Zacks Small-Cap Research

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POZEN, Inc. (POZN-NASDAQ)

POZN: Pozen To Acquire Canadian-Based Tribute Pharma and Become Aralez Pharmaceuticals plc of Ireland……

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	03/07/2007
Current Price (07/13/15)	$10.22
Target Price	**$13.50**

UPDATE

On June 8, 2015, Pozen announced the acquisition of Tribute Pharmaceuticals Inc. Under terms of the deal, Pozen will acquire Tribute Pharma for $146 million in stock. The acquisition, which has been unanimously approved by the Board of Directors of each of the constituent companies, is subject to stockholder approval from Pozen as well as from Tribute. Upon closing, the newly formed company, Aralez Pharmaceuticals plc, will be domiciled in Ireland. Aralez Pharma shares will trade on NASDAQ as well as on TSX. Pursuant to the agreement, Pozen will issue 0.1455 shares of common stock for each share of Tribute Pharmaceuticals. Pozen's management will be in charge of the new company, with Mr. Adams as CEO.

SUMMARY DATA

52-Week High	**$12.44**
52-Week Low	**$6.45**
One-Year Return (%)	**14.58**
Beta	**1.35**
Average Daily Volume (sh)	**975,485**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$329**
Short Interest Ratio (days)	**12.69**
Institutional Ownership (%)	**58**
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	4.8 E	5.3 E	6.5 E	20.1 E
2016					61.5 E
2017					63.8 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	$0.04 E	$0.06 E	$0.03 E	$0.15 E
2016					$0.75 E
2017					$0.74 E

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WHAT'S NEW

New Leadership / New Focus

It has been a very busy past several weeks for Pozen Inc. (POZN). Our last update on the company in mid-May 2015 followed the release of the first quarter 2015 financial results. At that time, we noted that the best investors could do was sit-tight and wait for an update on the planned re-filing of the U.S. NDA for Yosprala®, as there were not a lot of catalysts otherwise. We couldn't have been more wrong! On June 1, 2015, Pozen announced the surprise retirement of Dr. John R. Plachetka, the company's founder, Chairman and Chief Executive Officer. The Board of Directors appointed Adrian Adams to replace Dr. Plachetka as CEO and also appointed Mr. Adams to serve on the Board of Directors, effective immediately. Arthur Kirsch, who has served as an independent director since 2004, was appointed to serve as Chairman of Pozen's Board of Directors.

Adrian Adams has an extensive history has a pharmaceutical executive. Over his 30+ years of experience, Mr. Adams has developed a reputation for growing organizations by executing on business development opportunities and delivering value for shareholders, often ending with the company he runs being acquired by a larger pharmaceutical organization. His resume includes:

- ✓ CEO of Auxilium Pharmaceuticals Inc. (acquired by Endo International plc in January 2015).
- ✓ Chairman and CEO of Neurologix, Inc. (filed for chapter 7 bankruptcy).
- ✓ CEO of Inspire Pharmaceuticals, Inc. (acquired by Merck & Co.).
- ✓ CEO of Sepracor Inc. (acquired by Dainippon Sumitomo Pharma Co).
- ✓ CEO of Kos Pharmaceuticals, Inc. (acquired by Abbott Laboratories).

Pozen also announced that the Board of Directors had appointed Andrew Koven as President and Chief Business Officer, reporting to Mr. Adams. Mr. Koven most recently served as Chief Administrative Officer and General Counsel of Auxilium Pharmaceuticals Inc. Prior to joining Auxilium, Mr. Koven served as President and various other roles at Neurologix, Inspire Pharmaceuticals, Sepracor, and Kos Pharmaceuticals.

A few weeks later, Pozen expanded the leadership team to include Mark A. Glickman to serve in the role as Chief Commercial Officer, Eric L. Trachtenberg in the role of Deputy General Counsel, and Jennifer L. Armstrong in the role of Executive Vice President, Human Resources and Administration.

The day after Dr. Adams took over as President and CEO, Pozen announced it was forming a wholly owned Irish subsidiary, Pozen Limited, and transferring all intellectual property owned by the company to the foreign subsidiary. We believe the company is doing this to lower the tax rate on profits from commercialized and potential future products, as well as expand the company's geographic footprint by increasing foreign presence. Ultimately, we believe the company will seek approval for Yosprala® in the European Union. The creation of an Irish subsidiary came less than a week before the most significant news over the past month, a major acquisition.

On June 8, 2015, Pozen announced the acquisition of Tribute Pharmaceuticals Inc. Under terms of the deal, Pozen will acquire Tribute Pharma for $146 million in stock. The acquisition, which has been unanimously approved by the Board of Directors of each of the constituent companies, is subject to stockholder approval from Pozen as well as from Tribute. Upon closing, the newly formed company, Aralez Pharmaceuticals plc, will be domiciled in Ireland. Aralez Pharma shares will trade on NASDAQ as well as on TSX. Pursuant to the agreement, Pozen will issue 0.1455 shares of common stock for each share of Tribute Pharmaceuticals. Pozen's management will be in charge of the new company, with Mr. Adams as CEO.

- **Cardiovascular Portfolio**

Aralez intends to focus on the commercialization of specialty pharmaceutical products with an emphasis on the cardiovascular space. We expect Yosprala® (aspirin + omeprazole), once approved, to be the company's global flagship brand. Tribute will bring several additional cardiovascular drugs to the portfolio, including a sustained-release fibrate Bezalip® SR (Canadian & U.S. rights) for the treatment of mixed hyperlipidemia, another fibrate product called Fibricor® (U.S. rights) for severe hypertriglyceridemia and mixed dyslipidemia, and a synthetic beta-adrenergic blocker drug Visken® (Canada) for hypertension and angina. Tribute sells a combination product that includes the active ingredient in Visken® (pindolol) with a diuretic agent hydrochlorothiazide under the brand name Viskazide® (Canada).

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. The same sales force also promotes other Tribute products, including Cambia® and Soriatane®, which we discuss below.

Pozen is obviously still trying to get Yosprala® approved in the U.S. (more on this below). Once approved in the U.S., we believe Aralez will turn its attention to brining Yosprala® to the European and Canadian markets. The company has yet to have a detailed conversation with Health Canada on a path forward for Yosprala® in Canada; however, we believe the clinical work will be minimal and can likely either piggy-back off the U.S. approval (best case scenario) or any potential EU-based Phase 3 program (most likely scenario). Once approved in Canada, we believe Yosprala® fits nicely in with the company's existing focus, and in time we expect to see additional reps hired to expand the reach for all Aralez products in Canada. We believe Bezalip® SR peak sales in Canada are approximately CND$10 million, whereas Yosprala® has potential CND$20 million peak opportunity in Canada.

In the U.S., Tribute will focus on launching Fibricor® in the next few months. 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. Fibricor® is indicated as an adjunctive therapy for treatment of severe hypertriglyceridemia (TG ≥ 500 mg/dL), to reduce elevated LDL cholesterol, total cholesterol, triglycerides, apolipoprotein B (Apo B), and to increase HDL cholesterol. Fibricor® is an authorized generic fenofibrate. 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. Nevertheless, 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.

Tributes strategy over the next few months is to engage with KOL's and work with managed care in preparation of a luanch later in 2015. We suspect that Tribute (or Aralez depending on when the deal closes) will look to hire 20-25 representatives in the U.S. to begin active promotion of Fibricor®. Having built a specialized cardiovascular sales force in the past with Kos Pharma, current Pozen CEO, Adrian Adams, has significant experience in this area. We expect the initial "hand-picked" reps for Fibricor® will be tasked with establishing relationships and building Aralez brand recognition within the cardiovascular area. We expect Aralez to be disciplined and methodical on the initial Fibricor® roll-out, with an emphasis on market share and penetration. In time, this is the sales force that will promote Yosprala® in the U.S., and may ultimately grow to the 100-150 person size once the Yosprala® roll-out gains steam. We expect Aralez to be active in looking for a third (and fourth) cardiovascular product in the U.S. in 2016. Seeking approval for Bezalip® SR in the U.S. is a likely path forward, as is in-licensing or M&A to acquire new commericalized candidates that can be plugged into the existing model.

With respect to the status of the Yosprala® re-filing, we remind investors that Pozen held a Type A meeting with the U.S. FDA's Office of Compliance in January 2015 to try to better understand the deficiencies noted in the December 2014 complete response letter (CRL). At Pozen's Type A meeting, the FDA confirmed again that there are no outstanding clinical efficacy or safety issues. In February 2015, the active ingredient supplier informed Pozen that they received a warning letter relating to the Form 483 inspection deficiencies. The supplier has submitted a comprehensive plan of corrective actions to address the matters raised in the warning letter to the FDA. According to Pozen, the warning letter contained far fewer items than from the original April 2014 inspection report and CRL, meaning the API supplier is making progress, but clearly more is still needed.

Once the FDA reviews the supplier's comprehensive corrective plan, the agency will inspect the facility. If cleared, the supplier will receive a Good Manufacturing Practice (GMP) certification to make Yosprala®. Pozen believes that once the GMP certificate is issued they can re-file the NDA and hopefully receive a Class-1 (two month) review. This would be the most optimistic path forward, potentially still allowing for a new PDUFA late 2015. In the meantime, Pozen has been working on a backup plan since last year to identify and qualify alternative suppliers of this API (the API is aspirin by the way) if the need arises for a secondary supplier to come into the picture. The company is already ordering batches from this new supplier. However, receiving approval for a second supplier would have to come via filing an amendment to the NDA. This would likely be a Class-2 (six month) review. We are expecting an update on all of this when Pozen hosts its second quarter earnings call in early August 2015.

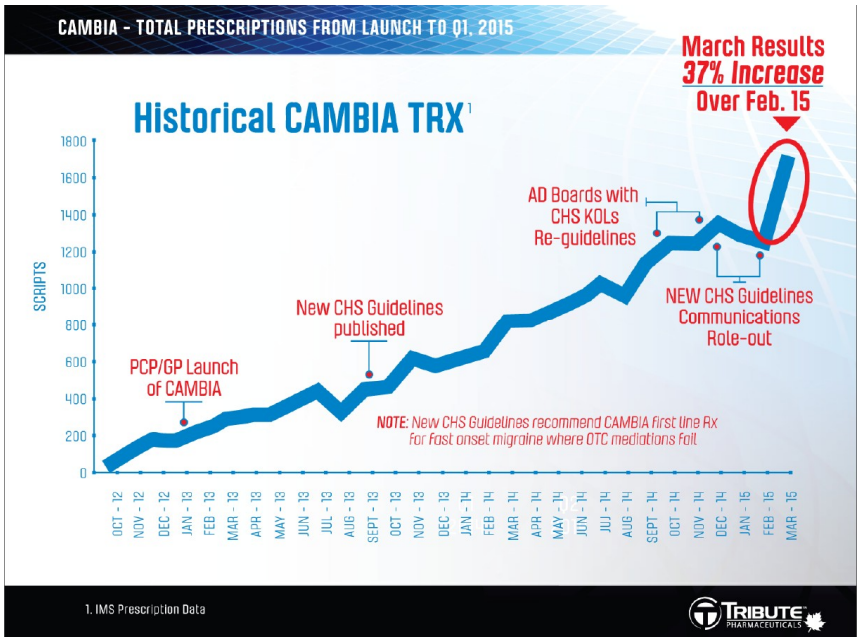
- **Pain / Neurology Portfolio**

Another key area of focus for Aralez Pharma will be on pain. Pozen will continue to collect royalties on sales of Vimovo® (naproxen + esomeprazole) in the U.S. from Horizon Pharma plc (HZNP) and outside the U.S. from AstraZeneca plc (AZN). We have heard that AstraZeneca is looking to sell the ex-U.S. rights to Vimovo®, so the potential exists that Aralez may be a bidder for both the Canadian rights (sales of around CND$20 million) or European rights (sales of around $40 million). Although we believe Aralez Pharma's initial focus will be on the North American market, we do believe the EU rights to Vimovo® are interesting for the company considering they are now domiciled in Ireland and have stated they would like to expand their international exposure. In this regard, Aralez may lead with Yosprala® in the EU and then follow-up with additional products, potentially like Vimovo®, in time.

Beyond pain drug Vimovo®, Tribute will bring an extended release tramadol product called Durela® (Canada), and two very important migraine / headache drugs in Cambia® (Canada) and Fiorinal® / Fiorinal® C (Canada). 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. We find it interesting that Aralez will market Cambia® (diclofenac) in Canada as a superior option for acute migraine (note Depomed, Inc. has the U.S. rights to Cambia®). Aralez still owns the ex-U.S. rights to Treximet, called MT-400, which may make a nice complement to Cambia® in Canada, or tension-type headache drugs Fiorinal® / Fiorinal® C.

Durela® sales in Canada are 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® (tramadol HCl extended release capsules) 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® is the primary growth drive 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 they suggested first-line therapy for migraine attacks where OTC products fail. This puts the products 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®.



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 are a very synergistic promote with Cambia®. As noted above, if Aralez did decide to move forward with developing MT-400 (sumatriptan + naproxen) 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.

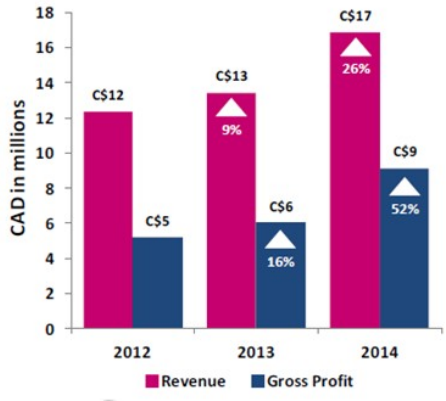
Resultz® (50% isopropyl myristate topical solution) was also acquired from Medical Futures. The product is indicated for the treatment of head lice infestations in individuals 2 years and older. Resultz® is a unique, non-toxic/pesticide free, patent protected, topical solution which is available without 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.

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 d the company look to commercialize Yosprala® or MT-400 in the EU, or look to acquire the EU rights to Vimovo® from AstraZeneca.

Tribute Brings a Sold Product Portfolio & Strong Operating History

Product	Region	Indication
Cardiovascular		
Fibricor®	US	HTG and mixed dyslipidemia
Bezalip® SR	US/CA	Mixed dyslipidemia
Visken®/Viskazide®	CA	Hypertension & angina
Pain		
Cambia®	CA	Acute migraine
Fiorinal®/Fiorinal® C	CA	Tension-type headaches
Various Specialty		
Soriatane®	CA	Severe psoriasis
NeoVisc®	WW	Osteoarthritis
Uracyst®	WW	Interstitial cystitis
Collatamp® G	CA	Post-operative infection
Bilastine (NDS)	CA	Allergic rhinitis and urticaria

Source: Tribute Pharma & Pozen Inc.



Significant Capital Infusion

The merger is expected to close in the fourth quarter 2015 (best guess is October 2015). The newly formed company will benefit from a significant capital infusion lead by Deerfield Management, a well-known premier investment management firm that provides growth capital for healthcare companies, and QLT Inc, alongside a number of other leading healthcare investors including Broadfin Capital, LLC. The group has committed up to $350 million in total capital to the new company, with the first $150 million expected to close simultaneously with the closing of the merger. The proposed investment in Aralez will be a combination of convertible debt and equity, including a $75 million equity stake at a purchase price of $7.20 per share (10.4 million shares) and $75 million in 2.5% convertible senior secured notes (due in six years with a conversion price of $9.54 per share). At closing, Pozen shareholders, Tribute shareholders, and the financing consortium led by Deerfield et al, will own approximately 54%, 28%, and 17%, respectively, of the combined company.

Another $200 million in senior secured debt will also be made available to "fund future acquisitions". We expect Aralez to very active on the product licensing and acquisition front throughout 2016 and beyond. The focus will likely be on the North American cardiovascular market, with an emphasis on low-risk, high-value assets. We are not expecting Aralez to undertake significant R&D efforts, and thus deals in 2016 or beyond will likely be limited to under review or already approved assets.

We remind investors that Pozen exited the first quarter 2015 with $43.9 million in cash and investments. The company is slightly cash flow positive based on royalties from Vimovo®. We had anticipated a non-dilutive capital infusion later in 2015 based on the company re-partnering Yosprala® after the re-filing of the U.S. NDA. However, we have removed those expectations and now believe that Aralez will commercialize the drug in the U.S. in 2016, and likely outside the U.S. in time.

Conclusion – What's Aralez Pharma Worth?

Our valuation model for Pozen has undergone some meaningful changes since our last update. For example, we now anticipate that Pozen will commercialize Yosprala® in the U.S. rather than just collect royalties from a commercial partner. We have removed the $25 million cash upfront payment we expected from a partner in 2016 from our model; however, instead of Pozen collecting 20% royalty on U.S. Yosprala® sales, we now anticipate the company netting an approximate 50-60% margin after manufacturing, marketing and promotional expenses. We have slightly increased our discount rate in our DCF model to account for the increased risk associated with building a sales force and promoting the product. Our assumptions for Vimovo® remain unchanged.

We have yet to fully merge our models for Pozen and Tribute, as the two companies will operate independently until the merger in the fourth quarter 2015. However, 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 in enterprise value. This is slightly above the $146 million deal price, as we believe synergies across the two portfolios will be great and profits will be high given the lower tax rate (modeling low-20's vs. low-30's) stemming from moving the headquarters to Ireland. We had previously believed Pozen shares were worth $400 million, or $12 per share. Our new model pegs the valuation of Pozen, prior to the equity investment lead by Deerfield, at $445 million in total value, or just over $13 per share. This included an estimated cash balance of approximately $44 million as of June 30, 2015.

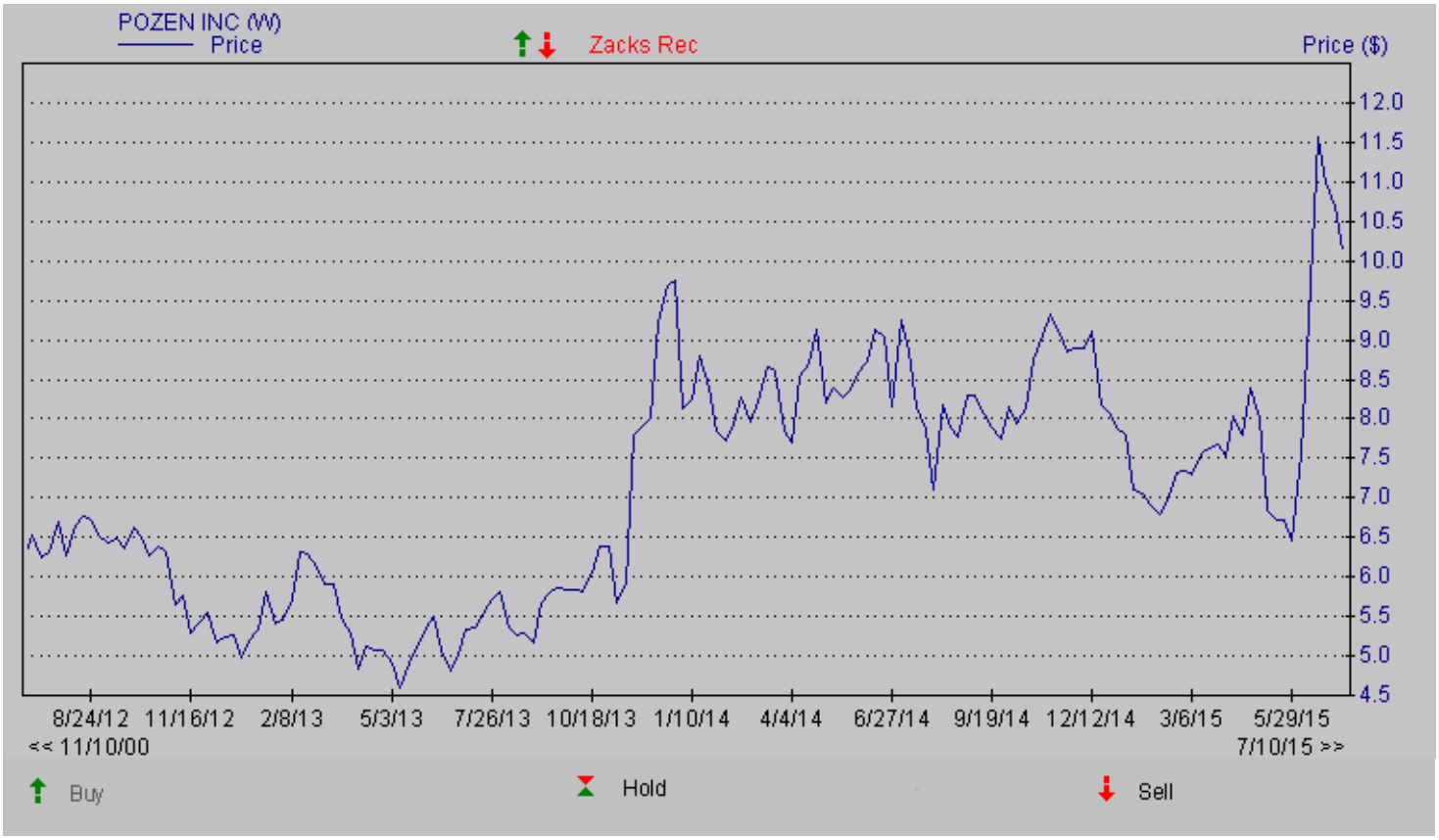
Our combined valuation for Pozen ($445 million) and Tribute ($175 million) is approximately $620 million. When we factor in the $150 million ($75 million cash + $75 million debt) investment from Deerfield, Broadfin, QTL, et al, we arrive at a new enterprise value of approximately $695 million. Based on deal terms and planned financings, we expect the basic share count to be approximately 63.7 million upon close of both transactions. This equates to a target price for Aralez of roughly $11 per share.

INCOME STATEMENT

Pozen, Inc.	2013 A	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E
Treximet / MT400 (royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Vimovo (royalty)	$6.3	$21.1	$4.4	$4.8	$5.3	$5.6	$20.1	$22.5	$20.0
YOY Growth	*30.4%*	*234.3%*	*-3.2%*	*-12.3%*	*-3.6%*	*-0.9%*	*-5.0%*	*12.1%*	*-11.1%*
PA-Franchise (royalty)	$0	$0	$0	$0	$0	$0	$0	$14.0	$43.8
YOY Growth	-	-	-	-	-	-	-	-	-
Licensing / Development	$4.0	$11.3	$0	$0	$0	$0	$0	$25.0	$0.0
Total Revenues	$10.3	$32.4	$4.4	$4.8	$5.3	$5.6	$20.1	$61.5	$63.8
YOY Growth	*93.0%*	*213.8%*	*-41.7%*	*-36.0%*	*-29.2%*	*-43.6%*	*-38.0%*	*206.3%*	*3.7%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
SG&A	$17.2	$10.1	$3.3	$2.4	$2.3	$2.4	$10.4	$9.0	$8.0
% SG&A	*166.3%*	*31.1%*	*74.1%*	*50.5%*	*43.1%*	*43.0%*	*51.6%*	*14.6%*	*12.5%*
R&D	$9.9	$5.7	$1.0	$0.9	$0.9	$1.1	$3.9	$4.0	$4.0
% R&D	*96.3%*	*17.7%*	*22.3%*	*18.9%*	*16.9%*	*19.7%*	*19.3%*	*6.5%*	*6.3%*
Operating Income	($16.8)	$16.6	$0.2	$1.5	$2.1	$2.1	$5.8	$48.5	$51.8
Operating Margin	*-162.6%*	*51.2%*	*3.6%*	*30.6%*	*40.1%*	*37.3%*	*29.0%*	*78.9%*	*81.2%*
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)	$1.5	$2.2	$2.1	$5.9	$48.6	$51.9
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($16.7)	$19.7	($0.0)	$1.5	$2.2	$2.1	$5.9	$48.6	$51.9
YOY Growth	*-33.9%*	*-217.8%*	-	-	-	-	*-69.9%*	*719.5%*	*6.7%*
Net Margin	*-161.9%*	*60.7%*	*-0.6%*	*31.0%*	*40.4%*	*37.6%*	*29.5%*	*79.0%*	*81.3%*
Reported EPS	($0.55)	$0.60	($0.00)	$0.04	$0.06	$0.03	$0.15	$0.75	$0.74
Fully Diluted Shares	30.4	32.8	32.3	33.1	34.0	63.7	40.8	65.0	70.0

Source: Jason Napodano, CFA - Zacks Investment Research, Inc.

HISTORICAL ZACKS RECOMMENDATIONS



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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- 17.2%, Hold/Neutral- 76.6%, Sell/Underperform – 5.5%. Data is as of midnight on the business day immediately prior to this publication.