

Pozen, Inc.

NASDAQ:POZN

Analyst: Pamela Juergens

Sector: Healthcare

BUY

Price Target: \$12.32

Key Statistics as of 3/12/2015

Market Price:	\$7.55
Industry:	Biotechnology
Market Cap:	\$231.0 M
52-Week Range:	\$5.96-9.73
Beta:	1.82

Thesis Points:

- Upcoming FDA approval of lead product candidate likely
- Increasing revenues combined with decreasing cost, increasing their bottom line
- Diversified product pipeline
- Possible acquisition target

Company Description:

Pozen, Inc. is a pharmaceutical company that develops products for the treatment of acute and chronic pain, and pain related conditions in the United States and internationally. The company's products include Treximet for acute treatment of migraine attacks with or without aura in adults, with which they are partnered with spec pharma company Pernix, and VIMOVO for relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, as well as to decrease the risk of developing gastric ulcers in patients at risk of developing non-steroidal anti-inflammatory drugs (NSAID) - associated gastric ulcers, with which they are partnered with sec pharma company Horizon in the United States and AstraZeneca in international markets. They are currently in the NDA stage of the product development process with YOSPLARA, formerly known as PA. YOSPLARA is an aspirin therapy for secondary prevention of cardiovascular and cerebrovascular disease in patients at risk for gastric ulcers.



Thesis

Pozen currently has a licensing and royalty deal for VIMOVO with Horizon in the United States, and AstraZeneca internationally. Horizon expects to see more growth in sales of VIMOVO, positioning Pozen to earn more in royalties. As well, they will see their royalty rate on international sales of VIMOVO increase in 2016. Pozen's lead product candidate YOSPLARA is set to launch in the United States in 2016, providing Pozen with an additional source of revenue. They were previously partnered with Sanofi U.S. for the commercialization of the drug, but mutually agreed to terminate the partnership in December 2014. Pozen is currently looking for a new partner for YOSPLARA, which gives them the potential to bring in another upfront payment as well as milestone payments and royalty payments.

Future of YOSPLARA

Delayed FDA Approval:

Pozen submitted a NDA for YOSPLARA, but in April the FDA issued a complete response letter (CRL). A CRL is issued by the FDA when the review of the file is completed but there are remaining questions that preclude the approval of the NDA in its current form. The CRL stated that during an inspection of the foreign manufacturing facility of an active ingredient supplier, a FDA investigator conveyed deficiencies to a representative of the facility. The deficiencies must be resolved before the NDA is approved. On December 17, 2014 Pozen received another CRL, stating the same issues. However, this was not because the facility had failed to rectify the situation but rather the FDA had not made another visit to the facility. The FDA has stated that it is a top priority to review the facility in the near future.

While the approval has been delayed, Pozen has put into place a second option, which involves using a different supplier, should the situation with the first supplier continue to be an issue. Additionally, the FDA has no other clinical or safety issues beyond the API issue, and once that is resolved YOSPLARA is likely to be approved, so there is not likely to be any delay in getting it to market once the approval comes. Also, Pozen is continuing to make commercialization preparations that

ensure whether they go with the original supplier or the backup supplier that they will still be able to bring YOSPLARA to market by 2016. Pozen is currently looking at all possible options to bring YOSPLARA to market by 2016, including a new licensee, doing it on their own or even an acquisition.

Partnership:

Pozen struck a licensing agreement for the commercialization of YOSPRALA in the U.S. with pharmaceutical giant Sanofi in September 2013. The deal came \$15 million in upfront cash, with an additional \$20 million in approval and commercial readiness milestones and 12.5% to 22.5% tiered royalties on sales. However, in December 2014 Pozen announced that they had mutually agreed to terminate their partnership and Sanofi surrendered all future rights to the drug back to Pozen. It may seem that this decision is related to the delay in approval of YOSPLARA, but in fact there is an underlying reason that better explains the decision, and in fact will be beneficial to Pozen in the long run.

Second, and more importantly Sanofi announced in November 2014 that they plan to introduce 18 new drugs by 2020, with sales estimated to be approximately \$37.5 billion. Analysts estimate that YOSPRALA's peak sales in the United States will be approximately \$300million. For a small, specialty pharma company this is a large amount of sales, but when compared with the billions of dollars in sales that Sanofi expects from other products in the future it is a very small amount. Sanofi would likely not focus as much attention on the marketing and sales of YOSPRALA as they would with a drug slated to make them billions of dollars, something that would severely hurt Pozen's royalty revenues. Even though having a large household name attached to a product could help sales, Pozen has had proven results with smaller spec pharma companies in the past, as seen with VIMOVO. When AstraZeneca forfeited their rights to VIMOVO in the United States and Horizon acquired the rights sales increased greatly. The same is true for Treximet, which GlaxoSmithKline forfeited the rights to which were subsequently sold to Pernix in May 2014. A spec pharma company will be more focused on YOSPRALA, and dedicate more resources toward the marketing. If Pozen can secure another commercialization agreement for YOSPRALA, it will likely be similar to that with Sanofi, and they will be able to secure an upfront payment in the range of the \$20 million payment Sanofi would have owed them in 2015.

Value Drivers

For the year ended 2014, Pozen recorded net income of \$19.7 million or \$0.60 per share on a fully diluted basis compared with a net loss of \$16.7 million of \$0.55 loss per share for the year ended 2013. Their net income as a percent of revenue was 61% for the year. Their revenue is royalty and milestone based, therefore there is no current cost of sales so much of their revenue streams to the bottom line. Their main value drivers are revenue growth coupled with decreased expenses.

Revenue Growth

For the year ended 2014, Pozen recorded revenue of \$32.4 million, \$21.1 million of VIMOVO royalty, \$11million amortization of the upfront payment for PA and \$0.3 million related to the Cilag agreement termination. Revenue for the year ended 2013 was \$10.3 million, including only \$6.3 million VIMOVO royalty. Revenue growth has been driven mainly by growth in sales of VIMOVO, of which Pozen receives a royalty rate of 10%. For the year ended December 2014, net sales for VIMOVO were \$163 million. This was the first full year that VIMOVO was commercialized by Horizon Pharma. In the last full year that VIMOVO was under the control of AstraZeneca, net sales were approximately \$20 million. This demonstrates Horizon's ability to drive sales growth of the drug. Horizon will continue to grow sales of VIMOVO, especially through their Prescriptions Made Easy (PME) program. Their PME program ensures patients receive the prescriptions at the lowest cost to them, and at the lowest hassle to the prescribing physicians. Currently, 38% of VIMOVO prescriptions are prescribed through their PME, and Horizon has a goal of 60%. Their increased investment in subsidizing scripts within PME is having the positive effect of driving prescriptions.

As Horizon grows sales of VIMOVO, Pozen's revenues will continue to grow because of the 10% royalty that they will continue to receive. In 2015, Pozen's rest of the world revenues from VIMOVO will remain relatively flat. However, in 2016 their royalty rate for the rest of the world jumps from 6% up to 10%, so expect to see increased revenues from rest of the world sales of VIMOVO beginning next year. Also, Pozen still expects to launch YOSPRALA in 2016, so they will begin recognizing royalty revenues from that beginning in 2016.

Decreasing Costs

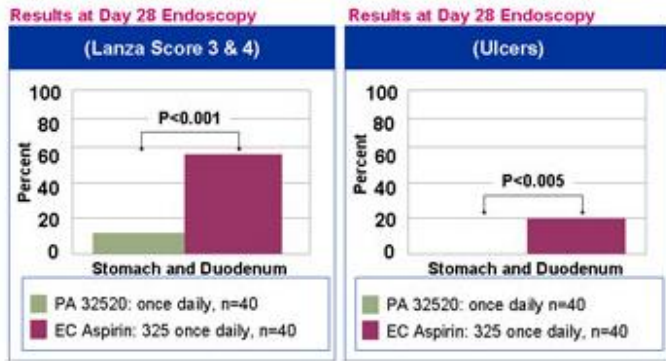
The second major factor that contributed to their profitability in 2014, was expense control. Operating expenses for FY 2014 were \$15.8 million, a significant decrease from expenses of \$27.1 million in FY 2013. For Q4 2014, operating expenses are down to \$3.1 million from \$6.9 million in Q4 2103. The costs are down as a result of fewer staff members, lower non-cash compensation expense, and lower costs related to YOSPRALA. Pozen expects that expenses will remain relatively flat, around \$3.1 million for most of 2015, only increase towards the end as they get ready to launch YOSPRALA in 2016. Lower, steady costs combined with revenues that will continue to increase

Robust Product Pipeline

Many guidelines recommend long-term use of aspirin for prevention of cardiovascular events among patients with prior cardiovascular disease or multiple risk factors to develop cardiovascular disease. However, regular aspirin use is associated with gastrointestinal bleeding.

Pozen's pipeline consists of PA products. These are a GI-safer form of aspirin franchise product candidates. The investigational pipeline includes cost effective, integrated therapies designed to enable the full power of aspirin by reducing gastrointestinal damage. The first candidates are PA8140 and PA32540 (now known as YOSPRALA), which are coordinated delivery tablets combining immediate release omeprazole, a proton pump inhibitor, layered around pH sensitive enteric coated aspirin. It is indicated for use for the secondary prevention of cardiovascular disease in patients at risk for aspirin-associate gastric ulcers. Top line results were published in March 2012, and they were shown to be significantly better than typical aspirin at preventing ulcers.

PA 32520 vs. 325mg EC Aspirin



(Proof of Concept Study Results)

backup plan, with a new supplier to ensure that YOSPLARA will be ready to market by 2016. Their cost control measures ensure that their revenues flow to the bottom line. Their diversified product pipeline gives them many assets to ensure revenue growth for years to come. All of these points also make them an attractive acquisition candidate for larger biotech companies looking expand their reach.

Possible Acquisition Target

Pozen makes for an attractive acquisition candidate for a larger biotech company. They have no debt, as well as cash on hand of \$43.3 million. Pozen has a diversified product portfolio that would be beneficial to a larger firm to acquire, as well as pipeline assets that address a large unmet need with high potential for future sales. Horizon Pharma is a potential acquirer for several reasons. They already have a working relationship with Pozen with VIMOVO. Horizon only has 5 drugs marketed currently, 4 of which are for the treatment of arthritis pain and inflammation, and the other is a rare disease therapy for the treatment of Chronic Granulomatous Disease, and sever, malignant osteopetrosis. Pozen is able to offer them a diversified pipeline, to help them expand their product portfolio. On March 13, Horizon closed a private placement of \$400 million aggregate principal amount of Exchangeable Senior Notes due 2022. Net proceeds from the offering were ~\$386.5 M, and the company stated that they will be used to fund general corporate purchases including future acquisitions. This debt along with the cash on hand they have gives Horizon the perfect opportunity to make a tender offer for Pozen.

Conclusion

Pozen has shown their ability to make a profit, which will continue to grow with likely approval of YOSPRALA upcoming. Even if the third party supplier does not correct the issues with their plant, Pozen has a

