POZEN Reports Fourth Quarter & Year End 2011 Results

The Associated Press

CHAPEL HILL, N.C.--(BUSINESS WIRE)--Feb 28, 2012-- POZEN Inc. (NASDAQ: POZN),a pharmaceutical company committed to transforming medicine that transforms lives, today announced results for the fourth quarter and year ended December 31, 2011.

Corporate Highlights of 2011 -- POZEN monetized future royalty and milestone payments for sales of Treximet(R) (sumatriptan / naproxen sodium) in the United States to a financial investor for $75.0 million (net proceeds of $71.9 million).

The Company retained rights to 20% of all royalty payments after the first quarter of 2018.

-- 2011 net sales of VIMOVO(TM) (naproxen / esomeprazole magnesium) delayed-release tablets were $33.8 million, generating an annual royalty of $2.9 million. VIMOVO has now been launched in a total of 28 countries.

-- The PA32540 Phase 3 pivotal studies have been fully enrolled. Top line data are anticipated in Q2 2012 and the New Drug Application (NDA) submission is targeted for Q3 2012.

-- A 12-month, Phase 3 study to evaluate the long-term safety of PA32540 in subjects who are at risk for developing aspirin-associated gastric ulcers has been completed. In the study, adverse events were as expected and consistent with what would be expected in this population of patients requiring cardio-aspirin therapy and with the known safety profile of the PA components.

-- Data from our Phase 1 Co-Rx study suggest that PA32540 given with clopidogrel, dosed at least 10 hours apart, resulted in significantly better inhibition of ADP-induced platelet aggregation (anti-clotting) when compared to a current standard of care (81 mg of EC aspirin, EC omeprazole 40 mg and clopidogrel dosed together). The results were presented at the AHA meeting in November and the clinical significance of these data is presently unknown.

-- The Company selected Keelin Reeds Partners LLC to assist in the strategic partner search for all PA assets, including PA32540 for both the U.S. and globally. Keelin Reeds is a global expert in helping life sciences companies value pipeline assets, develop business development strategies and execute partnership transactions.

-- The United States District Court for the Eastern District of Texas issued a favorable verdict in the litigation between POZEN and several generic pharmaceutical companies which had filed Abbreviated New Drug Applications (ANDAs) seeking approval from the U.S. Food and Drug Administration (FDA) to

market generic copies of Treximet. Treximet is marketed by POZEN's exclusive U.S. licensee, GlaxoSmithKline (GSK).

Each of the defendants has appealed the decision to the U.S. Court of Appeals for the Federal Circuit.

-- POZEN entered into a license agreement with Cilag GmbH International, a division of Johnson & Johnson, for the development and commercialization of MT 400 in Brazil, Colombia, Ecuador and Peru. MT 400 is POZEN's proprietary combination of sumatriptan and naproxen sodium, the first multiple mechanism triptan therapy for the treatment of migraine.

Fourth Quarter Results For the fourth quarter of 2011, POZEN reported revenue of $73.0 million, comprised of VIMOVO royalty of $1.1 million and the net proceeds from the monetization of the Treximet royalty of $71.9 million. For the fourth quarter of 2010, the Company reported total revenue of $29.0 million, resulting from royalty on sales of Treximet of $4.0 million, and $25.0 million from the approval of VIMOVO in a major ex-U.S. territory.

Operating expenses for the fourth quarter of 2011 totaled $11.5 million, as compared to $11.4 million for the comparable period in 2010. The slight increase in operating expenses in the fourth quarter of 2011 was primarily due to higher pre-commercialization costs partially offset by lower patent litigation and R&D costs.

The Company reported a net income of $61.5 million, or $2.04 per share on a diluted basis, for the fourth quarter of 2011, compared to net income of $18.4 million, or $0.61 per share on a diluted basis, for the fourth quarter of 2010.

Twelve Month Results For the twelve months ended December 31, 2011, POZEN reported revenue of $87.0 million compared to $68.5 million in 2010. The 2011 revenue is comprised of the monetization of the Treximet royalty stream, which resulted in $71.9 million in net revenue, $12.2 million of Treximet royalty and $2.9 million of VIMOVO royalty. The 2010 revenue was comprised of $45.0 million of milestone payments related to VIMOVO, $15.7 million of royalty from Treximet, $7.3 million of VIMOVO licensing fees and development revenues, and $0.5 million of royalty from VIMOVO.

Operating expenses for the twelve months ended December 31, 2011 were $44.8 million compared to $46.4 million in the same period in 2010.

The decrease in operating expenses is primarily a result of $8.4 million less in patent litigation costs, partially offset by higher PA32540 development and pre-commercialization costs.

The Company reported a net income of $42.3 million, or $1.40 per share on a diluted basis for the 2011 year compared to a net income of $23.1 million, or $0.76 per share on a diluted basis, for the same period in 2010.

Balance Sheet At December 31, 2011, cash, cash equivalents and short-term

investments totaled $119.6 million, of which $5.8 million relates to the unsettled short-term investments purchase in late December for which settlement did not occur until early January. This had the effect of increasing cash / short-term investments and liabilities by $5.8 million for the 3 days between purchase and settlement. Cash and short-term investments were $64.1 million at December 31, 2010. The 2011 increase was due to the Treximet royalty monetization. The Company had an accounts receivable balance of $1.1 million from AstraZeneca at December 31, 2011.

Outlook 2012 is an important year for POZEN. We are completing the pivotal Phase 3 studies for our leading product candidate PA32540. We expect to have the results of the studies in the second quarter and plan to file the NDA in the third quarter. We have made the decision to find a partner or partners for this and the other PA assets and, with the assistance of Keelin Reeds Partners LLC, are in discussions with potential partners. We are continuing to perform critical pre-commercialization activities required to ensure a timely launch by an eventual partner.

From a financial standpoint, in 2012 we expect our R&D costs will be substantially lower due to the completion of our PA32540 Phase 3 studies and we expect our SG&A to be slightly lower year on year. Our current plan targets a year-end cash and short-term investment balance of greater than $85.0 million.

Fourth Quarter Results Webcast POZEN will host a webcast to present fourth quarter and year end 2011 results and management's outlook on Tuesday, February 28, 2012 at 11:00 a.m. (ET). The webcast can be accessed live and will be available for replay at www.pozen.com [1].

About POZEN POZEN Inc. is a progressive pharmaceutical company that is transforming how the healthcare industry addresses unmet medical needs. 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 in two years. Funded by these milestone/royalty streams, POZEN is now creating 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 opportunity for its portfolio assets.

The Company's common stock is traded under the symbol "POZN" on The NASDAQ Global Market. For more detailed company information, including copies of this and other press releases, please visit www.pozen.com [1].

About PA POZEN is creating a portfolio of integrated aspirin therapies - the PA product platform. The products in the PA portfolio are intended to significantly reduce GI ulcers and other GI complications compared to taking aspirin alone.

The first candidate is PA32540. It is a coordinated-delivery tablet combining immediate-release omeprazole, a proton pump inhibitor, layered around pH-sensitive aspirin. This novel, patented product is administered orally once a day and

will be indicated for use for the secondary prevention of cardiovascular disease in patients at risk for aspirin-induced ulcers. POZEN has completed enrollment for the long-term safety study and the two pivotal studies, targeting a New Drug Application filing in 3Q12.

About VIMOVO VIMOVO(TM) (naproxen / esomeprazole magnesium) is a fixed-dose combination of delayed-release enteric-coated naproxen, a non-steroidal anti-inflammatory drug (NSAID), and immediate-release esomeprazole, a stomach acid-reducing proton pump inhibitor (PPI), approved for the relief of 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.VIMOVO is not recommended for use in children younger than 18 years of age. VIMOVO is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.VIMOVO should be used at the lowest dose and for the shortest amount of time as directed by your health care provider.

For Full Prescribing Information see www.vimovo.com [2].

About Treximet Treximet was approved by the U.S. Food and Drug Administration (FDA) in April 2008 for the acute treatment of migraine attacks, with or without aura, in adults. The product is formulated with POZEN's patented technology of combining a triptan with a non-steroidal anti-inflammatory drug (NSAID) and GlaxoSmithKline's (GSK) RT Technology(TM). This migraine medication contains sumatriptan, a 5-HT1 receptor agonist that mediates vasoconstriction of the human basilar artery and vasculature of human dura mater, which correlates with the relief of migraine headache. It also contains naproxen, an NSAID that inhibits the synthesis of inflammatory mediators. Therefore, sumatriptan and naproxen contribute to the relief of migraine through pharmacologically different mechanisms of action. As a result of this dual mechanism of action, Treximet has been shown to provide superior sustained pain relief compared to placebo and to both of the single mechanism of action components.

For Full Prescribing Information see www.treximet.com [3].

Forward-Looking Statements Statements included in this press release 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 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 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 the failure to obtain such approval of our product candidates, 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 for the sales and marketing of VIMOVO(TM); 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 Quarterly Report on Form 10-Q for the period ended September 30, 2011. 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 Inc. Statements of Operations (Unaudited) Three Months Ended December 31, Twelve Months Ended December 31, 2011 20102011 2010 Revenue: Sale of royalty rights, net of costs$71,870,283$-$71,870,283$- Royalty revenue1,130,0004,003,62215,080,23416,215,307 Other licensing revenue-25,000,000-52,201,080 Development revenue-35,104-132,283 Total revenue73,000,28329,038,72686,950,51768,548,670 Operating expenses: Selling, general and administrative6,978,7955,853,84421,752,29923,755,231 Research and development4,552,4405,561,65423,020,12922,650,554 Total operating expenses11,531,23511,415,49844,772,42846,405,785 Other income: Interest and other income, net24,541800,908161,444928,875 Income before income tax benefit61,493,58918,424,13642,339,53323,071,760 Income tax expense---- Net income attributable to common stockholders$61,493,589$18,424,136$42,339,533$23,071,760 Basic net income per common share$2.05$0.62$1.41$0.77 Shares used in computing basic net income per common share29,974,52529,904,27429,924,94429,879,624 Diluted net income per common share$2.04$0.61$1.40$0.76 Shares used in computing diluted net income per common share30,137,04730,249,78030,296,20030,246,488 POZEN Inc. Balance Sheets (Unaudited) December 31, December 31, 20112010 ASSETS Current assets: Cash and cash equivalents$104,990,723$31,232,083 Short-term investments14,629,41632,858,549 Accounts receivable1,130,0004,038,726 Prepaid expenses and other current assets700,3261,498,995 Total current assets121,450,46569,628,353 Equipment, net of accumulated depreciation102,91070,033 Total assets$121,553,375$69,698,386 LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable$2,269,271$2,972,309 Payable for unsettled investment purchases5,752,735- Accrued compensation2,168,3412,327,327 Accrued expenses3,577,6062,504,147 Accrued contract costs2,029,878- Deferred revenue257,300- Total current liabilities16,055,1317,803,783 Long-term liabilities: Accrued contract costs-1,266,491 Total liabilities16,055,1319,070,274 Total stockholders' equity105,498,24460,628,112 Total liabilities and stockholders' equity$121,553,375$69,698,386 This article has been truncated. You can see the

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