non-cash stock-based compensation expense as compared to $(2.7) million, or $(0.09) per share for the same period of 2012.

Revenue: We recognized total revenue of $10.3 million for the fiscal year ended December 31, 2013 as compared to total revenue of $5.3 million for the fiscal year ended December 31, 2012. The increase in revenue was primarily due to an increase of $4.0 million in amortization of PA licensing revenue from receipt of $15.0 million upfront fee for the PA agreement with Sanofi US and the increase in VIMOVO royalty. Revenue for the fiscal year ended December 31, 2013 consisted of $6.3 million of royalty revenue and $4.0 million of other licensing revenue compared to $4.8 million of royalty revenue and $0.5 million of other licensing revenue for 2012.

Research and development: Research and development expenses decreased by $2.0 million to $9.9 million for the fiscal year ended December 31, 2013, as compared to the same period of 2012. The decrease was due primarily to a decrease in

direct development costs for our PA program and in departmental costs, as compared to the same period of 2012. Direct development costs for the PA program decreased by $0.9 million to $6.5 million, primarily due to the completion of the clinical trial activities and other product development activities during the fiscal year ended December 31, 2012. Other direct departmental costs and departmental expenses decreased by $1.1 million primarily due to decreased personnel costs, as compared to the same period of 2012. We have included in our research and development total expenses the departmental personnel costs associated with our research and development activities and direct costs associated with pharmaceutical development, clinical trials, toxicology activities and regulatory matters.

Sales, general and administrative: Sales, general and administrative expenses decreased by $1.8 million to $17.2 million for the fiscal year ended December 31, 2013, as compared to the same period of 2012. The decrease was due primarily to lower market research and medical affairs costs as compared to the same period of 2012. The decrease was partially offset by an increase of $1.4 million in legal costs for patent defense and general and administrative expenses. Sales, general and administrative expenses consisted primarily of the costs of administrative personnel, facility infrastructure, business development expenses, and public company activities.

Other income: Interest and bond amortization income was $0.1 million and $0.3 million for the fiscal years ended December 31, 2013 and 2012, respectively.

Income Taxes

At December 31, 2014 and 2013, the Company had federal net operating loss carryforwards of approximately $53 million and $66.8 million respectively, state net economic loss carryforwards of approximately $78 million and $82.9 million respectively, and research and development credit carryforwards of approximately $14 million and $14 million, respectively. The federal and state net operating loss carryforwards begin to expire in 2028 and 2015, respectively, and the research and development credit carryforwards begin to expire in 2018. For financial reporting purposes, a valuation allowance has been recognized to offset the deferred tax assets related to the carryforwards, based on the Company's assessment regarding the realizability of these deferred tax assets in future periods. Of the total decrease in valuation allowance of $7.3 million, a decrease of $7.3 million was allocable to current operating activities. The utilization of the loss carryforwards to reduce future income taxes will depend on the Company’s ability to generate sufficient taxable income prior to the expiration of the loss carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership. The recognized tax benefit related to net operating loss carryforwards was approximately $4.8M, $0, and $0 for the years ended December 31, 2014, 2013 and 2012, respectively.

Liquidity and Capital Resources

At December 31, 2014, cash, cash equivalents and investments in warrants totaled $43.3 million, an increase of $10.4 million compared to December 31, 2013. The $10.4 million increase in cash and investments resulted from $17.7 million in operating expenses, offset by the receipt of approximately $17.2 million in VIMOVO royalty payments, $8.2 million from equity exercises and $2.7 million investment in Pernix warrants. Our cash is invested in money market funds that invest primarily in commercial paper and certificates of deposit guaranteed by banks.

We received $17.2 million in operating cash during the fiscal year ended December 31, 2014 pursuant to the terms of our collaboration agreements with AstraZeneca, Sanofi US and Horizon. In addition, our balance sheet included a $5.6 million accounts receivable for royalties under the AstraZeneca and Horizon agreements.

Based upon the indirect method of presenting cash flow, cash provided by operating activities totaled $0.4 million and cash used in operating activities totaled $0.9 million for the fiscal years ended December 31, 2014 and December 31, 2013, respectively. Net cash used in investing activities totaled less than $0.1 million during the fiscal year ended December 31, 2014 and net cash provided by investing activities during the year ended December 31, 2013 totaled $18.8 million reflecting investing activities associated with the purchase and sale of short-term investments. Net cash provided by financing activities during the fiscal year ended December 31, 2014 totaled $7.4 million and net cash used in financing activities totaled $53.5 million for the fiscal year ended December 31, 2013. Cash required for our operating activities during 2015 is projected to decrease from our 2014 requirements as a result of decreased development activities but may increase if we elect to undertake increased pre-commercialization activities. During the fiscal years ended December 31, 2014 and December 31, 2013 we recorded non-cash stock-based compensation expense of $1.9 million and $4.0 million, respectively, associated with the grant of stock options and restricted stock units.

As of December 31, 2014, we had $40.6 million in cash and cash equivalents. We believe that we will have sufficient cash reserves and cash flow to maintain our planned level of business activities, through 2015 and beyond. However, our

anticipated cash flow includes continued receipt of royalty revenue from Horizon and AstraZeneca's sale of VIMOVO. In addition, our expenses might increase during that period beyond currently expected levels if we decide to, or any regulatory agency requires us to, conduct additional clinical trials, studies or investigations for any of our product candidates, including in connection with the agency's consideration, or reconsideration, of our regulatory filings for our product candidates. Our decision to make a cash distribution in December 2013, resulted from the determination that we had surplus corporate cash, based on the decision not to undertake future development programs without a partner. We believe we have retained sufficient cash to fund our expected activities for the next several years.

As part of our ongoing assessment of our business and liquidity needs, we regularly assess available funding options and will consider available funding opportunities as they arise. We consider our current royalty stream as cash assets that could be monetized to accelerate the expected cash flow. We also could sell shares of common stock in the future to fund additional development or pre-commercialization activities and increase our working capital. We have filed with the Securities and Exchange Commission, or SEC, and are seeking effectiveness of a shelf registration statement on Form S-3 under which we may offer up to 8,500,000 shares of our common stock for sale in one or more public offerings. These shares will not be registered until this registration statement is declared effective by the SEC. John R. Plachetka, selling stockholder named in the prospectus for the registration statement, may offer up to an aggregate of 500,000 of such shares, and we will not receive any of the proceeds from the sales of shares made by the selling stockholder. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

Our forecast of the period of time through which we expect that our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary as a result of a number of factors. Our future capital requirements will depend on many factors, including:

- the number and progress of our clinical trials and other trials and studies;
- our success, or any delays, in obtaining, regulatory approval of our product candidates and success in, and manner of, commercializing our products;
- the success of our existing collaborations and our ability to establish additional collaborations;
- the extent to which we acquire or invest in businesses, technologies or products;
- costs incurred to enforce and defend our patent claims and other intellectual rights; and
- costs incurred in the defense of our VIMOVO patent against generic companies that have filed ANDAs with the FDA to market the product prior to the expiration of our and AstraZeneca's patents.

Obligations and Commitments

The following summarizes our contractual obligations as of December 31, 2014, and the expected timing of maturities of those contractual obligations. This table should be read in conjunction with the notes accompanying our financial statements included elsewhere in this Annual Report on Form 10-K.

	Payments Due by Period			
Contractual Obligations	**Total**	**2015**	**2016**	**2017-after**
		($ in thousands)		
Operating leases[1]	$ 375	$ 375	$ —	$ —
Product development agreements[2]	1,796	1,668	128	—
Total contractual obligations	$ 2,171	$ 2,043	$ 128	$ —

[1] These commitments are associated with operating leases. Payments due reflect fixed rent expense.

[2] Amounts represent open purchase orders for ongoing pharmaceutical development activities for our product candidates as of December 31, 2014. These agreements may be terminated by us at any time without incurring a termination fee.

New Accounting Pronouncements

Revenue from Contracts with Customers

In May 2014, the FASB issued new accounting rules related to revenue recognition for contracts with customers requiring revenue recognition based on the transfer of promised goods or services to customers in an amount that reflects consideration the Company expects to be entitled to in exchange for goods or services. The new rules supersede prior revenue recognition requirements and most industry-specific accounting guidance. The new rules will be effective for the Company in the first quarter of 2017 with Full retrospective and modified retrospective application provided. The Company does not expect

the adoption of the new accounting rules to have a material impact on the Company's financial condition, results of operations or cash flows.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The proceeds from revenue from our collaboration agreements have been invested in money market funds that invest primarily in short-term, highly-rated investments, including U.S. Government securities, commercial paper and certificates of deposit guaranteed by banks and short-term corporate fixed income obligations and U.S. Government and Government agency obligations. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Because of the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio.

Item 8. Financial Statements and Supplementary Data

Our financial statements and notes thereto are included elsewhere in this Annual Report on Form 10-K and incorporated herein by reference. See Item 15 of Part IV.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

The Company maintains disclosure controls and procedures designed to ensure information required to be disclosed in Company reports filed under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in Company reports filed under the Exchange Act is accumulated and communicated to management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Our management's report on internal control over financial reporting procedures (as defined in Rule 13a-15(f) under the Exchange Act) is included with the financial statements reflected in Item 8 of this Annual Report on Form 10-K and is incorporated herein by reference.

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Information required to be disclosed by this Item with respect to our executive officers is set forth under the caption "Officers and Key Employees" contained in Part I, Item 1of this Annual Report on Form 10-K.

Information required to be disclosed by this Item about our board of directors is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Nomination and Election of Directors" contained in our definitive proxy statement for our 2015 annual meeting of stockholders scheduled to be held on June 10, 2015, which we intend to file within 120 days of the end of our fiscal year.

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our definitive proxy statement for our 2015 annual meeting of stockholders scheduled to be held on June 10, 2015, which we intend to file within 120 days of the end of our fiscal year.

Information required to be disclosed by this Item about our board of directors, the audit committee of our board of directors, our audit committee financial expert, our Code of Business Conduct and Ethics, and other corporate governance matters is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Board of Directors and Corporate Governance Matters" contained in our definitive proxy statement related to our 2015 annual meeting of stockholders scheduled to be held on June 10, 2015, which we intend to file within 120 days of the end of our fiscal year.

The text of our Code of Business Conduct and Ethics, which applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) is posted in the "Corporate Governance" section of our website, www.POZEN.com. A copy of the Code of Business Conduct and Ethics can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and The NASDAQ Stock Market.

Item 11. Executive Compensation

Information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the sections entitled "Compensation for Executive Officers and Directors" and "Board of Directors and Corporate Governance Matters" contained in our definitive proxy statement for our 2015 annual meeting of stockholders scheduled to be held on June 10, 2015, which we intend to file within 120 days of the end of our fiscal year.

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

Information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the sections entitled "Principal Stockholders," "Stock Ownership of Directors, Nominees for Director, and Executive Officers" and "Compensation for Executive Officers and Directors" contained in our definitive proxy statement for our 2015 annual meeting of stockholders scheduled to be held on June 10, 2015, which we intend to file within 120 days of the end of our fiscal year.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section(s) entitled "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance Matters," "Compensation for Executive Officers and Directors, "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" contained in our definitive proxy statement for our 2015 annual meeting of stockholders scheduled to be held on June 10, 2015, which we intend to file within 120 days of the end of our fiscal year.

Item 14. Principal Accounting Fees and Services

This information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the section entitled "Audit and Other Fees" contained in our definitive proxy statement for our 2014 annual meeting of stockholders scheduled to be held on June 10, 2015, which we intend to file within 120 days of the end of our fiscal year.

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(a) Financial Statements and Schedules:

1. Financial Statements

The following financial statements and reports of independent registered public accounting firm are included herein:

2. Financial Statement Schedules

Not applicable.

3. List of Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant.*
3.2	Second Amended and Restated Bylaws of POZEN Inc., approved September 19, 2007 (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 20, 2007).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
4.1	See Exhibits 3.1, 3.2 and 3.3 for provisions of the Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws of the Registrant defining rights of the holders of Common Stock and Series A Junior Participating Preferred Stock of the Registrant.
4.2	Rights Agreement dated January 12, 2005 between Registrant and StockTrans, Inc. (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
10.1	Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 16, 2006).***
10.2	First Amendment to Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.3	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.4	First Amendment to Executive Employment Agreement with John E. Barnhardt, dated September 28, 2007 (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.5	Executive Employment Agreement with William L. Hodges dated August 3, 2004 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed October 27, 2004).***
10.6	First Amendment to Executive Employment Agreement with William L. Hodges, dated September 28, 2007 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.7	POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.8	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***

Exhibit No.	Description
10.9	Summary of Non-Employee Director Compensation (filed as Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed March 8, 2007).***
10.10	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed April 1, 2002).
10.11	Product Development and Commercialization Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Form 10-Q/A filed November 8. 2004).†
10.12	License Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.13	Collaboration and License Agreement dated September 3, 2003 between the Registrant and Valeant Pharmaceuticals NA (formerly Xcel Pharmaceuticals, Inc.) (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 6, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.14	Restricted Stock Unit Agreement dated May 4, 2004 between Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed July 30, 2004).***
10.15	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated May 4, 2004, between Registrant and John R. Plachetka (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.16	Form of Non-Qualified Stock Option Agreement for Trexima grants issued pursuant Registrant's Equity Compensation Plan, as amended and restated (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 7, 2005).***
10.17	Development, Option and License Agreement dated May 15, 2003 between the Registrant and Nycomed Danmark ApS (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 28, 2005, and Current Report on Form 8-K/A filed January 10, 2006).†
10.18	Collaboration and License Agreement dated August 1, 2006 between the Registrant and AstraZeneca AB (filed as Exhibit 10.1 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.19	Amendment No. 1 to the Collaboration and License Agreement, dated September 6, 2007, between the Registrant and AstraZeneca AB (filed as Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007). †
10.20	Side Letter dated September 19, 2006 Re: Collaboration and License Agreement dated as of August 1, 2006 by and between the Registrant and AstraZeneca AB (filed as 10.2 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.21	Side Letter Agreement, dated October 1, 2007, between the Registrant and AstraZeneca, AB (filed as Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007). †
10.22	Long-Term Cash Incentive Award Agreement between the Registrant and John R. Plachetka dated February 14, 2007 (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.23	First Amendment to Long Term Incentive Cash Award Agreement, dated September 28, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.24	Restricted Stock Unit Agreement with John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.25	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated February 14, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.26	Nonqualified Stock Option Grant issued to John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.27	Form of Nonqualified Stock Option Agreement for PN 400 Incentive Program under Second Amended and Restated 200 Equity Compensation Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 8, 2008).***

Exhibit No.	Description
10.28	Amendment No. 2 to the Collaboration and License Agreement, dated October 1, 2008, between the registrant and AstraZeneca, AB (filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed November 4, 2008). †
10.29	Lease Modification Agreement No. 1, dated as of February 16, 2009, by and between the Registrant and The Exchange at Meadowmont LLC (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 17, 2009).
10.30	Executive Employment Agreement, dated as of December 10, 2009, between the Company and John G. Fort, M.D. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 11, 2009).***
10.31	POZEN Inc. 2010 Omnibus Equity Compensation Plan (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 5, 2010).***
10.32	License Agreement, dated as of March 21, 2012, by and between POZEN Inc. and Cilag GmbH International (filed as Exhibit 10.1 to the Registrants Quarterly Report on Form 10-Q on March 5, 2011).†
10.33	Purchase and Sale Agreement, dates as November 23, 2011, by and between POZEN Inc. and CPPIB Credit Investments Inc. (filed as Exhibit 10.37 to the Registrants Annual Report on Form 10-K filed March 9. 2012).
10.34	Manufacturing Services Agreement, dates as December 19, 2011, by and between POZEN Inc. and Patheon Pharmaceuticals, Inc.†(filed as Exhibit 10.38 to the Registrants Amendment No.1 to the Annual Report on Form 10-K, filed June 29,2012).
10.35	Capital Expenditure and Equipment Agreement, dates as of December 19, 2011, by and between POZEN Inc. and Patheon Pharmaceuticals, Inc. (filed is Exhibit 10.39 to the Registrants Amendment No.11 to Annual Report on Form 10-K, filed June 29,2012).
10.36	First Amendment to Manufacturing Services Agreement, between Patheon Pharmaceuticals Inc., and POZEN Inc., dated as of July 10, 2013 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†
10.37	First Amendment to Capital Expenditure and Equipment Agreement, between Patheon Pharmaceuticals Inc., and POZEN Inc., dated as of July 10, 2013 (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†
10.38	License and Development Agreement, dated as of May 7, 2012, by and between POZEN Inc. and DESITIN Arzneimittel GmbH (filed as Exhibit 10.1 to Registrants Quarterly Report on Form 10-Q, filed on August 8, 2012).
10.39	Amendment No. 3 to the Collaboration and License Agreement between POZEN Inc. and AstraZeneca AB, dated as of September 16, 2013 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†
10.40	License and Collaboration Agreement between POZEN Inc. and sanofi-aventis U.S. LLC, dated as of September 3, 2013 (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†
10.41	Letter Agreement among POZEN Inc., AstraZeneca AB and Horizon Pharma U.S.A. Inc. dated as of November 18, 2013 (filed as Exhibit 10.43 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.42	Amendment No. 1 to Amended and Restated Collaboration and License Agreement for the United States by and between POZEN Inc. and Horizon Pharma U.S.A. Inc. dated as of November 18, 2013 (filed as Exhibit 10.44 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.43	Amended and Restated Collaboration and License Agreement for the United States by and between POZEN Inc. and AstraZeneca AB dated as of November 18, 2013 (filed as Exhibit 10.45 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.44	Amended and Restated Collaboration and License Agreement for outside of the United States by and between POZEN Inc. and AstraZeneca AB dated as of November 18, 2013 (filed as Exhibit 10.46 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.45	Letter Agreement, dated as of May 13, 2014, by and among POZEN Inc., CPPIB Credit Investments, Inc. Pernix Therapeutics Holdings, Inc. and Glaxo Group Limited (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 6, 2014).
10.46	First Amendment to Product Development and Commercialization Agreement, dated as of May 13, 2014, by and between POZEN Inc. and Pernix Therapeutics Holdings, Inc. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed November 6, 2014).
10.47	Second Amendment to Product Development and Commercialization Agreement dated as of July 30,

Exhibit No.	Description
	2014, by and between POZEN Inc. and Pernix Therapeutics Holdings, Inc. (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed November 6, 2014).
10.48	Termination Agreement, dated as of November 29, 2014, by and between POZEN Inc. and sanofi-aventis U.S. LLC.**
10.49	Termination Agreement, dated as of December 22, 2014, by and between POZEN Inc. and Cilag GmbH International ("Cilag"), a division of Johnson & Johnson. **
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.**
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
101	The following materials from POZEN Inc. Form 10-K for the fiscal year ended December 31, 2014, formatted in Extensible Business Reporting Language (XBRL): (1) Balance Sheets at December 31, 2014 and December 31, 2013, (iii) Statements and operations for the year ended December 31, 2014 and December 31, 2013, (iii) Statements and Cash Flows for the years ended December 31, 2014 and December 31, 2013, and (iv) Notes to the Financial Statements.

* Incorporated by reference to the same-numbered exhibit of the Registrant's Registration Statement on Form S-1, No. 333-35930.

** Filed herewith.

*** Compensation Related Contract.

† Confidential treatment requested. Confidential materials omitted and filed separately with Securities and Exchange Commission.

SIGNATURES

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

Registrant:

POZEN Inc.

Date: March 11, 2015

By: /s/ John R. Plachetka
John R. Plachetka
Chief Executive Officer

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

Signature	Title	Date
/s/ John R. Plachetka John R. Plachetka	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 11, 2015
/s/ William L. Hodges William L. Hodges	Senior Vice President, Finance and Administration and Chief Financial Officer (Principal Financial Officer)	March 11, 2015
/s/ John E. Barnhardt John E. Barnhardt	Vice President, Finance and Administration (Principal Accounting Officer)	March 11, 2015
/s/ Neal F. Fowler Neal F. Fowler	Director	March 11, 2015
/s/ Arthur S. Kirsch Arthur S. Kirsch	Director	March 11, 2015
/s/ Kenneth B. Lee, Jr. Kenneth B. Lee Jr.	Director	March 11, 2015
/s/ Seth A. Rudnick Seth A. Rudnick	Director	March 11, 2015

POZEN Inc.

Audited Financial Statements

Contents

Management's Report on Internal Control Over Financial Reporting

Management of POZEN Inc. (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, 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 accounting principles generally accepted in the United States. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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. Further, because of changes in conditions, effectiveness of internal control over financial reporting may vary over time. Management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the Company's internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (COSO). As a result of this assessment and based on the criteria in the COSO framework, management has concluded that, as of December 31, 2014, the Company's internal control over financial reporting was effective.

Ernst & Young LLP, the independent registered public accounting firm that audited the Company's financial statements included in this Annual Report on Form 10-K, has issued an attestation report on the Company's internal control over financial reporting, which is included herein.

/s/ John R. Plachetka	/s/ William L. Hodges
Chairman, Chief Executive Officer	Chief Financial Officer
March 11, 2015	March 11, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of POZEN Inc.

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

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 financial position of POZEN Inc. at December 31, 2014 and 2013, and the 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), POZEN 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

Raleigh, North Carolina
March 11, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of POZEN, Inc.

We have audited POZEN Inc. 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). POZEN 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, POZEN 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 balance sheets of POZEN Inc. as of December 31, 2014 and 2013 and the related statements of comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2014 and our report March 12, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Raleigh, North Carolina
March 11, 2015

POZEN Inc.

Balance Sheets

	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 40,582,415	$ 32,827,732
Investments in warrants	2,678,773	—
Accounts receivable	5,629,209	1,673,000
Prepaid expenses and other current assets	583,061	794,665
Total current assets	49,473,458	35,295,397
Property and equipment, net of accumulated depreciation	27,382	38,979
Noncurrent deferred tax asset	952,900	—
Total assets	$ 50,453,740	$ 35,334,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 606,948	$ 1,500,671
Accrued compensation	1,899,456	3,132,468
Accrued expenses	253,624	1,655,212
Deferred revenue	—	11,257,300
Current deferred tax liability	952,900	—
Total current liabilities	3,712,928	17,545,651
Preferred stock, $0.001 par value; 10,000,000 shares authorized, issuable in series, of which 90,000 shares are designated Series A Junior Participating Preferred Stock, none outstanding	—	—
Common stock, $0.001 par value, 90,000,000 shares authorized; 32,221,397 and 30,677,437 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively	32,221	30,677
Additional paid-in capital	143,613,024	134,337,213
Accumulated deficit	(96,904,433)	(116,579,165)
Total stockholders' equity	46,740,812	17,788,725
Total liabilities and stockholders' equity	$ 50,453,740	$ 35,334,376

See accompanying Notes to Financial Statements.

POZEN Inc.

Statements of Comprehensive Income (Loss)

	Year ended December 31,		
	2014	2013	2012
Royalty and licensing revenue:	$ 32,394,232	$ 10,322,000	$ 5,349,000
Operating expenses:			
Sales, general and administrative	10,078,771	17,160,810	19,024,164
Research and development	5,739,848	9,945,049	11,866,554
Total operating expenses	15,818,619	27,105,859	30,890,718
Interest and other income	3,099,119	75,560	258,697
Net income (loss) attributable to common stockholders	19,674,732	(16,708,299)	(25,283,021)
Change in unrealized gains/(loss) on marketable Securities	—	3,253	14,388
Comprehensive income (loss)	$ 19,674,732	$ (16,705,046)	$ (25,268,633)
Basic net income (loss) per common share	$ 0.63	$ (0.55)	$ (0.84)
Shares used in computing basic net income (loss) per common share	31,359,867	30,449,721	30,091,985
Diluted net income (loss) per common share	$ 0.60	$ (0.55)	$ (0.84)
Shares used in computing diluted net income (loss) per common share	32,810,587	30,449,721	30,091,985

See accompanying Notes to Financial Statements.

POZEN Inc.

Statements of Stockholders' Equity

	Common Stock	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2011	$ 29,975	$ 180,073,755	$ (17,641)	$ (74,587,845)	$ 105,498,244
Exercise of common stock options	253	1,306,106	-	-	1,306,359
Payments related to net settlement of stock awards	-	(188,528)	-	-	(188,528)
Issuance of common stock upon vesting of restricted stock	94	(94)	-	-	-
Stock-based compensation	-	2,729,920	-	-	2,729,920
Net loss	-	-	-	(25,283,021)	(25,283,021)
Other comprehensive income		-	14,388	-	14,388
Balance at December 31, 2012	30,322	183,921,159	(3,253)	(99,870,866)	84,077,362
Exercise of common stock options	151	661,823	-	-	661,974
Payments related to net settlement of stock awards	-	(522,439)	-	-	(522,439)
Issuance of common stock upon vesting of restricted stock	204	(204)	-	-	-
Distribution to shareholders	-	(53,685,512)	-	-	(53,685,512)
Stock-based compensation	-	3,962,386	-	-	3,962,386
Net loss	-	-	-	(16,708,299)	(16,708,299)
Other comprehensive income	-	-	3,253	-	3,253
Balance at December 31, 2013	30,677	134,337,213	-	(116,579,165)	17,788,725
Exercise of common stock options	1,484	7,587,445	-	-	7,588,929
Payments related to net settlement of stock awards	-	(192,536)	-	-	(192,536)
Issuance of common stock upon vesting of restricted stock	60	(60)	-	-	-
Stock-based compensation	-	1,880,962	-	-	1,880,962
Net income	-	-	-	19,674,732	19,674,732
Balance at December 31, 2014	$ 32,221	$ 143,613,024	$ -	$ (96,904,433)	$ 46,740,812

See accompanying Notes to Financial Statements.

POZEN Inc.

Statements of Cash Flows

Operating Activities	Year ended December 31, 2014	2013	2012
Net income (loss)	$ 19,674,732	$ (16,708,299)	$ (25,283,021)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	18,933	29,413	45,251
Loss on disposal of fixed assets	—	5,205	1,535
Bond amortization income	—	63,389	1,520,071
Gain on investments in warrants	(2,678,773)	—	—
Noncash compensation expense	1,880,962	3,962,386	2,729,920
Changes in operating assets and liabilities:			
Accounts receivable	(3,956,209)	(321,000)	(222,000)
Prepaid expenses and other current assets	211,604	63,758	(158,097)
Accounts payable and other accrued expenses	(3,528,323)	1,026,201	(4,782,946)
Deferred revenue	(11,257,300)	11,000,000	—
Net cash provided by (used in) operating activities	365,626	(878,947)	(26,149,287)
Investing activities			
Purchase of equipment	(7,336)	(1,652)	(15,821)
Purchase of investments	—	—	(35,922,138)
Sale and maturities of investments	—	18,838,000	24,395,000
Net cash (used in) provided by investing activities	(7,336)	18,836,348	(11,542,959)
Financing activities			
Proceeds from issuance of common stock	7,588,929	661,974	1,306,359
Distribution to shareholders	—	(53,685,512)	—
Payments related to net settlement of stock-based awards	(192,536)	(522,439)	(188,528)
Net cash provided by (used in) financing activities	7,396,393	(53,545,977)	1,117,831
Net increase (decrease) in cash and cash equivalents	7,754,683	(35,588,576)	(36,574,415)
Cash and cash equivalents at beginning of year	32,827,732	68,416,308	104,990,723
Cash and cash equivalents at end of year	$ 40,582,415	$ 32,827,732	$ 68,416,308

See accompanying Notes to Financial Statements.

1. Significant Accounting Policies

General

POZEN Inc. ("we" or "POZEN" or the "Company") was incorporated in the State of Delaware on September 25, 1996 and is operating in a single reportable segment. The Company has been a pharmaceutical company committed to transforming medicine that transforms lives. Since inception, the Company has focused its efforts on developing products which can provide improved efficacy, safety or patient convenience in the treatment of acute and chronic pain and pain related conditions and has developed a portfolio of integrated aspirin therapies. Historically, the Company has entered into collaboration agreements to commercialize its product candidates. The Company's licensing revenues include upfront payments, additional payments if and when certain milestones in the product's development or commercialization are reached, and the eventual royalty payments based on product sales.

We decided to retain ownership of our PA product candidates which contain a combination of a proton pump inhibitor and enteric coated aspirin in a single tablet through the clinical development and pre-commercialization stage and our chief commercial officer was responsible for developing the commercialization strategy for these products and conducting all the required pre-commercialization activities. On September 3, 2013, we entered into an exclusive license agreement with sanofi-aventis U.S. LLC, or Sanofi US, for the commercialization of POZEN's proprietary, investigational, coordinated-delivery tablets combining immediate-release omeprazole, a proton pump inhibitor, or PPI, and enteric-coated, or EC, aspirin in a single tablet, now known as YOSPRALA 81/40 and 325/40 ("PA" or "YOSPRALA"), including PA8140 and PA32540. On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The termination agreement further provides for the transfer of specified commercial know-how developed by Sanofi US relating to the PA products to us and allows us, and any future collaborators, to use this know-how to commercialize the products. We are currently evaluating all strategic options available to us now that we have full ownership of the PA products. In light of the warning letter sent to our active ingredient supplier and of the time requirements necessary to complete an assessment of its strategic options, and to properly prepare the market for the launch of our YOSPRALA product candidates, we believe the products will be available for commercialization in 2016.

With respect to future products we may develop, we have decided that we will no longer commit substantial resources to further drug development without a partner who agrees to pay the full cost of that development. Consistent with this model, we have reduced our R&D staff and other costs and expenses as our PA development program activities wind down and intend to continue to reduce staff that is no longer required to support our then current business activities. Our board of directors and management team continue to explore potential ways to return value to our stockholders. On November 21, 2013, our Board of Directors declared a special cash distribution of $1.75 per share to all stockholders of record as of the close of business on December 11, 2013, with a payment date of December 30, 2013. This distribution represented a surplus of corporate cash and is accounted for as a return of capital to stockholders. We are committed to return as much cash to our stockholders as is prudent and may consider other cash distributions in the future.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from the estimates and assumptions used.

Revenue Recognition

Revenue for the fiscal years ended December 31, 2014, 2013 and 2012 consisted of the following royalty revenue and other licensing revenue:

	For the year ended December 31,		
	2014	2013	2012
Royalty Revenue	$ 21,136,932	$ 6,322,000	$ 4,849,000
Other licensing revenue	11,257,300	4,000,000	500,000
Total licensing revenue	$ 32,394,232	$ 10,322,000	$ 5,349,000

With regard to royalty revenues, the Company's licensing agreements have terms that include royalty payments based on the manufacture, sale or use of the Company's products or technology. VIMOVO® (naproxen and esomeprazole magnesium) delayed release tablets royalty revenue has been recognized when earned, as will any other future royalty revenues. For VIMOVO or those future arrangements where royalties are reasonably estimable, the Company recognizes revenue based on estimates of royalties earned during the applicable period and reflects in future revenue any differences between the estimated and actual royalties. These estimates are based upon information reported to the Company by its collaboration partners. During the fiscal years ended December 31, 2014, December 31, 2013, and December 31, 2012 the Company recognized $21.1 million, $6.3 million, and $4.8 million, respectively, for VIMOVO royalty revenue.

Also, with regard to the licensing revenues, the Company's licensing agreements have had terms that include upfront payments upon contract signing and additional payments if and when certain milestones in the product's development or commercialization are reached. Historically, the non-refundable portion of upfront payments received under the Company's existing agreements is deferred by the Company upon receipt and recognized on a straight-line basis over periods ending on the anticipated date of regulatory approvals, as specified in the agreements relating to the product candidates, or the conclusion of any obligation on the part of the Company. If regulatory approvals or other events relating to our product candidates are accelerated, delayed or not ultimately obtained, then the amortization of revenues for these products is prospectively accelerated or reduced accordingly. Milestone payments along with the refundable portions of up-front payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

In September 2013, the Company announced the signing of an exclusive license agreement its PA products, including, PA8140 and PA32540, in the United States. to commercialize all PA combinations that contain 325 mg or less of enteric-coated aspirin in the United States. On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The Company received an upfront payment of $15.0 million which is included within the license revenue in the accompanying statements of comprehensive income (loss). The revenue for the fiscal years ended December 31, 2014 and December 31, 2013 was $11.0 million and $4.0 million, respectively.

On March 21, 2011, the Company entered into a license agreement with Cilag GmbH International ("Cilag") a division of Johnson & Johnson, for the exclusive development and commercialization of MT 400 in Brazil, Colombia, Ecuador and Peru. Cilag's upfront payment of $257,300 was deferred until the licensing agreement's termination and is included in other licensing revenue for the fiscal year ended December 31, 2014.

Cash, Cash Equivalents, Investments and Concentration of Credit Risk

Cash is invested in open-ended money market mutual funds, interest-bearing investment-grade debt securities and insured bank deposits. Cash is restricted to the extent of a $42,000 letter of credit in compliance with the terms of the Company's office lease. The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents.

The Company invests in high-credit quality investments in accordance with its investment policy, which attempts to minimize the possibility of loss. However, cash and cash equivalents include financial instruments that potentially subject the Company to a concentration of credit risk. Cash and cash equivalents are of a highly liquid nature and are held with high credit quality financial institutions and money market mutual fund managers. Cash held directly with financial institutions is insured up to $250,000 per account and any excess amounts are uninsured. Cash is also held in insured bank deposits through a cash management program that offers a bank network ensuring full FDIC insurance on all deposits. Approximately 55% of the Company's cash and cash equivalents are held in fully insured bank deposits and approximately 45% by money market mutual fund managers.

In connection with its acquisition of all rights, title and interest to develop, commercialize and sell Treximet® (sumatriptan / naproxen sodium) from GlaxoSmithKline ("GSK"), Pernix Therapeutics Holdings, Inc. ("Pernix") issued the Company a warrant to purchase 500,000 shares of Pernix common stock at an exercise price of $4.28 (the closing price of Pernix common stock as listed on the NASDAQ Global Market on May 13, 2014). The common stock underlying the warrants will be registered by Pernix with the Securities and Exchange Commission and the warrant is exercisable from August 20, 2014, the closing date of the acquisition, until February 28, 2018. We are valuing the warrant using the Black-Sholes option valuation model.

The warrant also provides for cashless exercise whereby the holder may elect to receive the number of shares of Pernix common stock equal to the number of shares being exercised multiplied by the fair market value of one share of Pernix common stock, less $4.28 (the exercise price) divided by the fair market value of one share of Pernix common stock. Assuming a cashless exercise at December 31, 2014, this would have resulted in 272,098 shares of Pernix common stock valued at $2.6 million. Because the warrant has not been registered by Pernix with the Securities and Exchange Commission, the Company cannot sell or transfer the warrant in reliance upon Rule 144 until after November 13, 2014 when the Company meets certain holding requirements. In November 2014 Pernix submitted a filing to register the underlying shares with the Securities and Exchange Commission but as of December 31, 2014 this had not been completed and, therefore, upon exercise of the warrant the Company is restricted from transferring or selling these shares until such time as such filing is declared effective or an exemption from registration is otherwise met.

The following table sets forth our financial instruments carried at fair value as of December 31, 2014 and December 31, 2013:

	Financial Instruments Carried at Fair Value	
	December 31, 2014	December 31, 2013
Assets:		
Cash and cash equivalents	$ 40,582,415	$ 32,827,732
Investments in Pernix warrants	2,678,773	—
Total cash and investments	$ 43,261,188	$ 32,827,732

Fair Value Measurements

Financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable and accounts payable. The carrying values of these amounts, other than the investment in warrants, approximate the fair value due to their short-term nature.

A part of its acquisition of Treximet® (sumatriptan / naproxen sodium) from GlaxoSmithKline (GSK), Pernix Therapeutics Holdings, Inc. (Pernix) granted POZEN a warrant to purchase 500,000 shares of Pernix common stock at an exercise price of $4.28. The common stock underlying the warrants was registered by Pernix with the Securities and Exchange Commission and is exercisable from August 20, 2014, the closing date of the acquisition, until February 28, 2018. The warrant is valued at $2,678,773 using Black-Sholes valuation model discounted for the warrant's lack of marketability and liquidity.

Short-term investments gains consisted of the investment in warrants valuation of $2,740,800 on August 20, 2014, with a mark to market adjustment of ($62,027) at December 31, 2014 and a net December 31, 2014 short-term gain of $2,678,773.

The Company defines fair value ("FV") as the price that would be received to sell an asset or paid to transfer a liability ("the exit price") in an orderly transaction between market participants at the measurement date. The FV hierarchy for inputs maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. The Company uses the following hierarchy of inputs to measure FV:

- Level 1 - quoted prices in active markets for identical assets and liabilities.

- Level 2 - observable inputs other than quoted prices in active markets for identical assets and liabilities, including quoted prices in active markets for instruments that are similar or quoted prices in markets that are not active for identical or similar instruments and model-derived valuations in which all significant inputs and value drivers are observable in active markets.

- Level 3 - unobservable inputs that are significant to the overall valuation, for which there is little or no market data available and which require the Company to develop its own assumptions.

The Company values investments using the most observable inputs available that are current as of the measurement date and classifies them according to the lowest level of inputs used. Observable inputs are inputs that market participants would use in pricing the asset or liability developed from market data obtained from independent sources. Unobservable inputs are inputs that reflect the Company's judgment concerning the assumptions that market participants would use in pricing the asset or liability developed from the best information available under the circumstances.

The financial assets for which we perform recurring measurements are cash equivalents and investments in warrants. As of December 31, 2014, financial assets utilizing Level 1 inputs included cash equivalents. Financial assets utilizing Level 2 inputs included investments in warrants.

Fair value is a market-based measure considered from the perspective of a market participant who holds the asset or owes the liability rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date.

Our Level 1 valuations are based on the market approach and consist primarily of quoted prices for identical items on active securities exchanges. Our Level 2 valuations may also use the market approach and are based on significant other observable inputs such as quoted prices for financial instruments not traded on a daily basis. We did not rely on Level 3 input for valuation of our securities at December 31, 2014.

The following table sets forth our financial instruments carried at fair value within the fair value hierarchy and using the lowest level of input as of December 31, 2014:

	Financial Instruments Carried at Fair Value			
	Quoted prices in active Markets for identical items (Level 1)	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**	**Total**
Assets:				
Cash and cash equivalents	$ 40,582,415	$ —	$ —	$ 40,582,415
Investment in warrants	—	2,678,773	—	2,678,773
Total cash and investments	$ 40,582,415	$ 2,678,773	$ —	$ 43,261,188

The Company targets investment principally in Level 1 and Level 2 cash equivalents and financial instruments and records them at FV. The Company expects that the carrying values of cash equivalents will approximate FV because of their short maturities.

Equipment

Equipment consists primarily of computer hardware and software and furniture and fixtures and is recorded at cost. Depreciation is computed using an accelerated method over the estimated useful lives of the assets ranging from five to seven years. Accumulated depreciation at December 31, 2014 and 2013 totaled $0.7 million.

Research and Development Costs, Including Clinical Trial Expenses

Research and development costs are charged to operations as incurred. The Company has included in research and development expenses the personnel costs associated with research and development activities and costs associated with pharmaceutical development, clinical trials, toxicology activities, and regulatory matters.

Interest and Other Income

Interest and bond amortization income was $43,100 and $138,900 for the fiscal years ended December 31, 2014 and 2013, respectively. Other income also included short-term investments gains consisting of the investment in warrants with an initial valuation of $2,740, 800 on August 20, 2014, with a mark to market adjustment of ($62,027) at December 31, 2014 and a net of $377,269 related to the disgorgement of short-swing profits arising from trades by a POZEN shareholder under Section 16(b) of the Securities and Exchange Act of 1934.

Taxes

Income taxes are computed using the asset and liability approach, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial

statements or tax returns. In estimating future tax consequences, the Company generally considers all expected future events other than enactment of changes in tax law or rates. If it is more likely than not that some or all of a deferred tax asset will not be realized, the Company records a valuation allowance.

Net Income (Loss) Per Share

Basic and diluted net income or loss per common share amounts have been computed using the weighted-average number of shares of common stock outstanding for the fiscal year ended December 31, 2014 and 2013. During the fiscal years ended December 31, 2014 and 2013, the Company had potential common stock equivalents related to its outstanding stock options. These potential common stock equivalents were not included, if the effect would have been antidilutive. The Company has excluded the impact of any shares which might be issued under the Rights Plan, detailed below, from the earnings per share calculation because the Rights are not exercisable since the specified contingent future event has not occurred.

Reconciliation of denominators for basic and diluted earnings per share computations:

	Years ended December 31,		
	2014	2013	2012
Basic weighted average shares outstanding	31,359,867	30,449,721	30,091,985
Effect of dilutive employee and director awards	1,450,720	—	—
Diluted weighted-average shares outstanding and assumed conversions	32,810,587	30,449,721	30,091,985

Patent Costs

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the Company's Statements of Comprehensive Income (Loss).

Stock-Based Compensation

Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. The fair value of restricted stock awards is determined by reference to the fair market value of our common stock on the date of grant. We use the Black-Scholes model to value service condition and performance condition option awards. For awards with only service conditions and graded-vesting features, we recognize compensation cost on a straight-line basis over the requisite service period. For awards with performance conditions granted we recognize compensation cost over the expected period to achieve the performance conditions, provided achievement of the performance conditions are deemed probable.

Contingencies

We, AstraZeneca and Horizon are engaged in Paragraph IV litigation with several generic pharmaceutical companies with respect to patents listed in the Orange Book with respect to VIMOVO currently pending in the United States District Court for the District of New Jersey which is described on page 17 of this Form 10-K.

On March 14, 2011, we and AstraZeneca received a Paragraph IV Notice Letter from Dr. Reddy's informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent in 2023. The '907 patent is assigned to POZEN and listed with respect to VIMOVO in the Orange Book. On September 19, 2011, Dr. Reddy's amended its ANDA to include a Paragraph IV certification against the '504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent, which are assigned to AstraZeneca or its affiliates and listed in in the Orange Book, with respect to VIMOVO. The patents listed in the Orange Book which are owned by AstraZeneca or its affiliates expire at various times between 2014 and 2018. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Dr. Reddy's. Accordingly, we and AstraZeneca filed suit against Dr. Reddy's on April 21, 2011 in the United States District Court for the District of New Jersey, asserting only the '907 patent against Dr. Reddy's. An amended complaint was filed on October 28, 2011 to include the AstraZeneca patents. On December 19, 2012, the District Court conducted a pre-trial "Markman" hearing to determine claim construction. On May 1, 2012, the Court issued a Markman Order construing the claim terms disputed by the parties. On April 15, 2013 a Stipulation of Partial Dismissal was filed which sought dismissal of all infringement claims relating to the '504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent (which are each assigned to AstraZeneca), as well as Dr. Reddy's defenses and counterclaims relating to those patents. On April 18, 2013, the District Court issued a Stipulation and Order dismissing with prejudice those claims and defenses. The first Dr. Reddy's case is considered the lead case and has been consolidated with the actions described below for the purpose of pre-trial and discovery. A scheduling order for this case, and all of the consolidated cases,

was issued by the Court on June 27, 2014. Fact discovery closed in the consolidated case on November 20, 2015. Expert discovery is ongoing and set to close May 21, 2015. In view of the upcoming retirement of presiding Judge Pisano, on February 9, 2015, the consolidated cases were reassigned to Judge Mary L. Cooper.

On June 13, 2011, we and AstraZeneca received a Paragraph IV Notice Letter from Lupin informing us that Lupin had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the POZEN and the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent and, each of which are assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Lupin's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Lupin and, accordingly, we and AstraZeneca filed suit against Lupin on July 25, 2011 in the United States District Court for the District of New Jersey. On November 19, 2014, an amended complaint was filed in which the 504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent, all assigned to AstraZeneca or its affiliates, were not asserted against Lupin. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On September 19, 2011, we and AstraZeneca AB received Paragraph IV Notice Letter from Anchen informing us that Anchen had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, the '085 patent, the '070 patent, and the '466 patent. The patents are among those listed with respect to VIMOVO in the Orange Book and expire at various times between 2018 and 2023. Anchen's Paragraph IV Notice Letter asserts that its generic product will not infringe those patents or that those patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Anchen and, accordingly, we and AstraZeneca filed suit against Anchen on October 28, 2011 in the United States District Court for the District of New Jersey. On October 4, 2013, Anchen filed an amendment to its ANDA seeking to change its Paragraph IV certification to a Paragraph III. It is unclear when or if the FDA will enter Anchen's amendment. On October 25, 2013, Anchen filed a Motion to Dismiss the case against it, based on its proposed re-certification. On November 18, 2013, we and AstraZeneca filed an Opposition to Anchen's Motion to Dismiss. On June 11, 2014, the Court granted Anchen's Motion and dismissed the case against them.

On November 20, 2012 we and AstraZeneca AB received a Paragraph IV Notice Letter from Dr. Reddy's, informing us that Dr. Reddy's had filed a second ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the POZEN and the 504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent and, each of which are assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Dr. Reddy's second Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Dr. Reddy's on its second ANDA filing and, accordingly, we and AstraZeneca filed suit against Dr. Reddy's on January 4, 2013, in the United States District Court for the District of New Jersey. On April 15, 2013 a Stipulation of Partial Dismissal was filed which sought dismissal of all infringement claims relating to the '504 patent, the '085 patent, the '872 patent, the '070 patent, and the '466 patent (which are each assigned to AstraZeneca), as well as Dr. Reddy's defenses and counterclaims relating to those patents. On April 18, 2013, the District Court issued the Stipulation and Order dismissing with prejudice those claims and defenses. On June 28, 2013 we and AstraZeneca filed a Motion for Summary Judgment relating to the second ANDA filing asserting that U.S. Patent No. 6,926,907 is not invalid. On August 12, 2013, DRL filed an opposition to the Motion for Summary Judgment. On March 28, 2014, the District Court denied the Motion. On October 11, 2013, DRL filed a Motion for Summary Judgment asserting that the product which is the subject matter of its second ANDA does not infringe the '907 patent. On November 4, 2013, POZEN and AstraZeneca filed a Motion for an Order Denying DRL's Motion for Summary Judgment Pursuant to Rule 56(d) and an Opposition to DRL's Motion. On May 29, 2014, the Court issued an order denying DRL's Motion. This case was consolidated with the originally filed Dr. Reddy's case and is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On March 29, 2013, we and AstraZeneca received a Paragraph IV Notice Letter from Watson, now Actavis, informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the '907 patent, which is assigned to the Company and the '504 patent, the '085 patent, the '424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Watson's Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Watson. On May 10, 2013, we and AstraZeneca filed a patent infringement lawsuit against Watson in the U.S. District Court of New Jersey. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy's case.

On May 16, 2013, POZEN and AstraZeneca AB received a Paragraph IV Notice Letter from Mylan informing us that it had filed an ANDA with the FDA seeking regulatory approval to market a generic version of VIMOVO before the expiration of the ‘907 patent, which is assigned to the Company and the ‘504 patent, the '085 patent, the ‘424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The patents are listed with respect to VIMOVO in the Orange Book and expire at various times between 2014 and 2023. Mylan’s Paragraph IV Notice Letter asserts that its generic product will not infringe the listed patents or that the listed patents are invalid or unenforceable. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement suit against Mylan. On June 28, 2013, we and AstraZeneca filed a patent infringement lawsuit against Mylan in the U.S. District Court of New Jersey. On February 13, 2015, the Court entered a joint stipulation of dismissal of counts related to certain patents, dismissing claims related to the ‘504 patent, the '085 patent, the ‘424 patent, the '872 patent, the '070 patent, and the '466 patent, each of which assigned to AstraZeneca or its affiliates. The case is currently consolidated for discovery and pretrial purposes with the first filed Dr. Reddy’s case.

On October 15, 2013, the United States Patent Office issued the ’285 patent. The ‘285 patent, entitled “Pharmaceutical compositions for the coordinated delivery of NSAIDs” and assigned to POZEN, is related to the ‘907 patent. AstraZeneca has advised us that it has elected to exercise its first right to prosecute the infringement of the ‘285 patent and, accordingly, on October 23, 2013, we, and AstraZeneca filed patent infringement lawsuits against DRL, Lupin, Watson and Mylan in the U.S. District Court of New Jersey alleging that their ANDA products infringe the ‘285 patent. On November 8, 2013, we, and AstraZeneca filed a Motion to Amend the Complaint in the actions against DRL, Lupin, Watson and Mylan or, in the alternative, to consolidate the actions involving the ‘285 patent with the existing consolidated action. DRL, Lupin, Watson and Mylan have each filed answers to the respective amended complaints, thus adding claims relating to the ‘285 patent against each of the Defendants to the consolidated case.

As part of Horizon’s purchase of all of AstraZeneca’s rights, title and interest to develop, commercialize and sell VIMOVO in the United States, Horizon has assumed AstraZeneca’s right to lead the above-described Paragraph IV litigation relating to VIMIVO currently pending in the United States District Court for the District of New Jersey and has assumed patent-related defense costs relating to such litigation, including reimbursement up to specified amounts of the cost of any counsel retained by us. On December 12, 2013, Horizon filed Motions to Join under Fed.R.Civ.Proc. 25(c) as a co-plaintiff in each of the above referenced actions and the consolidated action. On January 31, 2014 and February 2, 2014, the Court granted Horizon’s motions.

As with any litigation proceeding, we cannot predict with certainty the patent infringement suit against Dr. Reddy’s, Lupin, Mylan and Watson relating to a generic version of VIMOVO. We have incurred an aggregate of $17.5 million in legal fees through the fiscal year ended December 31, 2014. Furthermore, we will have to incur additional expenses in connection with the lawsuits relating to VIMOVO, which may be substantial. In the event of an adverse outcome or outcomes, our business could be materially harmed. Moreover, responding to and defending pending litigation will result in a significant diversion of management’s attention and resources and an increase in professional fees.

New Accounting Pronouncements

Revenue from Contracts with Customers

In May 2014, the FASB issued new accounting rules related to revenue recognition for contracts with customers requiring revenue recognition based on the transfer of promised goods or services to customers in an amount that reflects consideration the Company expects to be entitled to in exchange for goods or services. The new rules supersede prior revenue recognition requirements and most industry-specific accounting guidance. The new rules will be effective for the Company in the first quarter of 2017 with either full retrospective or modified retrospective application required. The Company does not expect the adoption of the new accounting rules to have a material impact on the Company’s financial condition, results of operations or cash flows.

2. License Agreements

We have entered into and may continue to enter into collaborations with established pharmaceutical or pharmaceutical services companies to develop, commercialize and/or manufacture our product candidates. Our existing collaborations are described below.

GlaxoSmithKline (GSK)

In June 2003, we signed an agreement with GSK for the development and commercialization of proprietary combinations of a triptan (5-$HT_{1B/1D}$ agonist) and a long-acting NSAID. The combinations covered by the agreement are among the combinations of MT 400. Under the terms of the agreement, GSK has exclusive rights in the U.S. to commercialize all combinations which combine GSK's triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. We were responsible for development of the first combination product, while GSK provided formulation development and manufacturing. Pursuant to the terms of the agreement, we received $25.0 million in initial payments from GSK following termination of the waiting period under the Hart-Scott-Rodino notification program and the issuance of a specified patent. In May 2004, we received a $15.0 million milestone payment as a result of our commencement of Phase 3 clinical trial activities. In October 2005, we received a $20.0 million milestone payment upon the FDA's acceptance for review of the NDA for *Treximet*, the trade name for the product. On April 26, 2008, we received, from GSK, $20.0 million in milestone payments which were associated with the approval of, and GSK's intent to commercialize, *Treximet*. In addition, GSK will pay us two sales performance milestones totaling $80.0 million if certain sales thresholds are achieved. Up to an additional $10.0 million per product is payable upon achievement of milestones relating to other products. GSK will pay us royalties on all net sales of marketed products until at least the expiration of the last to expire issued applicable patent (October 2, 2025) based upon the scheduled expiration of currently issued patents. GSK may reduce, but not eliminate, the royalty payable to us if generic competitors attain a pre-determined share of the market for the combination product, or if GSK owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach or by GSK at any time upon ninety (90) days' written notice to us for any reason or no reason. Among the contract breaches that would entitle us to terminate the agreement is GSK's determination not to further develop or to launch the combination product under certain circumstances. GSK has the right, but not the obligation, to bring, at its own expense, an action for infringement of certain patents by third parties. If GSK does not bring any such action within a certain time frame, we have the right, at our own expense, to bring the appropriate action. With regard to certain other patent infringements, we have the sole right to bring an action against the infringing third party. Each party generally has the duty to indemnify the other for damages arising from breaches of each party's representations, warranties and obligations under the agreement, as well as for gross negligence or intentional misconduct. We also have a duty to indemnify GSK for damages arising from our development and manufacture of MT 400 prior to the effective date of the agreement, and each party must indemnify the other for damages arising from the development and manufacture of any combination product after the effective date.

On November 23, 2011, we entered into the Purchase Agreement, with CII, pursuant to which we sold, and CII purchased, our right to receive future royalty payments arising from U.S. sales of MT 400, including *Treximet*.

On May 13, 2014, we, GSK, CII and Pernix, entered into certain agreements in connection with GSK's divestiture of all of its rights, title and interest to develop, commercialize and sell *Treximet*® in the U.S. to Pernix. Upon the closing of the divestiture on August 20, 2014, GSK assigned the Treximet Agreement to Pernix. Immediately following the closing of the divestiture, Amendment No. 1 between us and Pernix became effective. Amendment No. 1, among other things, amends the royalty provisions of the Agreement to provide for a guaranteed quarterly minimum royalty of $4 million for the calendar quarters commencing on January 1, 2015 and ending on March 31, 2018 and requires that Pernix continue certain of GSK's ongoing development activities and to undertake certain new activities, for which we will provide reasonable assistance. Amendment No. 1 also eliminates restrictions in the Agreement on our right to develop and commercialize certain dosage forms of sumatriptan/naproxen combinations outside of the United States and permits POZEN to seek approval for these combinations on the basis of the approved NDA for Treximet. Pernix has also granted us a warrant to purchase 500,000 shares of Pernix common stock at an exercise price equal to$4.28, the closing price of Pernix common stock as reported on the NASDAQ Global Market on May 13, 2014. The common stock underlying the warrants will be registered by Pernix with the Securities and Exchange Commission and will be exercisable from the August 20, 2014, the closing date of the divestiture until February 28, 2018. If the Divestiture is not consummated, the warrants will be null and void. Because the warrant has not been registered by Pernix with the Securities and Exchange Commission, the Company cannot sell or transfer the warrant in reliance upon Rule 144 until after November 13, 2014 when the Company meets certain holding requirements. Lastly, we, GSK, Pernix and CII executed a letter agreement whereby we expressly consented to the assignment by GSK and the assumption by Pernix of the Treximet Agreement. On July 30, the parties entered into Amendment No. 2 to the Treximet Agreement which will permit Pernix's Irish affiliate to which Pernix assigned its rights to further assign the Agreement without our prior written consent as collateral security for the benefit of the lenders which financed the acquisition. Amendment No. 2 became effective upon the closing of the divestiture on August 20, 2014.

AstraZeneca AB (AstraZeneca)

In August 2006, we entered into a collaboration and license agreement dated as of August 1, 2006 and effective September 7, 2006 with AstraZeneca, a Swedish corporation, regarding the development and commercialization of proprietary

fixed dose combinations of the PPI esomeprazole magnesium with the NSAID naproxen, in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID associated gastric ulcers, as amended, the "Original Agreement". Under the terms of the Original Agreement, we granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under our patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). Pursuant to the terms of the agreement, we received an upfront license fee of $40.0 million from AstraZeneca following termination of the waiting period under the Hart-Scott-Rodino notification program.

We retained responsibility for the development and filing of the NDA for the product in the U.S. AstraZeneca is responsible for all development activities outside the U.S., as well as for all manufacturing, marketing, sales and distribution activities worldwide. We agreed to bear all expenses related to certain specified U.S. development activities. All other development expenses, including all manufacturing-related expenses, will be paid by AstraZeneca. The agreement established joint committees with representation of both us and AstraZeneca to manage the development and commercialization of the product. The committees operate by consensus, but if consensus cannot be reached, we generally will have the deciding vote with respect to development activities required for marketing approval of the product in the U.S. and AstraZeneca generally will have the deciding vote with respect to any other matters.

In September 2007, we agreed with AstraZeneca to amend the Original Agreement effective as of September 6, 2007. Under the terms of the amendment, AstraZeneca has agreed to pay us up to $345.0 million, in the aggregate, in milestone payments upon the achievement of certain development, regulatory and sales events. In September 2007 we received a $10.0 million payment upon execution of the amendment and a $20.0 million payment in recognition of the achievement of the primary endpoints for the PN400-104 study, a study which compared acid suppression of different doses of VIMOVO (formerly PN 400), and achievement of the interim results of the PN200-301 study, a six month comparative trial of PN 200 as compared to EC naproxen in patients requiring chronic NSAID therapy, meeting mutually agreed success criteria. In May 2010, we received a $20.0 million payment for the NDA approval of VIMOVO. We also received an additional $25.0 million milestone in December 2010 when VIMOVO received approval (including pricing and reimbursement approval) in a major ex-U.S. market and up to $260.0 million will be paid as sales performance milestones if certain aggregate sales thresholds are achieved.

The amendment also revised the royalty rates we were to have received under the Original Agreement. Prior to the effective date of the amendment, under the terms of the Original Agreement, we were to receive a royalty based on annual net sales by AstraZeneca, its affiliates or sublicensees during the royalty term. The royalty rate varied based on the level of annual net sales of products made by AstraZeneca, its affiliates and sublicensees, ranging from the mid-single digits to the mid-teens. Under the amendment, we receive a flat, low double digit royalty rate during the royalty term on annual net sales of products made by AstraZeneca, its affiliates and sublicensees, in the U.S. and royalties ranging from the mid-single digits to the high-teens on annual net sales of products made by AstraZeneca, its affiliates and sublicensees outside of the U.S. The amendment also revised the rate of reduction to the royalty rate based upon loss of market share due to generic competition inside and outside of the U.S. to account for the new royalty structure. Our right to receive royalties from AstraZeneca for the sale of such products under the collaboration and license agreement, as amended, expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights relating to such products in that country, and (b) ten years after the first commercial sale of such products in such country.

We further amended the Original Agreement effective October 1, 2008 to shorten the timing of AstraZeneca's reimbursement obligation for certain development expenses incurred by us under the agreement and to update the description of the target product profile studies (as defined in the agreement) for VIMOVO.

On December 31, 2014 we accrued $5.6 million of VIMOVO royalty revenue, $4.3 million related to U.S. sales and $1.3 million related to ROW sales. The agreement, unless earlier terminated, will expire upon the payment of all applicable royalties for the products commercialized under the agreement. Either party has the right to terminate the agreement by notice in writing to the other party upon or after any material breach of the agreement by the other party, if the other party has not cured the breach within 90 days after written notice to cure has been given, with certain exceptions. The parties also can terminate the agreement for cause under certain defined conditions. In addition, AstraZeneca can terminate the agreement, at any time, at will, for any reason or no reason, in its entirety or with respect to countries outside the U.S., upon 90 days' notice. If terminated at will, AstraZeneca will owe us a specified termination payment or, if termination occurs after the product is launched, AstraZeneca may, at its option, under and subject to the satisfaction of conditions specified in the agreement, elect to transfer the product and all rights to us.

On May 3, 2013, AstraZeneca informed us that, after a strategic business review, it had decided to cease promotion and sampling of VIMOVO by the end of the third quarter of 2013 in certain countries, including the U.S. and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. We understand that

AstraZeneca will instead now focus on those countries where the product has shown growth and which AstraZeneca believes have the greatest potential for future growth.

On September 16, 2013, we and AstraZeneca entered into another amendment to the Original Agreement which made clarifications to certain intellectual property provisions of the Original Agreement to clarify that AstraZeneca's rights under those provisions do not extend to products which contain acetyl salicylic acid. On September 16, 2013, we and AstraZeneca also executed a letter agreement whereby we agreed that in the event that AstraZeneca divested its rights and obligations to market VIMOVO in the United States to a third party, AstraZeneca would be relieved of its obligations under the Original Agreement with respect to the United States as of the effective date of such divestiture, including its obligation under the Original Agreement to guarantee the performance of such assignee and/or sublicensee.

On November 18, 2013, AstraZeneca and Horizon entered into certain agreements in connection with AstraZeneca's divestiture of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon. In connection with this divestiture, on November 18, 2013 we and AstraZeneca entered into an Amended and Restated Collaboration and License Agreement for the United States, the "U.S. Agreement," and an Amended and Restated License and Collaboration Agreement for Outside the United States, the "ROW Agreement," which agreements collectively amend and restate the Original Agreement. AstraZeneca has assigned the U.S. Agreement to Horizon in connection with the Divestiture with our consent.

We and Horizon also entered into Amendment No. 1 to the U.S. Agreement which, among other things, amends the royalty provisions of the U.S. Agreement to provide for a guaranteed annual minimum royalty amount of $5 million in calendar year 2014, and a guaranteed annual minimum royalty amount of $7.5 million each calendar year thereafter, provided that the patents owned by us which cover VIMOVO are in effect and no generic forms of VIMOVO are in the marketplace. Amendment No. 1 also provides that Horizon has assumed AstraZeneca's right to lead the on-going Paragraph IV litigation relating to VIMIVO currently pending in the United States District Court for the District of New Jersey and will assume all patent-related defense costs relating to such litigation, including reimbursement up to specified amounts of the cost of any counsel retained by us, amends certain time periods for Horizon's delivery of quarterly sales reports to POZEN, and provides for quarterly update calls between the parties to discuss VIMOVO's performance and Horizon's commercialization efforts.

Further, the Company, AstraZeneca and Horizon executed a letter agreement whereby POZEN expressly consented to the assignment by AstraZeneca and the assumption by Horizon of the U.S. Agreement. In addition, the letter agreement establishes a process for AstraZeneca and Horizon to determine if sales milestones set forth in the Original Agreement are achieved on a global basis and other clarifications and modifications required as a result of incorporating the provisions of the Original Agreement into the U.S. Agreement and the ROW Agreement or as otherwise agreed by the parties.

sanof-aventis U.S. LLC

On September 3, 2013, we entered into an exclusive license and collaboration agreement with Sanofi US for .the commercialization of products containing a combination of immediate release omeprazole and 325 mg or less of delayed release aspirin, including PA32540 and PA8140 in the United States. On November 29, 2014, we executed a termination agreement with Sanofi US terminating the license agreement for PA. As of the termination date, all licenses granted to Sanofi US were terminated and all rights to the products licensed to Sanofi US under the agreement reverted to us. The termination agreement further provides for the transfer of specified commercial know-how developed by Sanofi US relating to the PA products to us and allows us, and any future collaborators, to use this know-how to commercialize the products.

Cilag GmbH International (Cilag)

On March 21, 2011, we entered into a license agreement with Cilag, a division of Johnson & Johnson, for the exclusive development and commercialization of MT 400 in Brazil, Colombia, Ecuador and Peru. In December 2014 we received an executed, mutual termination from Cilag. There was no dispute between the parties regarding the license agreement and, at our request, for a period of two years after termination, Cilag has agreed to negotiate in good faith commercially reasonable terms of a supply agreement whereby Cilag would supply us or our licensees, with MT400 for a period equal to the shorter of (i) two (2) years; or (ii) until we establish an alternative supplier. We recognized approximately $257,300 in licensing revenue in the fourth quarter of as a result of this termination that had previously been recorded as deferred revenue.

Patheon Pharmaceuticals Inc. (Patheon)

On December 19, 2011, we entered into a Manufacturing Services Agreement, or the Supply Agreement, and a related Capital Expenditure and Equipment Agreement, or the Capital Agreement, relating to the manufacture of PA32450. Under the terms of the Supply Agreement, Patheon has agreed to manufacture, and we have agreed to purchase, a specified percentage of

the Company's requirements of the PA32540 for sale in the United States. The term of the Supply Agreement extends until December 31st of the fourth year after the we notify Patheon to begin manufacturing services under the Supply Agreement, or the Initial Term, and will automatically renew thereafter for periods of two years, unless terminated by either party upon eighteen months' written notice prior to the expiration of the Initial Term or twelve months' written notice prior to the expiration of any renewal term. In addition to usual and customary termination rights which allow each party to terminate the Supply Agreement for material, uncured breaches by the other party, we can terminate the Agreement upon thirty (30) days' prior written notice if a governmental or regulatory authority takes any action or raises any objection that prevents us from importing, exporting, purchasing or selling PA32540 or if it is determined that the formulation or sale of PA32540 infringes any patent rights or other intellectual property rights of a third party. We can also terminate the Supply Agreement upon twenty-four (24) months' prior written notice if we license, sell, assign or otherwise transfer any rights to commercialize PA32540 in the Territory to a third party. The Supply Agreement contains general and customary commercial supply terms and conditions, as well as establishing pricing for bulk product and different configurations of packaged product, which pricing will be adjusted annually as set forth in the Supply Agreement. Under the terms of the Capital Agreement, we will be responsible for the cost of purchasing certain equipment specific to the manufacture of PA32540, the cost of which, based on current volume projections, is expected to be less than $150,000. If additional equipment and facility modifications are required to meet our volume demands for PA32540, we may be required to contribute to the cost of such additional equipment and facility modifications, up to a maximum of approximately $2.5 million in the aggregate.

The Supply Agreement and Capital Agreement were amended on July 10, 2013. The First Amendment to the Manufacturing and Services Agreement (the "Amendment to the Supply Agreement") expressly incorporates the Company's PA8140 product candidate into the Supply Agreement. The Amendment to the Supply Agreement also clarifies that the manufacturing services contemplated by the Supply Agreement include the manufacture of validation batches, but the placing of an order for such validation batches will not trigger the Commencement Date of the Initial Term (each as defined in the Supply Agreement), updates pricing for the Company's PA32540 product candidate and a incorporates a new pricing schedule for PA8140, as well as other conforming changes to the Supply Agreement. The First Amendment to the Capital Expenditure and Equipment Agreement (the "Amendment to the Capital Agreement"), replaces the existing Schedule A of the Capital Agreement, which lists dedicated and non-dedicated capital equipment and facility modifications to be funded in whole or in part by the Company, with a new updated schedule which reflects the parties' current assumptions regarding the need for and timing of capital equipment expenditures based upon Patheon's current and anticipated production capacity and current volume projections for thePA32540 and PA8140. Under the terms of the Capital Agreement, the Company was previously required to contribute to the cost of such additional capital equipment and facility modifications, up to a maximum of approximately $2.5 million in the aggregate. Pursuant to the terms of the Amendment to the Capital Agreement, the parties have agreed to reduce the amount of such maximum expenditure to approximately $1.2 million dollars in light of the revised capacity and volume assumptions.

3. Stockholders' Equity

Shares Reserved for Future Issuance

In January 2005, the Company approved a stockholder rights plan (the "Rights Plan"), pursuant to which the Company entered into a Rights Agreement dated January 12, 2005 with StockTrans, Inc., as Rights Agent, and the Company declared a dividend of a right to acquire one preferred share purchase right (a "Right") for each outstanding share of the Company's Common Stock, $0.001 par value per share, to stockholders of record at the close of business on January 28, 2005. Generally, the Rights only are triggered and become exercisable if a person or group acquires beneficial ownership of 15 percent or more of the Company's common stock or announces a tender offer for 15 percent or more of the Company's common stock. The Rights Plan is similar to plans adopted by many other publicly-traded companies. The effect of the Rights Plan is to discourage any potential acquirer from triggering the Rights without first convincing POZEN's Board of Directors that the proposed acquisition is fair to, and in the best interest of, the shareholders and the Company. The provisions of the Plan will substantially dilute the equity and voting interest of any potential acquirer unless the Board of Directors determines that the proposed acquisition is in the best interest of the shareholders. In connection with the Plan, the Company designated 90,000 shares of its authorized Preferred Stock as Series A Junior Participating Preferred Stock. Each Right, if and when exercisable, will entitle the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, $0.001 par value per share, at a purchase price of $80.00 for each one one-thousandth of a share, subject to adjustment. Each holder of a Right (except for the Acquiring Person (as defined in the Rights Plan), whose Rights will be null and void upon such event) shall thereafter have the right to receive, upon exercise, that number of shares of Common Stock of the Company (or, in certain circumstances, cash, property or other securities of the Company) which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of Common Stock at the date of the occurrence of such event. The Rights can be terminated by POZEN's Board of Directors and are subject to optional redemption by the Company at $0.001 per Right. The Rights Plan has a 10-year term and contains provisions requiring a periodic review and evaluation by the Board of Directors

If there is any change in the number or kind of shares of company stock outstanding or if the value of outstanding shares of company stock is substantially reduced as a result of an extraordinary dividend or distribution, the Company's 2010 Stock Option Plan requires that an equitable adjustment be made to all outstanding grants to preclude dilution of rights and benefits under the plan. Therefore, as a result of the December 31, 2013 cash dividend distribution, a dividend equivalent was provided to all outstanding grants. The adjustments were in the form of additional RSUs to RSU holders or an adjustment to both the outstanding number of options and their strike price; all adjustments were made in compliance with Sections 409A and 424 of the Internal Revenue Code. In addition, the 2010 Stock Option Plan provides for an adjustment to the number of common shares available for grant under the stock option plan. Therefore, as a result of the December 31, 2013 cash dividend distribution, the number of common shares available for grant was adjusted by 416,971 shares and that increase is reflected in the table below.

At December 31, 2014, shares of our common stock reserved for future issuance are as follows:

Common shares available for grant under stock option plans	2,474,430
Common shares issuable pursuant to options and restricted stock units granted under equity compensations plans	3,817,920
Rights Plan shares issuable as Series A Junior Participating Preferred Stock	90,000
Total Reserved	6,382,350

4. Accrued Expenses

Accrued expenses consist of the following at December 31:

	2014	2013
Research and development costs	$ 55,227	$ 1,025,995
Other	198,397	629,217
	$ 253,624	$ 1,655,212

5. Income Taxes

The Company did not record a provision for income taxes during the years ended December 31, 2014, 2013 and 2012.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows at December 31:

($ in thousands)	2014	2013
Current		
Deferred income tax assets		
Other current assets	$ 662	$ 1,080
Less valuation allowance	(647)	(1,080)
Total net deferred income tax assets, current	$ 15	$ -
Deferred income tax liabilities		
Investment in warrants	(968)	-
Total net deferred income taxes, current	$ (953)	$ -
Non-current		
Deferred income tax assets (liabilities)		
Tax loss carryforwards	$ 20,840	$ 25,909
Research and development credits	13,987	13,992
Equity compensation and other	6,683	7,549
Total gross deferred income taxes, non-current	41,510	47,450
Less valuation allowance	(40,557)	(47,450)
Total net deferred income taxes, non-current	$ 953	$ -
Total net deferred income taxes	$ -	$ -

At December 31, 2014 and 2013, the Company had federal net operating loss carryforwards of approximately $53 million and $66.8 million respectively, state net economic loss carryforwards of approximately $78 million and $82.9 million respectively, and research and development credit carryforwards of approximately $14 million and $14 million, respectively. The federal and state net operating loss carryforwards begin to expire in 2028 and 2015, respectively, and the research and development credit carryforwards begin to expire in 2018. For financial reporting purposes, a valuation allowance has been recognized to offset the deferred tax assets related to the carryforwards, based on the Company's assessment regarding the realizability of these deferred tax assets in future periods. Of the total decrease in valuation allowance of $7.3 million, a decrease of $7.3 million was allocable to current operating activities. The utilization of the loss carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the loss carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership. The recognized tax benefit related to net operating loss carryforwards was approximately $4.8M, $0, and $0 for the years ended December 31, 2014, 2013 and 2012, respectively.

The research and development credit, which had previously expired on December 31, 2011, was reinstated as part of the American Taxpayer Relief Act of 2012 enacted on January 2, 2013. This legislation retroactively reinstated and extended the credit from the previous expiration date through December 31, 2013. As a result, the Company adjusted its deferred tax assets in 2013 for both the 2013 and 2012 research and development credits, which resulted in an increase to the deferred tax assets and a corresponding increase to the valuation allowance of $0.02 million and $0.11 million, respectively.

On July 23, 2013, North Carolina enacted House Bill 998, which reduced the corporate income tax rate from 6.9% in 2013 to 6% in 2014 and to 5% in 2015. As a result of the new enacted tax rate, the Company adjusted its deferred tax assets in 2013 by applying the lower rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately $0.03 million.

The actual income tax benefit (expense) for the years ended December 31, 2014, 2013 and 2012, differed from the amounts computed by applying the U.S. federal tax rate of 35% to income (loss) before taxes as a result of the following:

($ in thousands)

	2014	2013	2012
(Loss) income before income tax	$ 19,675	$ (16,708)	$ (25,283)
Federal tax rate	35 %	35 %	35%
Federal income tax provision at statutory rate	6,886	(5,848)	(8,849)
State tax provision	224	(215)	(343)
	7,110	(6,063)	(9,192)
Decrease (increase) in income tax benefit resulting from:			
Research and development credits	4	66	—
Non-deductible expenses and other	177	302	409
Change in state tax rate	35	966	—
Change in valuation allowance	(7,326)	4,729	8,783
Income tax expense	$ —	$ —	$ —

The Company had gross unrecognized tax benefits of approximately $0.5 million as of January 1, 2014. As of December 31, 2014, the total gross unrecognized tax benefits were approximately $0.5 million and of this total, none would reduce the Company's effective tax rate if recognized. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company's effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next 12 months.

The Company's policy for recording interest and penalties associated with tax audits is to record them as a component of provision for income taxes. The Company has not recorded any interest or penalty since adoption of FASB ASC 740-10.

The Company has analyzed its filing positions in all significant federal, state and foreign jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. With few exceptions, the Company is no longer subject to US Federal and state and local tax examinations by tax authorities for years before 2011, although carryforward attributes that were generated prior to 2011 may still be adjusted upon examination by the Internal Revenue

Service (IRS) if they either have been or will be used in a future period. No income tax returns are currently under examination by taxing authorities.

Rollforward of gross unrecognized tax positions:

	($ in thousands)
Gross tax liability at January 1, 2014	$ 538
Additions/Decreases for tax positions of prior years	(1)
Additions/Decreases for tax positions of the current year	—
Gross tax liability at December 31, 2014	$ 537

6. Equity Compensation Plans

In 1996, the Company established a Stock Option Plan (the "Option Plan") and authorized the issuance of options to attract and retain quality employees and to allow such employees to participate in the growth of the Company. In June 2000, the stockholders approved the POZEN Inc. 2000 Equity Compensation Plan (the "2000 Plan") and the 2000 Plan became effective upon the completion of the Company's initial public offering in October 2000, after which time no further grants were made under the Option Plan. In May 2004, the stockholders approved an amendment to and restatement of the 2000 Plan. The amendment to the 2000 Plan provided for an increase in the number of shares of common stock authorized for issuance under the 2000 Plan from 3,000,000 to 5,500,000 shares. In June 2007, the stockholders approved the amendment and restatement of the 2000 Plan to, among other things, increase the number of shares authorized for issuance under the 2000 Plan to 6,500,000 shares and continue the various performance criteria for use in establishing specific vesting targets for certain awards. In June 2010, stockholders approved the POZEN Inc. 2010 Equity Compensation Plan, ("the 2010 Plan"), a successor incentive compensation plan to the 2000 Plan which was merged with and into the 2010 Plan and all grants outstanding under the 2000 Plan were issued or transferred under the 2010 Plan.

The 2010 Plan provides for grants of incentive stock options, nonqualified stock options, stock awards, and other stock-based awards, such as restricted stock units and stock appreciation rights ("SARs"), to employees, non-employee directors, and consultants and advisors who perform services for us and our subsidiaries. The 2010 Plan authorizes up to 7,452,327 shares of common stock for issuance, which includes 2,000,000 shares of our common stock which were in excess of the number of shares previously reserved under the 2000 Plan. The maximum number of shares for which any individual may receive grants in any calendar year is 1,000,000 shares. The Compensation Committee of the Board of Directors, which administers the 2010 Plan, will determine the terms and conditions of options, including when they become exercisable. Neither our Board nor the Committee can amend the 2010 Plan or options previously granted under the Plan to permit a repricing of options or SARs, without prior stockholder approval. If options granted under the 2010 Plan expire or are terminated for any reason without being exercised, or if stock awards, performance units, or other stock-based awards are forfeited or otherwise terminate, the shares of common stock underlying the grants will again be available for awards granted under the 2010 Plan.

If there is any change in the number or kind of shares of company stock outstanding or if the value of outstanding shares of company stock is substantially reduced as a result of a spinoff or the Company's payment of an extraordinary dividend or distribution, the 2010 Plan requires that an equitable adjustment be made to all outstanding grants to preclude dilution of rights and benefits under the plan. Consequently, as a result of the December 31, 2013 cash dividend distribution, a dividend equivalent totaling 987,000 shares was provided to all outstanding grants. The adjustments were in the form of additional RSUs to RSU holders or an adjustment to both the outstanding number of options and their strike price, in compliance with Sections 409A and 424 of the Internal Revenue Code.

Our Statements of Comprehensive Income (Loss) for the fiscal years ended December 31, 2014, 2013 and 2012 include the following stock-based compensation expense:

	Years ended December 31,		
	2014	2013	2012
Research and development	$ 295,631	$ 765,526	$ 461,118
Sales, general and administrative	1,585,331	3,196,860	2,268,802
Total expense	$ 1,880,962	$ 3,962,386	$ 2,729,920

Unrecognized stock-based compensation expense, including time-based options, performance-based options and restricted stock awards, expected to be recognized over an estimated weighted-average amortization period of 2.0 years, was $4.1 million at December 31, 2014.

Time-Based Stock Awards

No new time-based awards were granted during the year ended December 31, 2014. Previously, the fair value of each time-based award was estimated on the date of grant using the Black-Scholes option valuation model, which used the assumptions described below. Our weighted-average assumptions used in the Black-Scholes valuation model for equity awards with time-based vesting provisions granted for the years ended December 31, 2013 and 2012 are shown in the following table:

	2013	2012
Expected volatility	63.7%	68.0–72.3%
Expected dividends	0%	0%
Expected terms	6.0 Years	6.0 Years
Risk-free interest rate	1.25%	0.91–1.33%
Weighted average grant date fair value	$5.35	$4.87

For the years ended December 31, 2013 and 2012, the expected volatility rate was estimated based on an equal weighting of the historical volatility of POZEN common stock over approximately a six-year period. For the years ended December 31, 2013 and 2012, the expected term was based upon average historical terms to exercise. The risk-free interest rate was based on six-year U.S. Treasury securities. The pre-vesting forfeiture rates used of the years ended December 31, 2013 and 2012 were based on historical rates. We adjust the estimated forfeiture rate based upon actual experience.

A summary of the time-based stock awards as of December 31, 2014, and changes during the year ended December 31, 2014, are as follows:

Time-Based Stock Awards	Underlying Shares (000s)	Weighted-Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (000s)
Outstanding at December 31, 2013	4,315	$ 6.82	4.3	$ 8,553
Granted	—	—		
Exercised	(1,479)	5.34		
Forfeited or expired	(495)	8.52		
Outstanding at December 31, 2014	2,341	7.39	4.1	$ 4,382
Exercisable at December 31, 2014	1,865	$ 8.29	3.4	$ 2,402
Vested or expected to vest at December 31, 2014	2,270	$ 7.39	4.1	$ 4,248

The aggregate intrinsic value of options outstanding represents the pretax value (the period's closing market price, less the exercise price, times the number of in-the-money options) that would have been received by all option holders had they exercised their options at the end of the period. The exercise price of stock options granted during the years ended December 31, 2014, 2013 and 2012 was equal to the market price of the underlying common stock on the grant date. A total of 1,479,000 stock options were exercised during the year ended December 31, 2014 with an intrinsic value of $4.6 million, a total of 138,562 stock options were exercised during the year ended December 31, 2013 with an intrinsic value of $589,000 and a total of 252,398 stock options were exercised during the year ended December 31, 2012 with an intrinsic value of $304,000. The fair value of shares vested during the years ended December 31, 2014, 2013 and 2012 were $1.1 million, $0.6 million and $0.4 million, respectively.

A summary of the time-based nonvested awards as of December 31, 2014, and changes during the year ended December 31, 2014, are as follows:

	Underlying Shares (000s)	Weighted-Average Exercise Price
Nonvested outstanding at December 31, 2013	760	$ 4.06
Granted	—	—
Forfeited or expired	(7)	3.87
Vested	(276)	4.47
Nonvested outstanding at December 31, 2014	477	$ 3.85

Restricted Stock and Restricted Stock Units

For the years ended December 31, 2014, 2013 and 2012, the Company recognized $1.0 million, $1.2 million and $1.0 million, respectively, in compensation expense related to restricted stock units.

A summary of the restricted stock awards as of December 31, 2014, and changes during the year ended December 31, 2014, are as follows:

	Underlying Shares (000s)	Weighted-Average Exercise Price
Restricted stock outstanding at December 31, 2013	747	$ 6.22
Granted	450	8.32
Vested and released	(84)	5.32
Forfeited or expired	(4)	5.91
Restricted stock outstanding at December 31, 2014	1,109	$ 7.14

As of December 31, 2014 there was an aggregate $3.8 million of unrecognized compensation expense related to unvested restricted stock units. There were 627,000 unvested restricted stock units outstanding at December 31, 2014, 523,000 unvested restricted stock units outstanding at December 31, 2013, and 430,000 unvested restricted stock units outstanding at December 31, 2012. The total fair value of restricted stock that vested during the years ended December 31, 2014, 2013 and 2012 was $726,000, $863,000and $920,000, respectively.

Performance-Based Awards

In May 2008, pursuant to an incentive program (the “PN incentive program”) approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company’s employees, including its executive officers, to purchase an aggregate of 281,433 shares of common stock with an exercise price of $14.45 per share. In September 2008, additional stock options were granted under the PN incentive program, to purchase 11,700 shares of common stock at an exercise price of $10.82 per share. The stock options have a ten-year term and have an exercise price equal to the closing sale price of the Company’s common stock, as reported on the NASDAQ Global Market, on the date immediately preceding the date of grant. Twenty-five percent (25%) of the PN incentive program options granted vested in 2009, upon completion of the performance goal and the remaining seventy-five percent (75%) of the options granted vested in 2010 upon the completion of the remaining performance goals. The fair value of the performance-based options granted under the PN incentive program was estimated as of the grant date using the Black-Scholes option valuation model without consideration of the performance measures. The options also include provisions that require satisfactory employee performance prior to vesting. Additionally, 20,000 options were granted to an executive officer in May 2008 under the PN incentive plan, with similar grant and exercise terms. The Company recognized compensation costs for these awards over the expected service period.

In October 2011, pursuant to an incentive program (the “PA32540 incentive program”) approved by the Compensation Committee of the Board of Directors of the Company, stock options were granted to all of the Company’s employees, including its executive officers, to purchase an aggregate of 453,960 shares of common stock. The underlying stock options and RSUs were performance-based and focus on the successful completion of certain value-enhancing events for the Company’s Yosprala product candidate. The stock options have a ten-year term and have an exercise price equal to the closing sale price of the Company’s common stock, as reported on the NASDAQ Global Market, on the date immediately preceding the date of grant. The underlying stock options and RSUs vest in accordance with the following schedule: (a) one-third (1/3) upon the acceptance of the filing of a new drug application (the “NDA”) for Yosprala, assuming the NDA filing is made

prior to December 31, 2012, (b) one-third (1/3) upon first cycle NDA approval of Yosprala (otherwise 16.5% upon NDA approval after first cycle), and (c) one-third (1/3) upon execution of a significant partnering transaction for Yosprala in a major territory as determined by the Compensation Committee of the Company, in its sole discretion, at the time of such transaction, subject in each case to continued employment or service to the Company.

During a pre-submission meeting with respect to its NDA for Yosprala in April 2012, the FDA suggested that the Company also seek approval for a lower dose formulation of the product containing 81 mg of enteric coated aspirin as part of its NDA for Yosprala. The Company decided to include data and information relating to a lower dose formulation in its NDA. Generation of additional data with respect to lower dose formulation of Yosprala and incorporation of data into the NDA for Yosprala would delay submission of the NDA from the original planned submission date.

Therefore, in October 2012, the Compensation Committee granted performance-based incentive awards (the "PA8140 incentive program") both to compensate the employees for the expected loss of value under the PA32540 Incentive Program, as well as to provide additional incentive to employees to complete the value-added activities required for submission and approval of the lower dose product. The Compensation Committee granted an aggregate of 208,740 restricted stock units to various employees of the Company, including 105,000 restricted stock units granted to the Company's named executive officers. The restricted stock units were performance-based and vest in accordance with the following schedule: (a) one-half (1/2) upon the acceptance by the FDA of the filing of an NDA for a lower dose Yosprala product candidate, and (b) one-half (1/2) upon approval by the FDA of an NDA for a lower dose Yosprala product candidate. In 2012, 132,883 options were forfeited in acknowledgement that certain performance goals would not be met under the PA32540 incentive program.

In April 2014, the Compensation Committee granted an aggregate of 73,000 restricted stock units to various employees of the Company, including 65,000 restricted stock units granted to the Company's named executive officers. The restricted stock units were performance-based and vest in accordance with the following schedule: (i) 50% upon receipt of the milestone payment by Sanofi US under the License and Collaboration Agreement, dated as of September 3, 2013 (the "Agreement") to be received upon approval by the U.S. Food and Drug Administration of the PA product candidates; and (ii) 50% upon receipt of the milestone payment by Sanofi US upon achievement of commercial readiness (as defined in the Agreement). The entire award was forfeited in 2014 upon the termination of the Sanofi US agreement. In 2014, a total of 177,818 options were forfeited in acknowledgement that certain performance goals would not be met under the PA32540 and PA8140 incentive programs.

During the twelve months ended December 31, 2014, in acknowledgement that certain performance goals would not be met under the PA32540 and PA8140 incentive programs and as a result of the forfeitures and accompanying prior expense reversals, there was a net negative expense of $11,000 recorded related to the achievement of vesting criteria for performance-based awards under the PA32540 and PA8140 incentive programs. As of December 31, 2014, there was $6,000 in unrecognized compensation expense related to performance-based awards granted under the PA32540 and PA8140 incentive programs.

A summary of the performance-based stock awards as of December 31, 2014, and changes during the fiscal year ended December 31, 2014, are as follows:

	Underlying Shares (000s)	Weighted-Average Exercise Price
Performance-based outstanding at December 31, 2013	540	$ 6.76
Granted	73	7.89
Exercised	(46)	1.99
Forfeited or expired	(199)	5.77
Performance-based outstanding at December 31, 2014	368	$ 8.12

The December 31, 2014 amount is expected to be recognized at the time of the grant vesting over the period ending in second quarter 2015. Under the PA32540 and PA8140 incentive programs, there were 139,000 unvested performance-based options outstanding at December 31, 2014. No performance-based awards vested during the twelve months ended December 31, 2014 and December 31, 2012. A total of 231,000 performance-based awards vested during the twelve months ended December 31, 2013. There were 229,000 vested performance-based options outstanding at December 31, 2014. The total value of performance-based awards that vested during the year ended December 31, 2014, 2013 and 2012 was $0.0, $1.0 million and $0, respectively. There were 199,000 awards forfeited during the twelve months ended December 31, 2014, 37,000 awards forfeited during the twelve months ended December 31, 2013, and 204,123 awards forfeited during the year ended December 31, 2012. A total of 46,000 performance-based awards were exercised during the year ended December 31, 2014, 162,000 performance-based awards were exercised during the year ended December 31, 2013 and no performance-based awards were

exercised during the years ended December 31, 2012. At December 31, 2014, the performance-based options had an intrinsic value of $1.3 million and a remaining weighted contractual life of 5.2 years.

7. Leases

The Company leases its office space and certain equipment under cancellable and noncancellable operating lease agreements. Rent expense incurred by the Company was approximately $419,000, $419,000 and $419,000, for the fiscal years ended December 31, 2014, 2013 and 2012, respectively. At December 31, 2014 noncancellable future minimum lease payments for operating leases totaled $0.4 million, all relating to the 2015 lease agreement.

On February 16, 2009, the Company modified certain terms to our existing lease agreement, dated November 21, 2001, relating to approximately 17,009 square feet of office space located at Exchange Office Building, Chapel Hill, North Carolina. Under the terms of the modification, the lease term was extended for an additional 5 years and 7 months, terminating on September 30, 2015. The modification also provides the Company with a reduced notice period of 7 months for renewals of the lease. The Company is also entitled to a 3-year lease extension option available at the end of the term and a first offer right on available space located within the Exchange Office Building property. As a result of entering into the modification, the Company's noncancellable future minimum lease payments for operating leases increased by approximately $2.7 million over the lease term. The Company is recognizing rent expense on a straight-line basis over the term of the lease which resulted in a deferred rent balance of $62,600 at December 31, 2014.

8. Retirement Savings Plan

The Company has adopted a defined contribution 401(k) plan (the "Plan") covering substantially all employees who are at least 21 years of age. Based upon management's discretion, the Company may elect to make contributions to the Plan. During the fiscal years ended December 31, 2014, 2013 and 2012, the Company made contributions of $141,887 and $191,582 and $224,420 respectively, to the Plan.

9. Summary of Operations by Quarters (Unaudited)

	2014			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Revenue				
Licensed revenue	$ 7,548,676	$ 7,419,306	$ 7,539,741	$ 9,886,509
Total revenue	7,548,676	7,419,306	7,539,741	9,886,509
Operating expenses	4,651,396	4,426,615	3,628,176	3,112,431
Income before income tax expense	2,904,691	2,999,457	6,752,169	7,018,415
Income tax expense	—	—	—	—
Net income attributable to common stockholders	$ 2,904,691	$ 2,999,457	$ 6,752,169	$ 7,018,415
Basic net income per common share	$ 0.09	$ 0.10	$ 0.21	$ 0.22
Diluted net income per common share	$ 0.09	$ 0.09	$ 0.20	$ 0.21
Shares used in computing basic net income per common share	30,743,966	31,022,557	31,589,192	32,083,752
Shares used in computing diluted net income per common share	32,489,969	32,604,123	32,949,779	33,353,631
Comprehensive income	$ 2,904,691	$ 2,999,457	$ 6,752,169	$ 7,018,415

	2013			
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Revenue				
Licensed revenue	$ 1,415,000	$ 1,651,000	$ 2,583,000	$ 4,673,000
Total revenue	1,415,000	1,651,000	2,583,000	4,673,000
Operating expenses	7,217,983	5,654,378	7,364,190	6,869,308
Loss before income tax benefit	(5,777,932)	(3,987,996)	(4,767,193)	(2,175,178)
Income tax expense	—	—	—	—
Net loss attributable to common stockholders	$ (5,777,932)	$ (3,987,996)	$ (4,767,193)	$ (2,175,178)
Basic and diluted net loss per common share	$ (0.19)	$ (0.13)	$ (0.16)	$ (0.07)
Shares used in computing basic and diluted net loss per common share	30,336,398	30,403,670	30,476,562	30,353,631
Comprehensive Loss	$ (5,774,679)	$ (3,987,996)	$ (4,767,193)	$ (2,175,178)

Because of the method used in calculating per share data, the quarterly per share data will not necessarily add to the per share data as computed for the year.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant.*
3.2	Second Amended and Restated Bylaws of POZEN Inc., approved September 19, 2007 (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 20, 2007).
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
4.1	See Exhibits 3.1, 3.2 and 3.3 for provisions of the Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws of the Registrant defining rights of the holders of Common Stock and Series A Junior Participating Preferred Stock of the Registrant.
4.2	Rights Agreement dated January 12, 2005 between Registrant and StockTrans, Inc. (filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 12, 2005).
10.1	Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 16, 2006).***
10.2	First Amendment to Second Amended and Restated Executive Employment Agreement with John R. Plachetka dated March 14, 2006 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.3	Executive Employment Agreement with John E. Barnhardt dated July 25, 2001 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.4	First Amendment to Executive Employment Agreement with John E. Barnhardt, dated September 28, 2007 (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.5	Executive Employment Agreement with William L. Hodges dated August 3, 2004 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed October 27, 2004).***
10.6	First Amendment to Executive Employment Agreement with William L. Hodges, dated September 28, 2007 (filed as Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.7	POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.8	Certificate of Award dated August 1, 2001 issued to John R. Plachetka pursuant to POZEN Inc. 2001 Long Term Incentive Plan (filed as Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q filed October 31, 2001).***
10.9	Summary of Non-Employee Director Compensation (filed as Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed March 8, 2007).***
10.10	Lease Agreement between The Exchange at Meadowmont LLC and the Registrant dated as of November 21, 2001 (filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K filed April 1, 2002).
10.11	Product Development and Commercialization Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Form 10-Q/A filed November 8. 2004).†
10.12	License Agreement dated June 11, 2003 between the Registrant and Glaxo Group Ltd. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 12, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.13	Collaboration and License Agreement dated September 3, 2003 between the Registrant and Valeant Pharmaceuticals NA (formerly Xcel Pharmaceuticals, Inc.) (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 6, 2003 and Quarterly Report on Form 10-Q/A filed November 8. 2004).†
10.14	Restricted Stock Unit Agreement dated May 4, 2004 between Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed July 30, 2004).***
10.15	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated May 4, 2004, between Registrant and John R. Plachetka (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.16	Form of Non-Qualified Stock Option Agreement for Trexima grants issued pursuant Registrant's Equity Compensation Plan, as amended and restated (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 7, 2005).***

Exhibit No.	Description
10.17	Development, Option and License Agreement dated May 15, 2003 between the Registrant and Nycomed Danmark ApS (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 28, 2005, and Current Report on Form 8-K/A filed January 10, 2006).†
10.18	Collaboration and License Agreement dated August 1, 2006 between the Registrant and AstraZeneca AB (filed as Exhibit 10.1 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.19	Amendment No. 1 to the Collaboration and License Agreement, dated September 6, 2007, between the Registrant and AstraZeneca AB (filed as Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007). †
10.20	Side Letter dated September 19, 2006 Re: Collaboration and License Agreement dated as of August 1, 2006 by and between the Registrant and AstraZeneca AB (filed as 10.2 to the Registrant's Quarterly Report on From 10-Q filed November 3, 2006).†
10.21	Side Letter Agreement, dated October 1, 2007, between the Registrant and AstraZeneca, AB (filed as Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007). †
10.22	Long-Term Cash Incentive Award Agreement between the Registrant and John R. Plachetka dated February 14, 2007 (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.23	First Amendment to Long Term Incentive Cash Award Agreement, dated September 28, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.24	Restricted Stock Unit Agreement with John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.25	First Amendment, dated September 28, 2007, to Restricted Stock Unit Agreement, dated February 14, 2007, between the Registrant and John R. Plachetka (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed November 5, 2007).***
10.26	Nonqualified Stock Option Grant issued to John R. Plachetka dated February 14, 2007 under Registrant's 2000 Equity Compensation Plan as Amended and Restated (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed May 3, 2007).***
10.27	Form of Nonqualified Stock Option Agreement for PN 400 Incentive Program under Second Amended and Restated 200 Equity Compensation Plan (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 8, 2008).***
10.28	Amendment No. 2 to the Collaboration and License Agreement, dated October 1, 2008, between the registrant and AstraZeneca, AB (filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed November 4, 2008). †
10.29	Lease Modification Agreement No. 1, dated as of February 16, 2009, by and between the Registrant and The Exchange at Meadowmont LLC (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 17, 2009).
10.30	Executive Employment Agreement, dated as of December 10, 2009, between the Company and John G. Fort, M.D. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 11, 2009).***
10.31	POZEN Inc. 2010 Omnibus Equity Compensation Plan (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 5, 2010).***
10.32	License Agreement, dated as of March 21, 2012, by and between POZEN Inc. and Cilag GmbH International (filed as Exhibit 10.1 to the Registrants Quarterly Report on Form 10-Q on March 5, 2011).†
10.33	Purchase and Sale Agreement, dates as November 23, 2011, by and between POZEN Inc. and CPPIB Credit Investments Inc. (filed as Exhibit 10.37 to the Registrants Annual Report on Form 10-K filed March 9. 2012).
10.34	Manufacturing Services Agreement, dates as December 19, 2011, by and between POZEN Inc. and Patheon Pharmaceuticals, Inc.†(filed as Exhibit 10.38 to the Registrants Amendment No.1 to the Annual Report on Form 10-K, filed June 29,2012).
10.35	Capital Expenditure and Equipment Agreement, dates as of December 19, 2011, by and between POZEN Inc. and Patheon Pharmaceuticals, Inc. (filed is Exhibit 10.39 to the Registrants Amendment No.11 to Annual Report on Form 10-K, filed June 29,2012).
10.36	First Amendment to Manufacturing Services Agreement, between Patheon Pharmaceuticals Inc., and POZEN Inc., dated as of July 10, 2013 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†

Exhibit No.	Description
10.37	First Amendment to Capital Expenditure and Equipment Agreement, between Patheon Pharmaceuticals Inc., and POZEN Inc., dated as of July 10, 2013 (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†
10.38	License and Development Agreement, dated as of May 7, 2012, by and between POZEN Inc. and DESITIN Arzneimittel GmbH (filed as Exhibit 10.1 to Registrants Quarterly Report on Form 10-Q, filed on August 8, 2012).
10.39	Amendment No. 3 to the Collaboration and License Agreement between POZEN Inc. and AstraZeneca AB, dated as of September 16, 2013 (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†
10.40	License and Collaboration Agreement between POZEN Inc. and sanofi-aventis U.S. LLC, dated as of September 3, 2013 (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2013).†
10.41	Letter Agreement among POZEN Inc., AstraZeneca AB and Horizon Pharma U.S.A. Inc. dated as of November 18, 2013 (filed as Exhibit 10.43 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.42	Amendment No. 1 to Amended and Restated Collaboration and License Agreement for the United States by and between POZEN Inc. and Horizon Pharma U.S.A. Inc. dated as of November 18, 2013 (filed as Exhibit 10.44 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.43	Amended and Restated Collaboration and License Agreement for the United States by and between POZEN Inc. and AstraZeneca AB dated as of November 18, 2013 (filed as Exhibit 10.45 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.44	Amended and Restated Collaboration and License Agreement for outside of the United States by and between POZEN Inc. and AstraZeneca AB dated as of November 18, 2013 (filed as Exhibit 10.46 to the Registrant's Annual Report on Form 10-K, filed March 6, 2014). †
10.45	Letter Agreement, dated as of May 13, 2014, by and among POZEN Inc., CPPIB Credit Investments, Inc. Pernix Therapeutics Holdings, Inc. and Glaxo Group Limited (filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 6, 2014).
10.46	First Amendment to Product Development and Commercialization Agreement, dated as of May 13, 2014, by and between POZEN Inc. and Pernix Therapeutics Holdings, Inc. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed November 6, 2014).
10.47	Second Amendment to Product Development and Commercialization Agreement dated as of July 30, 2014, by and between POZEN Inc. and Pernix Therapeutics Holdings, Inc. (filed as Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed November 6, 2014).
10.48	Termination Agreement, dated as of November 29, 2014, by and between POZEN Inc. and sanofi-aventis U.S. LLC.**
10.49	Termination Agreement, dated as of December 22, 2014, by and between POZEN Inc. and Cilag GmbH International ("Cilag"), a division of Johnson & Johnson. **
21.1	List of subsidiaries of the Registrant.**
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.**
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
101	The following materials from POZEN Inc. Form 10-K for the fiscal year ended December 31, 2014, formatted in Extensible Business Reporting Language (XBRL): (1) Balance Sheets at December 31, 2014 and December 31, 2013, (iii) Statements and operations for the year ended December 31, 2014 and December 31, 2013, (iii) Statements and Cash Flows for the years ended December 31, 2014 and December 31, 2013, and (iv) Notes to the Financial Statements.

* Incorporated by reference to the same-numbered exhibit of the Registrant's Registration Statement on Form S-1, No. 333-35930.

** Filed herewith.

*** Compensation Related Contract.

† Confidential treatment requested. Confidential materials omitted and filed separately with Securities and Exchange Commission.

EXHIBIT 21.1

POZEN UK Limited

Jurisdiction of incorporation:	United Kingdom
Name under which business conducted:	POZEN UK Limited

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-170730) pertaining to the 2010 Omnibus Equity Compensation Plan of POZEN Inc. of our reports, dated March 11, 2015, with respect to the financial statements of POZEN Inc. and the effectiveness of internal control over financial reporting of POZEN Inc. included in this Annual Report (Form 10-K) of POZEN, Inc. for the year ended December 31, 2014.

/s/ Ernst & Young LLP

Raleigh, North Carolina
March 11, 2015

EXHIBIT 31.1

Section 302 Certification

I, John R. Plachetka**,** certify that:

1. I have reviewed this Annual Report on Form 10-K of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2015

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Section 302 Certification

I, William L. Hodges, certify that:

1. I have reviewed this Annual Report on Form 10-K of POZEN Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2015

/s/ William L. Hodges
William L. Hodges
Senior Vice President, Finance and Administration
and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CEO CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

In connection with the Annual Report on Form 10-K of POZEN Inc. (the "Company"), as filed with the Securities and Exchange Commission (the "Report"), I, John R. Plachetka, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2015

/s/ John R. Plachetka
John R. Plachetka, Pharm.D.
Chief Executive Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CFO CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

In connection with the Annual Report on Form 10-K of POZEN Inc. (the "Company") , as filed with the Securities and Exchange Commission (the "Report"), I, William L. Hodges, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2015

/s/ William L. Hodges
William L. Hodges
Chief Financial Officer

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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BOARD OF DIRECTORS

John R. Plachetka, Pharm.D.
Chairman, President and Chief Executive Officer
POZEN Inc.

Neal F. Fowler
Chief Executive Officer
Liquidia Technologies, Inc.

Nominating/Corporate Governance Committee
Compensation Committee

Arthur S. Kirsch
Senior Advisor
GCA Savvian Advisors, LLC

Audit Committee, Chairman
Compensation Committee
Nominating/Corporate Governance Committee

Kenneth B. Lee, Jr.
General Partner
Hatteras Venture Partners

Lead Independent Director
Audit Committee
Compensation Committee, Chairman

Seth A. Rudnick, M.D.
Venture Partner
Canaan Partners

Audit Committee
Nominating/Corporate Governance Committee, Chariman

CORPORATE INFORMATION

Corporate Headquarters
POZEN Inc.
1414 Raleigh Road, Suite 400
Chapel Hill, NC 27517
919.913.1030
www.pozen.com

Stock Transfer Agent and Registrar
Broadridge Financial Solutions, Inc.
1981 Marcus Avenue
Lake Success, NY 11042

Independent Accountants
Ernst & Young LLP
4130 ParkLake Avenue, Suite 500
Raleigh, NC 27612

Common Stock Listing
Ticker Symbol: POZN
NASDAQ Global Market

Annual Meeting
Wednesday, June 10, 2015

Stockholder Inquiries
Stockholders and prospective investors seeking information about POZEN should visit the Company's website at www.pozen.com or contact POZEN's Investor Relations Department at 919.913.1030.

Forward-Looking Statements

Statements included in this Annual Report that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results, our ability to return value to our stockholders, including any cash distributions, and our future prospects could differ materially from those contained in the forward-looking statements, which are based on current market data and research (including third party and POZEN sponsored market studies and reports), management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our inability to further license our YOSPRALA™ product candidates on terms and timing acceptable to us, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval of our product candidates, including as a result of the need to conduct additional studies or due to issues with third-party manufacturers, or the failure to obtain such approval of our product candidates for all expected indications, including as a result of changes in regulatory standards or the regulatory environment during the development period of any of our product candidates; uncertainties in clinical trial results or the timing of such trials, resulting in, among other things, an extension in the period over which we recognize deferred revenue or our failure to achieve milestones that would have provided us with revenue; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products, including our dependence on AstraZeneca and Horizon for the sales and marketing of VIMOVO®, our dependence on Patheon for the manufacture of YOSPRALA 81/40 and YOSPRALA 325/40; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events, including those discussed herein and in our Annual Report on Form 10-K for the period ended December 31, 2014. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

POZEN®

Transforming medicine. Transforming lives.

1414 Raleigh Rd | Suite 400 | Chapel Hill, NC | 27517 | pozen.com