Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Aralez Now to be Domiciled in Canada; Merger with Tribute to Finalize in 1Q16…

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	03/07/2007
Current Price (12/10/15)	$7.05
Target Price	**$13.50**

UPDATE

On December 7, 2015, Pozen Inc. and Tribute Pharmaceuticals Canada, Inc. announced that the planned merger between the two company's is proceeding and that the newly formed parent company, Aralez Pharmaceuticals, Inc., will now be domiciled in Canada instead of Ireland. The impetus for the change was clarified guidelines issued by the U.S. Treasury Department that limited the ability of U.S. corporations to combine with a foreign entity when the new foreign parent would be located in a "third country". The Canadian domicile for Aralez will offer a very similar corporate and tax structure to the Irish domicile, thus we don't view the change as having any material impact on our thesis, and we continue to have a 'Buy' rating on both Pozen and Tribute.

SUMMARY DATA

52-Week High	**$12.44**
52-Week Low	**$5.70**
One-Year Return (%)	**-23.62**
Beta	**1.56**
Average Daily Volume (sh)	**538,574**
Shares Outstanding (mil)	**33**
Market Capitalization ($mil)	**$234**
Short Interest Ratio (days)	**3.29**
Institutional Ownership (%)	**68**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/M**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/M**
P/E using 2016 Estimate	**13.6**

Risk Level	**Average**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	7.5 A	7.4 A	7.5 A	9.9 A	32.4 A
2015	4.4 A	5.2 A	5.8 A	6.5 E	21.4 E
2016					42.5 E
2017					105.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	$0.09 A	$0.09 A	$0.20 A	$0.21 A	$0.60 A
2015	-$0.00 A	-$0.50 A	-$0.25 A	$0.03 E	-$0.91 E
2016					-$0.28 E
2017					$0.14 E

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WHAT'S NEW

Aralez to be Domiciled in Canada

On December 7, 2015, Pozen, Inc. (POZN) and Tribute Pharmaceuticals Canada, Inc. (TBUFF) announced that the planned merger between the two companies is proceeding and that the newly formed parent company, Aralez Pharmaceuticals Inc., will now be domiciled in Canada instead of Ireland. The impetus for this change was new guidelines issued by the U.S. Treasury Department on November 19, 2015 that were issued in order to "…rein in corporate tax inversions."

The specific guidelines issued that relate to the formation of Aralez have to do with potential adverse tax consequences for a corporate inversion where the former owners of the U.S. company own between 60% and 80% of the newly combined entity. The Treasury department specifically listed inversions where:

> *"…a U.S. company combines with a smaller existing foreign corporation using a new foreign parent whose tax residence is different from that of the existing foreign corporation. In other words, the new foreign parent will be a tax resident of a 'third country.' The third country chosen generally will have a favorable tax system and income tax treaty with the United States."*

Under such a scenario, the Treasury Department decreed that stock of the foreign parent (i.e., Aralez) issued to shareholders of the existing foreign corporation (i.e., Tribute) would be disregarded for purposes of calculating the ownership attributable to the shareholders of the U.S. entity (i.e., Pozen). This is important, because current tax law stipulates that if shareholders of the former U.S. corporation own 80% or more of the newly formed foreign parent, then the new foreign parent is treated as a U.S. corporation (despite the new corporate address), thereby nullifying the corporate inversion for tax purposes.

Seeing as how Pozen (a U.S. company) was planning to acquire Tribute (a smaller existing foreign corporation) and domicile Aralez in Ireland (a 'third country'), the guidelines described above would most likely have applied to the merger. After taking into account the investment in Aralez by a group led by Deerfield Management, the final ownership distribution will be approximately 53%, 30%, and 17% for Pozen shareholders, Tribute shareholders, and Deerfield *et al*., respectively. The new Treasury guidelines would have likely resulted in the 30% ownership attributable to Tribute shareholders being disregarded for ownership purposes, thus Aralez would likely have been treated as a U.S. corporation for tax purposes.

Pozen and Tribute re-evaluated the proposed transaction structure and have agreed to proceed with the merger and have Aralez domiciled in Canada. The companies determined that such a Canadian-domiciled parent company is advantageous given Tribute's active business presence in Canada and the ability of the combined company to diversify revenue. The new Canadian-domiciled parent company will maintain the advantages of establishing in Ireland through Pozen's wholly owned Irish subsidiary, Pozen Limited. The companies believe that Ireland remains the preferable jurisdiction from which to access European markets, given Ireland's membership in the European Union, established pharmaceutical industry, including sophisticated workforce in pharmaceutical development, manufacturing, supply chain, and procurement. The Canadian based company continues to comply with the IRS requirements applicable to corporate inversions, applying the new guidelines.

Due to the change in plans, the proxy statements filed November 6, 2015 will be withdrawn and new filings will be made with the regulatory authorities, and thus both Tribute and Pozen cancelled the shareholder meetings scheduled for December 9 and 10, respectively. Upon approval by both company's stockholders, stock in Aralez will be distributed in a 1:1 fashion for Pozen shareholders, while shareholders of Tribute will receive 0.1455 shares of Aralez for each share of Tribute. Before factoring in the financing that will occur upon closing of the deal (discussed below), stockholders of Pozen will own approximately 64% of Aralez while stockholders of Tribute will own approximately 36%. Pozen's management will take charge of Aralez, with Mr. Adrian Adams as CEO, and Aralez is expected to apply to list its shares on the Nasdaq (ARLZ) and the TSX (ARZ).

In conjunction with the acquisition (which we now anticipate will close during the first quarter of 2016), a group of leading healthcare investors, led by Deerfield Management, has committed up to $350 million in capital for Aralez to

fund the anticipated commercial launch of YOSPRALA® and for "future acquisitions". The proposed investment in Aralez consists of $75 million in equity at a per share purchase price determined by the volume weighted average price per share of POZEN common stock over certain days before the close but in no event lower than $6.25 per share or greater than $7.20 per share, and $75 million in 2.5% convertible senior secured notes due in six years with a conversion price equal to a 32.5% premium to the aforementioned equity price. At an equity issuance price of $7.20 per share, the ownership distribution at close will be approximately 53%, 30%, and 17% for POZEN shareholders, Tribute shareholders, and Deerfield et al., respectively.

In addition to the $150 million to be invested in Aralez at closing, another $200 million in senior secured debt is available to the company to "fund future acquisitions". We believe this will translate into a number of deals that will transpire in 2016 and beyond to build Aralez into a company with a cardiovascular-based and North American focused portfolio of products. These deals are likely to focus on products that are already approved or very near approval that the company views as low-risk, high-value assets.

Aralez Overview

The strategy behind Aralez is that the company will become a cardiovascular focused specialty pharmaceutical company with support from a pain-focused franchise. We expect that the company will be centered on YOSPRALA®, once it is approved, which we believe will occur in 2016 (discussed further below). In the run-up to the launch of YOSPRALA®, the company will focus its efforts on increasing sales of Fibricor® in the U.S., which Tribute recently purchased from Sun Pharma and will begin promoting in the U.S. in the fourth quarter of 2015. Below we highlight the products that Aralez will market once the merger between Pozen and Tribute occurs.

Cardiovascular Products: YOSPRALA® is composed of a delayed-release aspirin and an immediate-release omeprazole intended for the secondary prevention of heart attack and stroke. For patients who have suffered a heart attack or stroke, taking daily aspirin has been shown to help prevent the occurrence a second heart attack or stroke. In the U.S., there are approximately 24 million secondary prevention patients, with approximately 70% of them taking daily aspirin. In addition, approximately 40% of prescribing physicians recommend that their patients take some form of gastric acid reducer. The reason for this is that daily use of nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin, is associated with an increased risk of developing gastric ulcers, thus the addition of an agent that decreases stomach acid production, such as the proton pump inhibitor (PPI) omeprazole, is intended to decrease the chance for the development of ulcers. Pozen has previously shown that patients taking YOSPRALA® develop significantly fewer gastric ulcers than patients taking enteric-coated aspirin after six months of treatment (Whellan *et al*., 2014). Patent coverage for YOSPRALA® expires in Feb. 2023, with the potential for filed patent applications to extend protection to 2032.

Fibricor® is a unique formulation of fenofibric acid and is indicated as an adjunctive therapy to diet for the treatment of severe hypertriglyceridemia (triglycerides ≥ 500 mg/dL), to reduce elevated LDL cholesterol, total cholesterol, triglycerides, apolipoprotein B (Apo B), and to increase HDL cholesterol. Fenofibrate was originally sold by Abbott Labs (now AbbVie Pharmaceuticals) as TriCor, with peak sales in excess of $1 billion. AbbVie brought a blockbuster next-generation product, Trilipix (fenofibric acid) to the market as a follow-on to TriCor, but now 80% of the market for fenofibrate and fenofibric acid is generic. As a reminder, Tribute only just recently acquired Fibricor® from Sun Pharma in May 2015. Tribute paid $10 million for the rights to the product, which included $5 million upfront, $2 million due in November 2015, and $3 million due in May 2016. Trailing twelve-month sales of Fibricor ending April 30, 2015 totaled $4.7 million, and that was with little to no promotion by Sun Pharma. We believe Aralez will utilize approximately 20-25 sales representatives to promote Fibricor® to approximately 3,500 cardiologists and primary care physicians beginning in the fourth quarter of 2015. Patent coverage for Fibricor expires in Feb. 2027.

Bezalip® SR (bezafibrate sustained release) is one of Tributes largest products, with sales in Canada of around CND$6-7 million. Beyond Canada, the product is approved in approximately 40 countries around the globe, but not yet approved (or filed) in the U.S. Bezalip® SR is indicated as an adjunct to diet and other therapeutic measures for the treatment of mixed hyperlipidemia, a condition defined as the elevation of plasma cholesterol, triglycerides (TGs), or both, or a low high-density lipoprotein (HDL) level that contributes to the development of atherosclerosis. The 400 mg Bezalip® SR tablet is designed for sustained release such that only once-daily dosing is sufficient to obtained therapeutic pharmacology. Tribute currently promotes Bezalip® SR with a 20-person primary-care focused sales force in Canada.

In addition to the products discussed above, Aralez will also have a synthetic beta-adrenergic blocker drug Visken® (approved in Canada) for hypertension and angina along with a combination product that includes the active

ingredient in Visken® (pindolol) with a diuretic agent hydrochlorothiazide under the brand name Viskazide® (approved in Canada).

As a reminder, the New Drug Application (NDA) for YOSPRALA® was originally filed in March 2013. On August 25, 2014, Pozen received a complete response letter (CRL) from the FDA, noting that deficiencies were found during an inspection of the facility that manufactures the active ingredient of YOSPRALA®. The supplier responded to the FDA and on June 30, 2014 the NDA was resubmitted. On December 17, 2014, Pozen received a second CRL, which contained identical wording to the first CRL. YOSPRALA® cannot be approved until there is satisfactory resolution to the deficiencies noted in the CRL. The active ingredient supplier is currently working to correct those deficiencies, and in the mean time Pozen is looking for a second supplier in case the deficiencies with the first supplier cannot be cleared up. At this point it is unclear whether after re-filing the NDA Pozen will receive a Class-1 (two month) review or a Class-2 (six month) review, however the use of a new active ingredient supplier would likely result in a Class-2 review. Regardless, we anticipate that YOSPRALA® will be approved in 2016.

Pain Products: Vimovo® is composed of the NSAID naproxen and the PPI esomeprazole, with the theory behind the drug identical to that of YOSPRALA®. Aralez will continue to collect royalties on sales of Vimovo® in the U.S. from Horizon and outside the U.S. from AstraZeneca. Patent coverage for Vimovo® expires in the U.S. in Oct. 2031.

Durela® is an extended release tramadol product with sales in Canada of approximately CND$1.5 million. Tribute acquired Durela® when the company closed on the Medical Futures acquisition just announced on June 17, 2015. Penetration rates for Durela® in Canada are extremely low and offer significant upside should Aralez management be able to improve uptake of the drug. The drug is patent protected in Canada until October 2022. We believe peak Durela® sales are approximately CND$5 million.

Cambia® (diclofenac) is the primary growth driver of the Canadian business at Tribute Pharma. The product was approved back in March 2012, but recently prescriptions have been accelerating thanks to new Canadian Headache Society (CHS) guidelines published back in October 2013 recommending the product as first-line therapy for migraine attacks where OTC products fail. This puts Cambia® ahead of triptans such as Maxalt®, Imitrex®, and Zomig®. Tribute (in collaboration with the CHS and KOLs) has developed and disseminated a national continuing education program based on the CHS guidelines to help drive awareness and uptake of Cambia®. The drug is patent protected in Canada until May 2017.

Tribute acquired the Canadian rights to Fiorinal® and Fiorinal® C in October 2014. The products are indicated for the relief of tension-type headache and would be easy to co-promote with Cambia®.

We remind investors that Pernix Pharma now has the U.S. rights to Pozen's Treximet® (naproxen + sumatriptan), one of the leading triptan products on the market for acute migraine. Aralez still owns the ex-U.S. rights to Treximet, called MT-400, which may make a nice complement to Cambia® or Fiorinal® / Fiorinal® C in Canada. If Aralez did decide to move forward with developing MT-400 in Canada, we believe the company would offer the best migraine/headache product suite for active promotion, and could see incredible synergistic uptake of all three products thanks to established awareness and strong KOL relationships.

Other Products: Other important drugs that Aralez will offer include Soriatane® (acitretin) in Canada for the treatment of severe psoriasis, Collatamp® G (gentamicin-impregnated collagen) for post-operative infection, Bilastine® (antihistamine) in Canada for allergic rhinitis and urticaria, Proferrin® for iron deficiency, and Resultz® (50% isopropyl myristate) for the treatment of head lice.

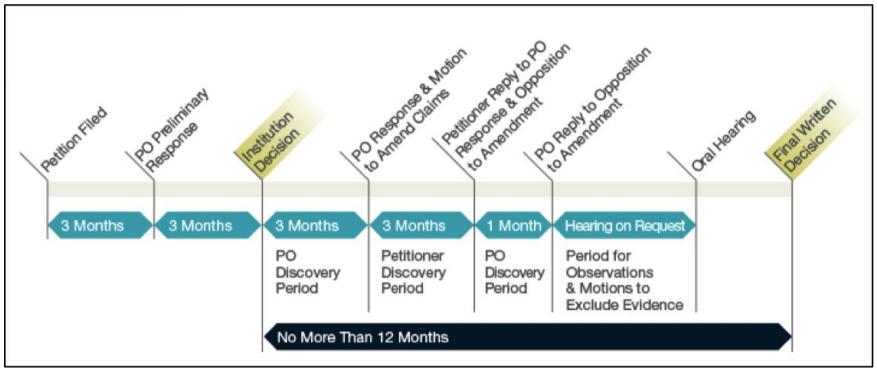
Tribute acquired the rights to Proferrin® via the Medical Futures acquisition in June 2015. Proferrin® is an iron supplement made up of heme iron polypeptide naturally sourced from bovine hemoglobin. The product is designed to provide high absorption of iron with low incidences of side effects commonly associated with iron treatments, such as cramping and constipation. Medical Futures was privately-owned prior to the acquisition by Tribute last month, so exact financials are not available; however, we have been told that sales of Proferrin® in Canada were about CND$4 million for the trailing twelve months. We believe Tribute will merge the Medical Futures sales force in with its own to promote the aforementioned products.

Resultz® (50% isopropyl myristate topical solution) was also acquired from Medical Futures. The product is indicated for the treatment of head lice infestations in individuals 2 years and older. Resultz® is a unique, non-toxic/pesticide free, patent protected, topical solution which is available without a prescription in pharmacies across Canada. Resultz® treatment for head lice infestations is simple and consists of only 1 to 2 applications to achieve efficacy. The drug is patent protected in Canada until Apr. 2023.

Tribute also has worldwide rights to NeoVisc® for osteoarthritis and Uracyst® for interstitial cystitis. Having two products on the market in Europe will certainly help should the company look to commercialize Yosprala® or MT-400 in the EU, or look to acquire the EU rights to Vimovo® from AstraZeneca.

First IPR Petition Filed Against Pozen Not Instituted

The Coalition for Affordable Drugs (CFAD) has filed petitions for *Inter Partes* Review (IPR) of three of Pozen's U.S. Patent's related to Vimovo® (Nos. 6,926,907, 8,858996, and 8,852636) as well as one owned jointly by Horizon and Pozen (No. 8,945,621) with the Patent Trials and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO). The IPR was instituted with the America Invents Act of 2011 to replace the *inter partes* reexamination, which up until that time was one of two methods for reexamination of a patent. However, reexamination had earned a reputation for taking a long time to finish and often with results that were ambiguous. The hope with establishing IPR was that a patent review would go quickly and involve the PTAB in the first instance, rather than on appeal as with *inter partes* reexamination. The timeline for IPR is indicated below:



Source: fishpostgrant.com

J. Kyle Bass, the hedge fund billionaire most famous for predicting the subprime mortgage crisis in 2008, established the CAFD (a wholly owned subsidiary of Bass' Hayman hedge fund) to challenge patents owned by several publicly traded pharmaceutical companies in an attempt to invalidate patents they viewed as being improperly granted, and thus pave the way for generics of the targeted drugs and lower drug costs. In addition to filing IPR petitions, CAFD takes short positions in the company's stock that they are targeting, thus attempting to profit off a decline in a company's stock price upon notice of the IPR petition or the successful invalidation of the company's patent.

On December 8, 2015, the PTAB announced that the IPR filed against patent 6,926,907 was not instituted and thus no challenge against that patent will proceed. This is important as it helps to remove any questions surrounding the company's IP position. Based on this, we do not anticipate the other three IPRs being instituted, and thus this is unlikely to be an issue for the company any longer.

Conclusion and Recommendation

The specialty pharmaceutical sector has been hit hard recently by a renewed interest in trying to bring drug prices under control. This was spurred by Hillary Clinton's drug pricing proposal, the controversy surrounding Turing Pharmaceuticals increasing the price of Daraprim® from $13 to $750 per pill, and the increased scrutiny afforded to the pricing practices of companies such as Valeant (VRX). Due to this, Pozen's stock price has fallen from approximately $10 on Sep. 16 to a current price of $7.05. In our opinion this is an overreaction, particularly since Aralez's business strategy will not be predicated on price increases driving growth. In addition, there is unlikely to be any serious attempt at price controls on pharmaceuticals in this country in the foreseeable future. Thus, the current environment could represent a meaningful opportunity to establish or add to a position in Pozen with good upside available once the merger goes through.

For modeling purposes, we are anticipating that Aralez will be promoting YOSPRALA® in the U.S. as opposed to partnering the drug and collecting royalties, and we are estimating an approximately 55% operating margin. We believe there are approximately 24 million Americans who would be eligible for secondary treatment with daily aspirin. Of those, approximately 70% of patients are currently on aspirin and represent the target population for YOSPRALA®. The company is planning to initially target those patients through the use of an approximately 100 person sales force targeting the top 20% of secondary prevention specialists. Over time, this sales force could

increase to 300, which would target approximately 40% of the market. In the end, we think YOSPRALA® is a potential $300-350 million drug in the U.S.

Based on our modeling for products like Bezalip® SR, Cambia®, Fibricor®, Proferrin®, and the remaining assets at Tribute, we believe Tribute is worth approximately $175 million. This is slightly above the original $146 million deal price, as we believe synergies across the two portfolios will be great and profits will be higher given the lower tax rate stemming from moving the headquarters to Canada. Our current model gives a net present value for Pozen of approximately $440 million, or just over $13 per share.

Looking ahead to Aralez's worth after the merger, when we combine the valuation for Pozen ($440 million) and Tribute ($175 million) we arrive at a combined valuation of $615 million. Adding in the cash to be received at closing from Deerfield of $75 million gives a net present value of $690 million. The basic share count for Aralez after the merger should be on the order of 62 million shares (33.2 million from Pozen shareholders, 18.4 million from Tribute shareholders, and 10.4 million from Deerfield equity purchase). This equates to a target price of just over $11 per share.

PROJECTED FINANCIALS

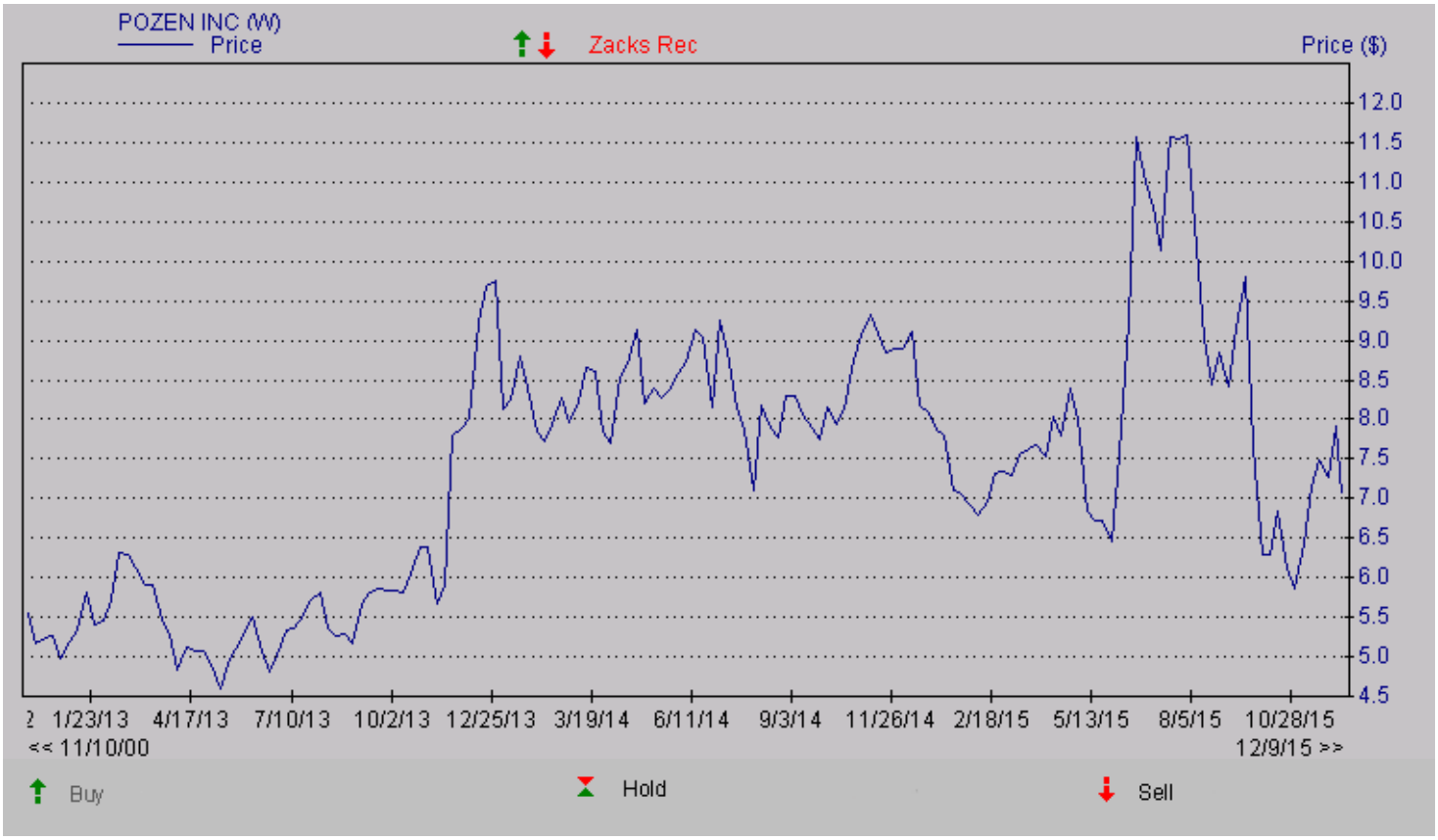
Pozen, Inc.
Income Statement

Pozen, Inc.	2013 A	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E
Treximet / MT400 (royalty)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Vimovo (sales)	$91.0	$243.6	$51.3	$39.8	$46.8	$62.0	$199.9	$225.0	$200.0
Vimovo (royalty)	**$6.3**	**$21.1**	**$4.4**	**$5.2**	**$5.8**	**$6.0**	**$21.4**	**$22.5**	**$25.0**
YOY Growth	*30.4%*	*234.3%*	*-3.2%*	*-4.0%*	*5.1%*	*6.6%*	*1.4%*	*5.0%*	*11.1%*
Yosprala	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$20.0**	**$80.0**
YOY Growth	-	-	-	-	-	-	-	-	-
Licensing / Development	**$4.0**	**$11.3**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$0.0**
Total Revenues	$10.3	$32.4	$4.4	$5.2	$5.8	$6.0	$21.4	$42.5	$105.0
YOY Growth	*93.0%*	*213.8%*	*-41.7%*	*-29.9%*	*-22.8%*	*-39.3%*	*-33.9%*	*98.4%*	*147.1%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$4	$8
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*90.6%*	*92.4%*
SG&A	$17.2	$10.1	$3.3	$18.2	$12.2	$18.0	$51.7	$60.0	$75.0
% SG&A	*166.3%*	*31.1%*	*74.1%*	*349.8%*	*209.7%*	*300.0%*	*241.1%*	*141.2%*	*71.4%*
R&D	$9.9	$5.7	$1.0	$2.3	$1.8	$1.1	$6.2	$6.5	$7.0
% R&D	*96.3%*	*17.7%*	*22.3%*	*44.3%*	*31.0%*	*18.3%*	*28.9%*	*15.3%*	*6.7%*
Operating Income	($16.8)	$16.6	$0.2	($15.3)	($8.2)	($13.1)	($36.4)	($28.0)	$15.0
Operating Margin	*-162.6%*	*51.2%*	*3.6%*	*-294.1%*	*-140.8%*	*-218.3%*	*-170.0%*	*-65.9%*	*14.3%*
Interest Income / Net	$0.1	$3.1	($0.2)	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($16.7)	$19.7	($0.0)	($15.3)	($8.2)	($13.1)	$36.3	$27.9	$15.1
Taxes	$0	$0	$0	$1	($0)	$0	$0	($8)	$4
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*30%*	*28%*
Net Income	($16.7)	$19.7	($0.0)	($16.3)	($8.1)	($13.1)	($36.3)	($19.5)	$10.9
YOY Growth	*-33.9%*	*-217.8%*	-	-	-	-	*-284.6%*	*-46.2%*	*-155.7%*
Net Margin	*-161.9%*	*60.7%*	*-0.6%*	*-313.0%*	*-140.0%*	*-218.0%*	*-169.6%*	*-46.0%*	*10.4%*
Reported EPS	($0.55)	$0.60	($0.00)	($0.50)	($0.25)	($0.21)	($0.91)	($0.28)	$0.14
Fully Diluted Shares	30.4	32.8	32.3	32.4	32.7	62.4	40.0	70.0	80.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 25.1%, Hold/Neutral- 56.2%, Sell/Underperform – 14.7%. Data is as of midnight on the business day immediately prior to this publication.