Zacks Small-Cap Research

October 1, 2015
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Tribute Pharmaceuticals (TBUFF-OTC)

TBUFF: On Track For Merger With Pozen, Inc. in Fourth Quarter of 2015…

Current Recommendation	**Buy**
Prior Recommendation	Hold
Date of Last Change	05/18/2014
Current Price (10/01/15)	$0.80
Target Price	**$1.40**

UPDATE

On August 17, 2015, Tribute Pharmaceuticals Canada, Inc. announced financial results for the second quarter of 2015 that ended June 30, 2015. Total revenues were $6.4 million and the company had a net loss of $8.8 million, or $0.08 per share.

The merger with Pozen, Inc. is still slated to transpire during the fourth quarter of 2015, which will result in the creation of Aralez Pharmaceuticals. Tribute shareholders will end up owning approximately 28% of Aralez upon final closing, when factoring in the financing from a group of healthcare investors led by Deerfield Management.

SUMMARY DATA

52-Week High	**$1.81**
52-Week Low	**$0.41**
One-Year Return (%)	**72.83**
Beta	**1.41**
Average Daily Volume (sh)	**45,464**
Shares Outstanding (mil)	**114**
Market Capitalization ($mil)	**$90**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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	**N/M**

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	3.5 A	4.0 A	3.9 A	5.5 A	16.9 A
2015	5.6 A	6.4 A	9.2 E	11.3 E	32.1 E
2016					49.0 E
2017					58.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.07 A	-$0.09 A	$0.03 A	-$0.01 A	-$0.08 A
2015	-$0.05 A	-$0.08 A	-$0.04 E	-$0.04 E	-$0.21 E
2016					-$0.10 E
2017					-$0.07 E

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WHAT'S NEW

Financial Update

On August 17, 2015, Tribute Pharmaceuticals Canada, Inc. (TBUFF) announced financial results for the second quarter of 2015. Total revenues for the quarter were $6.4 million, which was a 59% year-over-year increase compared to the same quarter of 2014, and resulted in a gross profit of $4.1 million, which was a 101% increase over the same period in 2014. The increase in revenue was driven by a 177.9% increase in domestic product sales and a 171.5% increase in international product sales in comparison to the second quarter of 2014.

Operating expenses for the quarter totaled $5.0 million and non-operating expenses were $7.9 million, including a warrant expense of $6.2 million. Net loss for the quarter was $8.8 million, or $0.08 per share. In comparison to 2014, there was an increase of $1.7 million in SG&A related to continued investment in existing products, operational expenses related to the acquisition of Fibricor®, and expenses related to the proposed merger with Pozen.

The company exited the second quarter of 2015 with $17.6 million in cash and cash equivalents, which was partly due to a private placement in May 2015 that resulted in gross proceeds to the company of $12 million. The company will have sufficient capital to fund operations up to the closing of the merger with Pozen.

Pozen to Acquire Tribute and Form Aralez Pharmaceuticals

The biggest news thus far this year for Tribute was the announcement that the company entered into an agreement with Pozen, Inc. (POZN) to be acquired and form the new company Aralez Pharmaceuticals. Aralez will be domiciled in Ireland, and upon closing is expected to trade on both the Nasdaq and TSX exchanges.

The deal is contingent upon approval by shareholders of both companies. Upon approval, 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 66% of Aralez while stockholders of Tribute will own approximately 34%. Pozen's management will take charge of Aralez, with Mr. Adrian Adams as CEO.

In conjunction with the acquisition (which we anticipate will close at some point in the fourth quarter), 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 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, or approximately 7.9 million shares). Thus, at closing the ownership distribution will be approximately 54%, 28%, 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.

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 both by Hillary Clinton's drug pricing proposal as well as the controversy surrounding Turing Pharmaceuticals increasing the price of Daraprim® from $13 to $750 per pill. Due to this, Tribute's stock price has fallen from approximately $1.40 on Sep. 16 to a current price of $0.80. In our opinion this is an overreaction, particularly given the fact that 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 Tribute with good upside available once the merger with Pozen 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, or $1.40 per share. 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 (eventually heading to the low 20's) stemming from moving the headquarters to Ireland. Our current model gives a net present value for Pozen of approximately $440 million, or just over $13 per share. This includes the $41.5 million in cash as of June 30, 2015.

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 61 million shares (32.4 million from Pozen shareholders, 18.2 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

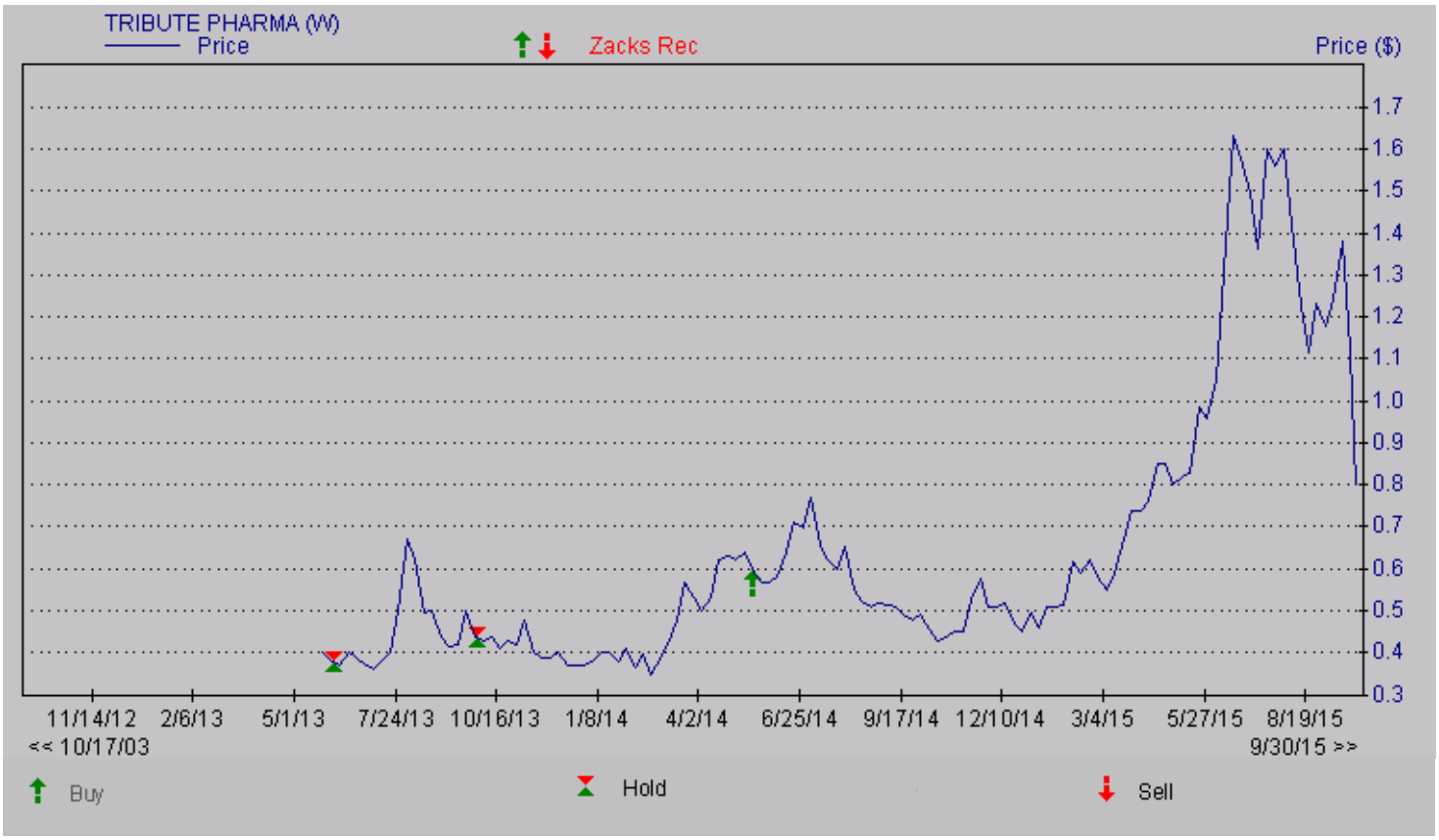
Tribute Pharmaceuticals Canada, Inc.
Income Statement

Tribute Pharma (in CDN)	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Total Canadian Product Sales	$15.23	$5.12	$5.46	$7.75	$9.45	$27.78	$42.50	$50.00	$56.50
YoY Growth	27%	70%	48%	130%	83%	82%	53%	18%	13%
International Product Sales	$1.62	$0.47	$0.97	$1.50	$1.80	$4.27	$6.50	$8.50	$10.00
YoY Growth	27%	1%	171%	202%	497%	164%	52%	31%	18%
Royalty & Licensing	$0.02	$0	$0	$0	$0	$0	$0	$0	$0
YoY Growth	-91%	-	-	-	-	-	-	-	-
Total Revenues	**$16.87**	**$5.59**	**$6.43**	**$9.25**	**$11.25**	**$32.05**	**$49.00**	**$58.50**	**$66.50**
YoY Growth	26%	60%	59%	139%	106%	90%	53%	19%	14%
Licensor sales & Distribution Fees	$5.90	$1.45	$1.54						
Cost of Sales & Inventory Expense	$1.84	$0.58	$0.78						
Total Cost of Goods Sold	$7.74	$2.03	$2.33	$4.02	$4.75	$13.12	$20.60	$23.20	$25.05
Gross Margin	54%	64%	64%	57%	58%	59%	58%	60%	62%
Selling, General & Admin	$10.15	$3.33	$4.14	$5.50	$6.50	$19.46	$24.50	$27.50	$30.00
EBITDA	($1.02)	$0.24	($0.03)	($0.27)	$0.00	($0.53)	$3.90	$7.80	$11.45
Amortization Expense	$1.51	$0.62	$0.89	$1.00	$1.20	$3.71	$4.50	$5.00	$5.00
Realized Non-Operating Items	($3.08)	($4.80)	($7.90)	($3.50)	($3.50)	($19.70)	($14.00)	($13.00)	($12.00)
Unrealized Items	$0	$0.04	($0.03)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Pre-Tax Income	($5.61)	($5.14)	($8.85)	($4.77)	($4.70)	($23.94)	($14.60)	($10.20)	($5.55)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	**($5.61)**	**($5.14)**	**($8.85)**	**($4.77)**	**($4.70)**	**($23.94)**	**($14.60)**	**($10.20)**	**($5.55)**
Net Margin	-	-							
EPS	**($0.08)**	**($0.05)**	**($0.08)**	**($0.04)**	**($0.04)**	**($0.21)**	**($0.10)**	**($0.07)**	**($0.04)**
YoY Growth	-42%	-19%	-6%	-209%	345%	166%	-0.496351936	-0.334637965	-0.483965844
Wte. Ave (Diluted) Shares Outstanding	71.9	96.7	108.8	127.0	130.0	115.6	140.0	147.0	155.0

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

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