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Zacks Small-Cap Research

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Tribute Pharma (TBUFF-OTC)

TBUFF: TBUFF Enters U.S. Market with acquisition of Fibricor! Another solid deal that could drive TBUFF shares to new highs.

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	5/12/2015
Current Price (5/29/15)	$0.92
Target Price	**$1.75**

OUTLOOK

On May 21, 2015, Tribute Pharma announced the acquisition of U.S. rights to Fibricor and its authorized generic from Sun Pharma. TBUFF financed the deal with a private placement of 13M common shares at a price of CAN$0.92 per share for aggregate gross proceeds of CAN$12 million. We expect the acquisition will be immediately accretive for Tribute. Perhaps more importantly, it gets Tribute into the U.S., a market where we expect they will be looking to add additional products. We maintain our Buy rating and continue to feel the shares trade below fair value. We have raised our target price to $1.75/share.

SUMMARY DATA

52-Week High	**$1.03**
52-Week Low	**$0.41**
One-Year Return (%)	**67.18**
Beta	**0.74**
Average Daily Volume (sh)	**112,109**
Shares Outstanding (mil)	**114**
Market Capitalization ($mil)	**$106**
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/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**-93.6**
P/E using 2016 Estimate	**35.1**
Zacks Rank	**N/A**

Risk Level	**High,**
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	$3.4A	$4.0A	$3.8A	$5.5A	$16.8A
2015	$5.1A	$6.3E	$7.5E	$8.3E	$28.6E
2016					$36.4E
2017					$41.1E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-0.06A	-0.09A	$0.03A	-0.01A	-0.08A
2015	-0.05A	0.00E	$0.007E	$0.01E	$0.006E
2016					$0.04E
2017					$0.06E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

WHAT'S NEW

TBUFF Enters U.S. Market with acquisition of Fibricor! Another solid deal that could drive TBUFF shares to new highs.

On May 21, 2015, Tribute Pharma announced that its wholly owned subsidiary, Tribute Pharmaceuticals International Inc., a Barbados corporation, acquired the U.S. rights to Fibricor® and its related authorized generic from a wholly owned step-down subsidiary of Sun Pharmaceutical Industries Ltd. for U.S.$10 million. Tribute paid US$5 million on closing; and the remaining amount of $5 million is divided into 2 payments; $2 million to be paid in 6 months and $3 million to be paid in 12 months from closing.

TBUFF financed the deal with a private placement of 13M common shares at a price of CAN$0.92 per share for aggregate gross proceeds of CAN$12 million. The offering was conducted by a syndicate of agents led by Dundee Securities Ltd., KES 7 Capital Inc., and Bloom Burton & Co. Ltd. In connection with the private placement, all of the agents received a cash commission equal to 7.0% of the gross proceeds of the offering. In addition, the company granted the syndicate 456,529 non-transferable compensation options at an exercise price of CAN $0.92. The options are for common stock of TBUFF and exercisable within 2 years of the financing date, May 21, 2015. The proceeds of the offering was used to fund the Fibricor acquisition and for general working capital purposes.

The shares closed at $0.80 on May 20th, the day prior to the deal announcement and have rallied almost 28% since. The stock is up about 100% over the last six months. The drivers of the share price growth include a number of factors including improvements in Tribute's annual (2014) and quarterly earnings (Q1 2015) as well as strategic acquisitions of accretive products such as this Fibricor deal.

Background on Fibricor…

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, a fenofibrate, is converted to fenofibric acid in the body that in turn increases the activity of lipoprotein lipase, an enzyme that breaks down triglycerides. It also affects production, transportation, and storage of triglycerides.

Hypercholesterolemia (high cholesterol) is one of the most common risk factors for atherosclerotic cardiovascular disease. Adults who reported taking prescription cholesterol-lowering medications comprised of those diagnosed with cardiovascular disease (71%), diabetes (63%), and hypercholesterolemia (53%)[1]. Although several FDA approved drugs are currently available in the market to treat adults with hypertriglyceridemia and mixed dyslipidemia, there is extensive and consistent evidence supporting the use of statins, in addition to lifestyle changes, to treat lipid disorders and reduce cardiovascular disorders. The 2013 cholesterol treatment guidelines updated recommendations for statin therapy on the basis of LDL cholesterol levels and atherosclerotic cardiovascular disease risks[2]. Statin drugs that are most widely used include Pfizer's (PFE) Lipitor® and AstraZeneca's (AZN) Crestor®, that are known to reduce LDL cholesterol, VLDL cholesterol, triglycerides, and total cholesterol, while modestly increasing HDL cholesterol. Besides statins, fibrate products such as AbbVie's (ABBV) TriCor® and Trilipix have shown to reduce triglycerides. However, revenue from AbbVie's lipid-lowering franchise comprised of the blockbuster drugs Tricor/TriLipix (fenofibrate) and Niaspan (niacin) plummeted after losing patent protection in 2011 and 2013.

Cardiovascular disease has been the leading cause of mortality in the U.S. Despite making dietary and lifestyle changes an aging population is expected to significantly increase the dyslipidemia market in the U.S. The National Cholesterol Education Program guidelines recommend concomitant use of fibrate with a statin for certain adults whose triglycerides exceed 200 mg/dL. Fibricor is a unique and patent-protected fenofibric acid formulation that competes in the ~$2.5 billion triglyceride lowering medication market in the U.S. Fenofibrates account for 75% of the market share of fibrates in the U.S. (fenofibric acid is not available in Canada). Fibricor contains the lowest dose of fenofibrate available in the U.S., consisting of 105mg and 35mg tablet presentations. As Fibricor is a non-statin LDL and triglyceride lowering agent, physicians adopting this product combined with a lower price point could make

[1] National Center for Health Statistics Data Brief, Prescription Cholesterol-lowering Medication Use in Adults Aged 40 and Over: United States, 2003–2012

[2] Stone NJ, Robinson JG, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.

it a very attractive asset for TBUFF. Fibricor sales during the twelve-month period ending April 30, 2015 were approximately US$4.7 million.

TBUFF's strategic plan…

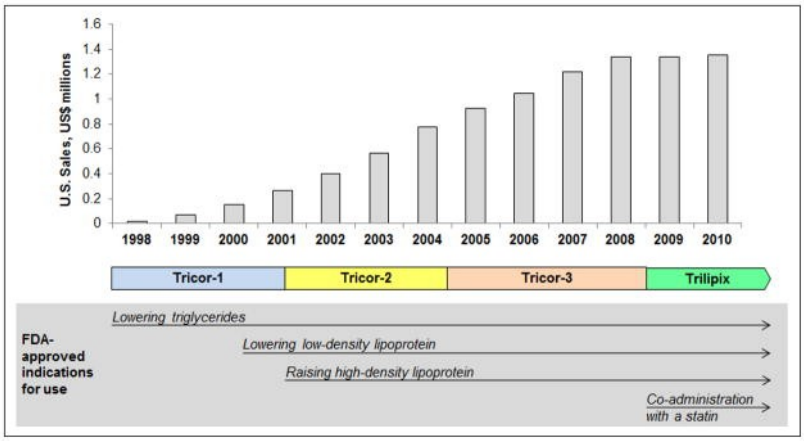
Tribute intends to use Fibricor as a springboard to carve out a foothold into the U.S. fibrate market. This could be an important milestone as it supports their overall goal of exploring new opportunities in the U.S. pharmaceutical marketplace that is 20X larger than Canada. Furthermore, Tribute Pharma has added Mr. William Maichle as the President to the company's newly created U.S. operations Tribute Pharmaceuticals US, Inc. Mr. Maichle has over 18 years of experience and expertise in the pharmaceutical industry including responsibilities in the fibrate, cardiovascular and generic markets. This included spearheading the U.S. launch of the fenofibrate, Lipofen, while COO with ProEthic Pharmaceuticals.

We think Mr.Maichle will be a high caliber addition to Tribute's management team and expect him to play a key role in guiding the company's efforts in the U.S. market, as well as the company's initiatives in future investments.

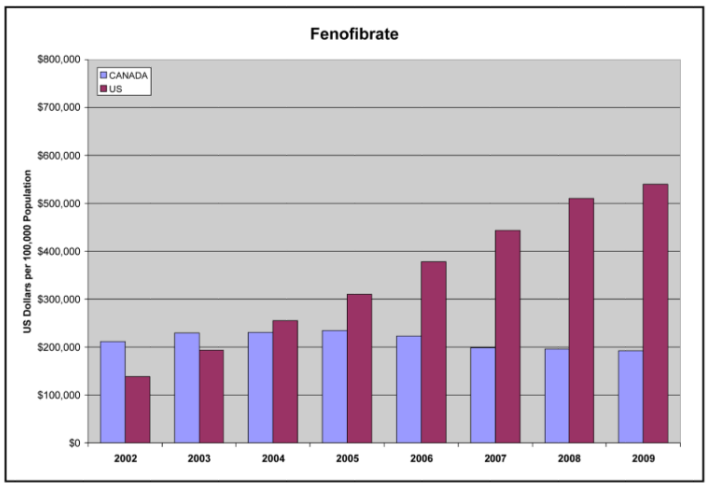
Expectation for 2015 and beyond…

Management had mentioned over the past year that they are looking to close another product acquisition in the near future. This follows the impressive transaction history over the past few years that include acquiring Cambia, Novartis products and most recently Fibricor.

We would also like to remind investors that Tribute holds an exclusive license for Bezalip SR in the U.S. Tribute is hoping to expand their operations into the U.S. through a licensing arrangement and partnership with a U.S. healthcare company to develop, sell and market Bezalip SR, contingent upon the approval of an NDA in the U.S. We estimate that the U.S. opportunity with Fibricor and Bezalip is significant for a small company such as Tribute. We are very up-beat on Bezalip gaining U.S. regulatory approval.



Source: Arch Intern Med. 2012 May 14; 172(9): 724–730.



Source: JAMA. 2011 March 23; 305(12): 1217–1224.

Abbott was the first to launch branded fenofibrate (Tricor) and more recently Trilipix (fenofibric acid), a metabolite of fenofibrate. In the U.S., fibrate sales for Abbott peaked 10 years after its launch and sales eclipsed $1 billion by 2007. Tricor was the most commonly used fenofibrate in the U.S. and Abbott garnered 90% of the fenofibrate market until 2011 when Tricor/Trilipix lost patent protection. Since then generic versions have provided stiff competition to branded Tricor. Today, approximately ~80% of prescriptions are filled by fenofibrate generics.[3]

While the fenofibrate market, estimated at approximately $1.3B, remains significant, the presence of generics will likely provide meaningful competition to Fibricor and its authorized generic (AG) and may put a ceiling on pricing. Trailing twelve-month sales of Fibricor ending April 30, 2015 totaled $4.7 million. Tribute has the exclusive rights to both branded and the AG version of Fibricor, patent-protect with four patents through 2027. We speculate that the growth in prescriptions from Fibricor and its AG may be only moderate due to expectations that TBUFF will allocate few resources towards marketing the products. . However, the rising population of high cholesterol patients along with the fact that Fibricor being the lowest dose of fenofibrate available in the U.S. (105mg and 35mg tablet – which may provide competitive differentiation) may help spark incremental growth in prescriptions and push revenue beyond the current $5 million annual run-rate.

We model only modest revenue contribution from Fibricor and its AG throughout the remainder of the current year. But we expect the acquisition will be immediately accretive for Tribute as the company should bolt on ~$5 million in new annual revenue with little additional in the way of OpEx. Perhaps more importantly, it gets Tribute into the U.S., a market where we expect they will be looking to add additional products. The entry of Bezalip SR in the U.S. dyslipidemia market, if and when it happens, will be a nice addition to TBUFF's cardiology products.

In our financial model, our forecast shows anticipated revenues of about $2.3M for the remainder of 2015 from Fibricor sales alone. We had modeled total revenues in 2015 to be $26.3 million and $32 million in 2016. Adding Fibricor sales brings up total revenues to $28.6M in 2015 and approaching $36.4 in 2016.

Tribute will continue to work with Mutual Pharmaceutical Company, Inc., based in Philadelphia, PA, to manufacture and distribute the authorized generic and branded Fibricor in the U.S. Management hopes to to increase Fibricor's market share via non-personal promotional programs across multiple channels. By gathering and analyzing research data from IMS/Symphony Health, management expects to gain insight into how fibrates are prescribed and sold. This will aid in segmenting their customers well enough to target health-care practitioners based on the feedback gathered. We believe such a method can be executed at a considerably lower cost than employing a team of sales reps across the country. This allows for Fibricor to gain incremental revenue during the initial years under Tribute. We think management might eventually set up a U.S. team as they add more products to their portfolio for the U.S. market.

We think this assumption is reasonable given the company will use third-party distribution network in the U.S., and awareness and marketing efforts directed at physicians that would result in a greater rate of adoption of Fibricor. While we anticipate that SG&A expenses will remain as forecasted, we do not plan modelling a sizeable increase in SG&A spend until our thesis is supported by Tribute's initiatives to considerably intensify marketing and sales strategies to promote Fibricor. In the past Tribute's execution of their strategic vision and operational plans has been stellar and the company needs to continue to achieve its targeted milestones for our forecast to materialize.

Although Tribute raised capital through equity financing (an additional 13 million shares and 450,000 warrants) it minimally impacted the dilution to shareholders. We maintain our Buy rating and continue to feel the shares trade below fair value. We have raised our target price to $1.75/share.
Tribute has been added to the 2015 OTCQX® Best 50, a ranking of 50 top performing companies traded on the OTCQX Best Marketplace in 2014. The OTCQX Best 50 is the first ever annual ranking of strong performing U.S. and international companies traded on the OTCQX marketplace. The ranking is calculated based on an equal weighting of one-year share price performance and average daily dollar volume growth in the previous calendar year.

[3] http://www.ashp.org/menu/AboutUs/ForPress/PressReleases/PressRelease.aspx?Source=Press&Type=Rss&Id=794

KEY POINTS

- Tribute Pharmaceuticals Inc. is a specialty pharmaceutical company headquartered in Canada with annual revenues of over $13M.
- Tribute has aggressively grown its pharmaceutical business in recent years with the addition of a number of lucrative pharmaceutical products such as Bezalip SR, Soriatane and CAMBIA through strategic partnerships with global companies. These partnerships allow Tribute to acquire exclusive licenses for the sales and marketing of their products that also comes with the benefit of low R&D costs.
- The company offers a complementing portfolio of targeted therapeutic products that address a diverse set of ailments. These include a number of patented drugs which have their exclusivity locked up during which Tribute can ramp up sales of the same.
- Entering lucrative U.S. market at a time when Affordable Care Act is just commencing implementation could help Tribute's sales efforts in the U.S.
- The launch of CAMBIA in October 2012 put Tribute in direct competition with triptans in the migraine market – a full twelve years before CAMBIA's patent is due to expire. Management believes that the momentum in sales from the end of 2013 may carry forward to the next couple of years, providing significant revenue growth to the company in the short-term. The company hopes to increase the proportion of private insurers providing reimbursement for CAMBIA in an effort to speed adoption of the drug by physicians and patients. CAMBIA has been the primary revenue driver since launch.
- Bezalip SR has a strong position in the Canadian dyslipidemia market and Tribute has obtained IND approval in the U.S. Bezalip SR targets aging populations and with longer life expectancies, we expect the market size for this class of drugs to grow in the coming years.
- From May 3, 2014 Tribute began trading on the TSX-V: TRX and as of August 5, 2014 Tribute began trading on the OTCQX: TBUFF. This offers a better access to Canadian capital markets and investors.

BACKGROUND

Tribute Pharmaceuticals Canada Inc. (TBUFF) is a Canadian specialty pharmaceutical company engaged in the acquisition, licensing, development and management of pharmaceutical and healthcare products with a primary focus on the Canadian market. The company's primary business is the commercialization of drugs in various therapeutic areas, such as migraine, cardiology, dermatology, pain and urology. Tribute also engages in marketing medical devices for the prevention and treatment of surgical site infections. Tribute is headquartered in Milton, Ontario, Canada and was founded in 1996. Stellar Pharmaceuticals was founded in London, Ontario in 1997 and the two companies merged in December 2011 and officially changed its name to Tribute Pharmaceuticals Canada Inc. in January 2013.

Tribute operates in the global pharmaceutical industry, which is highly competitive and tightly regulated. Pharmaceutical sales in Canada have a 2.5 percent share of the global market, making Canada the 8th largest pharmaceutical market in the world. The national healthcare plan in Canada covers 100% of its population. For prescription drugs that are sold in Canada, approximately 10% are paid for by the patient (non-reimbursed medical expense), 45% by private insurance and 45% by government reimbursement plans. The pharmaceutical industry in

Canada is comprised of brand-name products that account for 76% of Canadian sales and 37% of prescriptions. Generics account for the remainder.

Galen	UK & Ireland
Medac	Germany & Austria
EuroCept Pharma	Netherlands & Belgium
CPH Companhia	Portugal
Laboratories Inibsa	Spain
Jeilmedix	Korea
Navamedic	Scandinavia & Iceland
Ecupharma Italia	Italy

Some of Tribute's Global Partners (Source: tributepharma.com)

Tribute is actively partnering with Actavis (ACT: NASDAQ), Depomed Inc. (DEPO: NASDAQ) formerly Nautilus Neurosciences until Depomed acquired Nautilus in December 2013 and EUSA Pharma (JAZZ: NASDAQ) in Canada as well as with other well-known companies internationally.

Tribute sells products in both the primary care and specialty care markets. Tribute's current portfolio includes 6 products, all 6 of which have received regulatory approval in Canada. Tribute sells CAMBIA® (diclofenac potassium for oral solution), Bezalip® SR (bezafibrate), Soriatane® (acitretin), NeoVisc® (1.0% sodium hyaluronate solution), Uracyst® (sodium chondroitin sulfate solution 2%) and Collatamp® G (gentamicin-impregnated collagen).

Additionally, the company holds an exclusive license for Bezalip SR in the U.S. Tribute is hoping to expand their operations into the US through a licensing arrangement and partnership with a US healthcare company to develop, sell and market Bezalip SR, contingent upon the approval of an NDA in the U.S. Tribute is expecting an additional patent to be granted in Europe for Uracyst this year which will present new opportunities for the product and for the company, and its international partners in this market. Tribute intends to expand their visibility by selling their proprietary and licensed products in other global markets that are currently untapped.

Tribute focuses on targeting the acquisition of mature products that have undergone significant R&D and have regulatory approvals in Canada or require approvals for commercialization in global markets. In the past, Tribute has focused on research and development, manufacturing, sales and out-licensing of their proprietary products, Uracyst and NeoVisc globally. Such products address a niche market and have limited market size. The development of lucrative drugs that caters to large populations is risky due to competition from large drug companies and further, requires significant investment in research and development. It is more cost effective for a company like Tribute to in-license products like Bezalip SR that can be marketed to a larger audience. Tribute's core business model has evolved into marketing, sales and life-cycle management of licensed products that are in the final stages of qualifying for a regulatory approval. For example, Tribute negotiates for the exclusive license to sell products developed by companies like Pfizer in the Canadian market. The expanded business model has necessitated the addition of sales and distribution infrastructure to help distribute and sell their products to doctors, hospitals and clinics throughout Canada.

Tribute acquires the licenses to market these products mainly for the Canadian market with appropriate regulatory and pre-marketing approvals containing all manufacturing, pre-clinical, and clinical trial results that for the most part lower the risks with their model. Tribute has shown strong revenue growth due to the addition of in-licensed products, however, this has added layers of selling expenses and squeezed margins due to up-front licensing fees. We expect that with the added sales force, larger customer base and a portfolio of diverse products, Tribute will be able to significantly increase their revenue and achieve positive cash flow in the near term.

PRODUCTS

Primary Care Products

CAMBIA

CAMBIA® (diclofenac potassium for oral solution) is the only available, approved, fast-acting, prescription non-steroidal anti-inflammatory drug (NSAID) in Canada for the treatment of acute migraine attacks with or without aura (feelings and symptoms a person notices shortly before the headache begins) in adults (18 years or older). CAMBIA, owned by Nautilus Neurosciences Inc., was pre-launched in Canada to neurologists and headache specialists in October 2012 and more broadly launched to Primary Care Physicians (PCPs) in February 2013. The United States and Canadian rights to CAMBIA were recently acquired by Depomed, Inc. (NASDAQ: DEPO) through the acquisition of Nautilus Neurosciences, Inc. Tribute is currently in an exclusive Canadian sub-licensing agreement with Depomed Inc. to develop, register, promote, manufacture, use, market, distribute and sell CAMBIA in Canada. CAMBIA received approval from Health Canada in March 2012.

(Source: http://www.tributepharma.com/Products/Cambia)

Background on Migraine: A migraine headache is a neurovascular disorder characterized by an intense throbbing or a pulsing sensation in one area of the head. It is usually accompanied by nausea, vomiting, and extreme sensitivity to light and sound. For a few people, the migraine headache is preceded or accompanied by sensory warning symptoms (aura), such as flashes of light, blind spots, or tingling sensation in the arm or leg. The initial as well as recurring attacks, which may be moderate to severe in intensity, may be triggered either by psychological, biological or environmental factors or a combination of these. Medications, if used at the time of onset of the headache, can help reduce the frequency and severity of migraines.

Pharmacology: Acute migraine treatment options can be broken down into three main categories: (i) triptans or 5-HT1 receptor agonists (e.g. sumatriptan, rizatriptan); (ii) ergot alkaloids (e.g. ergotamine, dihydroergotamine); and (iii) NSAIDs (e.g. CAMBIA). Additionally, β-blockers, calcium-channel blockers, serotonin-receptor agonists, tricyclic analgesics, and NSAIDS (naproxen sodium) have also been shown to be effective in prophylactic (preventive) treatment of migraine[4]. NSAIDs and triptans (Sumatriptan) are used in moderate intensity migraine attacks. Although Sumatriptan is fast acting, it is recommended not be taken in the aura phase, and has a higher rate of headache recurrence after 24 hours. Dihydroergotamine (DHE) is a 5-HT1 receptor agonist and hence works similar to but has a longer duration of action than sumatriptan (lower recurrence rate). Generally, triptans are considered superior to ergot alkaloids from both an efficacy and side-effect perspective. However, intolerance of side effects (blood vessel constriction, chest pain/pressure/tightness, esophageal spasm, dizziness, fatigue, nausea, light headedness, etc.), is a major cause of dissatisfaction with triptan users directing the need for a viable alternative, such as CAMBIA (NSAID).

[4] William E.M. Pryse-Phillips, MD; David W. Dodick, MD; John G. Edmeads, MD; Marek J. Gawel, MD; Robert F. Nelson, MD; R. Allan Purdy, MD; Gordon Robinson, MD; Denise Stirling, MD; Irene Worthington (1997), BScPhm, Guidelines for the diagnosis and management of migraine in clinical practice, Journal of Canadian Medical Association ;156:1273-87

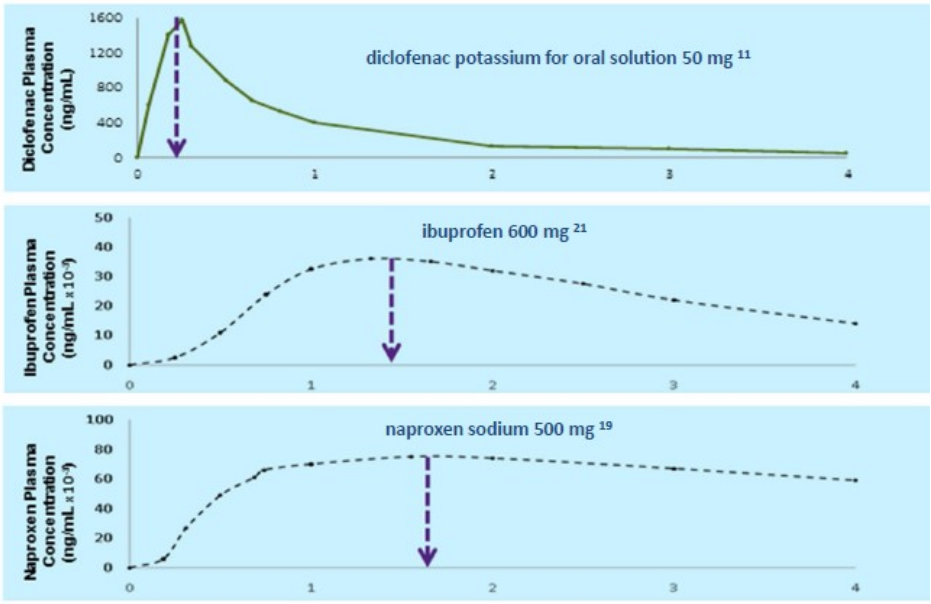
NSAIDs possess anti-inflammatory, analgesic and anti-pyretic proprieties. NSAIDs primarily act by inhibiting the enzyme cyclooxygenase with subsequent decrease in prostaglandin biosynthesis, which are involved in the pathophysiology of migraine headaches. Prostaglandins are known to be involved in excitation and sensitization of peripheral pain receptors associated with tissue damage or inflammation. Since NSAIDs inhibit the production of prostaglandins, they can be regarded as mild peripheral analgesics[5]. NSAIDs are most effective at locations where inflammation causes the impulse discharge of polymodal thin fiber nociceptors. Among NSAIDs, the principal differences lie in the time to onset and duration of action.

Acetylsalicylic acid (ASA), ibuprofen, naproxen, and acetaminophen are known to have anti-inflammatory or sub analgesic effects and are most commonly used for mild attacks of migraine. Acetaminophen, although effective in reducing fever and offering headache pain-relief, is not known to be as effective against pain associated with inflammation. NSAIDs have been a suggested replacement or a supplement to triptans for treatment of acute migraine attacks. Although NSAIDs have been a standard option for headache treatment, the speed of onset of NSAIDs as compared with triptans has been a limiting factor in their use.

Prostaglandins play a major role in causing inflammation, pain, and fever. Inhibition of prostaglandin biosynthesis has found to be the mechanism of action in clinical studies using the potassium salt of diclofenac (the active ingredient in Cambia). CAMBIA was specifically developed to address a widespread underserved need among migraine sufferers for quick relief of headache and associated symptoms such as nausea, sensitivity to light and sensitivity to sound. CAMBIA is not indicated for prophylactic therapy of migraines attacks nor is it indicated for other types of headaches.

In a clinical trial involving diclofenac in powder form, tablet and a placebo, CAMBIA demonstrated that its composition significantly offers pain-free symptoms in moderate to severe headache with sustained relief for 24 hours post treatment and reduction of the associated symptoms of migraine compared with diclofenac in tablet form and placebo. CAMBIA offers a first-line treatment for migraine, in treatment for patients who cannot tolerate or do not respond to other medications, and/or as an adjunctive treatment to existing pain-relief options[6]. It can additionally be helpful to patients who are unable to swallow tablets, as CAMBIA is in powder form and can be dissolved to form an oral solution. Once dissolved in liquid, CAMBIA has a rapid onset of pain-relief (15 minutes)[7] while the pharmacokinetic data showed other oral tablets such as ibuprofen, and naproxen sodium took effect up to two hours after consumption.

[5] Narbone, M. C., M. Abbate, and S. Gangemi. "Acute drug treatment of migraine attack." *Neurological Sciences* 25, no. 3 (2004): s113-s118.
[6] Kahn, K. (2011). Cambia® (diclofenac potassium for oral solution) in the management of acute migraine. *US Neurology*, *7*(2), 139-43.
[7] Lipton, R. B., Grosberg, B., Singer, R. P., Pearlman, S. H., Sorrentino, J. V., Quiring, J. N., & Saper, J. R. (2010). Efficacy and tolerability of a new powdered formulation of diclofenac potassium for oral solution for the acute treatment of migraine: results from the International Migraine Pain Assessment Clinical Trial (IMPACT). *Cephalalgia*, *30*(11), 1336-1345.



Achievement of Peak Absorption for Tablets can take up to Two Hours vs. 15 Minutes for CAMBIA
(Source: www.tributepharma.com)

Other products containing diclofenac

Brand Name	*Type*	*Salt Form*	*Form*	*Tmax*[1]	*Indication*
Cambia®	NSAID	potassium	Power for oral solution	15 minutes	Acute migraine
Cataflam®	NSAID	potassium	Immediate release tablets	1 hour	Acute pain/osteoarthritis
Voltaren®	NSAID	sodium	Immediate release tablets	2.5 hours	Rheumatoid & osteoarthritis
Voltaren®-XR	NSAID	sodium	Slow release tablets	5.3 hours	Rheumatoid & osteoarthritis
Zipsor®	NSAID	potassium	Oral liquid filled capsules	47 minutes	Mild to moderate acute pain
Zorvolex®	NSAID	potassium	Immediate release capsules	3.32 hours	Mild to moderate acute pain

[1] T_{max} maximum threshold; time to maximum [concentration] of the drug

The triptan class of drugs (also known as the 5-hydroxytryptamine agonists) remains the most commonly prescribed medications for migraine in Canada. There are seven approved triptans in Canada including, Relpax® (eletriptan) Pfizer, Imitrex® (sumatriptan) GSK, Axert® (almotriptan) Johnson & Johnson, Zomig® (zolmitriptan) Astra Zeneca, Amerge® (naratriptan) GSK, Frova® (frovatriptan) Teva Neuroscience and Maxalt® (rizatriptan) Merck. These products are popular drug choices for migraine in Canada and are only available by prescription. All seven of these products have lost their market exclusivity in Canada except for Frova. The patents have expired on Frova but as of the writing of this report, no generics have yet been introduced in Canada. Sumatriptan, a generic equivalent, holds about 24% market share of the migraine market in Canada. Branded products range in retail price from $5 to $25 per tablet compared to generic diclofenac potassium 50 mg tablets that sells for around $0.07 to $0.20 per tablet. Cambia is the only medication for acute migraine that is actively promoted to physicians in Canada.

Migraine Market (Canada)

Management estimates the prescription migraine market in Canada is valued at about $140 million. An estimated 4 million people suffer from migraine headaches, with approximately 60% of sufferers experiencing two or more attacks per month and 25% having at least one attack per month. Migraines disproportionately affect women at a rate of 3 to 1 and are the most common among people between the ages of 25 and 55. Migraine is inadequately treated. We estimate that most of this age group is backed by private insurance and will additionally benefit from the co-pay assistance cards (rebate to cover all or part of the copay cost of the medication) issued by the manufacturer. Despite the available third-party reimbursement, we think that most patients initially seek self-treatment with over-the-counter (OTC) medications. OTC medications such as Advil (ibuprofen), Aleve (naproxen), and Excedrin (acetaminophen / aspirin combination), help relieve the symptoms of an acute attack, are affordable and readily available.[8] Of those patients who seek medical help, a majority go to PCPs, rather than specialists as a first step. As a result, most prescriptions come from PCPs. The PCP, as compared to a neurologist has very little specialized training related to migraine diagnosis and treatments. By contrast, a neurologist is well- informed on the research

[8] The Canadian Rx Atlas, Third Edition, Dec 2013, UBC center for health Services and Policy Research.

regarding migraine, typically will spend time with the patient to diagnose and assess the impact of pain on the patient, has a clear understanding of the appropriate treatments available, has more knowledge in communicating these benefits to the patients and can offer practical strategies to reduce the occurrence of the migraine attack. Therefore, the adoption of new drugs in the migraine market is readily welcomed by specialists, especially neurologists. However, since most prescriptions come from PCPs rather than neurologists, we believe that Tribute is making a good move by marketing CAMBIA to PCPs. This will help boost CAMBIA sales in the Canadian market.

Bezalip SR

Tribute also offers Bezalip SR (bezafibrate) to the Canadian market. Bezalip SR is a pan-peroxisome proliferator-activated receptor (pan-PPAR) activator to treat hyperlipidemia. Bezalip SR is approved in over 40 countries across the globe.

Background on Hyperlipidemia: Lipids are composed mainly of cholesterol, triglycerides (fatty acid molecules), lipoproteins, and phospholipids. Hyperlipidemia is a very common chronic condition and is characterized by abnormal elevation in levels of plasma cholesterol, and/or triglycerides (TGs), and/or lipoproteins. Hyperlipidemia, in general, can be divided into two subcategories: Hypercholesterolemia, in which there is a high level of cholesterol; and Hypertriglyceridemia (HTG), in which there is a high level of triglycerides, the most common form of fat.

(Source: www.tributepharma.com/Products/Bezalip_SR/en)

Pharmacology: Severe hypertriglyceridemia (SHTG) is a condition in which triglyceride levels are elevated, often caused or exacerbated by uncontrolled diabetes mellitus, obesity, and sedentary habits. High levels of cholesterol and triglycerides have been shown to increase the risk of atherosclerosis, angina and heart attacks (coronary artery disease). Bezalip SR belongs to a family of fibrates used for treating patients with SHTG.

In clinical trials, Bezalip SR has been shown to significantly reduce triglyceride levels, increase high-density lipoproteins (HDL) levels while providing small decreases in low-density lipoproteins (LDL) thereby improving the lipid profile. Bezalip SR's unique mechanism of action may provide certain advantages compared to other currently marketed products, including an increase in insulin sensitivity, especially in patients with type 2 diabetes.

Bezalip SR, 400mg tablet, is designed for sustained release of the bezafibrate continuously over the day so that only one dose is required to be taken each day. The tablets must be swallowed whole to avoid damaging the sustained-release action.

Cholesterol-lowering drugs currently offered in the market include statins, niacin, bile-acid resins, fibric acid derivatives (fibrates), and cholesterol absorption inhibitors. All classes of cholesterol-lowering medicines are most effective when combined with therapeutic lifestyle changes such as increased exercise and a low-fat, high-fiber diet. Statins are most commonly used for people who require LDL-lowering therapy. The statin class includes some of the largest-selling prescription products in the world (Lipitor®, Zocor®, Crestor®, etc.). Statins dominate single-agent prescriptions for the treatment of lipid disorders. Fibrates or niacin is beneficial for people who need to lower triglycerides and increase high-density lipoprotein. The niacin (nicotinic acid – vitamin B3) class includes brands such as Niaspan®, which work primarily on increasing HDL cholesterol. The fibrates class of cholesterol lowering treatments is composed of three competing molecules: gemfibrozil (Lopid®), bezafibrate (Bezalip SR), and fenofibrate (Lipidil® in Canada or Tricor® in the U.S.). Omega 3 fatty acids (Lovaza®, Vascepa®) may reduce the synthesis of triglycerides in the liver because eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are poor substrates for the enzymes responsible for triglyceride synthesis, and EPA and DHA inhibit esterification of other fatty acids.

All fibrates are PPARs-alpha agonists that have the ability to decrease triglyceride and increase HDL. However, bezafibrate has a unique characteristic profile of action since it activates all three PPAR subtypes (alpha, gamma and delta) at comparable doses. Unlike other fibrates, bezafibrate decreases blood glucose level, HbA1C, insulin resistance, and reduces the incidence of type 2 diabetes. Bezafibrate significantly decreased LDL levels, induced atherosclerotic plaque regression in thoracic and abdominal aorta and improved endothelial function. In clinical trials bezafibrate was highly effective for cardiovascular risk reduction in patients with metabolic syndrome and atherogenic dyslipidemia. Although evidence supports statin's role in treating dyslipidemia (LDL was reduced) as well as preventing cardiovascular events (atherosclerosis), fibrates, including bezafibrate, have shown a stronger effect on triglycerides and HDL than statins.[9]
Bezafibrate has consistently shown a significant beneficial effect on patients with type 2 diabetes and high lipid levels. Further, recent reports have indicated that there is potential for statins to slightly increase diabetes risk. Studies done on bezafibrate monotherapy showed that it may be appropriate for treating early-onset type 2 diabetes coexisting with hypertriglyceridemia. On the other hand, studies suggest that hyperglycemic patients with poor blood glucose control might benefit from simultaneous administration of bezafibrate and a diabetes drug[10].

Dyslipidemia market

Canada: The Canadian cholesterol drug market is valued at $1.6 billion while the fibrate sub-market is valued at about $50M. Cholesterol levels are likely to increase with age, with adult men developing heart disease 10 years earlier than adult women on average. Hence, the increased use of cholesterol-lowering drugs among older adults is expected to grow as life expectancy continues to rise. Tribute holds the exclusive license from Actavis (ACT:NYSE) to market Bezalip SR in Canada where according to IMS data it enjoys about 13% share of the fibrate market in that country.

U.S.: It is estimated that nearly four million (Ford ES, 2009) people in the U.S. suffer from SHTG[11]. Pharmacological treatment for SHTG (severe hypertriglyceridemia) includes fibrate drugs such as fenofibrate and gemfibrozil and Omega-3 fatty acid (fish oil) products. The combined sale of all of the above fibrate drugs was approximately $3.5 billion in the U.S. in 2013. Research indicates that there is a strong preference for prescribing brand-name over generic fenofibrate products in the United States. Of the cholesterol-lowering drugs, fibrates accounted for 9.4% market share in the U.S. while only 5.3% in Canada as of 2009[12]. Fenofibrates comprised of 75% of the market share of fibrates in the United States (fenofibric acid is not available in Canada).

Tribute has also obtained the exclusive license from Actavis to develop and commercialize Bezalip SR in the U.S. The Investigational New Drug application (IND) submitted to the FDA in the U.S. for the proposed development program for Bezalip® SR tablets was cleared by the regulatory agency in November 2013. The NDA will be the final step required before Tribute can start selling Bezalip SR in the U.S. Tribute expects to exploit the five years of market exclusivity of Bezalip SR in the U.S. that will be available to Tribute upon NDA approval. Tribute has entered into an agreement with JSB-Partners (JSB), a global life sciences advisor with extensive transaction experience and large network of pharmaceutical and biotech contacts, to support Tribute in negotiating contracts related to the co-development and commercialization of Bezalip SR in the U.S. Tribute intends to submit a Special Protocol Assessment (SPA) in the U.S. to establish the safety and efficacy of Bezalip SR.

[9] Teramoto, Tamio, Kohji Shirai, Hiroyuki Daida, and Nobuhiro Yamada. "Effects of bezafibrate on lipid and glucose metabolism in dyslipidemic patients with diabetes: the J-BENEFIT study." *Cardiovasc Diabetol* 11 (2012): 29.
[10] Tenenbaum, A., & Fisman, E. Z. (2012). Balanced pan-PPAR activator bezafibrate in combination with statin: comprehensive lipids control and diabetes prevention. *Cardiovasc Diabetol*, *11*, 140.
[11] Ford, Earl S., Chaoyang Li, Guixiang Zhao, William S. Pearson, and Ali H. Mokdad. "Hypertriglyceridemia and its pharmacologic treatment among US adults." Archives of Internal Medicine 169, no. 6 (2009): 572-578.
[12] Cynthia A. Jackevicius, Jack V. Tu, Joseph S.Ross, Dennis T. Ko, Daniel Carreon, and Harlan M. Krumholz," Use of Fibrates in the United States and Canada", JAMA. 2011 March 23; 305(12): 1217–1224.

Other PPAR and Triglyceride Lowering Medicines

COMPOUND	LOWER TGs	INCREASE HDL	LOWER LDL	INCREASE INSULIN SENSITIVITY	POSITIVE EFFECT ON GLUCOSE METABOLISM
Bezalip SR	✓	✓	✓**	✓	✓
Fenofibrate	✓	✓	✓	INCONSISTENT RESULTS	
Gemfibrozil	✓	✓	✓	NO	NO
Rx fish oil	✓	?	NO*	NO	NO
Rosiglitazone	NO	NO	NO	✓	✓
Pioglitazone	NO	NO	NO	✓	✓

* Is neutral in SHTG patients
** Limited data in SHTG patients

(Source: www.tributepharma.com)

Provided Tribute is able to gain required NDA clearance and significant market share in the U.S., this could be a game-changer for Tribute as the potential market size for Bezalip SR in the U.S. will be much larger than all of the other products in Tribute's portfolio combined.

Abbott Laboratories' (NYSE: ABT) Tricor and Trilipix and are the major players in the fibrate space, and yielded almost $1billion in U.S. sales in 2011. GlaxoSmithKline's (NYSE: GSK) drug Lovaza, Amarin's Vascepa and AstraZeneca's Epanova, made up of omega-3 fatty acid similar to Bezalip SR, compete for share of this growing dyslipidemia subpopulation. In addition, as Bezalip SR is a sustained release drug that needs to be swallowed whole, patients might prefer this pill (11mm in size) as opposed to the aforementioned drugs that are at least 118% greater in size. However, it remains to be seen if Bezalip SR will be able to gain a significant share of the fibrate market given that it has to compete with a number of established drugs.

Soriatane

Soriatane (acitretin) is used for the treatment of severe psoriasis without suppressing the immune system. Soriatane is a registered trademark, Heath Canada approved and under license from Actavis Group PTC ehf.

(Source: www.lemoniteurdespharmacies.fr)

Pharmacology: Psoriasis is a skin condition associated with the formation of bubbles or large areas of reddish inflammatory skin and other disorders of keratinization. Soriatane's primary ingredient is acitretin. Acitretin, an organic chemical compound and a synthetic analogue of retinoic acid, is a derivative of vitamin A. Retinoids have a structure similar to vitamin A and are involved in the normal growth of skin cells. Soriatane®, a prescription medication, works by inhibiting the excessive cell growth, plaque formation and scaling, and keratinization (process by which skin cells become thickened due to the deposition of protein within them), the condition seen in psoriasis (includes erythrodermic and pustular types). Soriatane is involved in the controlled growth and maturation of healthy epidermal cells and affects certain immune reactions in the second dermis. These two mechanisms lead to the formation of the epidermal cells. New epidermal overgrowth can be prevented by the containment of horny scales and existing epidermal overgrowth can be replaced within days. Since it is a very lipophilic (having an affinity for lipids) substance, it penetrates well into tissues.

Psoriasis can be triggered by biological as well as environmental factors. Systemic psoriasis may be treated orally by biologic treatments (ustekinumab (Stelara®), infliximab (Remicade®), etanercept (Enbrel®), alefacept (Amevive®), and adalimumab (Humira®)), cytotoxic agents (Methotrexate®), immunosuppressant's (cyclosporine), or retinoids. The activity of the immune cells that become overactive in psoriasis is decreased when using biologic treatments. While the biologic agents (TNF-alpha inhibitors) are generally known to be well-tolerated and highly effective, they are significantly more expensive and reimbursement varies widely. Cytotoxic agents work by blocking the function of an enzyme that helps to slow down the rapid overgrowth of skin cells. As the name suggests, immunosuppressant's work by decreasing the activity of the immune system thereby controlling the skin cell overgrowth as seen in psoriasis. Cyclosporine is known to have a rapid onset but is used only as a short-term option. Topical corticosteroids as well as phototherapy offer an alternative treatment option. Acitretin has a slow onset but is known to be most effective as a maintenance therapy, after the disease has been stabilized by other treatment medications.

Psoriasis Market: According to GBI Research, the systemic psoriasis therapeutic market is expected to grow at a CAGR of 11.1% with an increase in disease awareness and diagnosis rates expected to drive the growth in psoriasis treatment. Although generic and non-prescription treatments dominate the market, increase in reimbursement pressures, especially for the biologics, might be the limiting factor in market expansion.

Bilastine

Allergic rhinitis and urticaria are both allergic conditions that impair productivity of any individual. The typical symptoms of allergic rhinitis are nasal itching, congestion, rhinorrhoea and sneezing. For urticaria, the characteristic symptoms include itchy skin lesions with a central swelling and painful areas of deeper swelling involving the skin and mucous membranes. Both types of allergies are highly prevalent.

Bilastine is a non□sedating H1□antihistamine for symptomatic treatment of allergic rhinitis and urticaria in adults and children older than 12 years of age. It is an innovative and patent protected new molecule developed by Faes in Spain. Bilastine has been studied in over 30 clinical trials including 5 pivotal Phase III trials in allergic rhinitis or urticaria. Upon approval by Health Canada, Bilastine will be granted a minimum of 8 years of market exclusivity.

Allergy market: On May 13, 2014, Tribute entered into an exclusive license agreement with Faes Farma, S.A. ("Faes"), a Spanish pharmaceutical company, for the exclusive rights to sell Bilastine (inclusive of prescription and non-prescription for adults and pediatric patients), a product for the treatment of Allergic Rhinitis and Chronic Idiopathic Urticaria (hives) in Canada. Tribute intends to get this long term growth product to market in 2016. According to the Canadian Allergy, Asthma and Immunology foundation, Allergic Rhinitis affects 20% to 25% of Canadians. As per IMS Health reports the Canadian oral antihistamines market had sales of approximately $120 million in 2013.

Fiorinal and Fiorinal C

The primary types of headaches are migraine, tension-type, and cluster headaches. Migraine and cluster headaches are episodic and recurring conditions. A tension headache is the most common type of headache occurring in adults, affecting more than 80% of the people around the world and generally characterized by diffuse pain and/or muscle tightness around the pericranial or cervical region. The intensity of the headache is known to vary widely. The etiology of this headache is poorly understood and is known to be triggered by anxiety, stress, over-exertion or fatigue. Women are known to be twice as likely to be affected as men. These types of headaches are different from migraine headaches in that there are no associated neurological symptoms. Tension-type headache is usually episodic but like migraine, it can become chronic, occurring daily or almost daily for more than 15 days a month. Many patients suffering from both migraine and tension-type headaches have coexisting medical problems.

Over the counter (OTC) medications such as aspirin, ibuprofen, acetaminophen, NSAIDs, or combinations of these agents with caffeine or sedating medications are usually the first line of treatment recommended for episodic tension-type headaches. However, these drugs are known to cause liver damage and gastrointestinal bleeding if used in high doses over extended periods of time. Regular uses of the OTC drugs have also been linked to headaches arising from medication overuse. When the OTC medicines fail, physicians recommend a prescription strength pain relief.

Fiorinal and Fiorinal C are prescription medications used in the treatment of tension headaches. Fiorinal contains a combination of aspirin, butalbital, and caffeine. Fiorinal C consists of acetylsalicylic acid (ASA), butalbital, caffeine, and codeine. Aspirin (benzoic acid, 2-(acetyloxy)-) has anti-inflammatory properties and aids in pain relief. Butalbital

(5-allyl-5-isobutylbarbituric acid) is a barbiturate that relaxes muscle contractions involved in a tension headache. Caffeine (1,3,7-trimethylxanthine) is a central nervous system stimulant that relaxes muscle contractions in blood vessels to improve blood flow. ASA belongs to the group of medications called analgesics (pain relievers), anti-inflammatories and antipyretics (fever reducers). Codeine (7,8-Didehydro-4,5α-epoxy-3-methoxy-17-methylmorphinan-6α-ol phosphate (1:1) (salt) hemihydrate) is an opiate which acts on the central nervous system through agonistic action on opiate receptors. Research has demonstrated that Fiorinal is significantly and consistently superior to placebo in randomized, double-blind, placebo-controlled, multi-center trials.

Fiorinal has been in the Canadian market since early 70's. While the patents on Fiorinal and Fiorinal C rolled off more than two decades ago, there remains a loyal following of doctors and consumers who prefer to use these branded medications in lieu of alternatives or generics. The headache markets for these drugs are well-established with many years of historically-confirmed consumer demand. About 40% of Canadians suffer from tension type headaches.

Visken and Viskazide

Viskazide (pindolol and hydrochlorothiazide) combines the antihypertensive activity of two agents: a beta-adrenergic receptor-blocking agent (pindolol) and a diuretic (hydrochlorothiazide). Pindolol is a non-selective beta-adrenergic receptor blocking agent which possesses partial agonist activity. It works to calm the sympathetic nervous system by blocking the neurotransmitter norepinephrine. The main ingredient in Visken is pindolol. It is used in the treatment of hypertension and/or the prophylaxis of angina pectoris.

Fibricor

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, a fenofibrate, is converted to fenofibric acid in the body that in turn increases the activity of lipoprotein lipase, an enzyme that breaks down triglycerides. It also affects production, transportation, and storage of triglycerides.

Hypercholesterolemia (high cholesterol) is one of the most common risk factors for atherosclerotic cardiovascular disease. Adults who reported taking prescription cholesterol-lowering medications comprised of those diagnosed with cardiovascular disease (71%), diabetes (63%), and hypercholesterolemia (53%)[13]. Although several FDA approved drugs are currently available in the market to treat adults with hypertriglyceridemia and mixed dyslipidemia, there is extensive and consistent evidence supporting the use of statins, in addition to lifestyle changes, to treat lipid disorders and reduce cardiovascular disorders. The 2013 cholesterol treatment guidelines updated recommendations for statin therapy on the basis of LDL cholesterol levels and atherosclerotic cardiovascular disease risks[14]. Statin drugs that are most widely used include Pfizer's (PFE) Lipitor® and AstraZeneca's (AZN) Crestor®, that are known to reduce LDL cholesterol, VLDL cholesterol, triglycerides, and total cholesterol, while modestly increasing HDL cholesterol. Besides statins, fibrate products such as AbbVie's (ABBV) TriCor® and Trilipix have shown to reduce triglycerides. However, revenue from AbbVie's lipid-lowering franchise comprised of the blockbuster drugs Tricor/TriLipix (fenofibrate) and Niaspan (niacin) plummeted after losing patent protection in 2011 and 2013.

Cardiovascular disease has been the leading cause of mortality in the U.S. Despite making dietary and lifestyle changes an aging population is expected to significantly increase the dyslipidemia market in the U.S. The National Cholesterol Education Program guidelines recommend concomitant use of fibrate with a statin for certain adults whose triglycerides exceed 200 mg/dL. Fibricor is a unique and patent-protected fenofibric acid formulation that competes in the ~$2.5 billion triglyceride lowering medication market in the U.S. Fenofibrates account for 75% of the market share of fibrates in the U.S. (fenofibric acid is not available in Canada). Fibricor contains the lowest dose of fenofibrate available in the U.S., consisting of 105mg and 35mg tablet presentations. As Fibricor is a non-statin LDL and triglyceride lowering agent, physicians adopting this product combined with a lower price point could make it a very attractive asset for TBUFF. Fibricor sales during the twelve-month period ending April 30, 2015 were approximately US$4.7 million.

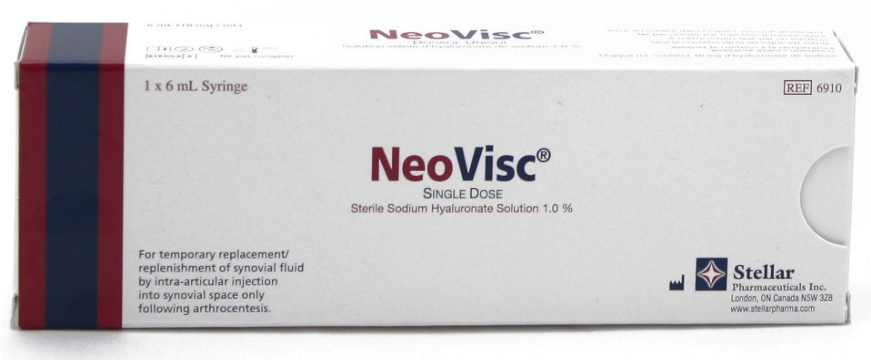
[13] National Center for Health Statistics Data Brief, Prescription Cholesterol-lowering Medication Use in Adults Aged 40 and Over: United States, 2003–2012

[14] Stone NJ, Robinson JG, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.

Specialty Care Products
NeoVisc and Uracyst are Tribute's proprietary products that are developed and manufactured in Canada.

NeoVisc
NeoVisc® is a 1.0% solution of a highly purified, linear high molecular weight sodium hyaluronate which is derived entirely from non-animal sources used to improve joint mobility and reduce joint pain. NeoVisc is available as a single dose (6mL pre-filled syringe) and in a triple dose (2mL pre-filled syringes) format. Tribute is currently the only company in Canada to provide such a product. In addition to Canada, NeoVisc is approved for sales in other international markets, but has not yet been approved in the U.S. Tribute's most recent approval was in September 2013 from the regulatory office of Hong Kong for the sale of NeoVisc.

Pharmacology: Viscosupplementation is one of the non-pharmacological strategies besides physical therapy and exercise to reduce joint pain and improve joint mobility. Viscosupplementation products may be quite effective when simple pain killers are not. Viscosupplements are administered through an intra-articular injection (injections into the synovial space of the joint, especially the knee). The treatment is localized to the affected area and it helps improve the natural viscosity of the synovial fluid. By increasing lubrication at the joint, joint pain is reduced while joint mobility is improved.
However, it is important to note that the relief period on the single dose may not be as long as the current triple dosed NeoVisc treatment. Visits to the clinic are convenient for the patient as they can make two separate visits for the single dose treatment instead of three consecutive visits for the triple dose treatment annually. Although higher in cost per injection, the single-injection products offer increased convenience for patients in terms of shorter treatment times as well as sufficient dosage for smaller joints. The competitors to the NeoVisc single dose product in Canada include Sanofi's Synvisc/Synvisc®-One, Pendopharm's Monovisc® and Bioventus Canada's Durolane®.



(Source: NeoVisconline.comerciabil.ro)

NeoVisc for Osteoarthritis
Patients with osteoarthritis (OA) typically experience pain and loss of mobility due to changes to the internal environment of the affected joint. An aging population and increase in obesity rates are expected to contribute towards growth in osteoarthritis prevalence. Currently NSAIDs and analgesics are the preferred treatment for OA. Globally, an increase in product awareness among physicians as well as patients opting for specialty medications will likely drive the sales of viscosupplements. Management has estimated that the market for NeoVisc in Canada at roughly $25 million.

Uracyst
Uracyst, a sodium chondroitin sulfate solution, is Tribute's patented technology for the treatment of non-common cystitis and interstitial cystitis (IC), an inflammatory disease of the urinary bladder wall. Uracyst® is a fluid that is instilled into the bladder. It contains 2% sterile sodium chondroitin sulfate solution and is effective in reducing the symptoms of painful bladder syndrome (PBS/IC).

Tribute outsources the manufacturing of its proprietary products to third party contractors. These facilities are known to be in compliance with Health Canada, and the Canadian Therapeutic Products Directorate (TPD) division medical device guidelines and current Good Manufacturing Practice (cGMP) regulations.

Pharmacology: Bladder surface mucus is composed of glycosaminoglycans (GAGs) and proteoglycans on the outer surface of the transitional cell apical membrane (urothelium that contracts or expands to accommodate the

volume of fluid). The glycosaminoglycan layer (GAG) is a mucosal lining of the bladder that acts as a protective barrier against the bladder wall and the urine metabolites. Disruption of this layer is presumed to lead to migration of potassium (and possibly other components of the urine) across the mucosal surface. This results in depolarizing of nerves and muscles and leads to tissue injury and pain. The main symptoms of PBS/IC are painful bladder, increased frequency of urination, and an increased urge to urinate. Since urothelium in IC is dysfunctional and the permeability barrier is lost, restoration and maintenance of the urothelial mucus GAG/proteoglycan layer remains one of the therapeutic measures for PBS/IC. Chondroitin sulfate is believed to be the major proteoglycan responsible for the GAG barrier function, which is lost due to PBS/IC. Uracyst works by replenishing the bladder with a protective coating of chondroitin sulfate, restoring its impermeability.

Interstitial cystitis is managed non-pharmacologically using strategies such as physical therapy, and diet but is treated pharmacologically by restoring the mucus/GAG layer, inhibiting neurological activity, suppression of allergies (anti-histamines), and/or using analgesics (amitriptyline). Drugs for bladder instillation include hyaluronic acid (Cystistat®, Bioniche Life Sciences Inc.), sodium pentosan polysulfate (Elmiron®), Dimethyl sulfoxide (DMSO), Intravesical heparin, Hydrodistension, and sodium chondroitin sulphate solution (Uracyst®). Elmiron is an oral agent used to treat ICs and is known to have a very slow onset. Uracyst provides significant competitive advantages over heparin, pentosan polysulfate, and hyaluronan in simple barrier restoration (curing a dysfunctional urothelium).

(Source: shop.navamedic.com)

Interstitial Cystitis (Bladder) Market

The global IC therapeutics market is estimated to grow at a CAGR of 6.3% over the next eight years according to Global Data analysis. As per management's estimate, the global IC market is valued at $150M. This market is limited in size due to low diagnosis rate, lack of approvals of new products as well as limited availability of existing approved products.

Tribute has global licensing agreements for marketing Uracyst and has long-term patents in the U.S., Canada, Europe and other international territories. The company sells Uracyst in Canada through its own sales force. Tribute received its second patent in Canada issued July 10, 2012, as Canadian Patent No. 2,515,512 entitled "Cystitis Treatment with High Dose Chondroitin Sulfate". The new patent for Tribute's proprietary product Uracyst is valid through 2024.The drug is also being sold globally through licensing agreements. Tribute is actively seeking partners and regulatory approvals in Israel, the U.S., China, Japan and South Korea plus other markets globally.

Collatamp G

Collatamp G is a fully resorbable, gentamicin-collagen hemostat used both as a surgical implant for hemostasis and for the local delivery of high doses of gentamicin. Collatamp G is made out of collagen, a "natural" substance found in the skin. Collatamp G is a fully resorbable, gentamicin-impregnated collagen "sponge" that can be easily implanted during orthopedic, abdominal, cardiac, plastic or vascular surgery that can reduce the risk of surgical site infections. It provides hemostasis and delivers a high concentration of gentamicin directly to the target tissue. It also provides a localized antibiotic action while maintaining systemic gentamicin levels well below the toxicity threshold.

On June 20, 2012 Tribute acquired the Canadian rights to Collatamp G from Theramed Corporation. Collatamp G is approved in over 50 countries. Collatamp G is a registered trademark and under license from EUSA Pharma (Europe) Limited. The market for such devices is valued at $20M.

FINANCIAL CONDITION

Tribute's cash position as of May 21, 2015 was $12M. The cash balance should be sufficient to meet their expenses in the current quarter. With Tribute possibly turning cash flow positive in 2H 2015 and their strong revenue stream, they should have sufficient capital to work with in the near term.

Tribute has liabilities of $26.4M of which $14M is in the form of a loan with SWK Holdings. The loan matures on December 31, 2018. As per guidance from management there is potential for Tribute to acquire or in-license new products in either pain management and/or dermatology and/or cardiology sectors.

VALUATION/RECOMMENDATION

The pharmaceutical industry is a regional market served by very few specialty pharmaceutical companies, such as Tribute. Management believes that Tribute has a competitive advantage within its chosen therapeutic areas over other Canadian companies or multi-national subsidiaries seeking to license or acquire products in Canada. Tribute has been strategic in acquiring licensed products that have high revenue potential in diverse markets. Tribute is gaining traction as the company has adopted the route to rapidly and effectively target smaller market niches that have a need for specific drugs. Tribute also holds defendable patents for certain of its products. As Tribute continues to develop new partnerships and further expand its business in the U.S. and Canada, there is a possibility of seeing new pharmaceutical products being added to their portfolio. Tribute has seen consistent growth in domestic sales from its proprietary as well as in-licensed products. CAMBIA, Bezalip SR and Soriatane are expected to provide the bulk of revenue and drive earnings in the future. Management has several opportunities under evaluation and is looking into expanding its portfolio with complementing products or products used by a large set of population. Although such a step can have a significant bearing on debt pay off we feel that Tribute may become profitable over time.

We think there is upside to the current share price, driven by the recent significant (and expected continued) improvement in financial results as well as a number of upcoming inflection events. Near-term catalysts include Tribute filing NDS for bilastine in Canada, new products acquisitions or in-licensing and the possibility of turning cash flow positive in the second half of this year. Tribute can now be perceived as a low-risk opportunity as they generate increasing revenues with efficient and diligent operations. We think the shares trade significantly cheaper than warranted and does not accurately reflect the strong fundamentals (financial and operational) of the company.

Tribute's market cap is $107M based on a share count of 114 million. We valued Tribute using a 10-year Discounted Cash Flow (DCF) model. We use a 9% discount rate and 2% terminal growth rate. Based on our 10-year DCF model, Tribute is valued at $217M. We are raising our target price to $1.75/share and maintaining Buy recommendation.

RISKS

Patent cliff: As branded drugs near patent expiration, the loss of drug exclusivity could significantly reduce Tribute's revenue growth going forward. As such branded drugs compete against generic alternatives that are cheaper.

Customer Concentration: More than 50% of Tribute's entire product sales are from three wholesale customers. The loss of any one of the customers due to economic downturns, changing market scenarios, or for any other reason could reduce order volumes resulting in decreased revenues.

Regulatory Approvals: Tribute is involved in the acquisition of pharmaceutical products that have yet to be approved by regulatory agencies in the respective territories they are marketed in. This is an extensive process that tends to be time-intensive in nature. The evolving regulatory compliance issues of local government agencies may cause further delays or non-approvals that could negatively impact Tribute's business.

Reimbursement: The increase in use of premium-priced drugs (complexity of manufacturing, special storage and handling, patient-specific dosing, and mode of administration) has changed the reimbursement landscape considerably. Despite the global economic recovery, cost pressures can result in lower levels of reimbursement that might constrain the sales of specialty pharmaceutical products such as those offered by Tribute.

Generic Equivalents: Although the specialty-care drugs are difficult to replicate after patent expiration, they are quite often challenged by the generics industry. Generic companies are well-positioned to be the alternative healthcare solution, providing low-cost, reasonably high-quality drugs that could reduce Tribute's market share.

PROJECTED FINANCIAL STATEMENT

TributePharmaceuticals Inc.

	2014 A	Q1A	Q2E	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E	2019 E
Revenue	$16,871.8	$5,122.70	$6,330.0	$7,505.0	$8,280.0	$28,616.6	$36,437.6	$41,135.4	$45,400.1	$50,304.5
YOY Growth	*25.5%*	*46.6%*	*56.6%*	*94.0%*	*51.4%*	*69.6%*	*27.3%*	*12.9%*	*10.4%*	*10.8%*
Cost of Goods Sold	$7,690.4	$2,027.3	$1,925.0	$2,179.0	$2,407.5	$8,552.0	$10,656.3	$11,901.0	$13,201.3	$14,596.9
Write down of inventories	$53.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Profit	$9,129.1	$3,095.4	$4,405.0	$5,326.0	$5,872.5	$20,064.6	$25,781.3	$29,234.4	$32,198.8	$35,707.6
Gross Margin	*54.1%*	*60.4%*	*69.6%*	*71.0%*	*70.9%*	*70.1%*	*70.8%*	*71.1%*	*70.9%*	*71.0%*
SG&A	$10,149.9	$3,325.9	$3,228.3	$3,392.3	$3,436.2	$14,880.5	$16,761.3	$17,276.9	$17,706.0	$18,612.7
%SG&A	*60.2%*	*76.0%*	*51.0%*	*45.2%*	*41.5%*	*52.0%*	*46.00%*	*42.00%*	*39.00%*	*37.00%*
D&A	$1,511.02	$621.6	$657.6	$657.6	$657.6	$2,630.50	$2,630.50	$2,630.50	$2,630.50	$2,630.50
% D&A	*9.0%*	*12.1%*	*10.4%*	*8.8%*	*7.9%*	*9.2%*	*7.2%*	*6.4%*	*5.8%*	*5.2%*
Operating Income	($2,531.8)	($852.1)	$519.1	$1,276.1	$1,778.7	$2,553.7	$6,389.5	$9,327.0	$11,862.3	$14,464.4
Operating Margin	-	-	*8.2%*	*17.0%*	*21.5%*	*8.9%*	*17.5%*	*22.7%*	*26.1%*	*28.8%*
Change in Derivative/Warrant Value	($115.79)	$2,739.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Net Interest Expense	$1,441.73	$595.85	$467.69	$467.69	$467.69	$1,870.75	$1,870.75	$1,870.75	$1,870.75	$1,870.75
Accretion Expense	$167.56	$73.99	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Change in fair Value of liabilities	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Loss on Extinguishment of Loan	$1,641.24	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Loss on Disposal of equipment/asset	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Loss on ForEx on debt	$0	$1,433.46	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
R&D	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($5,607.0)	($5,138.1)	$51.4	$808.4	$1,311.0	$682.9	$4,518.8	$7,456.3	$9,991.5	$12,593.7
Taxes (benefit)	$0.0	$0.0	$18.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.00	$0.00
Tax Rate	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Net Income	($5,607.0)	($5,138.1)	$33.4	$808.4	$1,311.0	$682.9	$4,518.8	$7,456.3	$9,991.5	$12,593.7
Net Margin	-	-	-	*10.8%*	*15.8%*	*2.4%*	*12.4%*	*18.1%*	*22.0%*	*25.0%*
EPS	($0.08)	($0.05)	$0.0	$0.007	$0.01	$0.006	$0.04	$0.06	$0.08	$0.10
	-	-	-	-	-	-	-	-	-	-
Diluted Shares O/S	71,940	100,503	113,796	114,046	114,296	114,296	115,296	117,502	125,502	128,602

Source: Zacks Investment Research *Anita Dushyanth*

MANAGEMENT TEAM

Rob Harris
President and CEO
Rob Harris has 35 years of pharmaceutical industry experience in both Canada and the United States in sales, marketing, business development and general management. Prior to co-founding Tribute Pharmaceuticals, Rob was the President & CEO of Legacy Pharmaceuticals Inc. Rob also has previous experience at Biovail Corporation where as VP of Business Development he was involved, led and successfully concluded numerous business development transactions, including the licensing of new chemical entities, the acquisition of mature products, the completion of co-promotion deals, distribution agreements, product development and reformulation transactions. Rob joined Biovail in 1997 as the GM of Biovail Pharmaceuticals Canada at a time when the company experienced rapid growth in the Canadian division. Before Biovail, Rob worked in various senior commercial management positions during his twenty-year tenure at Wyeth (Ayerst) and has been involved in numerous product launches during his career.

Scott Langille
Chief Financial Officer
Scott Langille has over 25 years of experience in the pharmaceutical industry in both Canada and the United States. Prior to Tribute Pharmaceuticals, Scott was Chief Financial Officer of Virexx Medical Corp, a biotechnology company located in Alberta listed on the American Stock Exchange and the Toronto Stock Exchange. Scott was responsible for strategic direction, business development initiatives, investor relations, corporate financing activities, and financial operations. Past financial experience includes Director, Corporate Finance at Biovail Corporation, Director of Finance at Biovail Pharmaceuticals Canada, Biovail's sales and marketing division in Canada as well as Vice President at Biovail Pharmaceuticals Inc., Biovail's sales and marketing division in the United States. Other prior management positions include Director Finance at AltiMed Pharmaceuticals Company and Controller at Zimmer Canada. Scott has a professional accounting designation and an MBA from the University of Toronto.

Dr. Bernard Chiasson
Chief Scientific Officer
Dr. Bernard Chiasson, Ph.D. has nearly two decades of experience in working with the pharmaceutical and biotechnology industry. He has held positions of increasing responsibility in R and D including drug discovery, medical affairs, business development and licensing, regulatory affairs and executive management. Bernie has successfully patented technologies in the area of neuroscience and has worked on several small molecules, biologics and biotechnology products at all stages of development including the final registration phase with Health Canada and the US FDA. He is a trained Neuroscientist and Pharmacologist. He has created development and commercialization strategies as well as franchise management approaches for various categories including Hematology, Oncology, Inflammation and Nephrology. He has obtained his industry training with Novartis, Draxis, Bayer, Amgen and OptumInsight. Most recently, Bernie was VP of US Strategic Regulatory Affairs and Global Medical Services at OptumInsight where he was responsible for a team of scientists and physicians supporting client drug development, safety and regulatory strategies and operations. Bernie received his University training at Dalhousie University and the University of Toronto.

Janice Clarke
V.P. Finance & Administration
Janice Clarke has over twenty years of office administration and financial management experience with proven abilities to implement and manage various financial systems and office procedures. Janice joined Stellar Pharmaceuticals Inc. in August 2000 and currently manages its administrative and financial processes.

Ann Hartshorn
V.P. Marketing
Ann has over 25 years of experience in the pharmaceutical industry with progressive positions spanning sales and marketing, new product launches, and life cycle management throughout various therapeutic areas with family practice and specialized medicine. Prior to joining Tribute Pharmaceuticals, Ann was a principal of a pharmaceutical consulting firm that assisted numerous international pharmaceutical companies in their life cycle management activities, including Astra Zeneca, Servier Pharma, and Pfizer. Prior to her consulting activities, Ann was Director, Hospital and Specialty Business Unit for Crystaal Corporation in which capacity she successfully launched several products in Canada. While at Crystaal, Ann also served as Director of Marketing and Director of New Product

Planning. Ann also has previous marketing experience with Wyeth and Astra Zeneca. Born and educated in England, Ann graduated from the University of Reading and the Royal Berkshire Hospital as a State Registered Nurse and Midwife. After immigrating to Canada, she worked in the ICU, CCU and NICU at Ottawa Civic and Ottawa General Hospitals.

Murray Roach
VP Sales
Mr. Roach has 20 years of pharmaceutical sales and marketing experience in Canada, including Vice President, Sales and Marketing for Taro Pharmaceuticals in Canada. In this capacity Mr. Roach gained an extensive experience in the dermatology market nationally in all aspects of the business.
Prior to Taro Pharmaceuticals, Mr. Roach spent 15 years at Wyeth Canada in several senior sales and marketing positions including Director of Sales, Pharmaceuticals, Director of Sales, Biopharmaceuticals and Product Manager for Effexor® (venlafaxine). Mr. Roach enjoyed many years of success at Wyeth Canada and won numerous sales and marketing awards during his career with Wyeth. He began his career with Wyeth as a sales representative in Saskatchewan and is a graduate of the University of Saskatchewan, College of Education.

David Butts
B.SC., V.P. International Business
David Butts V.P, International Business is a senior executive with over 25 years in the life sciences industry with progressive sales, marketing and clinical experience. He has a proven track record and success in the area of new business development and product licensing. A graduate from Carleton University, Ottawa, Mr. Butts has a good knowledge of the clinical development process and experience in many key pharmaceutical segments; urology, orthopedics, respiratory, allergy and cardiology.

Paul MacPherson
V.P. Manufacturing & Operations
Paul joined Tribute in May 2007, with 15 years of experience in process engineering and production within the pharmaceutical and biotech fields. He holds Bachelor's and Master's Degrees in Chemical Engineering from McMaster University.

Darrin Statchuk
Director of Quality & Regulatory Affairs
Darrin Statchuk, Director of Quality and Regulatory Affairs, joined the company in 2004. Mr. Statchuk has over 15 years of experience in the manufacturing sector specializing in Quality Management and Regulatory aspects for both large and small international companies. Darrin graduated from the University of Western Ontario, where he earned his Bachelor of Science in Chemistry.

Luigi Berardelli
Director Specialty Products
Luigi Berardelli, Director of Sales and Marketing for Tribute's Specialty Care Group has over 20 years of experience in the pharmaceutical market in Canada. Past experience includes Business Unit Director for Synvisc/Surgical Devices at Genzyme (now Sanofi), Director of Sales at Biovail's Canadian operations and Director of Sales at Rhone Poulenc Canada.

Jesse Ledger
Director of Business Development
Jesse Ledger, Director of Business Development has over 10 years of industry experience. Previous experience includes Director of Business Development for Sterimax Inc., where he was responsible for numerous licensing transactions and Manager of Business Development at Methapharm Inc. Jesse has an honours BBA from Trent University in Peterborough, Ontario.

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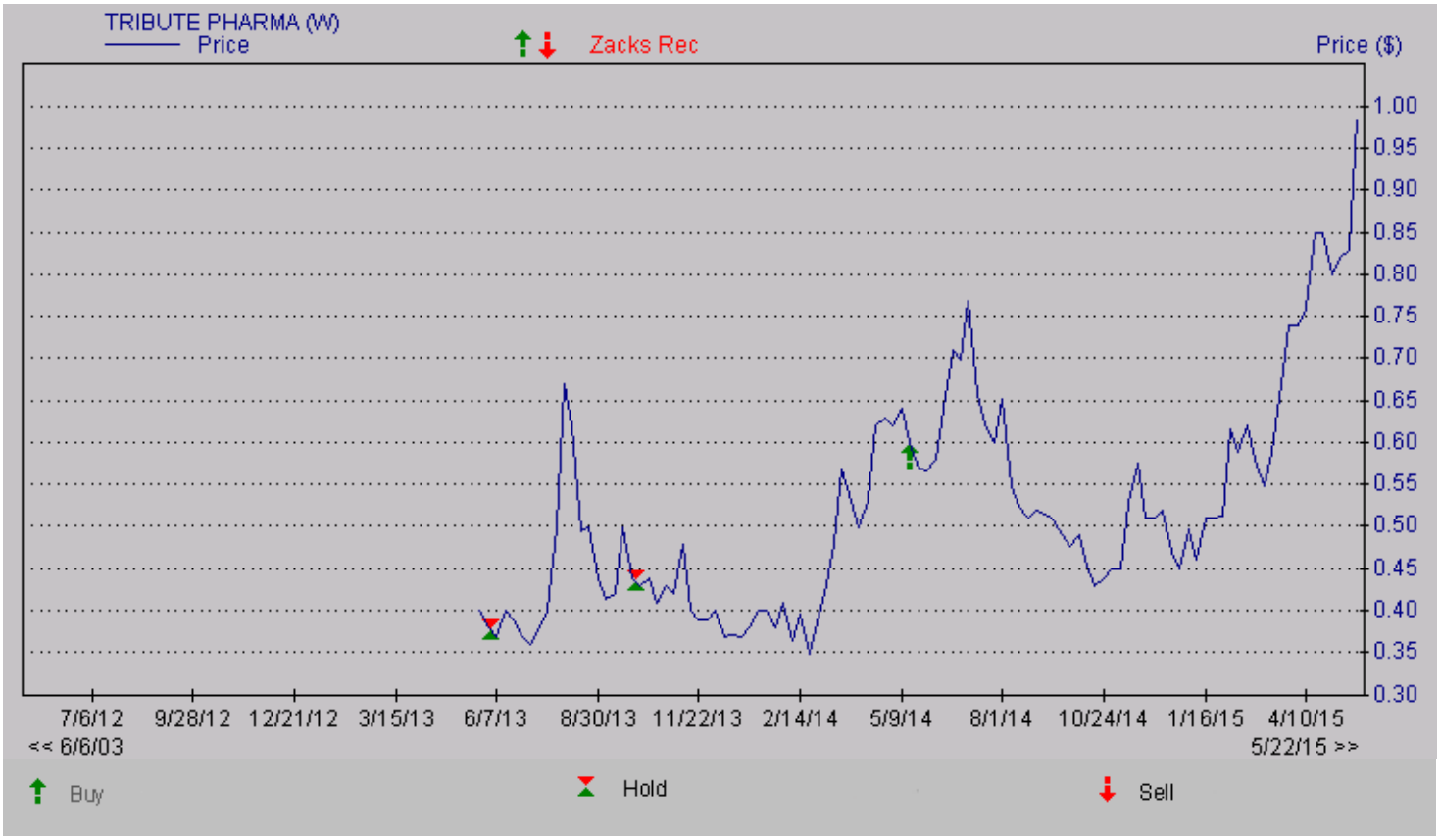

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.5%, Hold/Neutral- 75.4%, Sell/Underperform – 7.0%. Data is as of midnight on the business day immediately prior to this publication.