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Zacks Small-Cap Research

Anita Dushyanth, PhD
312-265-9434
adushyanth@zacks.com
Brian Marckx, CFA
312-265-9474
bmarckx@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Tribute Pharma (TBUFF-OTC)

TBUFF: Interim Update

OUTLOOK

TBUFF announced the acquisition of the Canadian rights to Fiorinal®, Fiorinal C®, Visken® and Viskazide® from Novartis on October 2, 2014. Fiorinal and Fiorinal C are indicated for the relief of tension-type headache and Visken and Viskazide are used in the treatment of mild-moderate hypertension. We are positive on this transaction as Tribute is growing its specialty pharma business efficiently. We expect high revenue numbers from fourth quarter earnings from the new products. We are maintaining Outperform rating.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/12/2014
Current Price (1/20/15)	$0.51
Target Price	**$1.40**

SUMMARY DATA

52-Week High	**$1.10**
52-Week Low	**$0.32**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**5,200**
Shares Outstanding (mil)	**94**
Market Capitalization ($mil)	**$48**
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 2014 Estimate	**-15.0**
P/E using 2015 Estimate	**10.0**
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)
2013	$3.4 A	$3.3 A	$3.5 A	$3.2 A	$13.4 A
2014	$3.5 A	$4.0 A	$3.8 A	$6.5 E	$18.0 E
2015					$29.5 E
2016					$35.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-0.04 A	-0.03 A	-0.02 A	-0.03 A	-0.13 A
2014	-0.07 A	-0.09 A	$0.03 A	-0.04 E	-0.10 E
2015					-0.02 E
2016					-0.01 E

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

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INTERIM UPDATE

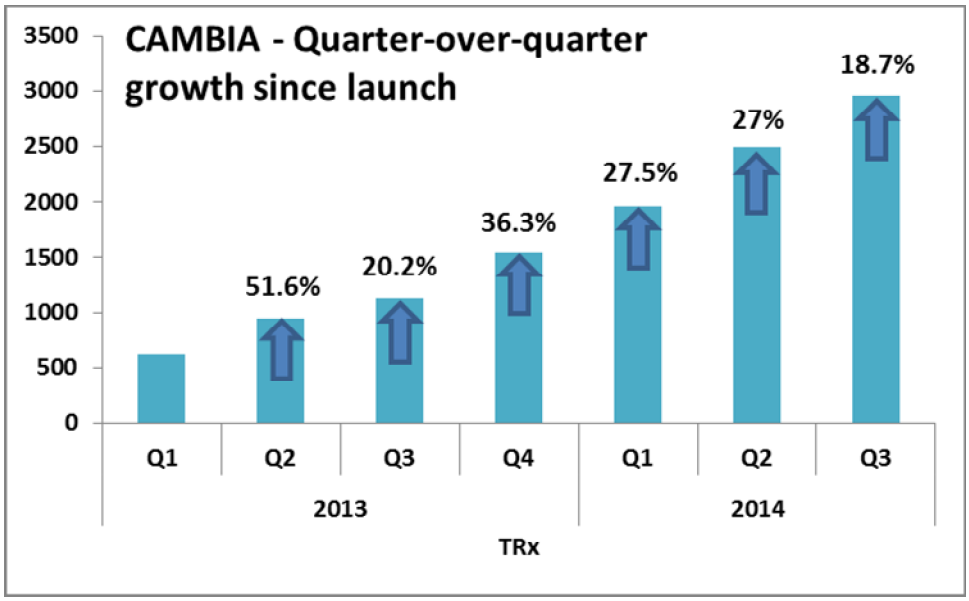
Tribute's management has been very focused and consistent with growing the business and giving it the right direction. We anticipate high revenues in Q4 2014 from the sales of their new products Fiorinal, Fiorinal C, Visken and Viskazide as well as from their existing product Cambia that has shown consistent upward trend in market adoption since launch in 2013. Despite these factors, TBUFF remains undervalued and we maintain our Outperform rating.

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WHATS NEW

Q3 Results

Tribute pharma announced their Q3 results on November 10, 2014. Domestic and international product sales increased by 25.4% and 42.8% respectively compared to Q3 2013 and beat our conservative estimates. IMS health reported an 18.7% increase in total prescriptions written for Cambia® during the third quarter of 2014. We were slightly more optimistic on revenue estimates for Cambia as we saw the consistent upward trend of uptake of the drug in the market. However, this could be attributed to the seasonal swings in the sales of certain type of drugs. The combined effect of foreign currency exchange rates, Tribute's continued efforts in marketing to grow its existing products, as well as an increase in business development related expenses resulted in increased operating expenses.



One of the Tribute's proprietary products, Uracyst, recently received additional patents from the U.S. Patent and Trademark Office (USPTO) and the European Patent Office (EPO). In addition to expanding the scope of this drug, the patents are likely to trigger a boost in sales and make Uracyst lucrative. Tribute's other products getting ready to hit the market in 2016 are Bezalip SR (in the U.S.), indicated for mixed hyperlipidemia, and Bilastine (in Canada), indicated for allergic rhinitis and chronic idiopathic urticaria (hives). Management expects to file regulatory approval for Bilastine sales in Canada in the first quarter of 2015. The key products that are expected to provide increase in Q4 revenues are Fiorinal, Fiorinal C, Visken and Viskazide. As the synergistic products (Fiorinal, Fiorinal C and Cambia) fall under Tribute's umbrella of headache therapeutics, we do not expect to see additional expenses in the promotion and marketing of Fiorinal and Fiorinal C. Tribute anticipates a more productive outcome from using the existing twenty sales representatives both for marketing drugs for tension headaches and migraine headaches.

Tribute announced the acquisition of Canadian rights to Fiorinal®, Fiorinal® C, Visken® and Viskazide® from Novartis (NVS) for CDN$32M, an all-cash deal acquired using proceeds received from Tribute's July 2014 equity offering as well as with US $6 million loan from SWK Holdings. Fiorinal and Fiorinal C address headaches arising from tension and Visken and Viskazide are used in the treatment of mild-to-moderate hypertension. While in-licensing has been the lifeline of Tribute Pharma, the company's strategic direction of focusing on acquisition of branded drug products continues to be a priority. Tribute expects the acquisition of these products to have an immediate positive net effect on accretive earnings.

Our reasons to be delighted on this acquisition are manifold – primarily, it is an accretive deal of a mature products that fit seamlessly into Tribute's existing portfolio. Tribute currently markets CAMBIA (diclofenac for oral solution) for the treatment of migraine headaches. Having gained a foothold in the Canadian headache migraine market last year via CAMBIA, Tribute has made yet another strategic move by acquiring Fiorinal and Fiorinal C; drugs that address tension headaches. Tribute's strong presence in the headache market will help drive the growth of these

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new products. Tribute hopes to maximize the economic value by expanding the indications for Tribute's headache therapeutics.

It's a win-win situation for both the giant pharma company (Novartis) as well as for Tribute, a smallcap specialty pharmaceutical firm. For Novartis, a relative behemoth with a highly diverse product portfolio spanning a wide range of indications, they can monetize value for off-patent products that may not fit well with a sales-force and marketing heavy business model through divestiture to Tribute. By contrast, TBUFF has a relatively concentrated product suite with a synergistic focus on similar indications. This affords Tribute the ability to maximize value of these acquired drugs with very little to no incremental operating spend as their reps detail to their existing customer base. Acquiring from the branded drug company helps Tribute market the product with the already built reputation of Novartis. Further, Tribute is able to focus on smaller regional markets.

Per management, the combined net sales of the four acquired products during the twelve month period ending August 31, 2014 were approximately CDN$10.8 million. And while perhaps not meaningful for Novartis, it is highly significant for a small-cap company such as Tribute. We believe that the sale price of 3x revenue is fair given that the drugs yield a stable revenue base for Tribute.

Products:

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.

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.

Financial Condition:
The proceeds from Tribute's public offering in July 2014 yielded roughly $30M in additional capital. We anticipated this amount to fund business development activities in the future. As expected, the increase in cash position helped in part in furthering their business development by acquiring the Canadian rights for Fiorinal, Fiorinal C, Visken and Viskazide. In our model we forecast sales from these products beginning Q4 2014. In the past Tribute has raised capital through equity as well as debt financing. As part of the acquisition Tribute issued 740,000 warrants.

We anticipated a net loss of about $1M and an EPS of (0.01) for third quarter of this year. However, Q3 results revealed a net income of $3M and an EPS of $0.03. This discrepancy is due to the change in fair value of the warrant liability that resulted in a decrease in the warrant expense yielding a positive net income. This also had a significant impact on the EPS. Going forward we expect an increase in amortization expense of $2M per year due to the recent acquisition of the Novartis products.

The cash flow used in operating activities was $1.3M. Tribute's cash balance remains at about $3M. The company has a loan outstanding in the amount of $14M with SWK Holdings. We are maintaining our Outperform rating.

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 for Q2 2014.
- 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.
- Tribute completed a public equity offering of 42,895,000 common shares of stock on July 15, 2014 issued at a price of $0.70 per unit resulting in gross proceeds of just over $30 million. This is expected to aid Tribute develop its strategic initiatives related to business development and acquisition of complementing products.

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[1]. 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).

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[2]. 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[3]. 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)[4] while the pharmacokinetic data showed other oral tablets such as ibuprofen, and naproxen sodium took effect up to two hours after consumption.

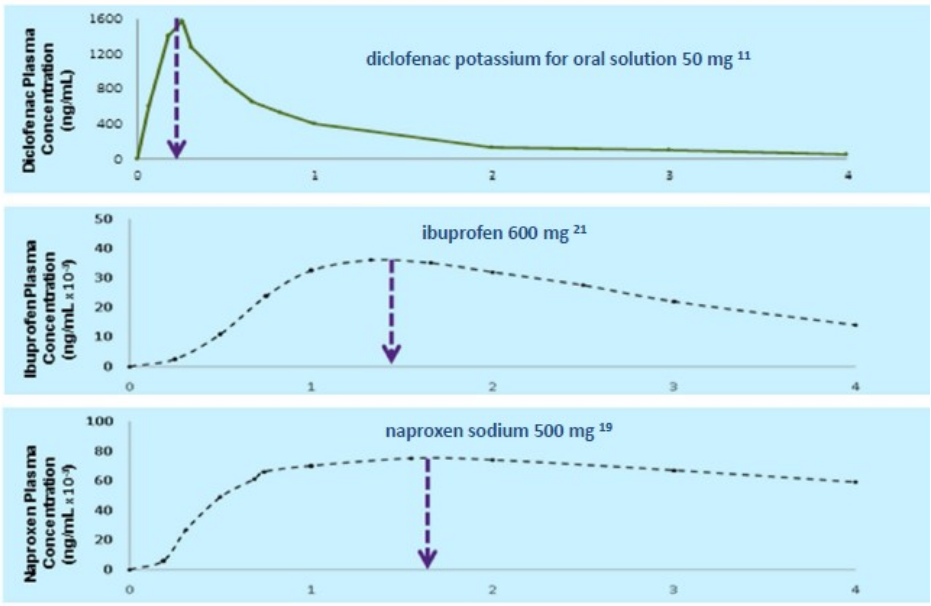
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[1] William E.M. Pryse-Phillips, MD; David W. Dodick, MD; John G. Edmeads, MD; Marek J. Gawel, MD; Robert F. Nelson, MD; R. Allan Purdy, MD; Gordon Robinson, MD; Denise Stirling, MD; Irene Worthington (1997), BScPhm, Guidelines for the diagnosis and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

[2] Narbone, M. C., M. Abbate, and S. Gangemi. "Acute drug treatment of migraine attack." *Neurological Sciences* 25, no. 3 (2004): s113-s118.

[3] Kahn, K. (2011). Cambia® (diclofenac potassium for oral solution) in the management of acute migraine. *US Neurology*, *7*(2), 139-43.

[4] 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.[5] 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

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

training related to migraine diagnosis and treatments. By contrast, a neurologist is well- informed on the 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.[6]
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[7].

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[8]. 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[9]. 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.

[6] 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.
[7] 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.
[8] 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.
[9] 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.

Specialty Care Products

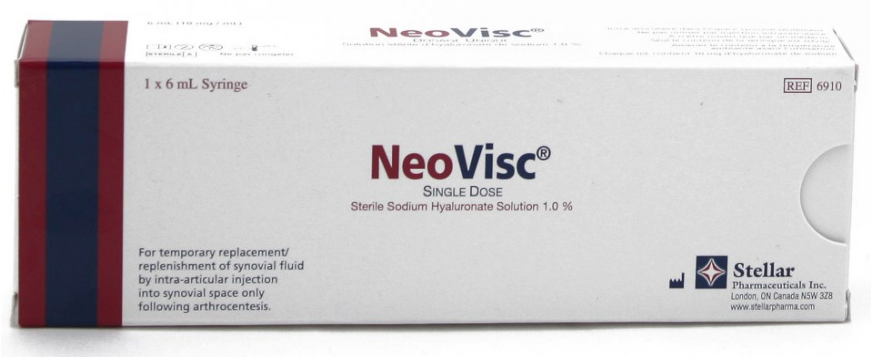
NeoVisc and Uracyst are Tribute's proprietary products that are developed and manufactured in Canada.

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

Cash

In the general procedure of obtaining licensing and manufacturing agreements and regulatory approvals, Tribute is obligated to pay an up-front licensing fee and additional milestone payments in increments based on aggregate net sales. Management has openly discussed their intentions and ambitions to grow their business through future business development activities such a product acquisitions and licensing.

On July 15, 2014, subsequent to Q2 2014, Tribute completed a public offering of common stock of 42,895,000 units issued at a price of $0.70 per unit for gross proceeds of about $30M. The proceeds from Tribute's public offering in July 2014 yielded roughly $30M in additional capital. We anticipated this amount to fund business development activities in the future. As expected, the increase in cash position helped in part in furthering their business development by acquiring the Canadian rights for Fiorinal, Fiorinal C, Visken and Viskazide. In our model we forecast sales from these products beginning Q4 2014.

The cash flow used in operating activities was $1.3M. Tribute's cash balance remains at about $3M.

Debt / Liabilities

SWK Holdings offers significant amount of debt capital for Tribute's business development activities and also allows them to draw on their debt facility as need arises. The debt facility from SWK Holdings increased from $8 million to $17 million. Tribute drew $6 million towards the recent acquisition. They also have access to another $3 million from SWK to use, if necessary. As part of the acquisition Tribute issued 740,000 warrants.

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.

TBUFF currently trades at $0.46/share, well below our calculated and targeted fair value. The strategic investment opportunity that Tribute provides grows stronger with each acquisition. Tribute has a history of acquiring mature products that are already in commercialization stage. Their core strength is their ability to make tactical acquisitions that help complement or strengthen their existing diverse portfolio of products.

Per management, the acquired products have gross margins of about 90%. Per our conversation with management, Novartis, on behalf of Tribute, will continue to manufacture and distribute the acquired products during the transition period to ensure availability of the drugs. Tribute anticipates the transfer to complete by end of 2015. Due to their strong financial discipline we expect Tribute to perform well in the coming quarters. The company has built strong revenue generating product portfolio and is well-positioned to compete with peers in the pharmaceutical industry.

Tribute has a well-established relationship with neurologists, headache specialists and PCPs due to their marketing of CAMBIA. We believe the company can increase their profitability since most of the costs associated with the promotion of CAMBIA have already been invested. By reconnecting and closely working with established clinicians, we believe Tribute can successfully launch Fiorinal and Fiorinal C this year. We anticipate little to no incremental operating expenses related to sales and marketing of Fiorinal and Fiorinal C. We expect the G&A expenses to be minimal as the products acquired are complementary and address issues within a bigger umbrella of headache and cardiovascular disease. With the operational expenses under control, the company is well-poised to deliver shareholder value in the coming quarters. As a result of high margins and low incremental SG&A, most of the revenue flows towards free cash flow.

We anticipated a net loss of about $1M and an EPS of (0.01) for third quarter of this year. However, Q3 results revealed a net income of $3M and an EPS of $0.03. This discrepancy is due to the change in fair value of the warrant liability that resulted in a decrease in the warrant expense (non-cash) yielding a positive net income. This also had a significant impact on the EPS. Going forward we expect an increase in amortization expense of $2M per year due to the recent acquisition of the Novartis products.

We reduced the discount rate used in our valuation as the company becomes more stable. When paired with their operational efficiencies, we expect Tribute to achieve positive cash flow by end of 2015. We believe the company should be valued at $150 million with the current portfolio. The updates to our model following this acquisition have resulted in our per-share target price increasing from $1.00 to $1.40. We are maintaining our Outperform rating.

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

	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E	2017 E	2018 E	2019 E
Revenue	$13,440.4	$3,493.6	$4,041.3	$3,868.9	$6,475.0	$18,332.3	$29,134.7	$35,012.0	$40,954.3	$46,966.8	$53,055.4
YOY Growth	*8.9%*	*2.1%*	*21.4%*	*11.2%*	*101.8%*	*36.4%*	*58.9%*	*20.2%*	*17.0%*	*14.7%*	*13.0%*
Cost of Goods Sold	$7,386.2	$1,758.9	$1,987.5	$1,988.4	$2,256.5	$7,966.1	$10,104.4	$12,215.6	$14,560.0	$16,914.5	$18,831.9
Write down of inventories	$56.9	$0.0	$13.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Profit	$5,997.3	$1,734.7	$2,040.4	$1,880.5	$4,218.5	$10,366.2	$19,030.3	$22,796.4	$26,394.2	$30,052.3	$34,223.6
Gross Margin	*44.6%*	*49.7%*	*50.5%*	*48.6%*	*65.2%*	*56.5%*	*65.3%*	*65.1%*	*64.4%*	*64.0%*	*64.5%*
SG&A	$9,830.1	$3,222.7	$2,409.7	$2,529.53	$3,561.25	$11,723.1	$16,024.1	$18,206.2	$18,429.4	$18,786.7	$19,630.5
%SG&A	*73.1%*	*92.2%*	*59.6%*	*65.4%*	*55.0%*	*63.9%*	*55.00%*	*52.00%*	*45.00%*	*40.00%*	*37.00%*
D&A	$1,245.8	$290.35	$296.57	$296.72	$845.00	$1,728.65	$3,380.00	$3,380.00	$3,380.00	$3,380.00	$3,380.00
% D&A	*9.3%*	*8.3%*	*7.3%*	*7.7%*	*13.1%*	*9.4%*	*11.6%*	*9.7%*	*8.3%*	*7.2%*	*6.4%*
Operating Income	($5,078.7)	($1,778.3)	($665.8)	($945.7)	($187.8)	($3,085.6)	($373.8)	$1,210.2	$4,584.8	$7,885.6	$11,213.1
Operating Margin	-	-	-	-	-	-	-	*3.5%*	*11.2%*	*16.8%*	*21.1%*
Change in Derivative/Warrant Value	$399	$1,212	$3,402.78	($4,270.45)	$2,731.66	$3,075.75	$0.00	$0.00	$0.00	$0.00	$0.00
Net Interest Expense	$523	$267	$298.01	$246.06	$467.69	$1,278.68	$1,870.75	$1,870.75	$1,870.75	$1,870.75	$1,870.75
Accretion Expense	$104	$31	$34.41	$36.74	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Change in fair Value of liabilities	$0	$0	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Loss on Extinguishment of Loan	$621	$0	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Loss on Disposal of equipment/asset	$161	$0	$0.00	$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	$0.0
Pre-Tax Income	($6,887.2)	($3,288.2)	($4,401.0)	$3,041.9	($3,387.1)	($7,440.0)	($2,244.6)	($660.6)	$2,714.1	$6,014.8	$9,342.3
Taxes (benefit)	$314.9	$0.0	$0.00	($13.16)	$0.00	$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%*	*35.0%*
Net Income	($6,572.3)	($3,288.2)	($4,401.0)	$3,055.1	($3,387.1)	($7,440.0)	($2,244.6)	($660.6)	$2,714.1	$6,014.8	$9,342.3
Net Margin	-	-	-	-	-	-			*6.6%*	*12.8%*	*17.6%*
EPS	($0.13)	($0.06)	($0.09)	$0.03	($0.04)	($0.10)	($0.02)	($0.01)	$0.03	$0.05	$0.08
	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares O/S	49,169	51,420	51,581	94,476	94,476	73,065	101,909	104,683	106,499	113,390	113,390

Anita Dushyanth

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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

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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.

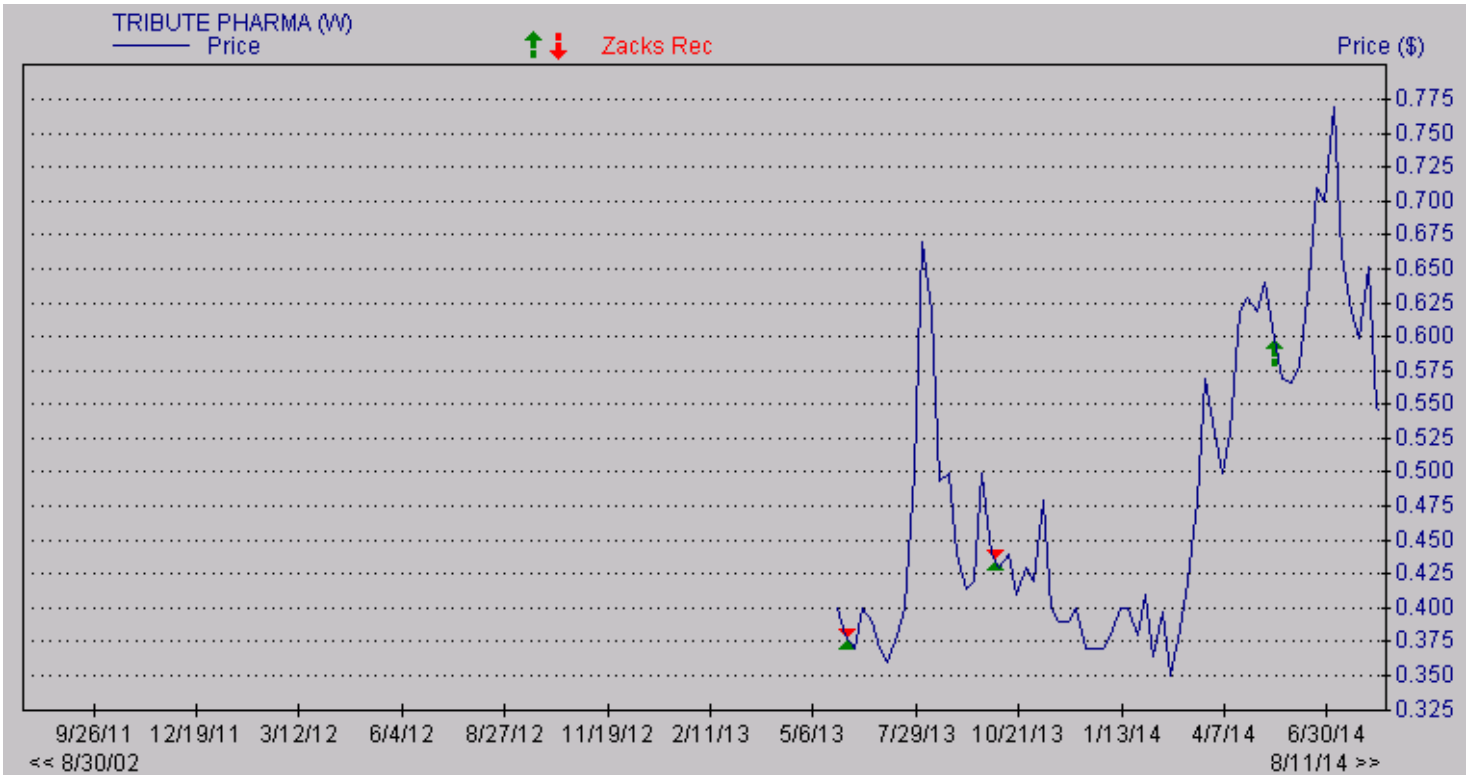
Paul MacPherson
V.P. Manufacturing & Operations
Paul joined Tribute in May 2007, with 15 years of experience in process engineering and production within the pharmaceutical and biotech fields. He holds Bachelor's and Master's Degrees in Chemical Engineering from McMaster University.

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

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