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David Martin PhD, MBA  
Analyst  
416-642-8865  
dmartin@bloomburton.com

### Research Initiation – Healthcare Sector Overview

Bloom Burton & Co. Ltd. (“Bloom Burton”) is re-launching equity research coverage of the healthcare sector, publishing investment recommendations today for 7 companies in the space.

Company	Ticker	Currency	Price	Rating	Risk	Target	Return to Target
Aurinia Pharmaceuticals	TSX:AUP NASDAQ:AUPH	USD	\$3.65	Buy	Speculative	\$6.00	64%
Bellus Health	TSX:BLU	CDN	\$1.47	Buy	Speculative	\$3.00	104%
Cardiome Pharma	TSX:COM NASDAQ:CRME	USD	\$9.10	Hold	Above Average	\$10.00	10%
Concordia Healthcare	TSX:CXR	CDN	\$43.42	Accumulate	Average	\$49.50	14%
Knight Therapeutics	TSX:GUD	CDN	\$6.79	Accumulate	Average	\$8.00	18%
Tribute Pharmaceuticals	TSXV:TRX	CDN	\$0.53	Buy	Above Average	\$1.00	89%
Trillium Therapeutics	TSX:TR	CDN	\$7.56	Buy	Speculative	\$20.75	174%

Our initial coverage list focuses on Canadian biotechnology and specialty pharmaceutical companies; however, moving forward we also plan to seek out unique investment ideas on a global scale, as well as ideas in other healthcare subsectors including medical devices. Our goals are to provide an understandable assessment framework and list of recommendations for Canadian investors who may not specialize in the sector, and also to introduce investors in the United States, Europe, and other regions, to Canadian healthcare investment ideas.

This report is priced as of prior trading day's market close.  
All values in C\$ unless otherwise noted.



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## Introduction

Bloom Burton & Co. is re-launching equity research coverage of the healthcare sector, publishing investment recommendations today for 7 companies in the space (Exhibit 1).

Exhibit 1. Bloom Burton & Co. Research Coverage List

Company	Ticker	Currency	Price	Shares (MM)	Market Capitalization (MM)	Rating	Risk	Target	Return to Target
Aurinia Pharmaceuticals	TSX:AUP NASDAQ:AUPH	USD	\$3.65	31.8	\$116.1	Buy	Speculative	\$6.00	64%
Bellus Health	TSX:BLU	CDN	\$1.47	47.4	\$69.7	Buy	Speculative	\$3.00	104%
Cardiome Pharma	TSX:COM NASDAQ:CRME	USD	\$9.10	16.5	\$150.3	Hold	Above Average	\$10.00	10%
Concordia Healthcare	TSX:CXR	CDN	\$43.42	28.9	\$1,253.2	Accumulate	Average	\$49.50	14%
Knight Therapeutics*	TSX:GUD	CDN	\$6.79	92.7	\$629.8	Accumulate	Average	\$8.00	18%
Tribute Pharmaceuticals	TSXV:TRX	CDN	\$0.53	94.5	\$50.1	Buy	Above Average	\$1.00	89%
Trillium Therapeutics	TSX:TR	CDN	\$7.56	4.3	\$32.4	Buy	Speculative	\$20.75	174%

\*Pro-forma financing

Source: Bloom Burton estimates; Bloomberg

Our initial coverage list focuses on Canadian biotechnology and specialty pharmaceutical companies; however, moving forward we also plan to seek out unique investment ideas on a global scale, as well as ideas in other healthcare subsectors including medical devices. Our goals are to provide an understandable assessment framework and list of recommendations for Canadian investors who may not specialize in the sector, and also to introduce investors in the United States, Europe, and other regions, to Canadian healthcare investment ideas. Before diving into specific stocks, this report begins with an overview of healthcare sector dynamics...and to kick off things, we begin with a discussion of key reasons to invest in this vibrant and rewarding industry.

## Why Invest in the Healthcare Sector?

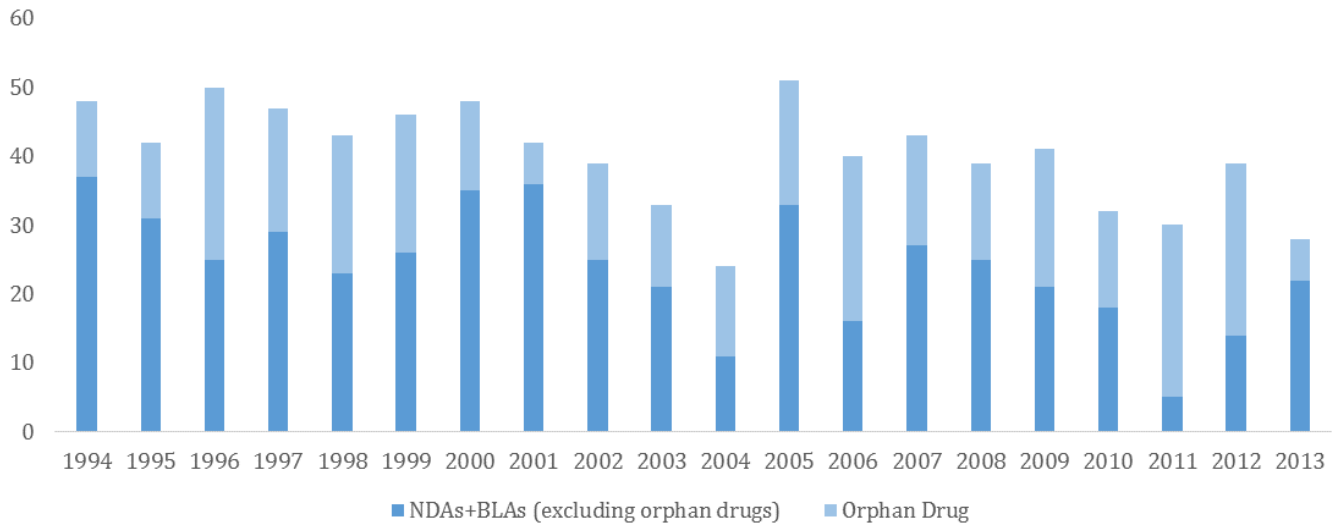
### Long Term Sector Outperformance and Potential for Spectacular Binary Event Returns!

There is broad fundamental strength in the healthcare sector across multiple foundations: 1) demographic trends continue to support the need for better drugs to treat a growing aging population; 2) drugs representing major advances (new targets, novel mechanisms of action) are moving into late clinical and commercial stages at an accelerating pace – these products represent the windfall of quantum leaps in our basic knowledge of the molecular biology of disease that occurred around the turn of the century; 3) genericization of many of big pharma’s aging list of blockbuster drugs has made room for high cost biotech drugs for orphan diseases; 4) the FDA, with its main mission seeming to swing periodically from “approver of drugs” to “policeman of adverse events”, is currently gravitating to the more accommodating end of the spectrum bolstered by the absence of any fresh safety scares on the scale of Vioxx, and with adequate funding thanks to increased PDUFA-mandated user fees, and 5) the Affordable Care Act is increasing the number of insured Americans by millions.

With many factors contributing to a positive overall environment for drug discovery, development and commercialization, it is perhaps surprising that the number of new drugs approved annually has not seen steady increases in recent years (Exhibit 2).



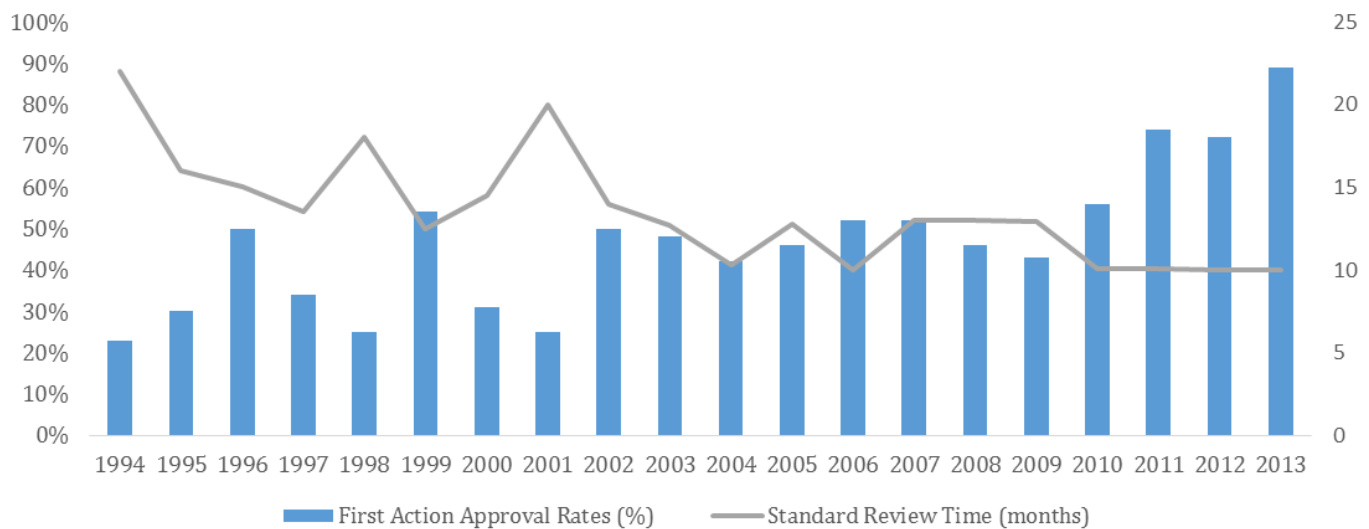
### Exhibit 2. FDA Drug Approvals



Source: Nicolaou 2014 Advancing the Drug Discovery and Development Process. Angew. Chem. Int. Ed: 53:2-15

Regulators do not appear to be the bottleneck – the standard review time for new drugs over the last 20 years has been decreasing, and the percent of first-action approval rates for new drugs has been increasing (Exhibit 3) – positive trends that speak to both the regulatory environment and the quality of marketing applications submitted to the FDA.

### Exhibit 3. First Action Approval Rates and Review Times



Source: FDA FY-2013 PDUFA Report

It is likely that the sluggish drug approval numbers are the result of the “low hanging fruit” in drug discovery having already been picked. Opportunities that remain are becoming increasingly challenging to reach. While this may seem negative for the drug industry overall, it plays into the hands and increases



the value of innovative biotechnology companies which possess the knowledge and the new technologies needed to “reach the higher fruit”.

In 2014, 22 new drugs were approved in the first half of the year, and a total of 50 could be approved by the end of the year which would be a strong showing for the industry. Notable second half approvals include Merck & Co.’s (NYSE: MRK; unrated) Keytruda, Gilead Sciences’ (NASDAQ: GILD; unrated) Harvoni, Roche’s (VX: ROG; unrated) Esbriet and Biogen Idec’s (NASDAQ: BIIB; unrated) Plegridy. In general, the graduating class of 2014 is expected to include smaller products, with peak estimates for most falling below the \$1 billion mark (*Source: Evaluate Pharma*).

The strength of the biotechnology sector can be seen in the recurring outperformance of the NASDAQ Biotechnology Index (“NBI”), shown in Exhibit 4. The S&P/TSX Healthcare Index (TTHC) has also performed well, however, the Canadian index currently includes only 3 components: Valeant Pharmaceuticals International (NYSE: VRX, TSX: VRX; unrated), Extendicare (TSX: EXE; unrated) and Catamaran (NASDAQ: CTRX, TSX: CCT; unrated), representing specialty pharma, senior care and healthcare IT segments within healthcare. This does not mean that Canadian Healthcare has not had other winners, only that many of the successful companies have been acquired, including Paladin Labs by Endo International (NASDAQ: ENDP; unrated) in 2014, Cangene by Emergent BioSolutions (NYSE: EBS; unrated) in 2014, Medicago by Mitsubishi Tanabe Pharma (Tokyo: 4508; unrated) in 2013, YM BioSciences by Gilead in 2013, Arius Research by Roche in 2008, CryoCath Technologies by Medtronic (NYSE: MDT; unrated) in 2008, Aspreva Pharmaceuticals by Galenica Group (SW: GALN; unrated) in 2007, AnorMED by Genzyme in 2006, ID Biomedical by GlaxoSmithKline (NYSE: GSK; unrated) in 2005, and Biochem Pharma by Shire (NASDAQ: SHPG; unrated) in 2000.

Exhibit 4. Stock Index Performance

Period	DJI	S&P 500	NASDAQ	NDXT	S&P/TSX	DRG	TTHC	NBI
2014 YTD	5%	9%	11%	22%	4%	14%	15%	34%
2013	27%	30%	38%	37%	10%	27%	40%	66%
2012	7%	13%	16%	7%	4%	11%	11%	32%
2011	6%	0%	-2%	-6%	-11%	9%	13%	12%
2010	11%	13%	17%	22%	14%	-1%	40%	15%
2009	19%	23%	44%	80%	31%	13%	28%	16%
2008	-34%	-38%	-41%	-45%	-35%	-19%	-29%	-13%
2007	6%	4%	10%	8%	7%	-2%	-25%	5%
2007-13	33%	30%	73%	78%	6%	36%	67%	197%

Source: Bloomberg

Between 2007 and 2013, the NBI outperformed all other indices tracked in Exhibit 4 in three of seven years, and increased 197% over the seven year interval, beating the second place, NASDAQ Technology Sector Index (NDXT), by a wide margin. Year to date, the NASDAQ Biotech Index is again outperforming the other indices, up 34%. Even during the financial crisis of 2008, the NBI outperformed, losing only 13%, demonstrating that the sector can resist negative macroeconomic factors better than others, due in part to regular clinical and regulatory value drivers, positive demographic trends, and the defensive nature of healthcare in general.

Investors in biotechnology stocks stand to achieve spectacular event-driven returns due mainly to the high risk/high reward nature of drug development which warrants heavy discounting of products, including potential blockbusters, during lengthy clinical programs. As a result, opportunities exist for savvy investors to identify big market products early on, and to invest with an understanding of the risks and expected timing of value driving milestones. So equipped, the investor will have an improved chance of buying a stock at the right time and right price, then exiting with a big win – possibly upon approval of



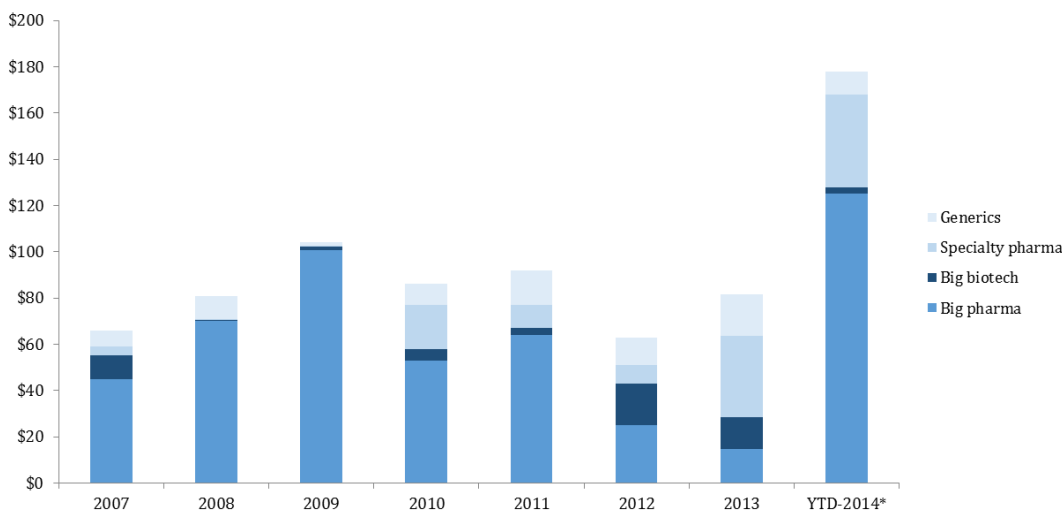
the product; or following achievement of key validating clinical results; or at the time of a partnering or acquisition event; or even when a certain disease or drug class “hits the radar” of the broader biotech investing community. Examples of outsized event-related returns in recent years include:

- Vertex Pharmaceutical’s (NASDAQ:VRTX; unrated) 45% jump to a \$22 billion market cap this June following positive phase 3 results for cystic fibrosis drug Lumacaftor.
- InterMune’s 170% one-day jump this February on the back of positive phase 3 results for idiopathic pulmonary fibrosis drug, pirfenidone. In August, Roche announced that it was acquiring InterMune for \$8.3 billion representing a 38% premium to the stock’s closing price.
- Intercept Pharmaceuticals’ (NASDAQ:ICPT; unrated) 515% rise in January following positive phase 2 primary endpoint data for obeticholic acid in the treatment of non-alcoholic steatohepatitis.
- Chelsea Therapeutic’s 480% rise during 2013 driven by the FDA’s reversal in February of an earlier request for another study of nervous system disorder drug, Northera. A year later, in February 2014, the FDA approved Northera, and in May, H. Lundbeck (CO: LUN; unrated) announced that it would buy Chelsea for \$658 million - both events combined to drive a further 60% upside this year.
- Sarepta Therapeutic’s (NASDAQ: SRPT; unrated) 475% increase in during 2012, driven by the announcement in July of positive 36-week phase 2b results for Duchenne Muscular Dystrophy exon-skipping RNA drug, Eteplirsen (145% one day increase) followed by an announcement in October of positive 48-week results for the same drug and clinical trial (200% one day increase). The stock continued to climb in 2013 before falling back to earth in Q4-2013 when the FDA requested the company conduct a confirmatory study prior to filing a NDA.
- Pharmasset’s 490% rise during 2011 related to its March release of preliminary results for Hepatitis C drug PSI-7977 (Sovaldi) indicating that the oral drug may be a cure for the disease, then the company’s acquisition by Gilead later that year for \$11 billion

These success stories clearly demonstrate the potential for clinical and regulatory events to drive significant value appreciation. But also, the interest of strategic suitors, often coming shortly after positive clinical results, can drive even more upside.

Overall, M&A activity in the sector has been robust, albeit somewhat volatile, for more than a decade as pharma has clamored to fill development pipelines and commercial portfolios, and embraced new drug discovery paradigms. Exhibit 5 shows the dollar value of M&A deals in the biotech sector over the last 8 years.

Exhibit 5. Value of Life Sciences M&A Deals (US\$ billions)



\*as at September 30, 2014

Source: Capital IQ





Not surprisingly, big pharma was spending aggressively in the depths of the 2008-2009 recession when target valuations softened and pharma balance sheets were flush with cash. By 2012 and 2013, big biotech, with its rising valuations, had increased its M&A firepower, and became a formidable competitor in the bidding for smaller biotech assets.

So far in 2014, the value of life sciences M&A transactions has jumped materially ahead of previous years, driven primarily by a major reversal of big pharma's previously eroded M&A status. During the first 9 months of 2014, big pharma spent more than \$100 billion buying companies and, in some cases, swapping assets. In December alone, we have seen Japanese pharma Otsuka Holdings announce its acquisition of Avanir Pharmaceuticals (NASDAQ: AVNR; unrated) for \$3.5 billion, and Merck announce its acquisition of Cubist Pharmaceuticals (NASDAQ: CBST; unrated) for \$9.5 billion. It appears that big pharma's lengthy exercise in product rationalization has paid off, with many portfolios reflecting strategic focus, and companies looking to grow in their areas of strength.

As far as headwinds for the industry, while drug pricing power has been high, drug prices came under stepped up scrutiny, in particular as payors grappled with the potential impact of Gilead's hepatitis C drug, Sovaldi, which carries a price tag of \$84,000 for a U.S. infected patient population approaching 3 million. However, it is notable that expenditure on drugs is a fraction of the overall healthcare budget. In 2012, for example, CMS reported that total healthcare spending in the United States was \$2.8 trillion, of which \$263 billion was spent on prescription drugs. And, in many cases including Sovaldi, it can be argued that the cost of drug therapy is lower than other options. Regardless, we do expect that drug pricing justification will become more and more a topic of discussion and negotiation, and in the meantime, payers will be inclined to find reasons to reject reimbursements and raise co-pays, especially for drugs expected to substantially impact budgets. In the long run though, the societal benefits of superior medicines should continue to be the main market force that provides an attractive economic return for developers of innovative and necessary drugs.

Sharing biotech's positive demographics, high margins, and in some cases, high intellectual property barriers, the specialty pharma sector usually also offers lower and/or more diversified risks compared to small cap biotech. This can be very attractive, however, commercial drug portfolios are less discounted so there is typically not as much upside around binary events, and the key opportunities and risks, at least for Canadian specialty pharma companies which build mainly through acquisition, reside in managements' execution of business development strategies. Value drivers include acquisition discipline with respect to target price; speed to achieving revenue critical mass and positive cash flow; portfolio quality; and tax strategy.

The specialty pharma sector has benefited from big pharma's streamlining, happy to swallow non-strategic products. Tax rule changes implemented mid-year raised hurdles for tax avoidance inversions and led to the scuttling of several high profile M&A deals, most notably Abbvie's (NYSE: ABBV; unrated) \$54 billion plan to takeover Shire. However, the ready availability of low cost debt and the potential to extract cost-cutting synergies have kept the specialty pharma M&A fire going with Actavis (NYSE: ACT; unrated) stepping in as the white knight to buy Allergan (NYSE: AGN; unrated) in mid-November which, if the deal closes, will be the largest announced in 2014 at \$66 billion.

## Societal Benefit

In addition to wealth creation, the promise of medical innovation and products which benefit our families, friends, and society in general, also motivates investment in the healthcare sector. And, as the industry's knowledge of disease biology and clinical trial design increases, the potential to accelerate medical innovation grows.

Over the past 20 years, advances in disease screening and treatment have combined to substantially increase 5-year survival rates for many common cancers such as breast, prostate and colorectal; HIV has become a chronic manageable infection instead of a near-term death sentence; HCV can be cured; and many children are now living later into adulthood due to treatments with recombinant protein drugs



which replace crucial molecules missing due to genetic disorders.

We expect that over the next 5-10 years, the winning companies will be ones developing and bringing to market clearly differentiated drugs and devices which materially advance the efficacy and safety of disease treatment, especially if those products also reduce the overall cost of caring for the patient. The FDA should continue to favor drugs for orphan indications (diseases with fewer than 200,000 patients), bestowing upon sponsors, streamlined and accelerated reviews, as well as extended exclusivity periods.

## But What About Valuations?

The NASDAQ Biotechnology Index has risen almost without pause from 650 in February 2009 to its current level of 3,175, building off a low base following the 2008 recession, and fueled by numerous positive clinical and regulatory events. Many stocks are now trading close to all-time highs, most set in recent days or weeks (Exhibit 6).

Exhibit 6. Current, 10-Year High and 10-Year Low Stock Prices and P/E Ratios of Bloom Burton Covered Stocks and Select United States Biotech and Specialty Pharma Companies

Company	Ticker	Price			P/E (ttm)		
		Current	10-yr High	10-yr Low	Current	10-yr High	10-yr Low
<b>Coverage List Stocks</b>							
Aurinia Pharmaceuticals	AUP	\$4.26	\$4.85	\$1.50			
Bellus Health	BLU	\$1.47	\$881.70 *	\$0.24			
Cardiome Pharma	COM	\$10.75	\$78.00 *	\$1.23			
Concordia Healthcare	CXR	\$43.42	\$49.00	\$7.80			
Knight Therapeutics	GUD	\$6.79	\$7.24	\$3.51			
Tribute Pharmaceuticals	TRX	\$0.53	\$0.98	\$0.45			
Trillium Therapeutics	TR	\$7.56	\$22.20	\$6.30			
<b>Select U.S. Biotechnology Stocks</b>							
Gilead Sciences	GILD	\$102.40	\$116.83	\$7.70	18.2	44.8	9.9
Amgen	AMGN	\$163.48	\$173.14	\$39.97	24.2	25.5	9.6
Biogen Idec	BIIB	\$332.89	\$358.89	\$34.45	31.5	45.7	11.4
Illumina	ILMN	\$181.21	\$197.37	\$4.04	95.2	123.2	21.6
Regeneron Pharmaceuticals	REGN	\$410.99	\$437.64	\$5.11			
Alexion Pharmaceuticals	ALXN	\$182.08	\$203.30	\$3.39			
Pharmacyclics	PCYC	\$131.03	\$154.89	\$0.75			
Medivation	MDVN	\$106.62	\$117.23	\$1.10			
Biomarin Pharmaceuticals	BMRN	\$87.21	\$96.36	\$4.13			
Incyte	INCY	\$75.58	\$80.78	\$2.34			
Acorda Therapeutics	ACOR	\$38.47	\$39.95	\$2.22			
Seattle Genetics	SGEN	\$32.14	\$55.99	\$4.00			
Ariad Pharmaceuticals	ARIA	\$6.36	\$9.83	\$0.85			
<b>Select U.S. Specialty Pharma Stocks</b>							
Mylan	MYL	\$55.26	\$59.60	\$5.77			
Actavis	ACT	\$260.90	\$272.75	\$5.62			

\*indicates stocks which have reverse split in period

Source: Bloomberg





Sector fundamentals remain strong as discussed above; however, we do view valuation in the industry as a risk. Other risks are systemic, such as the impact of sliding commodity prices on global economies and markets, and interest rates which have remained very low for years, but may be set to rise slowly going forward.

Outside the sphere of higher profile names in the sector, there remain opportunities to buy micro and small cap healthcare stocks that stayed mainly under the radar of investors during the extended bull-run, and which we believe offer compelling investment risk/reward profiles – a number of these stocks are highlighted as BUYs in our coverage universe.

We are buyers of quality “under the radar” and attractively valued stocks, and mindful of upcoming milestone events which may drive valuations. Exhibit 7 lists expected upcoming milestones for the companies covered by Bloom Burton, as well as select near-term events for U.S. biotech companies.

#### Exhibit 7. Select Biotech Industry Milestones

Company	Milestone	Expected Timing
<b>Coverage List Stocks</b>		
Cardiome Pharma	Remove clinical hold on ACT V trial - atrial fibrillation	Q4-14 to H1-15
Trillium Therapeutics	Pre-IND meeting - oncology	January, 2015
Tribute Pharmaceuticals	Bilastine file NDS - urticaria	Q1-2015
Concordia Healthcare	Photofrin Phase 3 interim analysis - cholangiocarcinoma	2015-2016
Trillium Therapeutics	File SIRPαFC IND - oncology	H2-2015
Aurinia Pharmaceuticals	Voclosporin Phase 2b 24-week primary endpoint data release - lupus nephritis	Q1-2016
Bellus Health	Eprodisate (KIACTA) Phase 3 trial completion - AA Amyloidosis	mid-2016
<b>U.S. Biotech Stocks</b>		
Enanta Pharmaceuticals (NASDAQ: ENTA; unrated)	ABT-450/Norvir ritonavir combination FDA action - HCV	December, 2014
Ligand Pharmaceuticals (NASDAQ: LGND; unrated)	Duavee EU approval - symptoms of menopause	December, 2014
Cubist Pharmaceuticals (NASDAQ: CBST; unrated)	Ceftolozane/tazobactam PDUFA	December, 2014
Jazz Pharmaceuticals (NASDAQ: JAZZ; unrated)	Leukotac Phase 3 data release - graft vs host disease	End 2014/Early 2015
Celgene (NASDAQ: CELG; unrated)	Otezla EU approval - psoriatic arthritis and psoriasis	January, 2015
Alexion Pharmaceuticals (NASDAQ: ALXN; unrated)	asfotase alpha CHMP opinion - hypophosphatasia	January, 2015
Vertex Pharmaceuticals (NASDAQ: VRTX; unrated)	Kalydeco CHMP opinion - cystic fibrosis	Jan-Feb 2015
Neurocrine BioSciences (NASDAQ: NBIX; unrated)	Elagolix Phase 3 data release - endometriosis	Early 2015
CTI BioPharma (NASDAQ: CTIC; unrated)	pacritinib Phase 3 data release - myelofibrosis	Early 2015
ISIS Pharmaceuticals (NASDAQ: ISIS)	Kynamro Phase 3 safety data release - hypercholesterolemia	Early 2015
Portola Pharmaceuticals (NASDAQ: PTLA; unrated)	Andexanet alfa Phase 3 data release (2nd part) - reverse anticoagulant	Early 2015
United Therapeutics (NASDAQ: UTHR; unrated)	dinutuximab CHMP opinion - neuroblastoma	Q1-2015
The Medicines Company (NASDAQ: MDCO; unrated)	Angiomax Phase 3 data release - H2H vs heparin in high risk PCI	March, 2015
Orexigen Therapeutics (NASDAQ: OREX; unrated)	Contrave EU approval - obesity	Q1-2015
The Medicines Company (NASDAQ: MDCO; unrated)	oritavacin EU approval - cSSTi	Q1/Q2-2015
Biogen Idec (NASDAQ: BIIB; unrated)	ocrelizumab Phase 3 data release - multiple sclerosis	Q1-2015
Clovis Oncology (NASDAQ: CLVS; unrated)	rociletinib Phase 2/3 data release - NSCLC	Q2-2015
Ono Pharmaceuticals (OTCQX: OPHLY; unrated)	nivolumab Phase 3 data release - NSCLC	Q2-2015
Vertex Pharmaceuticals (NASDAQ: VRTX; unrated)	lumacraftor/Kalydeco CHMP opinion - cystic fibrosis	Q2-2015
Galapagos (BR: GLPG; unrated)	filgotinib Phase 2 data release - Crohn's disease	Q2-2015
BioMarin Pharmaceutical (NASDAQ: BMRN; unrated)	BMN-111 Phase 2 data release - achondroplasia	Q2-2015
Immunomedics (NASDAQ: IMMU; unrated)	epratuzumab Phase 3 data release - systemic lupus erythematosus	H1-2015
Incyte (NASDAQ: INCY; unrated)	Jakafi EU approval - polycythemia vera	H1-2015
Pharmacyclics (NASDAQ: PCYC; unrated)	Imbruvica Phase 3 data release - MCL/CLL	H1-2015

Source: Company reports, BioCentury, Bloomberg

Aurinia Pharmaceuticals Inc. (TSX: AUP, NASDAQ: AUPH, US\$3.65)

December 18, 2014

 David Martin PhD, MBA  
 Analyst  
 416-642-8865  
 dmartin@bloomburton.com

Rating:	BUY
Risk:	Speculative
12 month Price Target:	US\$6.00

Price	US\$3.65
Implied Return	64.4%
Fiscal Year End	31-Dec
52 Week Range	\$1.41-\$5.39
Shares Outstanding (MM)	31.82
Market Cap. (MM)	\$116.1
Float (MM Shares)	14.72
Book Value/Share (latest Qtr. end)	\$1.55
Avg. Daily Volume (MM)	0.01

	2013A	2014E	2015E	2016E
EPS	(\$0.43)	(\$0.58)	(\$0.55)	(\$0.50)



This report is priced as of prior trading day's market close.  
 All values in US\$ unless otherwise noted.

## Research Initiation – Good Chance of Success in Lupus Nephritis Trial

We are initiating investment research coverage of Aurinia Pharmaceuticals Inc. (TSX:AUP, NASDAQ: AUPH) with a BUY recommendation (SPECULATIVE risk) and a 12 to 18-month target price of US\$6.00. Senior members of Aurinia management have a track record of success in lupus nephritis, previously serving in medical affairs, regulatory and operations roles at Aspreva which was acquired by Galenica Group (SWX: GALN; unrated) in 2007. Aurinia is currently running a phase 2b voclosporin trial for which results are expected in Q1-2016. We forecast that the company is funded to beyond the primary readout.

### Highlights

Moderate to high probability of phase 2b success. Voclosporin inhibits calcineurin, and by doing so, suppresses immune T cell activity. Previous clinical trials have demonstrated efficacy and safety of voclosporin in kidney transplant and psoriasis, conditions with etiology similar to lupus nephritis (LN). Two other calcineurin inhibitors (CNI), tacrolimus and cyclosporine, have demonstrated robust efficacy in LN patients, serving as an additional positive proxy for Aurinia's phase 2b trial.

Sales potential of voclosporin will be determined by its eventual position on a continuum of nephrotoxicity and differentiation. Aurinia intends to establish voclosporin as the only CNI with a FDA approved indication for treatment of LN. Possible benefits of voclosporin which could further raise the competitive bar, include: a more consistent PK/PD relationship which is advantageous for safely dosing drugs with narrow therapeutic windows (such as CNI); reduced glucose intolerance (vs. tacrolimus), and reduced interaction with mycophenolate mofetil (vs. cyclosporine). The homerun opportunity for voclosporin lies in the possibility that the drug at low doses, combined with the current standard of care, induces complete remissions of LN, causing minimal nephrotoxicity.

Initiating AUP, AUPH coverage with BUY rating (ABOVE AVERAGE risk) and a 12 to 18-month target price of US\$6.00. In our opinion, the ongoing voclosporin phase 2b trial has a moderate to high probability of achieving the proteinuria complete response primary endpoint. We used probability-weighted scenario analysis to arrive at our target price, testing peak sales forecast sensitivities based on varying levels of potential voclosporin efficacy, safety and product differentiation in the lupus nephritis indication. We considered 4 scenarios to value Aurinia. For each scenario, we assumed that at the time of completion of phase 3 (anticipated H2-2019), Aurinia will be valued at a 3x multiple of forecast peak sales. The valuations were then discounted annually using a 15% discount rate. Our models assume that Aurinia will raise US\$100 million prior to phase 3. Our weighting for the worst case scenario, failure of the voclosporin lupus nephritis phase 2b trial, is 35% - lower than typical for this stage of drug development, but supported by previous large voclosporin trials in psoriasis and kidney transplant, and the efficacy demonstrated by other CNI in lupus nephritis.



## Company Overview

Aurinia Pharmaceuticals is a Victoria-based biotechnology company focused on development of its lead immunosuppressive drug candidate, voclosporin, for treatment of patients with lupus nephritis.

The company was formed following the merger of Aurinia Pharmaceuticals Inc. (private) and Isotechnika Pharma Inc. in October 2013. Aurinia was a spin-out from Vifor Pharma, a subsidiary of the Switzerland-based Galenica Group. Its leadership team was comprised primarily of former senior managers, Directors and Officers of Aspreva Pharmaceuticals which had previously developed CellCept (mycophenolate mofetil) for the treatment of lupus nephritis, prior to being acquired by Galenica in 2008 for C\$915 million. On the other side of the merger, Isotechnika had struggled for years, attempting to establish superiority of voclosporin in kidney transplant and psoriasis, clinical indications dominated by similar drugs Neoral (cyclosporine) and Prograf (tacrolimus). Aurinia's strategy is to shift development focus to a disease, lupus nephritis, in which immunosuppressive drugs are known to be effective, but in which cyclosporine and tacrolimus are not approved and not likely to be developed in the future. Aurinia shares are traded on the TSX (AUP) and on NASDAQ (AUPH). Basic shares outstanding: 31.5 million basic; fully diluted: 39.8 million. Cash and short term investments at September 30, 2014 were US\$35.5 million, and the monthly burn rate is approximately \$1.4 million. Top shareholders include venBio, ILJIN Life Science, New Enterprise Associates, Redmile, RA Capital and Great Point.

Voclosporin is currently being tested in a 258-patient phase 2b clinical trial in patients with active lupus nephritis. The trial initiated in June 2014, and primary endpoint results are expected in Q4-2015 to Q1-2016.

## Lead Value Driver – Voclosporin Lupus Nephritis Program

### Current Treatment Options Often Inadequate

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease characterized by the appearance of autoantibodies against nuclear antigens, and immunological events that occur and cause damage within multiple organs. While precise triggers of SLE are not well understood, aberrations in both the innate and adaptive arms of the immune system play roles in the progression of the disease, implicating both B cells and T cells in SLE-related inflammation and tissue damage (Pathak and Mohan, 2011 *Arthritis Res Ther* 13:241, and Mak and Kow, 2014 *J Immun Res* 2014:1).

Initial symptoms of SLE can range from fatigue, skin rashes, joint inflammation and muscle pain which can progress to organ failure and death. The Lupus Foundation of America estimates that about 1.5 million Americans have a form of lupus, although only about one third of patients are diagnosed. While there is no cure for SLE, it is treated with NSAIDs, corticosteroids, antimalarials, BLYS-specific inhibitors, and in severe cases, immunosuppressive agents and chemotherapy.

Kidney inflammation caused by SLE is called lupus nephritis (LN), and it is estimated that 40%-60% of diagnosed SLE patients, or about 200,000 people in the U.S., have clinical LN requiring treatment. LN can progress to end-stage renal disease requiring hemodialysis or transplant, and may be fatal. The condition is treated with drugs that suppress the immune system.

Current standard treatment of acute LN includes induction with high dose corticosteroid to reduce inflammation in the kidney plus a drug such as cyclophosphamide or mycophenolate mofetil to suppress the immunological attack on the organ. Thereafter, maintenance therapy to sustain the responses and prevent relapses involves tapering the steroid dose and, depending on laboratory parameters, continued immunosuppression. The drugs used to treat LN all carry notable risks, such that each used alone at a safe dose, is not as effective as combinations. In many cases, induction treatment is effective in eliciting responses in many patients (complete and partial remissions), however, even with available therapies, 10%-30% of people with LN progress to kidney failure (National Institute of Diabetes and Digestive and Kidney Diseases, NIDDK).



The ALMS study, sponsored by Aspreva, was instrumental in establishing MMF as a standard of care in the treatment of LN. ALMS demonstrated that in combination with prednisone, mycophenolate mofetil (MMF) was as effective as cyclophosphamide (an alkylating agent with significant side effects and toxicities) in the induction of responses in active LN patients over a 24-week period, and more effective than azathioprine (an immunosuppressive purine synthesis inhibitor) in preventing relapse over a 36 month maintenance period (Appel et al., 2009 J Am Soc Nephrol 20:1103 and Dooley et al., 2011 N Engl J Med 365:1886).

Despite the success of ALMS, room was left for improvement. The overall response rate achieved with both MMF and cyclophosphamide during the induction phase was 50%+, however, complete remission (CR) rates were less than 10% (8.6% for MMF, 8.1% for cyclophosphamide). Patients in both groups did continue to improve during the 36-month maintenance period, with CR rates increasing to 39% (MMF) and 36% (cyclophosphamide), however, this still left many patients with suboptimal terminal outcomes, or prolonged delays to CR.

On this backdrop, there is growing acceptance that patients achieving complete remission of LN (and SLE) have superior long term outcomes compared with patients achieving only partial remission, and that the faster a patient achieves CR, the less the kidney is damaged (Chen et al., 2008 Am Soc Nephrol 3:46, Korbet et al., 2012 Nephrol Dial Transplant 27:2813, and Doria et al., 2014 Autoimmunity Reviews 13:770). For example, Chen et al., reported that in a study of 86 patients with diffuse lupus glomerulonephritis, 10-year survival was 95% among patients who attained complete remission (n=37); 76% among patients who attained partial remission (n=21); and 46% among patients who did not respond (n=28). Patient survival without end-stage disease at 10 years followed a similar pattern: 92% (CR); 43% (PR); 13% (no remission).

Concurrently, clinical data has also emerged suggesting that the addition of calcineurin inhibitors (such as tacrolimus, cyclosporine and potentially voclosporin) materially increase the proportion of patients achieving CR.

## Robust Efficacy of CNI in Lupus Nephritis Bodes Well for Voclosporin Phase 2b

Numerous studies support that calcineurin inhibitors (CNI), a drug class that includes voclosporin, improve remission rates in lupus nephritis patients by suppressing the activity of immune T cells. Two approved CNI drugs, cyclosporine and tacrolimus suppress immune T cell function by blocking the activity of an enzyme called calcineurin (Cn). Cn normally activates a downstream molecule - nuclear factor of activated T cells (NFAT) - which leads to production of proinflammatory and immune signaling cytokines such as interleukin-2 and interferon. By blocking the activation of NFAT by Cn, CNI suppress T cell activity, halting or slowing immunological attack on tissue and cells. This immunosuppressive effect has proven beneficial in the prevention of organ rejection in transplant patients, and treatment of autoimmune diseases such as psoriasis and rheumatoid arthritis. Cyclosporine and tacrolimus have also been tested successfully in patients with lupus nephritis, however, except in Japan, neither drug is approved for the indication. In other countries including the United States, the approved CNI are used off label occasionally to treat severe Class V nephrotic LN patients.

Multiple studies have reported positive results when tacrolimus is used to treat lupus nephritis (Miyasaka et al., 2009 Mod Rheumatol 19:606, Bao et al., 2007 J Am Soc Nephrol 19:2001, Liu et al., 2012 J Am Soc Nephrol 23:88A, Takahashi et al., 2011 Mod Rheumatol 21:282, Cortes-Hernandez et al., 2010 Nephrol Dial Transplant 25:3939).

Miyasaka's group reported that treatment of LN patients with tacrolimus combined with steroid (n=28) for 26 weeks led to a 32.9% mean improvement of the lupus nephritis disease activity index compared to a 2.3% mean worsening among patients treated with placebo and steroid (n=35; p<0.001). Daily urinary protein excretion also showed a significant improvement in the tacrolimus group (p<0.001). This study was submitted in support of the approval of tacrolimus for treatment of lupus nephritis which occurred in Japan in 2008. By 2011, Aurinia estimates that sales of tacrolimus for treatment of LN in Japan had





reached more than US\$80 million.

Bao’s group reported that 50% and 65% complete remission (CR) rates were achieved at 6 and 9 months, respectively, among patients treated with MMF+tacrolimus+steroid (n=20), compared with 5% and 15% CR rates for patients treated with cyclophosphamide+steroid (n=20). Overall remission rates (OR = CR + partial remission) for the MMF+tacrolimus group were 90% (6 months) and 95% (9 months).

Lui et al., reported OR and CR rates of 93% and 43.7% among LN patients treated with MMF+steroid+tacrolimus vs 64% and 23.2% among patients treated with steroid+cyclophosphamide (n=362). There was no significant difference in the overall number of adverse events between the two groups, however, the MMF/tacrolimus group had lower incidence of GI symptoms, liver enzyme elevation and leucopenia, but higher incidences of tremor and new onset hypertension.

Although Bao’s and Liu’s studies did not compare tacrolimus+MMF to MMF alone, clinical trials in which MMF has been used to treat lupus nephritis have reported CR rates in the range of 8%-22% (Appel et al., 2009 J Amer Soc Nephrol 20:1103; Ginzler et al., 2005 New Engl J Med 353:2219).

Takahashi’s group reported that 11 of 13 patients achieved CR when treated with steroid+tacrolimus without MMF after a mean treatment period of 7.7±6.7 months - 2 patients experienced flare-up after achieving CR.

Efficacy of cyclosporine has also been demonstrated in LN (Fu et al., 1998 Br J Rheumatol 37:217, Moroni et al., 2006 Clin J Am Soc Nephrol 1:925). Similar to tacrolimus, the older CNI reduced flares and improved proteinuria. Creatinine clearance trended down, but the differences were not statistically significant, and MMF was not used in either study.

## So, why are CNI’s not Already Mainstays in LN Therapy, and can this be changed?

Rheumatologists and nephrologists treat lupus nephritis patients, and they routinely use CNI to treat other related conditions. This raises the obvious question: Why, except in Japan, are cyclosporine and tacrolimus not used more to treat LN?

Part of the answer is that Japan is the only country in which tacrolimus is approved for the indication. The other part of the answer is that CNI, although mainstays in kidney (and other) transplant cases, have a reputation for causing nephrotoxic effects. This was especially the case when CNI drugs were first used to treat patients in the 1970’s. Today, the combination of CNI with new immunosuppressive drugs allows for use of lower doses of CNI (approximately half the dose levels used 20 years ago), and transplant patients can be treated stably on CNI-containing regimens for years (Exhibit 1).

Exhibit 1. Changing Recommended Doses of Prograf (tacrolimus) over the Years since Approval

YEAR of LABELING	Intravenous Injection		
	1994	2001	2013
Starting Dose (mg/kg/day) in Patient Population			
Adult Patients (general)	0.05-0.10	0.03-0.05	0.01-0.05
Pediatric Patients (general)	0.1	0.03-0.05	0.03-0.05
Adult Kidney Transplantation	N/A	N/A	0.03-0.05
Adult Liver Transplantation	N/A	N/A	0.03-0.05
Adult Heart Transplantation	N/A	N/A	0.01
Typical Whole Blood Trough Concentration	9.8-19.4 ng/mL	5-20 ng/mL	4-20 ng/mL
Dosage Forms and Strengths	5mg/mL	5mg/mL	5mg/mL

Source: Astellas

Short term exposure to CNI has been linked to functional renal impairment due to vasoconstriction of arterioles in the kidney which leads to glomerular ischemia – markers of functional impairment



include increasing serum creatinine levels, and decreasing creatinine clearance and glomerular filtration rates. These effects are reversible if patients discontinue CNI, or in many cases if doses are titrated down. Long term exposure to CNI is associated with histological damage including renal cortical fibrosis and atrophy of the tubules which are responsible for reabsorption and secretion of many molecules into and out of the blood.

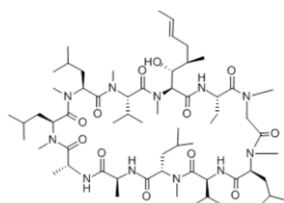
In current medical practice, the side effects and toxicities of CNI are dealt with by monitoring and titrating to lowest effective dose, and by combining CNI with other immunosuppressive drugs to drive the lowest effective dose even lower. Additionally, because CNI are so effective – indispensable in organ transplant - benefit is deemed to outweigh the risk at appropriate doses, and the side effects are tolerated.

## The Voclosporin Opportunity

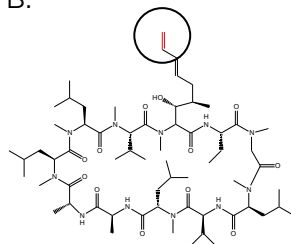
Voclosporin is a novel calcineurin inhibitor created by the addition of one carbon molecule at the amino acid-1 residue of cyclosporine (Exhibit 1). This modification enhances binding of voclosporin-cyclophilin complexes to calcineurin and leads to faster elimination of major metabolites of voclosporin. As a result, voclosporin is approximately 3-fold more potent, and has a more predictable pharmacokinetic/pharmacodynamic relationship.

Exhibit 2 – Molecular structures of cyclosporine (A) and voclosporin (B)

A.



B.



Source: company

Under development by Isotechnika, voclosporin was tested in 3 late stage clinical trials in psoriasis (phase 3), kidney transplant (phase 2b) and uveitis (phase 3).

In the phase 3 ESSENCE trial, 642 patients with stable plaque psoriasis were randomized to voclosporin (0.4mg/kg bid), placebo, or cyclosporine (1.5 mg/kg bid). The primary endpoint was achieving a “clear” or “almost clear” SPGA score after 12 weeks of treatment. Voclosporin was superior to placebo (34.8% vs 6.3%;  $p < 0.001$ ), however the secondary objective of showing non-inferiority to cyclosporine was not achieved (34.8% vs 51.9%). A higher dose of voclosporin likely would have improved the response rate since other clinical trials have demonstrated clear dose response. All major adverse events including hypertension (9.4% vs 14.7%) and increased blood creatinine (2.3% vs 5.4%) occurred less frequently in the voclosporin arm.



In the phase 2b PROMISE trial, 334 low risk renal transplant recipients were randomized to receive low dose voclosporin (0.4mg/kg bid), mid dose voclosporin (0.6mg/kg bid), high dose voclosporin (0.8mg/kg bid) or tacrolimus (standard dose – 0.1mg/kg/day titrated to 0.08mg/k/day). The primary endpoint was biopsy proven acute rejections (BPAR). High dose voclosporin-treated patients had the fewest BPAR events (2.3%), but the incidence of new onset diabetes (NODAT) was very high (17.7%) and Nankivell estimated GFR, a marker for renal function, was statistically lower than in the tacrolimus arm. Low dose voclosporin had a good adverse event profile, but the lowest efficacy. The arm that most closely matched tacrolimus was voclosporin mid dose. Patients in this arm had more BPAR events (7 vs 5), but fewer were Banff Grade II (2 vs 5) – the rest were less severe Banff Grade I events. 6-month measures of kidney function were similar between voclosporin mid dose and tacrolimus, as were the incidence of hypertension and other adverse events. The main difference between the two arms was the rate of new onset of diabetes (voclosporin 5.7%; tacrolimus 16.4%), a difference that could be important in lupus nephritis, since LN patients are at elevated risk of developing diabetes.

Another late stage trial, run by Isotechnika's partner at the time, Lux BioSciences, failed to meet its primary endpoint: change from baseline in vitreous haze in patients suffering from uveitis.

Shortly after reporting failure of the uveitis trial, Isotechnika announced that it would merge with Aurinia. Aurinia's strategy is to move voclosporin into an area not dominated by cyclosporine and tacrolimus; leverage some of the potential differentiators of voclosporin; leverage management's expertise in lupus nephritis; and exploit the emerging evidence that treating lupus nephritis patients to complete remission leads to superior long term outcomes.

## Voclosporin in Lupus Nephritis

We are more bullish on Aurinia's strategy of targeting a new indication compared to Isotechnika's strategy of going head-to-head against cyclosporine and tacrolimus in their established markets, but realize there are some risks: 1) except in Japan, cyclosporine and tacrolimus are not generally used to treat lupus nephritis; 2) if Aurinia successfully develops voclosporin for treatment of LN, generic cyclosporine and tacrolimus may compete.

In our opinion, there are two key drivers for Aurinia: 1) improve perceptions about CNI through better management of risks and better understanding of benefit, 2) get an approved label for voclosporin and demonstrate differentiation to strengthen competitive positioning.

We think that driver 1) is achievable for several reasons:

- CNI have demonstrated robust efficacy in LN studies, and there is growing awareness that treating lupus nephritis to complete remission results in superior long term outcomes
- CNI doses used currently are much lower and safer compared to the 1970's when cyclosporine was approved, and are lowest in non-transplant indications
- New drugs added to combination therapies are allowing even lower dosing of CNI
- In the case of combining CNI with MMF, a number of studies indicate a protective effect of MMF that seems to offset the nephrotoxicity of CNI (Nankivell et al., 2007 Am J Transplant 7:366, Biselli et al., 2009 Clin Transplant 23:191, Bao et al., 2007 J Am Soc Nephrol 19:2001)
- Aurinia's development program for voclosporin is likely to increase awareness of all of the above

Based on previous voclosporin trials in transplant and psoriasis, and demonstrated CNI efficacy/safety in LN, we think there is a moderate to high probability that Aurinia's phase 2b trial will successfully meet its proteinuria complete response primary endpoint and that renal function will be stable following the relatively short treatment period. Key risks: voclosporin has not been tested previously in LN, so the optimal dose has not yet been established, and we are unaware of LN studies which have directly



compared MMF+CNI vs. MMF alone.

We think there is a moderate to high probability that Aurinia's phase 2b trial results will be positive.

Phase 2b success and possible approval after a phase 3 program would not guarantee voclosporin's commercial success. We think this will be driven by the eventual position of voclosporin on a continuum of nephrotoxicity and differentiation. To date, voclosporin appears to be similar to cyclosporine and tacrolimus with respect to acute kidney effects (ESSENCE and PROMISE, discussed above). Assuming there are no red flags in future studies, non-inferior nephrotoxicity should be enough to make voclosporin a marketable drug in lupus nephritis. Beyond this, there are opportunities to differentiate voclosporin in potentially meaningful ways.

Potential Differentiation: Voclosporin has a more predictable PK/PD relationship which is advantageous for safely dosing drugs with narrow therapeutic windows; in addition to early signs that the drug is less diabetogenic (vs. tacrolimus) and has reduced PK interaction with mycophenolate mofetil (vs. cyclosporine).

This June, Aurinia initiated a 258-patient phase 2b clinical trial (AURA-LV) evaluating voclosporin as part of a multi-targeted therapeutic regimen to treat Lupus Nephritis. Patients are randomized 1:1:1 to receive one of two doses of voclosporin (23.7mg or 39.5mg bid) with mycophenolate mofetil+steroids, or placebo+MMF+steroids. It is expected that approximately half of the patients enrolling in the trial will be naïve to MMF, and half will have been treated with MMF, without achieving complete remission.

There will be a primary analysis to determine complete remission (protein/creatinine ratio of  $\leq 0.5$ mg/mg and no confirmed decrease from baseline in eGFR of  $\geq 20\%$ ) at week 24 and various secondary analyses at week 48 which include biomarkers and markers of non-renal SLE. Using a two-sided alpha level of 0.05 and assuming a response rate of 20% in the placebo arm, a sample size of 74 subjects per arm will provide 87% power to detect a significant difference should either of the active voclosporin arms have a response rate of 45% at 24 weeks (odds ratio= 3.27).

Management expects patient recruitment to be completed within approximately 12 months. The flat voclosporin doses used in AURA-LV roughly equate to doses slightly above and below the dose used in the ESSENCE psoriasis phase 3 trial.

## Competing Programs

GSK's B cell suppressive drug, Benlysta is currently in phase 3 testing for LN. In 2011, Benlysta became the first new drug in 50 years approved in the U.S. for treating SLE based on phase 3 trials that demonstrated improved SLE response rates when Benlysta was added to standard of care therapy. Post hoc analysis of patients in the Benlysta phase 3 trials who had renal involvement at baseline, showed trends that favored Benlysta, although most renal outcomes were not significant (Dooley et al., 2013 Lupus 22:63).

BMS's rheumatoid arthritis drug, CTLA-4 fusion protein, abatacept, has been tested in LN on top of standard of care. Although proteinuria improved, complete response (CR) rate and time to CR were not changed in a 12-month 300-patient phase 2/3 trial (Furie et al., 2014 Arthritis Rheumatol 66:379).

Biogen Idec is developing an antibody against TWEAK (tumor necrosis factor-like weak inducer of apoptosis) which is believed to have anti-inflammatory activities and a protective effect against glomerular and tubular damage, which may make it an attractive adjunct to CNI. The anti-TWEAK program is currently in phase 2.



Active Biotech and partner Teva have tested phase 3 multiple sclerosis drug, Laquinimod, an APC/T cell modulator, in a 46-patient lupus nephritis phase 2a trial. When added to MMF and steroids, 62.5% of patients receiving laquinimod achieved renal response compared to 33.3% who received placebo plus the standard of care treatment – a positive result, but falling below the 90%+ response rates reported for studies, discussed above, testing tacrolimus combined with MMF and steroids.

Regarding cyclosporine and tacrolimus, we think it is unlikely either will be developed for regulatory approval of the lupus nephritis indication in most markets (except Japan), since both drugs are now generic. However, both are expected to compete to a greater or lesser extent, depending on the emerging profile of voclosporin.

## Valuation

Our probability-weighted target for Aurinia is US\$6.00 per share. With the stock trading at \$3.65, the return to our risk adjusted target is 64%. BUY (SPECULATIVE risk).

We considered 4 scenarios to value Aurinia. For each scenario, we assumed that at the time of completion of phase 3 (anticipated H2-2019), Aurinia will be valued at a 3x multiple of forecast peak sales. These values were then discounted annually using a 15% discount rate, and the share count adjusted based on expectation that if phase 2b is positive, Aurinia will raise US\$100 million prior to phase 3. Our valuation scenarios are detailed below:

- 1) Effective; low nephrotoxicity; differentiation vs cyclosporine and tacrolimus – 12 month target valuation US\$20.26. In this scenario, we assume U.S. peak penetration of CNI for LN induction will be 35% among new patients; 17.5% for existing patients, and that 20% of patients induced with voclosporin will continue to be maintained on the drug. Assumed annual cost of voclosporin treatment: \$12,000. Using these assumptions, our peak U.S. sales forecast is \$421 million (worldwide \$569 million).
- 2) Effective; low nephrotoxicity; but no differentiation vs cyclosporine and tacrolimus – 12 month target valuation US\$6.66. In this scenario, all assumptions are the same as in Scenario 1 except we assume that generic CNI will take 40% of the market. Assumed annual cost of voclosporin treatment: \$8,000. Using these assumptions, our peak U.S. sales forecast is \$150 million (\$187 million worldwide).
- 3) Effective; nephrotoxicity perceived to be materially inferior to tacrolimus – 12 month target valuation US\$1.56 per share. In this scenario, all assumptions are the same as in Scenario 2 except we assume peak penetration of CNI among new patients is 25%; 12.5% among existing patients; and that generic CNI will capture 75% of the market. Using these assumptions, our peak U.S. sales forecast is \$40 million (worldwide \$44 million).
- 4) Failure of the program – 12 month target valuation US\$0

Based on our assessment of voclosporin, we have assigned the following probabilities to each scenario: 21.7% (Scenario 1); 21.7% (Scenario 2); 21.7% (Scenario 3); 35% (Scenario 4). Weighting the scenario valuations using these probabilities, we arrive at a value of US\$6.17, which we round down to US\$6.00 for our 12 to 18-month target price.



## Financial Forecasts

Balance Sheet (US\$000)	FY2013 (CAD)	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E
<b>Current Assets</b>								
Cash & Short-Term Investments	\$ 1,937	\$ 43,289	\$ 39,093	\$ 25,533	\$ 21,756	\$ 21,756	\$ 5,874	\$ 29,181
Short term investment	\$ -	\$ -	\$ -	\$ 9,994	\$ 9,994	\$ 9,994	\$ 9,994	\$ -
Short-Term Receivables	\$ 113	\$ 100	\$ 114	\$ 50	\$ 50	\$ 50	\$ 50	\$ 50
Other Current Assets	\$ 180	\$ 138	\$ 1,406	\$ 1,604	\$ 1,604	\$ 1,604	\$ 1,604	\$ 1,604
<b>Total current assets</b>	<b>\$ 2,230</b>	<b>\$ 43,527</b>	<b>\$ 40,613</b>	<b>\$ 37,181</b>	<b>\$ 33,404</b>	<b>\$ 33,404</b>	<b>\$ 17,522</b>	<b>\$ 30,835</b>
<b>Long-term Assets</b>								
Net Property, Plant & Equipment	\$ 39	\$ 25	\$ 59	\$ 52	\$ 38	\$ 38	\$ -	\$ -
Intangible Assets	\$ 22,210	\$ 19,579	\$ 19,223	\$ 18,878	\$ 18,519	\$ 18,519	\$ 17,083	\$ 15,647
Other Assets	\$ 162	\$ 145	\$ 284	\$ 284	\$ 284	\$ 284	\$ 284	\$ 284
<b>Total Assets</b>	<b>\$ 24,641</b>	<b>\$ 63,276</b>	<b>\$ 60,179</b>	<b>\$ 56,395</b>	<b>\$ 52,245</b>	<b>\$ 52,245</b>	<b>\$ 34,889</b>	<b>\$ 46,766</b>
<b>Liabilities and Shareholders' Equity</b>								
Accounts Payable	\$ 3,087	\$ 1,436	\$ 2,643	\$ 2,283	\$ 2,283	\$ 2,283	\$ 2,283	\$ 2,283
Deferred revenue	\$ 242	\$ 217	\$ 218	\$ 217	\$ 217	\$ 217	\$ 217	\$ 217
Other Current Liabilities	\$ 3,104	\$ 2,834	\$ 1,873	\$ 155	\$ 155	\$ 155	\$ 155	\$ 155
<b>Total Current Liabilities</b>	<b>\$ 6,433</b>	<b>\$ 4,487</b>	<b>\$ 4,734</b>	<b>\$ 2,655</b>	<b>\$ 2,655</b>	<b>\$ 2,655</b>	<b>\$ 2,655</b>	<b>\$ 2,655</b>
Deferred revenue	\$ 1,185	\$ 1,010	\$ 955	\$ 901	\$ 901	\$ 901	\$ 901	\$ 901
Provisions	\$ 2,861	\$ -	\$ 154	\$ 155	\$ 155	\$ 155	\$ 155	\$ 155
Contingent consideration	\$ -	\$ 3,158	\$ 3,263	\$ 3,368	\$ 3,368	\$ 3,368	\$ 3,368	\$ 3,368
<b>Total Liabilities</b>	<b>\$ 10,479</b>	<b>\$ 8,655</b>	<b>\$ 9,106</b>	<b>\$ 7,079</b>	<b>\$ 7,079</b>	<b>\$ 7,079</b>	<b>\$ 7,079</b>	<b>\$ 7,079</b>
<b>Shareholders' Equity</b>								
Common Shares	\$ 220,480	\$ 257,084	\$ 257,131	\$ 257,790	\$ 257,790	\$ 257,790	\$ 257,790	\$ 287,790
Warrants	\$ 2,326	\$ 11,886	\$ 11,873	\$ 11,691	\$ 11,691	\$ 11,691	\$ 11,691	\$ 11,691
Contributed Surplus	\$ 10,029	\$ 11,372	\$ 11,807	\$ 12,093	\$ 12,093	\$ 12,093	\$ 12,093	\$ 12,093
Accumulated loss	\$ -	\$ (805)	\$ (805)	\$ (805)	\$ (805)	\$ (805)	\$ (805)	\$ (805)
Deficit	\$ (218,673)	\$ (224,916)	\$ (228,933)	\$ (231,453)	\$ (235,603)	\$ (235,603)	\$ (252,959)	\$ (271,082)
<b>Total shareholders' equity</b>	<b>\$ 14,162</b>	<b>\$ 54,621</b>	<b>\$ 51,073</b>	<b>\$ 49,316</b>	<b>\$ 45,166</b>	<b>\$ 45,166</b>	<b>\$ 27,810</b>	<b>\$ 39,687</b>
<b>Total Liabilities &amp; Shareholders' Equity</b>	<b>\$ 24,641</b>	<b>\$ 63,276</b>	<b>\$ 60,179</b>	<b>\$ 56,395</b>	<b>\$ 52,245</b>	<b>\$ 52,245</b>	<b>\$ 34,889</b>	<b>\$ 46,766</b>





Income Statement (US\$000)	FY2013 (CAD)	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E
Sales	\$ 1,010.0	\$ 67.0	\$ 71.0	\$ 72.0	\$ 72.0	\$ 282.0	\$ 282.0	\$ 282.0
Research & Development	\$ 2,059.0	\$ 1,040.0	\$ 2,547.0	\$ 2,433.0	\$ 2,433.0	\$ 8,453.0	\$ 10,218.6	\$ 10,729.5
G&A expense	\$ 2,376.0	\$ 2,373.0	\$ 1,713.0	\$ 1,405.0	\$ 1,405.0	\$ 6,896.0	\$ 5,901.0	\$ 6,196.1
Restructuring	\$ 1,570.0	\$ 569.0	\$ 403.0	\$ 60.0	\$ -	\$ 1,032.0	\$ -	\$ -
Amortization (intangibles)	\$ 817.0	\$ 359.0	\$ 359.0	\$ 359.0	\$ 359.0	\$ 1,436.0	\$ 1,436.0	\$ 1,436.0
Amortization (property and equipment)	\$ 49.0	\$ 10.0	\$ 10.0	\$ 14.0	\$ 14.0	\$ 48.0	\$ 38.0	\$ -
Contract services	\$ 1.0	\$ 8.0	\$ 10.0	\$ 11.0	\$ 11.0	\$ 40.0	\$ 44.0	\$ 44.0
Other expense (income)	\$ 955.0	\$ 899.0	\$ (954.0)	\$ (1,690.0)	\$ -	\$ (1,745.0)	\$ -	\$ -
Loss before income taxes	\$ (6,817.0)	\$ (5,191.0)	\$ (4,017.0)	\$ (2,520.0)	\$ (4,150.0)	\$ (15,878.0)	\$ (17,355.6)	\$ (18,123.6)
Income Tax (recovery)	\$ (4,106.0)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Net loss	\$ (2,711.0)	\$ (5,191.0)	\$ (4,017.0)	\$ (2,520.0)	\$ (4,150.0)	\$ (15,878.0)	\$ (17,355.6)	\$ (18,123.6)
Translation adjustment	\$ -	\$ (605.0)	\$ -	\$ -	\$ -	\$ (605.0)	\$ -	\$ -
Comprehensive loss	\$ (2,711.0)	\$ (5,796.0)	\$ (4,017.0)	\$ (2,520.0)	\$ (4,150.0)	\$ (16,483.0)	\$ (17,355.6)	\$ (18,123.6)
Loss per share	\$ (0.43)	\$ (0.24)	\$ (0.13)	\$ (0.08)	\$ (0.13)	\$ (0.58)	\$ (0.55)	\$ (0.50)

Statement of Cash Flow (US\$000)	FY2013 (CAD)	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E
Net Change in Cash	\$ 1,753	\$ 41,352	\$ (4,196)	\$ (13,560)	\$ (3,777)	\$ 19,819	\$ (15,882)	\$ 23,306
Cash beginning period	\$ 184	\$ 1,937	\$ 43,289	\$ 39,093	\$ 25,533	\$ 1,937	\$ 21,756	\$ 5,874
Cash end period	\$ 1,937	\$ 43,289	\$ 39,093	\$ 25,533	\$ 21,756	\$ 21,756	\$ 5,874	\$ 29,181

Bellus Health Inc. (TSX: BLU, \$1.47)

December 18, 2014

 David Martin PhD, MBA  
 Analyst  
 416-642-8865  
 dmartin@bloomburton.com

Rating:	Buy
Risk:	Speculative
12-18 month Price Target	\$3.00

Price	\$1.47
Implied Return	104.1%
Fiscal Year End	31-Dec
52 Week Range	\$0.38-\$1.80
Shares Outstanding (MM)	47.43
Market Cap. (MM)	\$69.7
Float (MM Shares)	27.95
Book Value/Share (latest Qtr. end)	\$0.17
Avg. Daily Volume (MM)	0.21

	2013A	2014E	2015E	2016E
EPS	(\$0.02)	(\$0.06)	(\$0.07)	(\$0.08)

## Research Initiation - "Swing for the Fence" in 12-18 Months

We are initiating investment research coverage of Bellus Health Inc. (TSX: BLU-CA) with a BUY recommendation (SPECULATIVE risk) and a 12- to 18-month target price of C\$3.00. In our opinion, pipeline lead, Kiacta, has a reasonable chance of becoming the first disease modifying drug targeting the serious orphan kidney disease, AA amyloidosis. Orphan drugs are very attractive in the pharmaceutical industry due to regulatory and market exclusivity advantages and premium pricing.

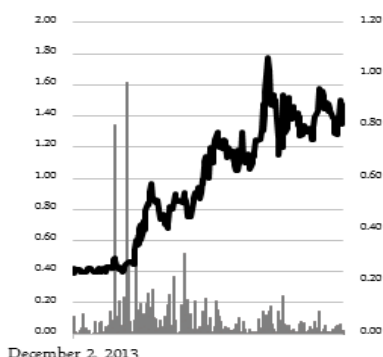
We arrive at our target price of \$3.00 for BLU stock by assigning a 50% probability of achieving a weighted upside valuation of C\$6.00 per share if the current Kiacta phase 3 trial is successful (completion expected mid-2016). Downside, for purposes of the valuation model is \$0, although we forecast that Bellus will hold \$0.10 per share cash at the end of 2016, and the company's pipeline may support a nominal residual value. Based on the return to our risk-adjusted target, our rating is BUY, but we caution that an investment in BLU carries substantial binary event risk.

### Highlights

Kiacta mechanism targets key disease protein; previous pre-clinical and clinical results encouraging. Pre-clinical studies demonstrated that Kiacta blocks formation of amyloid A fibrils and their deposition in tissue. Phase 2/3 results published in 2007 in the New England Journal of Medicine support a disease-delaying effect of Kiacta - Cox proportional-hazards analysis of time to disease worsening revealed a 42% risk reduction ( $p=0.02$ ), and key secondary endpoints also trended in favor of Kiacta. However, there were some confounding issues, discussed in this report, which tempered what would have otherwise been a clear-cut win. The current phase 3 trial design has been "tweaked" to strengthen the outcome - it is larger ( $n \approx 250$  vs. 183), and should enroll more patients with nephrotic syndrome - a subgroup in the phase 2/3 in which Kiacta benefit was strongest.

Phase 3 results are expected in Mid-2016, and we forecast that the company has adequate funding to the data point. The trial will conclude when 120 patients reach the primary endpoint of disease worsening. This May, Bellus announced that >60 primary events had occurred, up from >40 in January, so a mid-2016 timeline is achievable. At June 30, Bellus held \$13.1 million cash and cash equivalents, and the monthly burn rate was approximately \$0.3 million, which should give the company ample runway to complete the phase 3.

Trade sale possible. Bellus has disclosed that investment bank, Lazard, has been retained to explore a sale of Kiacta. Based on comparable transactions, Bellus's substantial lead over potential competitors, and the high unmet medical need, we think Kiacta would be a valuable target for a suitor if the phase 3 trial is successful in 2016, and that it is also possible an attractive structured deal could be announced prior to completion of phase 3.



This report is priced as of prior trading day's market close.  
 All values in C\$ unless otherwise noted.



## Company Overview

Bellus Health is a Montreal-based biotechnology company focused on developing drugs for rare diseases. The company changed its name from Neurochem in 2008 following failure of phase 3 Alzheimer's drug candidate, Alzhemed.

### Exhibit 1 - Bellus Health Product Pipeline

<b>Drug</b>	<b>Indication</b>	<b>Development Stage</b>
Kiacta	AA amyloidosis	Phase 3
Kiacta	Sarcoidosis	Phase 1
Shigamab	STEC-related hemolytic uremic syndrome	Phase 1
	AL amyloidosis	Discovery

Source: Company

BLU shares are traded on the TSX (47.4 million basic; 65.7 million fully diluted). Cash and short term investments at September 30, 2014 were \$12.7 million, and the monthly burn rate was \$0.13 million. At September 30, 2014, Bellus had \$5.2 million debt maturing in 2016. On November 26, the company announced that it had sold all of its asset-backed commercial paper notes ("ABCP Notes") for a total consideration of \$5.3 million and used the proceeds thereof to settle the debt facilities. The Bellini family owns approximately 30% of Bellus; Power Corporation owns an additional 30%; and Pharmascience owns approximately 10%.

In April 2010, Bellus entered a partnership with healthcare focused private equity firm, Celtic Therapeutics (later changed to Auen Therapeutics). Celtic (Auen) assumed 100% funding of Kiacta's development costs, including studies in AA amyloidosis and sarcoidosis. In return, overall proceeds of an outright or structured sale of Kiacta are expected to be shared 50:50 between Auen and Bellus. In December 2010, Bellus and Celtic (Auen) initiated a confirmatory phase 3 clinical trial of Kiacta to assess the safety and efficacy of the drug in patients diagnosed with AA amyloidosis. Management expects the trial will conclude in 2016.

Later this year, a phase 2 Kiacta clinical trial in sarcoidosis patients is scheduled to begin at the Icahn School of Medicine at Mt. Sinai Hospital in New York. The proof of concept trial is expected to be completed within approximately 18 months. Several groups have reported a link between serum amyloid A and inflammation in patients with sarcoidosis, providing the basis for this study (Chen et al., 2010 Am J Respir Crit Care Med 181:360; Bargagli et al., 2011 Respir Med 105:775).

Shigamab, acquired along with Thallion Pharmaceuticals in 2013, is an antibody designed to bind and neutralize shiga toxin which is secreted by E. coli O157:H7 following ingestion and gut colonization. Safety in humans has been established in phase 1. Within the next 12 months, management plans to meet with regulators to agree on a go-forward development plan, while in parallel running proof of concept treatment studies in animal models of STEC-related hemolytic uremic syndrome.

In October 2103, Bellus announced a partnership with Amorchem, a Montreal-based venture fund, which will finance a research project to identify and develop drug candidates for AL amyloidosis. Management believes this program may generate pre-clinical proof of concept within 12 months. AL amyloidosis, similar to AA amyloidosis, is characterized by formation of insoluble protein deposits in tissues. In this case, the deposits consist of "light chains" which are secreted by dysfunctional antibody-producing cells of the immune system. Ahead of Bellus in the AL amyloidosis space is Prothena (NASDAQ: PRTA) which is shortly expected to start phase 2/3 testing of its lead antibody drug NEOD001.

## Lead Value Driver – Kiacta AA Amyloidosis Program

### Serious Orphan Disease

Amyloid A (AA) amyloidosis is a form of systemic amyloidosis, a group of rare diseases characterized by deposition of insoluble protein fibrils in the extracellular space of tissues, leading to organ dysfunction and death. AA amyloidosis is secondary to chronic inflammatory conditions (e.g., rheumatoid arthritis) or chronic infections (e.g., osteomyelitis), which cause the liver to produce soluble serum amyloid A protein (SAA) under the regulation of cytokines. Fragments of SAA interact with the glycosaminoglycan (GAG) heparan sulfate, which promotes assembly of insoluble fibrils and stable deposition of these fibrils in organs including kidney, liver, spleen and heart. The kidney is most frequently affected, and deposition of fibrils in this organ results in progressive loss of renal function. Treatment to address the underlying inflammation can improve organ function, but in many patients, production of SAA and deposition of amyloid fibrils continues, and organ function progressively worsens. 25% to 50% of patients diagnosed with the disease die within five years of diagnosis.

The autopsy incidence of AA amyloidosis in western nations ranges from 0.5 to 0.86% (Simms et al., 1994 *Baillieres Clin Rheumatol* 8:627). The European Medicines Agency estimates that AA amyloidosis affects approximately 1.7 in 10,000 people in the EU, or about 64,000 individuals. Market research conducted by Navigant Consulting (contracted by Bellus), more conservatively estimated that between 9,100 and 15,500 individuals in the U.S. are affected by AA amyloidosis, and that 75% (6,800 to 11,600) would be eligible for treatment with Kiacta due to kidney involvement, but prior to dialysis. Navigant estimated that 3,500 eligible patients live in the five largest European economies, with 2,000 additional across developed rest of world markets, bringing the total addressable market to between 12,300 and 17,100.

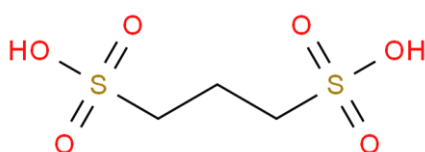
Based on the low prevalence of AA amyloidosis, Kiacta has received orphan drug status in the United States and European Union. As a result, Bellus receives a number of advantages including tax credits for research and development costs, assistance in trial design, and 7-year market exclusivity if Kiacta is approved (an added layer of protection on top of intellectual property which extends to 2026).

Additionally, drugs that treat rare diseases carry some of the highest price tags, with annual treatment costs typically ranging from just under \$100,000 (e.g., Jakafi and Esbriet) to more than \$400,000 (e.g., Soliris). Although there is no set formula, pricing of orphan drugs in the United States seems to be based mainly on the size of the disease population, the presence or absence of competing drugs, and effectiveness of the drug.

### Kiacta Targets Disease-Causing Molecule

Kiacta (eprodinate) is a low molecular weight negatively charged sulfonated molecule that is structurally similar to the glycosaminoglycan (GAG) heparan sulfate (Exhibit 2). A number of studies in the late 1980s demonstrated that heparan sulfate binding induces pro-aggregation conformational changes in serum amyloid A protein, which leads to intimate association of heparan sulfate with AA amyloid fibrils. Both characteristics indicate a key role for heparan sulfate in the pathogenesis of amyloidosis (McCubbin et al., 1988 *Biochem J* 256:775 and Snow et al., 1987 *Lab Invest* 57:687).

Exhibit 2 - Molecular Structure of Kiacta (eprodinate)



Source: Company

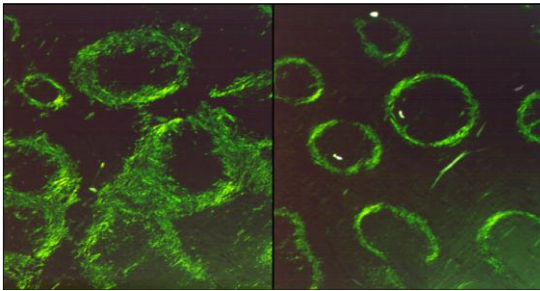


Kisilevsky et al. (Nature Medicine 1995 1:143) first demonstrated that GAG mimetics such as eprodisate competitively bind to the GAG binding sites on SAA and interfere with AA amyloid fibril polymerization in a dose-dependent manner *in vitro*, and in mice, reduce AA amyloid progression (Exhibit 3).

### Exhibit 3 – Kiacta Decreases the Amyloid Burden in Spleen of AA Amyloidotic Mice

Control

Kiacta (30mg/ml)



Source: Company

## Prior Clinical Experience

Phase 1 testing showed that Kiacta has good oral bioavailability, and is safe and very well tolerated. The drug is primarily excreted by the kidneys. The dose for phase 2/3 was selected to maintain Kiacta/SAA plasma concentration ratio in patients at levels at least 50x higher than the effective plasma concentration determined in preclinical studies.

Results of the phase 2/3 clinical trial were published in the New England Journal of Medicine in 2007 (Dember et al. 2007 NEJM 356:2349). 183 patients diagnosed with AA amyloidosis from 27 centers were randomly assigned to receive either Kiacta or placebo for 24 months. The primary composite endpoint was an assessment of renal function or death. Disease was classified as worsened if any one of the following occurred: doubling of serum creatinine level, reduction in creatinine clearance by 50% or more, progression to end-stage renal disease, or death. Two statistical tests were applied: Cochran-Mantel-Haenszel row mean-scores test (testing number of primary events in each dosing arm of the trial) and Cox proportional-hazards analysis (comparing time to primary event).

At 24 months, disease was worsened in 24 of 89 patients who received Kiacta (27%), and 38 of 94 patients given placebo (40%,  $p=0.06$ ). The hazard ratio for worsening of disease with Kiacta treatment was 0.58 (95% confidence interval, 0.37 to 0.93;  $P=0.02$ ), indicating a risk reduction of 42%.

The study had a number of confounding issues: in the placebo arm of the trial, baseline serum creatinine was higher (median 1.3 vs. 1.1 mg/dL) and there were more patients with nephrotic syndrome (42 vs. 38), which may have favored patients in the Kiacta group.

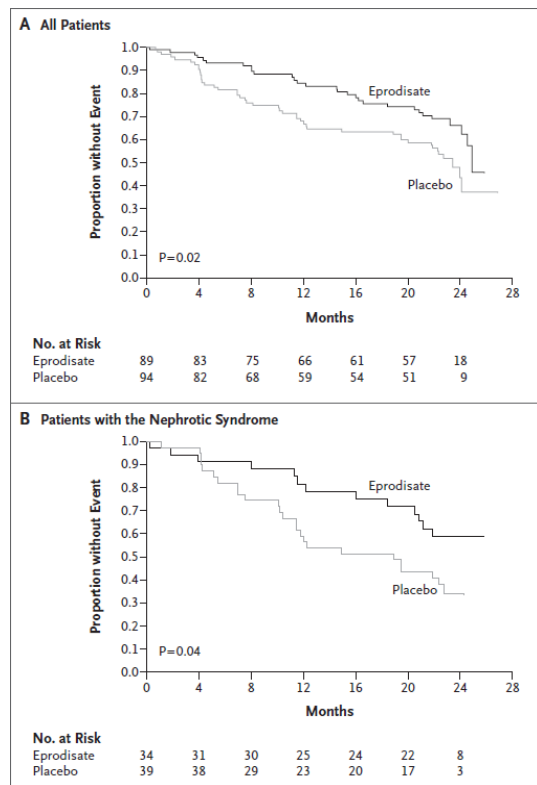
However, the risk reduction persisted when the analyses were adjusted for baseline creatinine parameters and nephrotic status. Furthermore, Kiacta treatment slowed the decline in creatinine clearance during the two year treatment period and this effect was observed across the total patient population (10.9 vs. 15.6 ml per minute per 1.73m<sup>2</sup> of body-surface area per year;  $P=0.025$ ), and within patient subgroups regardless of baseline creatinine clearance (unpublished data).

While there were more patients with nephrotic syndrome in the placebo arm of the trial, Kiacta's efficacy appeared even stronger among these patients (Exhibit 4). The possibility of greater demonstrable benefit among sicker patients in a relatively short clinical trial is logical, and we view it as a plus for the current phase 3 that it should include more nephrotic patients based on a minor adjustment to the inclusion criteria.





Exhibit 4 - Kiacta Phase 2/3 Kaplan-Meier Curves (Time to disease worsening)



Source: Company

Fewer patients treated with Kiacta progressed to end stage renal disease (7 vs. 13; hazard ratio, 0.54), and while this effect was not statistically significant (p=0.20), it served as another positive trend in favor of Kiacta. In our view, the possibility of achieving statistical significance on this secondary endpoint in the phase 3 trial has been bumped up on three fronts: 1) the larger patient population in phase 3 (230-250 vs. 183); 2) the expected higher proportion of patients with nephrotic syndrome; and 3) extension of the phase 3 trial to 120 events compared with 62 in the phase 2/3. Demonstrating a statistically significant reduction in progression to end stage renal disease is not necessary for success of the phase 3, but it may influence pricing of the Kiacta if the primary outcome is achieved and the drug is approved.

In April 2006, Bellus (Neurochem) submitted a New Drug Application to the FDA seeking approval of Kiacta (eprodinate) for the treatment of AA amyloidosis, based on data up to and including the phase 2/3 clinical trial. In August 2006, the agency issued an approvable letter requesting additional efficacy and safety data which could be provided by an additional clinical trial or significant follow-up of the phase 2/3 trial. The decision was made to run a confirmatory trial, with the company securing a Special Protocol Assessment (SPA) agreement with the FDA regarding the outstanding requirements for approval of Kiacta. On this basis, we believe that if the ongoing phase 3 trial meets its primary goal: delaying the time to kidney function worsening, that the FDA will be in a position to issue an approval.

### Make-or-Break Phase 3

In December 2010, Bellus and Celtic (Auvea) initiated a confirmatory phase 3 clinical trial to confirm the safety and efficacy of Kiacta in patients diagnosed with AA amyloidosis. On May 27, 2014, the partners announced that enrollment of the targeted 230 patients had been reached and that once enrollment closed, the total number of patients on trial would slightly exceed 230.



The phase 3 trial will conclude when 120 patients reach the composite primary endpoint of disease worsening - defined as persistent 80% increase in serum creatinine or persistent 40% decrease in creatinine clearance, or progression to end stage renal disease/dialysis. The primary analysis will be done using the log-rank test. This is a 'time to first worsening event' analysis that is very similar to the Cox proportional hazard analysis. In the prior phase 2/3 study, the analysis of the primary composite endpoint using the log-rank test led to a p-value= 0.018.

Management expects the trial will end in 2016 - this May, Bellus announced that >60 primary events had occurred, up from >40 in January, so a mid-2016 completion is achievable.

## Valuation

Our C\$3.00 valuation for BLU stock assumes a 50% probability of achieving an upside valuation of C\$5.90 per share if the current Kiacta phase 3 trial is successful (completion expected mid-2016). Downside, for purposes of the valuation model is \$0, although we forecast that Bellus will have \$0.10 per share of cash by YE-2016, and the company's pipeline may support a nominal residual value.

We arrive at the \$5.90 per share upside valuation by applying a 3.0x multiple to our base case peak Kiacta sales scenarios generated using the following assumptions:

- 9,225 eligible patients in the U.S.; 5,500 eligible patients in ROW markets
- Peak U.S. market penetration rate: 25%
- Annual cost of Kiacta treatment US\$100,000

Exhibit 5. Kiacta Peak Sales Estimates Based on Various Assumptions.

		U.S. pricing			
		\$50,000	\$100,000	\$200,000	\$300,000
US peak penetration	10%	\$ 17.3	\$ 34.5	\$ 69.0	\$ 103.5
	20%	\$ 82.6	\$ 165.3	\$ 330.5	\$ 495.8
	25%	\$ 115.3	\$ 230.6	\$ 461.3	\$ 691.9
	30%	\$ 148.0	\$ 296.0	\$ 592.0	\$ 888.0
	50%	\$ 278.8	\$ 557.5	\$ 1,115.0	\$ 1,672.5
	60%	\$ 344.1	\$ 688.3	\$ 1,376.5	\$ 2,064.8

Source: Bloom Burton estimates

Based on the base case peak sales estimates in Exhibit 5 (US\$230 million), we apply a multiple of 3.0x to generate valuations of Kiacta at the presumed time of phase 3 completion (expected in 12-18 months). Bellus would realize 50% of the value of Kiacta (the other 50% owned by Auvencor), and this amount is divided by Bellus's fully diluted shares outstanding (65.7 million) to arrive at a non-risk adjusted forecast base case BLU share price of C\$5.90 (Exhibit 6).

Exhibit 6.

		U.S. pricing			
		\$50,000	\$100,000	\$200,000	\$300,000
US peak penetration	10%	\$ 0.44	\$ 0.88	\$ 1.76	\$ 2.65
	20%	\$ 2.11	\$ 4.23	\$ 8.45	\$ 12.68
	25%	\$ 2.95	\$ 5.90	\$ 11.79	\$ 17.69
	30%	\$ 3.78	\$ 7.57	\$ 15.14	\$ 22.71
	50%	\$ 7.13	\$ 14.26	\$ 28.51	\$ 42.77
	60%	\$ 8.80	\$ 17.60	\$ 35.20	\$ 52.80

Source: Bloom Burton estimates



Our base case amount is discounted by 50% to adjust for the downside scenario (phase 3 failure), generating a risk-adjusted value of C\$2.95 which we round up to C\$3.00. Based on the recent closing price of BLU stock, we believe it is trading well below its risk-adjusted value, and we rate the stock BUY (SPECULATIVE risk), however, emphasizing the high risk/high reward nature of the stock.

In summary, we believe Kiacta is active and provides benefit in AA amyloidosis. However, we find it difficult to confidently predict the level of impact on the primary endpoint in the phase 3 trial. So, with a lot of upside and downside surrounding the binary event, BLU represents, as the title indicates, a “swing for the fence”.



## Financial Forecasts

Balance Sheet (CAD\$000)	FY2013	Q1A	Q2A	Q3E	Q4E	FY 2014E	FY 2015E	FY 2016E
<b>Current Assets</b>								
Cash and equivalents	\$ 11,279	\$ 9,996	\$ 9,036	\$ 9,271	\$ 8,626	\$ 8,626	\$ 5,093	\$ 4,637
Short term investments	\$ 4,018	\$ 4,035	\$ 4,052	\$ 3,416	\$ 3,416	\$ 3,416	\$ 3,416	\$ -
Receivables	\$ 174	\$ 219	\$ 238	\$ 147	\$ 147	\$ 147	\$ 147	\$ 147
Other Current Assets	\$ 1,501	\$ 1,473	\$ 1,409	\$ 1,059	\$ 465	\$ 465	\$ 465	\$ 465
<b>Total current assets</b>	<b>\$ 16,972</b>	<b>\$ 15,723</b>	<b>\$ 14,735</b>	<b>\$ 13,893</b>	<b>\$ 12,654</b>	<b>\$ 12,654</b>	<b>\$ 9,121</b>	<b>\$ 5,249</b>
<b>Long-term Assets</b>								
Investments in ABCP Notes	\$ 4,605	\$ 4,690	\$ 4,712	\$ 4,705	\$ -	\$ -	\$ -	\$ -
Other Assets	\$ 2,053	\$ 1,970	\$ 2,028	\$ 2,091	\$ 2,091	\$ 2,091	\$ 2,091	\$ 2,091
<b>Total Assets</b>	<b>\$ 23,630</b>	<b>\$ 22,383</b>	<b>\$ 21,475</b>	<b>\$ 20,689</b>	<b>\$ 14,745</b>	<b>\$ 14,745</b>	<b>\$ 11,212</b>	<b>\$ 7,340</b>
<b>Liabilities and Shareholders' Equity</b>								
Accounts Payable	\$ 1,581	\$ 1,228	\$ 1,248	\$ 1,441	\$ 1,441	\$ 1,441	\$ 1,441	\$ 1,441
Other Current Liabilities	\$ 1,680	\$ 1,690	\$ 1,680	\$ 1,680	\$ 1,680	\$ 1,680	\$ 1,680	\$ 1,680
<b>Total Current Liabilities</b>	<b>\$ 3,261</b>	<b>\$ 2,918</b>	<b>\$ 2,928</b>	<b>\$ 3,121</b>	<b>\$ 3,121</b>	<b>\$ 3,121</b>	<b>\$ 3,121</b>	<b>\$ 3,121</b>
Credit facilities	\$ 5,188	\$ 5,192	\$ 5,188	\$ 5,193	\$ -	\$ -	\$ -	\$ -
Deferred Revenue	\$ 3,360	\$ 2,957	\$ 2,520	\$ 2,100	\$ 2,100	\$ 2,100	\$ 2,100	\$ 2,100
Other Liabilities	\$ 1,003	\$ 1,044	\$ 1,086	\$ 1,130	\$ 1,130	\$ 1,130	\$ 1,130	\$ 1,130
<b>Total Liabilities</b>	<b>\$ 9,551</b>	<b>\$ 9,193</b>	<b>\$ 8,794</b>	<b>\$ 8,423</b>	<b>\$ 3,230</b>	<b>\$ 3,230</b>	<b>\$ 3,230</b>	<b>\$ 3,230</b>
<b>Shareholders' Equity</b>								
Share Capital	\$ 418,592	\$ 418,592	\$ 418,592	\$ 418,592	\$ 418,592	\$ 418,592	\$ 418,592	\$ 418,592
Other equity	\$ 33,346	\$ 33,464	\$ 33,582	\$ 33,697	\$ 33,697	\$ 33,697	\$ 33,697	\$ 33,697
Accumulated other comprehensive income	\$ 20	\$ 60	\$ 177	\$ 195	\$ 195	\$ 195	\$ 195	\$ 195
Deficit	\$(442,263)	\$(442,943)	\$(433,680)	\$(444,390)	\$(445,141)	\$(445,141)	\$(448,674)	\$(452,546)
<b>Total Shareholders' Equity</b>	<b>\$ 9,695</b>	<b>\$ 9,173</b>	<b>\$ 8,671</b>	<b>\$ 8,094</b>	<b>\$ 7,343</b>	<b>\$ 7,343</b>	<b>\$ 3,810</b>	<b>\$ (62)</b>
Non-controlling interest	\$ 1,123	\$ 1,099	\$ 1,082	\$ 1,051	\$ 1,051	\$ 1,051	\$ 1,051	\$ 1,051
<b>Total Liabilities &amp; Shareholders' Equity</b>	<b>\$ 23,630</b>	<b>\$ 22,383</b>	<b>\$ 21,475</b>	<b>\$ 20,689</b>	<b>\$ 14,745</b>	<b>\$ 14,745</b>	<b>\$ 11,212</b>	<b>\$ 7,340</b>



Income Statement (CAD\$000)	FY2013	Q1A	Q2A	Q3E	Q4E	FY 2014E	FY 2015E	FY 2016E
<b>Total Revenues</b>								
Sales	\$ 2,256	\$ 475	\$ 420	\$ 420	\$ 420	\$ 1,735	\$ 1,562	\$ 1,405
Research & Development	\$ 1,270	\$ 464	\$ 369	\$ 406	\$ 406	\$ 1,645	\$ 1,727	\$ 1,814
G&A expense	\$ 4,275	\$ 890	\$ 847	\$ 810	\$ 820	\$ 3,367	\$ 3,280	\$ 3,280
EBIT (Operating Loss)	\$ (3,289)	\$ (879)	\$ (796)	\$ (796)	\$ (806)	\$ (3,277)	\$ (3,446)	\$ (3,688)
Finance income	\$ 846	\$ 240	\$ 127	\$ 126	\$ 125	\$ 618	\$ 213	\$ 116
Finance costs	\$ (200)	\$ (69)	\$ (99)	\$ (73)	\$ (70)	\$ (311)	\$ (300)	\$ (300)
Gain on acquisition	\$ 1,672	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Net Loss</b>	<b>\$ (971)</b>	<b>\$ (708)</b>	<b>\$ (768)</b>	<b>\$ (743)</b>	<b>\$ (751)</b>	<b>\$ (2,970)</b>	<b>\$ (3,533)</b>	<b>\$ (3,872)</b>
Unrealized gain	\$ 22	\$ 44	\$ -	\$ -	\$ -	\$ 44	\$ -	\$ -
Total comprehensive loss for the period	\$ (949)	\$ (664)	\$ (768)	\$ (743)	\$ (751)	\$ (2,926)	\$ (3,533)	\$ (3,872)
Net loss attributable to:								
Owners of the Company	\$ (872)	\$ (680)	\$ (737)	\$ (710)	\$ (718)	\$ (2,845)	\$ (3,427)	\$ (3,756)
Non-controlling interest	\$ (99)	\$ (28)	\$ (31)	\$ (33)	\$ (33)	\$ (125)	\$ (106)	\$ (116)
	\$ (971)	\$ (708)	\$ (768)	\$ (743)	\$ (751)	\$ (2,970)	\$ (3,533)	\$ (3,872)
Total comprehensive loss attributable to:								
Owners of the Company	\$ (852)	\$ (640)	\$ (737)	\$ (710)	\$ (718)	\$ (2,805)	\$ (3,427)	\$ (3,756)
Non-controlling interest	\$ (97)	\$ (24)	\$ (31)	\$ (33)	\$ (33)	\$ (121)	\$ (106)	\$ (116)
	\$ (949)	\$ (664)	\$ (768)	\$ (743)	\$ (751)	\$ (2,926)	\$ (3,533)	\$ (3,872)
Loss per share (basic and diluted)	\$ (0.02)	\$ (0.01)	\$ (0.02)	\$ (0.02)	\$ (0.02)	\$ (0.06)	\$ (0.07)	\$ (0.08)

Statement of Cash Flow (CAD\$ millions)	FY2013A	FY 2014E	FY 2015E	FY 2016E
Net Change in Cash	\$ 473	\$ (2,653)	\$ (3,533)	\$ (456)
Cash and equivalents, beginning period	\$ 10,745	\$ 11,279	\$ 8,626	\$ 5,093
Effect of foreign exchange	\$ 61	\$ -	\$ -	\$ -
Cash and equivalents, end of period	\$ 11,279	\$ 8,626	\$ 5,093	\$ 4,637



David Martin PhD, MBA  
Analyst  
416-642-8865  
dmartin@bloomburton.com

Rating:	Hold
Risk:	Above Average
12 month Price Target:	\$10.00

Price	\$9.10
Implied Return	9.9%
Fiscal Year End	31-Dec
52 Week Range	\$5.84-\$11.00
Shares Outstanding (MM)	16.52
Market Cap. (MM)	\$165.2
Float (MM Shares)	12.99
Book Value/Share (latest Qtr. end)	\$1.42
Avg. Daily Volume (MM)	0.07

	2013A	2014E	2015E	2016E
Revenues (MM)	\$4.51	\$31.20	\$36.98	\$45.93
EBITDA (MM)	(\$16.05)	(\$11.22)	(\$7.27)	\$0.29
EPS	\$0.37	(\$0.99)	(\$0.61)	(\$0.26)
P/CFPS	(\$1.01)	(\$1.09)	(\$0.81)	(\$0.47)
	Q1A	Q2A	Q3A	Q4E
EPS -BASIC	2014 (\$0.20)	(\$0.26)	(\$0.30)	(\$0.23)

## Research Initiation – Getting the Most from Brinavess

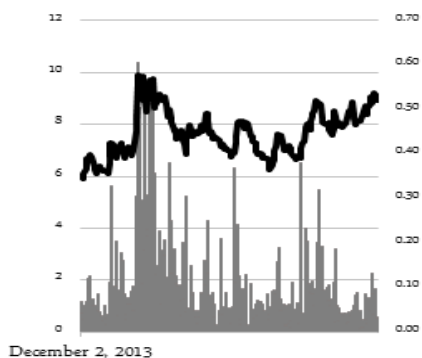
We are initiating research coverage of Cardiome Pharma Corp. (NASDAQ: CRME TSX: COM) with a HOLD rating (ABOVE AVERAGE risk) and a 12-month target price of US\$10.00. Following many set-backs on the path to bringing atrial fibrillation drug, vernakalant, to the global market, management engineered a corporate turn-around that has included: 1) strengthening the balance sheet, 2) building a small sales force for Brinavess (IV vernakalant) in certain European countries, 3) entering commercial agreements with regional specialty pharmaceutical companies in other European and other ex-U.S. countries, and 4) executing the synergistic acquisition of Correvio LLC which brought with it worldwide (ex-U.S.) commercial rights to a mature GP IIb/IIIa inhibitor, Aggrastat (annual 2013 revenues US\$30+ million); a small European hospital-based sales force; and a network of specialty distributors in other countries.

### Highlights

CRME stock has risen more than 5-fold from lows in late 2012, as the new commercial strategy has unfolded. Currently, we believe the stock prices in the turn-around and, in our opinion, potential upside catalysts are balanced by downside risks. For instance, we expect that Cardiome's own sales force and new regional partners will put more effort into promoting Brinavess than did previous partner, Merck, however, our sales expectations for Brinavess in ex-U.S. territories are conservative due to the high price of Brinavess in markets that for decades have relied on electrical cardioversion and generic cardioversion drugs. Likewise, the expanded approval of Aggrastat in Germany (as the Reference Member State) for treatment of myocardial infarction patients prior to angioplasty, is balanced by risk of increased generic competition (Aggrastat generics have been recently launched in Germany, France, Finland and Turkey), and overall stable-to-declining use of GP IIb/IIIa inhibitors due to bleeding risk.

Cardiome is in discussions with the FDA to restart phase 3 testing of IV vernakalant in the United States – the program was stopped in August 2008 when a patient enrolled in the ACT V clinical trial died due to cardiogenic shock. We believe there is a moderate probability that the FDA will allow Cardiome to restart the program, and this would be a positive near-term catalyst for the stock.

Our US\$10.00 target for CRME stock is based on probability-weighted DCF analysis of up and downside scenarios. In our base case DCF, Brinavess revenues peak at \$51.9 million in ex-US markets generating a value of \$5.42 per share (9% discount rate; 0% terminal growth). If Cardiome is permitted to re-start development of the IV and oral programs for vernakalant in the U.S., our peak sales estimates would quadruple. Assuming an estimated funding requirement of \$75 million for clinical trials, our NPV per share for this scenario would be \$14.56 (15% discount rate). We arrive at our \$10.00 target price by assigning a 50% probability to the upside scenario; 50% to the base case scenario.



This report is priced as of prior trading day's market close.  
All values in US\$ unless otherwise noted.



## Company Overview

Cardiome Pharma is a Vancouver-based specialty pharmaceutical company focused on the development and commercialization of cardiovascular therapies. The company's shares are traded on the NASDAQ Capital Market (NASDAQ: CRME) and the Toronto Stock Exchange (TSX: COM). Cardiome has two marketed, in-hospital, cardiology products. Brinavess (IV vernakalant) and Aggrastat (tirofiban HCl). Brinavess is approved in Europe and certain other territories for the conversion of recent onset atrial fibrillation to sinus rhythm in adults. Aggrastat is an anti-platelet GP IIb/IIIa inhibitor indicated for use in patients with acute coronary syndrome and patients with myocardial infarction intended for angioplasty. Cardiome obtained worldwide (ex-U.S.) commercial rights to Aggrastat when it acquired Correvio LLC in November 2013, in exchange for 19.9% of Cardiome's outstanding shares (pro forma ownership of approximately 16.6%) and deferred cash consideration of \$12 million to be paid in monthly instalments on or before December 1, 2019 (total cost approximately \$25 million).

Following Merck & Co.'s (NYSE: MRK; unrated) return of commercial rights for Brinavess in September 2012, Cardiome has entered into a series of commercialization agreements with specialty pharma companies covering certain European, Middle Eastern, African, and South American markets, and also increased its direct European sales force from 10 to 25 representatives following the acquisition of Correvio. In total, Cardiome or its partners have sales representation in approximately 50 countries, and specialty distributors in a number of others. Brinavess is currently available in over 30 countries worldwide, with near term launches (<2 years) expected in Italy, France, Belgium, the UK and several other countries (in August, Cardiome submitted reimbursement dossiers to Belgian and French authorities). Aggrastat is sold in more than 60 countries. Exhibit 1 shows the evolution of Cardiome's direct sales force, and its network of commercialization partners.

### Exhibit 1. Cardiome Commercial Structure

Company	Countries	Brinavess	Aggrastat
Cardiome	9 direct reps - Germany, Spain, Sweden, Belgium, Netherlands, Luxembourg	prior	
AOP Orphan	Austria, Switzerland, Hungary and 16 Eastern European countries	3-Jul-13	
Tzamal Medical Group	Israel	17-Sep-13	
Lifepharm (ZAM)	Cyprus	24-Sep-13	
Biospifar S.A.	Colombia	9-Oct-13	
Algorithm SAL	14 Middle Eastern and North African countries	21-Oct-13	
Correvio LLC	28 direct reps - Germany, France, Italy, UK, Netherlands, Belgium; Specialty distributors elsewhere - combined 60 countries		18-Nov-13
Tamro AB	Sweden	11-Feb-14	
Nomeco A/S	Denmark	18-Feb-14	
Logista Pharma SA	Spain	19-Mar-14	
Vianex SA	Greece	28-Mar-14	
UDG Healthcare	Ireland	5-May-14	
AOP Orphan	Austria, Hungary, Switzerland, other Eastern EU countries		20-May-14
Eurolab EM	Argentina	25-Aug-14	
Aspen	South Africa	17-Nov-14	
Cardiome	23-25 reps - Norway, Sweden, Finland, Denmark, Germany, Netherlands, Belgium, Luxembourg, France, Spain, Italy, UK, Ireland	current	current

Source: Company reports

At September 30, 2014, Cardiome had cash and cash equivalents of \$17.6 million and \$12 million debt. Shares outstanding were 16.5 million, and 1.1 million common shares are issuable upon the exercise of stock options at a weighted-average of CAD\$4.42 per share. During the third quarter of 2014, Cardiome's monthly operating burn rate was about \$0.6 million. The company's largest shareholders are Fidelity, Adage and CarCor (the shareholder from which Cardiome purchased Correvio). On July 18, 2014, Cardiome announced the closing of a senior, secured term loan facility of up to \$22 million provided by MidCap Financial, LLC in two tranches with an interest rate of Libor plus 8%. The first trench of up to \$12 million will be used for working capital and general corporate development purpose, such as sales and marketing for Brinavess and Aggrastat expansion in EU. A second trench may be used for product or company acquisitions.



## Atrial Fibrillation

Atrial fibrillation (AF) is a condition in which an irregular heart rhythm occurs in the top chambers of the heart due to uncoordinated atrial electrical activity. While AF events are generally not as acutely dangerous as ventricular arrhythmias, one of the main complications of atrial fibrillation is stroke due to the enhanced formation of thrombus (blood clots) in dysfunctional atria. Individuals with atrial fibrillation have a risk of stroke that is 2 to 7 times greater than those without atrial fibrillation.

AF events may terminate spontaneously, and if this is the case, the AF is designated paroxysmal. If a patient has two or more AF events, the condition is considered recurrent. If the AF is sustained and only terminates after pharmacological or electrical cardioversion, the AF is considered persistent. Long-standing cases of persistent AF usually lead to permanent AF.

AF is often associated with heart disease, and is also associated with arterial hypertension, dyslipidemia, diabetes and other vascular diseases (Russo et al. 2013 Eur Rev Med Pharmacol Sci 17:3132), although it also occurs in many patients with no detectable disease.

According to the American Heart Association, AF is the most common cardiac dysrhythmia, affecting 0.4% of the general population, and its prevalence increases with age (>6% in those over 80 years of age). Currently, approximately 3-5 million individuals in the U.S. have AF, and about 8.8 million in the EU. AF is projected to affect 8 million Americans and 18 million Europeans by 2050 (Rahman et al. 2014 Nat Rev Cardiol advance online publication). One third of hospitalization in Europe for cardiac rhythm disturbances are attributed to AF, accounting for 3.3% to 10% of emergency admissions (Laguna et al. 2004 Ann Emerg Med 44:3). In the United States, approximately 520,000 visits to emergency departments and 350,000 hospitalizations are attributable to AF, and the total annual medical cost is estimated at greater than \$6.5 billion (Singh 2012 Clinico Econ Outcomes Res 4:79).

## Management of AF – Rate Control or Rhythm Control

Two general strategies are widely used by physicians to manage AF: 1) Rhythm Control - restore and maintain sinus rhythm, or 2) Rate Control - allow AF to continue and ensure that ventricular rate is controlled. Both strategies may be augmented with anticoagulation therapy depending on the patients' risk of stroke. If the decision is made to pursue rhythm control, restoration of normal sinus rhythm can be accomplished either with drugs (pharmacological cardioversion) or shock (electrical cardioversion). Maintenance of sinus rhythm is then attempted with pharmacological therapy. For some AF patients whose symptoms are not well maintained with drugs, catheter ablation may be effective.

Although maintenance of sinus rhythm may be considered optimal from the standpoint of symptom relief and avoidance of cardiomyopathy, data from large randomized clinical trials does not support that rhythm control provides significant benefits over rate control strategy in terms of mortality (Wyse et al. 2002 N Engl J Med.347:1825). Other factors including age and co-morbidities play into consideration of whether to embark on a rhythm or rate control management program.

## Rhythm Control - First-line Cardioversion

If rhythm control is selected, restoration of normal sinus rhythm is the first step, and this may be accomplished using electrical or pharmacological cardioversion. Cardioversion carries a risk of thromboembolism, and this risk is greater if the AF has been present >48 hours. In these patients, systemic anticoagulation for 3 weeks prior to cardioversion is standard, unless transesophageal echocardiography (TEE) has excluded left atrial thrombosis, or hemodynamic instability necessitates urgent action. For patients with AF<48 hours, a recent large retrospective analysis of more than 4,000 patients treated over 8 years in two Finnish hospitals demonstrated that successful cardioversion within 12 hours of presentation was associated with lower risk of stroke compared to patients in whom cardioversion occurred after 12 hours (Nuotio et al., 2014 JAMA 312:646).



**DC Cardioversion.** Direct current cardioversion applies an electrical shock synchronized with the intrinsic activity of the heart. Although electrical cardioversion has a high success rate in restoring sinus rhythm (80%-90%) and is more effective than drugs in AF >48 hours, the procedure requires prior fasting and sedation, can be very traumatizing for the patient, and early recurrence is fairly common (>15%), although this can be reduced if patients receive adjunctive antiarrhythmic drugs (Li et al., 2004 Am J Cardiol 93:45).

**Pharmacological Cardioversion.** An alternative to DC cardioversion is pharmacological cardioversion, which is effective mainly in patients presenting with recent onset AF (<48 hours). Class Ic (slow association/dissociation sodium channel blocking) and Class III (potassium channel blocking) Vaughn-Williams Class antiarrhythmic drugs form the backbone of current pharmacological cardioversion therapy. Class I drugs decrease excitability of cardiac tissue by blocking fast sodium channels that are responsible for rapid depolarization. Class III drugs work by slowing repolarization and prolonging the action potential and refractory period, thereby preventing re-entrant arrhythmias.

**Vaughn-Williams Class Ic Drugs.** Class Ic drugs including flecainide (Tambocor) and propafenone (Rythmol) are recommended for the cardioversion of patients with AF without structural heart disease and with good LV function (about 80% of patients with paroxysmal AF and 50% with persistent AF), although in practice, use is around 17% and 13%, respectively (Aliot et al., 2011 Europace 13:161). Both are contraindicated in patients with prior myocardial infarction or reduced LV function because of negative inotropic effects and risk of ventricular proarrhythmia, however, in patients with structurally normal hearts, the frequency of ventricular proarrhythmia is low, significant QT prolongation is rare, and only a few cases of serious proarrhythmia have been reported (Shantsila et al., 2007 Europace 9:37). Class Ic agents may cause atrial flutter in some patients (Daubert 2009 Cardiol J 16:491).

Cardiome's Brinavess (IV vernakalant) has been compared head-to-head against oral formulations of flecainide and propafenone in a study run in Buenos Aires in which 150 patients with recent onset AF (<48 hours) were treated and assessed for conversion to normal sinus rhythm. The conversion rate with Brinavess was higher (90% at 2 hours vs 80% at 8 hours for both flecainide and propafenone), and the median time to conversion was shorter (12 minutes vs 162 minutes and 151 minutes, respectively). Median length of stay in emergency care was 243 minutes for patients treated with Brinavess vs 410 and 422 minutes for flecainide and propafenone (Conde et al., 2013 JAFIB 6:7).

The Buenos Aires results are positive, but we note that IV infusions of flecainide and propafenone are faster acting, and/or able to convert a higher proportion of patients compared with oral tablets or capsules (Martinez-Marcos et al., 2000 Am J Cardiol 86:950 and Bellandi et al., 1996 Cardiovasc Drugs Ther 10:153) and, as a result, a comparison of Brinavess to IV formulations of flecainide and propafenone would likely have resulted in more similar profiles. We also note that Conde's results are better than previous results for IV vernakalant in recent onset AF patients (52%-62% conversion rates) without a clear reason.

**Vaughn-Williams Class III Drugs.** Class III antiarrhythmic drugs (e.g., sotalol, ibutilide, dofetilide) predominately inhibit potassium channels, thereby prolonging repolarization and increasing the atrial refractory period. Prolongation of the action potential duration, combined with the maintenance of normal conduction velocity, prevent re-entrant arrhythmias. However, the Class III agents also prolong the QT interval in a dose dependent manner, which in turn, induces serious ventricular arrhythmias (which can be fatal if untreated) in up to 10% of patients.

Amiodarone is classified as a Class III agent because of its potassium channel blocking activities. However it also has Class I, II (beta blocking) and IV (calcium channel blocking)





electrophysiological properties. QT prolongation is common, but incidence of torsades de pointes is very rare. Oral amiodarone has the best efficacy with respect to maintaining sinus rhythm and, although not approved by the FDA for AF, is the most commonly prescribed drug for AF, representing 45% of annual drug prescriptions, despite liver, thyroid and lung toxicity associated with chronic use of the drug (Zimetbaum 2012 Circulation 125:381). Because loading doses are required and drug effect is delayed 6-8 hours, amiodarone is not useful for acute cardioversion, however, by 24 hours, the placebo-corrected efficacy of amiodarone is in the range of 50%, and it is the only drug considered safe for use in patients with severe heart disease.

Overall, we find the cardioversion space adequately serviced by quick options for emergent situations (electrical cardioversion) and otherwise healthy patients (electrical cardioversion or Class Ic antiarrhythmic drugs), as well as relatively safe options for patients with significant CAD or LV dysfunction for whom speed may not be the primary goal (amiodarone or electrical cardioversion). This is not to say that the current armamentarium is optimal, only that for many patients, there are already adequate options. In the United States, where IV formulations of flecainide and propafenone are not available, there is more of a “gap” that could be filled by a new AF cardioversion drug such as vernakalant. Regarding AF maintenance/prophylaxis, there is more of a need for new drug(s) due to the chronic toxicity of mainstay amiodarone and risks associated with unmonitored daily use of the other available Class I and III antiarrhythmics.

## Brinavess (IV vernakalant)

Brinavess is a sodium and potassium channel blocker with atrial-selective action. It is approved in 50 countries and currently sold in more than 30. The drug is indicated for conversion of recent-onset AF to sinus rhythm in adult non-surgery patients with AF of <7 days, and for adult post-cardiac surgery patients with AF of <3 days' duration. The European Society of Cardiology AF Guidelines has recommended Brinavess as first-line in hemodynamically stable patients with moderate or no structural heart disease. In seven phase 2 and 3 clinical trials, IV vernakalant was found to be an effective agent for rapid conversion to normal sinus rhythm in patients with recent onset AF (Exhibit 2).

Exhibit 2. IV Vernakalant Clinical Trials

Clinical trials	N (#of patients)	Clinical setting	Control group	Primary endpoint	Vernakalant (i.v) vs control P-value	Median time to CV (min)
CRAFT	56	AF duration 3h-72h	Placebo	AF termination within 30 min	56% vs 5% (p<0.001)	14
ACT I	416	AF duration 3h-7d	Placebo	AF termination within 90 min	51.7% vs 4% (p<0.001)	11
ACT II	210	AF post-cardiac surgery	Placebo	AF termination within 90 min	47% vs 14% (p<0.001)	12.4
ACT III	254	AF duration 3h-7d	Placebo	AF termination within 90 min	51.2% vs 3.6% (p<0.0001)	8
ACT IV	254	AF duration 3h-7d	-	AF termination within 90 min	Vernakalant 50.9%	14
AVRO	232	AF duration 3h-48h	Amiodarone	AF termination within 90 min	53.4% vs 5.2% (p<0.0001)	11
ACT V	450	recent onset AF 3h-7d	Placebo	Rate of Conversion	Hold by FDA	

Source: Company and Russo et al., 2013 Eur. Rev. Med. Pharmacol. Sci 17: 3132





The drug has an attractive safety profile in patients with moderate to no structural heart disease, but should be used with caution in patients with NYHA Class I and II heart failure because of increased risk of hypotension and non-sustained ventricular arrhythmias. Throughout clinical development of Brinavess, no significant proarrhythmias were reported.

However, during a phase 3b clinical trial (ACT V) requested by the FDA following an Approvable Letter issued in August 2008, a death due to cardiogenic shock experienced by a patient with aortic stenosis, led to the trial being suspended. Cardiome is currently studying the underlying factors leading to the death, and based on investigations to date, management believes the event was likely triggered by vernakalant's mild negative inotropic effect. If this proves to be the case, the risk should be manageable with standard supportive measures, and by avoiding patients with valvular disease. Cardiome has initiated dialogue with the FDA and hopes to wrap-up its investigation and have the agency lift the clinical hold by the end of 2014.

In the European Union, Brinavess was approved in September 2010 as first-line treatment for AF, and based on the approval, Cardiome received a \$30 million milestone payment from Merck according to an earlier marketing and development agreement between the two companies. Unfortunately, the patient death in ACT V occurred a month later, Merck discontinued development of oral vernakalant in March 2012, then the final shoe fell in September 2012 when Merck returned marketing and development rights for vernakalant (oral and IV) to Cardiome.

As mentioned in the Company Overview section, Cardiome has since executed a masterful turn-around - negotiating its way out of a \$50 million debt owed to Merck; recapitalizing the company; building a small sales force and lining up commercial partners in ex-U.S. markets; and acquiring Correvio. Management now intends to get the clinical hold on ACT V lifted by the end of 2014, and have plans in place for continuation of development of IV vernakalant in the United States, and oral vernakalant globally.

A possible strategy for oral vernakalant may include clinical trials in a short term indication such as post-open heart surgery. This may allow Cardiome to avoid the huge time, expense and risk of a development program focused on chronic prophylaxis of AF.

Composition of matter patents protecting the vernakalant molecule expire in 2024 in Europe and 2025 in the United States. It is uncertain the length of patent term extension that would be available in the United States due to the clinical hold.

## Aggrastat

On November 18, 2013, Cardiome completed the acquisition of Correvio LLC, a privately held pharmaceutical company headquartered in Geneva, Switzerland, focused on the worldwide marketing, excluding the United States, of Aggrastat, a reversible GP IIb/IIIa inhibitor indicated for Acute Coronary Syndrome. The drug was originally developed by Merck, and approved in the U.S. in 1998. In 2000, a 5,000 patient study demonstrated that J&J and Eli Lilly's competing drug, ReoPro, was safer. Subsequently, Merck sold commercial rights for the U.S. to Medicure Inc. (TSX: MPH, unrated) and rest of world rights to Correvio.

At their peak, GP IIb/IIIa inhibitors had worldwide sales of \$600-\$700 million: Integrilin ~\$300 million; ReoPro ~\$300 million and Aggrastat ~\$115 million (Heartwire 2003). Since then, the general reduction in use of this drug class has driven a decrease in sales to about \$365 million in 2012. Newer, less expensive anticoagulants have been developed with lower risk of bleeding complications including P2Y12 platelet inhibitors (e.g., Plavix and Effient), and thrombin inhibitors (e.g., Angiomax). Currently, use of GP IIb/IIIa inhibitors has become limited primarily to the setting of PCI particularly in high risk patients or patients not adequately pretreated with P2Y12 antagonists (Bledzka et al., 2013 Circ Res 112:1189).

Correvio's ex-U.S. annual sales of Aggrastat prior to its acquisition by Cardiome were US\$30+ million. In the United States, Medicure's revenues from net sales of Aggrastat were \$5.1 million in the fiscal year ended May 31, 2014, compared with \$2.6 million in fiscal year 2013. The year-over-year increase in the United States was attributed to FDA approval of a new high dose bolus dosing regimen for



Aggrastat in October 2013. This same regimen had been approved in Germany in 2010, and in other European member states in 2011 and 2012.

In October 2013 just prior to its acquisition by Cardiome, Correvio received approval from the German regulatory agency BfArM, acting as the Reference Member State in the European Mutual Recognition Procedure (MRP), to include the reduction of major cardiovascular events in patients with acute myocardial infarction intended for primary PCI as an indication for Aggrastat. This is positive because, as discussed above, GP IIb/IIIa inhibitors are now mainly used only in this indication. The label expansion could therefore result in reaccelerated growth of Aggrastat, however, the competing GP IIb/IIIa inhibitors are more entrenched in this indication, with arguably better data, and the recent launch of generic versions of Aggrastat in Germany, France, Finland and Turkey may mitigate a potential upside.

## Valuation

Our US\$10.00 target for CRME stock is based on probability-weighted DCF analysis of base case and upside scenarios.

In our base case DCF, Cardiome's revenues for Brinavess peak at \$51.9 million in ex-US markets (15% penetration in Europe and 5% ROW of atrial fibrillation cardioversions of Class I and II heart failure patients with AF<48 hours - Exhibit 3) generating a NPV of \$5.42 per share (9% discount rate; 0% terminal growth).

### Exhibit 3. Brinavess Revenue Forecasts

	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
BRINAVERS (I.V. form of Vernakalant for atrial fibrillation)							
Cardioversions in Europe	1,200,000	1,236,000	1,273,080	1,311,272	1,350,611	1,391,129	1,432,863
With structural heart disease (65%)	780,000	803,400	827,502	852,327	877,897	904,234	931,361
With Class I or II heart failure (85%)	663,000	682,890	703,377	724,478	746,212	768,599	791,657
AF<48 hours (80%)	530,400	546,312	562,701	579,582	596,970	614,879	633,325
Brinavess penetration	1%	3%	7%	9%	12.5%	15%	15%
Brinavess patients treated	5,304	16,389	39,389	52,162	74,621	92,232	94,999
Sales (US\$; EUR350 per patient)	\$ 2,320,500	\$ 7,170,345	\$ 17,232,729	\$ 22,821,057	\$ 32,646,790	\$ 40,351,432	\$ 41,561,975
Cardioversions in ROW	\$ 2,400,000	\$ 2,472,000	\$ 2,546,160	\$ 2,622,545	\$ 2,701,221	\$ 2,782,258	\$ 2,865,726
With structural heart disease (65%)	\$ 1,560,000	\$ 1,606,800	\$ 1,655,004	\$ 1,704,654	\$ 1,755,794	\$ 1,808,468	\$ 1,862,722
With Class I or II heart failure (85%)	\$ 1,326,000	\$ 1,365,780	\$ 1,406,753	\$ 1,448,956	\$ 1,492,425	\$ 1,537,197	\$ 1,583,313
AF<48 hours (80%)	\$ 1,060,800	\$ 1,092,624	\$ 1,125,403	\$ 1,159,165	\$ 1,193,940	\$ 1,229,758	\$ 1,266,651
Brinavess penetration	0.5%	1%	2%	3%	4%	5%	5%
Brinavess patients treated	\$ 5,304	\$ 10,926	\$ 22,508	\$ 34,775	\$ 47,758	\$ 61,488	\$ 63,333
Sales (US\$; EUR350 per patient)	\$ 2,320,500	\$ 4,780,230	\$ 9,847,274	\$ 15,214,038	\$ 20,893,946	\$ 26,900,955	\$ 27,707,984
Total Brinavess sales	\$ 4,641,000	\$ 11,950,575	\$ 27,080,003	\$ 38,035,095	\$ 53,540,735	\$ 67,252,387	\$ 69,269,959
Total Brinavess sales	\$ 4,641,000	\$ 11,950,575	\$ 27,080,003	\$ 38,035,095	\$ 53,540,735	\$ 67,252,387	\$ 69,269,959
Direct (50%)	\$ 2,320,500	\$ 5,975,288	\$ 13,540,001	\$ 19,017,548	\$ 26,770,368	\$ 33,626,194	\$ 34,634,979
Partners (50%)	\$ 2,320,500	\$ 5,975,288	\$ 13,540,001	\$ 19,017,548	\$ 26,770,368	\$ 33,626,194	\$ 34,634,979
Deduct 50% for partner sales	\$ 1,160,250	\$ 2,987,644	\$ 6,770,001	\$ 9,508,774	\$ 13,385,184	\$ 16,813,097	\$ 17,317,490
Total Cardiome Brinavess revenues	\$ 3,480,750	\$ 8,962,931	\$ 20,310,002	\$ 28,526,321	\$ 40,155,552	\$ 50,439,290	\$ 51,952,469

Source: Bloom Burton & Co. estimates

If Cardiome is permitted to re-start the IV and oral programs for vernakalant in the U.S., our peak sales estimates would quadruple (upside scenario). Assuming an estimated additional funding requirement of \$75 million for clinical trials, the NPV per share for this scenario would be \$14.56 (15% discount rate). The higher discount rate for the upside scenario is warranted based on the clinical and regulatory risk associated with a substantial portion of forecast revenues.

We arrive at our \$10.00 target price by assigning a 50% probability to the upside scenario; 50% to the



base case scenario.

Each of Bloom Burton's valuation scenarios assume a 10% annual decrease in Aggrastat sales, and a 9% tax rate (Cardiome is subject to taxation in Switzerland).

## Financial Forecasts

<b>Balance Sheet (US\$000)</b>	<b>FY2013</b>	<b>Q1A-14</b>	<b>Q2A-14</b>	<b>Q3A-14</b>	<b>Q4E-14</b>	<b>FY 2014E</b>	<b>FY 2015E</b>	<b>FY 2016E</b>	<b>FY 2017E</b>	<b>FY 2018E</b>	<b>FY2019E</b>	<b>FY2020E</b>
<b>Current Assets</b>												
Cash & Short-Term Investments	\$ 10,984	\$ 13,236	\$ 9,353	\$ 17,582	\$ 13,313	\$ 13,313	\$ 35,963	\$ 24,186	\$ 18,375	\$ 20,400	\$ 33,106	\$ 48,855
Restricted cash	\$ 2,323	\$ 2,349	\$ 2,428	\$ 2,321	\$ 2,321	\$ 2,321	\$ 2,321	\$ 2,321	\$ 2,321	\$ 2,321	\$ 2,321	\$ 2,321
Short-Term Receivables	\$ 6,674	\$ 7,175	\$ 7,313	\$ 7,884	\$ 8,199	\$ 8,199	\$ 9,864	\$ 12,550	\$ 14,370	\$ 17,277	\$ 19,839	\$ 19,822
Inventories	\$ 6,597	\$ 7,434	\$ 6,455	\$ 5,572	\$ 5,795	\$ 5,795	\$ 6,905	\$ 8,785	\$ 10,059	\$ 12,094	\$ 13,887	\$ 13,876
Other Current Assets	\$ 1,749	\$ 2,904	\$ 3,034	\$ 1,818	\$ 1,818	\$ 1,818	\$ 1,818	\$ 1,818	\$ 1,818	\$ 1,818	\$ 1,818	\$ 1,818
<b>Total current assets</b>	<b>\$ 28,327</b>	<b>\$ 33,098</b>	<b>\$ 28,583</b>	<b>\$ 35,177</b>	<b>\$ 31,446</b>	<b>\$ 31,446</b>	<b>\$ 56,871</b>	<b>\$ 49,661</b>	<b>\$ 46,942</b>	<b>\$ 53,910</b>	<b>\$ 70,972</b>	<b>\$ 86,692</b>
<b>Long-term Assets</b>												
Net Property, Plant & Equipment	\$ 618	\$ 586	\$ 564	\$ 341	\$ 321	\$ 321	\$ 161	\$ 80	\$ 40	\$ 20	\$ 10	\$ 5
Intangible Assets	\$ 18,069	\$ 17,580	\$ 17,093	\$ 16,642	\$ 16,242	\$ 16,242	\$ 14,618	\$ 13,156	\$ 11,840	\$ 10,656	\$ 9,591	\$ 8,632
Other assets	\$ -	\$ -	\$ -	\$ 808	\$ 808	\$ 808	\$ 808	\$ 808	\$ 808	\$ 808	\$ 808	\$ 808
Goodwill	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318	\$ 318
<b>Total Assets</b>	<b>\$ 47,332</b>	<b>\$ 51,582</b>	<b>\$ 46,558</b>	<b>\$ 53,286</b>	<b>\$ 49,135</b>	<b>\$ 49,135</b>	<b>\$ 72,775</b>	<b>\$ 64,023</b>	<b>\$ 59,949</b>	<b>\$ 65,712</b>	<b>\$ 81,698</b>	<b>\$ 96,455</b>
<b>Liabilities and Shareholders' Equity</b>												
Accounts Payable	\$ 14,003	\$ 9,517	\$ 9,327	\$ 9,477	\$ 9,817	\$ 9,817	\$ 9,845	\$ 10,191	\$ 9,229	\$ 8,212	\$ 9,349	\$ 9,342
Current portion of long-term debt	\$ -	\$ -	\$ -	\$ 686	\$ 686	\$ 686	\$ 686	\$ 686	\$ 686	\$ 686	\$ 686	\$ 686
Other Current Liabilities	\$ 3,688	\$ 4,157	\$ 4,769	\$ 3,390	\$ 3,390	\$ 3,390	\$ 3,390	\$ 3,390	\$ 3,390	\$ 3,390	\$ 3,390	\$ 3,390
<b>Total Current Liabilities</b>	<b>\$ 17,691</b>	<b>\$ 13,674</b>	<b>\$ 14,096</b>	<b>\$ 13,553</b>	<b>\$ 13,893</b>	<b>\$ 13,893</b>	<b>\$ 13,921</b>	<b>\$ 14,267</b>	<b>\$ 13,305</b>	<b>\$ 12,288</b>	<b>\$ 13,425</b>	<b>\$ 13,418</b>
Long term debt	\$ -	\$ -	\$ -	\$ 11,314	\$ 10,614	\$ 10,614	\$ 7,814	\$ 5,014	\$ 2,214	\$ -	\$ -	\$ -
Deferred consideration	\$ 6,997	\$ 5,657	\$ 4,317	\$ 4,973	\$ 4,973	\$ 4,973	\$ 3,973	\$ 2,973	\$ 1,973	\$ 973	\$ -	\$ -
	\$ 24,688	\$ 19,331	\$ 18,413	\$ 29,840	\$ 29,480	\$ 29,480	\$ 25,708	\$ 22,254	\$ 17,492	\$ 13,261	\$ 13,425	\$ 13,418
<b>Shareholders' Equity</b>												
Common Stock	\$ 272,083	\$ 284,522	\$ 284,518	\$ 284,519	\$ 284,520	\$ 284,520	\$ 324,520	\$ 324,524	\$ 324,528	\$ 324,532	\$ 324,536	\$ 324,540
Additional paid-in capital	\$ 33,349	\$ 33,489	\$ 33,625	\$ 33,962	\$ 33,962	\$ 33,962	\$ 33,962	\$ 33,962	\$ 33,962	\$ 33,962	\$ 33,962	\$ 33,962
Deficit	\$(300,746)	\$(303,880)	\$(308,120)	\$(312,487)	\$(316,279)	\$(316,279)	\$(328,867)	\$(334,169)	\$(333,485)	\$(323,495)	\$(307,677)	\$(292,917)
Accumulated other comprehensive income	\$ 17,958	\$ 18,120	\$ 18,122	\$ 17,452	\$ 17,452	\$ 17,452	\$ 17,452	\$ 17,452	\$ 17,452	\$ 17,452	\$ 17,452	\$ 17,452
	\$ 22,644	\$ 32,251	\$ 28,145	\$ 23,446	\$ 19,655	\$ 19,655	\$ 47,067	\$ 41,769	\$ 42,457	\$ 52,451	\$ 68,273	\$ 83,037
<b>Total Liabilities &amp; Shareholders' Equity</b>	<b>\$ 47,332</b>	<b>\$ 51,582</b>	<b>\$ 46,558</b>	<b>\$ 53,286</b>	<b>\$ 49,135</b>	<b>\$ 49,135</b>	<b>\$ 72,775</b>	<b>\$ 64,023</b>	<b>\$ 59,949</b>	<b>\$ 65,712</b>	<b>\$ 81,698</b>	<b>\$ 96,455</b>

Income Statement (US\$000)	FY2013	Q1A-14	Q2A-14	Q3A-14	Q4E-14	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
Revenue:												
Product Revenue	\$ 4,012	\$ 6,562	\$ 6,500	\$ 6,931	\$ 7,109	\$ 27,102	\$ 32,879.18	\$ 41,834.63	\$ 47,898.48	\$ 57,590.50	\$ 66,130.74	\$ 66,074.78
Licensing and other fees	\$ 499	\$ 1,030	\$ 1,167	\$ 876	\$ 1,024	\$ 4,097	\$ 4,097	\$ 4,097	\$ 4,097	\$ 4,097	\$ 4,097	\$ 4,097
Total Revenues	\$ 4,511	\$ 7,592	\$ 7,667	\$ 7,807	\$ 8,133	\$ 31,199	\$ 36,976	\$ 45,932	\$ 51,995	\$ 61,687	\$ 70,228	\$ 70,172
COGS	\$ 936	\$ 1,493	\$ 2,243	\$ 2,673	\$ 2,765	\$ 9,174	\$ 11,093	\$ 11,483	\$ 10,399	\$ 9,253	\$ 10,534	\$ 10,526
	\$ 3,575	\$ 6,099	\$ 5,424	\$ 5,134	\$ 5,368	\$ 22,025	\$ 25,883	\$ 34,449	\$ 41,596	\$ 52,434	\$ 59,694	\$ 59,646
Expenses:												
Research & Development	\$ 476	\$ 245	\$ 59	\$ 234	\$ 179	\$ 717	\$ 753	\$ 790	\$ 830	\$ 872	\$ 915	\$ 961
SG&A expense	\$ 16,446	\$ 7,999	\$ 8,808	\$ 7,863	\$ 7,863	\$ 32,533	\$ 32,396	\$ 33,367	\$ 34,368	\$ 35,400	\$ 36,461	\$ 37,555
Acquisition costs	\$ 1,494	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Restructuring	\$ 1,207	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Amortization	\$ 649	\$ 536	\$ 564	\$ 510	\$ 500	\$ 2,110	\$ 1,899	\$ 1,709	\$ 1,538	\$ 1,384	\$ 1,246	\$ 1,121
Operating income (loss)	\$ (16,697)	\$ (2,681)	\$ (4,007)	\$ (3,473)	\$ (3,174)	\$ (13,335)	\$ (9,164)	\$ (1,418)	\$ 4,860	\$ 14,779	\$ 21,071	\$ 20,008
Other income (expenses)												
Interest Expense	\$ (87)	\$ 254	\$ 226	\$ 495	\$ 500	\$ 1,475	\$ 1,146	\$ 852	\$ 516	\$ 174	\$ -	\$ -
Gain on settlement of debt	\$ 20,834	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Other income	\$ 633	\$ (99)	\$ (18)	\$ 217	\$ -	\$ 100	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Foreign exchange gain	\$ 192	\$ 181	\$ (131)	\$ 68	\$ -	\$ 118	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Pretax Income	\$ 4,875	\$ (3,017)	\$ (4,084)	\$ (4,253)	\$ (3,674)	\$ (15,028)	\$ (10,310)	\$ (2,270)	\$ 4,344	\$ 14,605	\$ 21,071	\$ 20,008
Income Taxes	\$ 102	\$ 117	\$ 156	\$ 114	\$ 118	\$ 505	\$ 2,278	\$ 3,031	\$ 3,660	\$ 4,614	\$ 5,253	\$ 5,249
Net income (loss)	\$ 4,773	\$ (3,134)	\$ (4,240)	\$ (4,367)	\$ (3,792)	\$ (15,533)	\$ (12,588)	\$ (5,302)	\$ 683	\$ 9,991	\$ 15,818	\$ 14,760
Foreign currency translation adjustment	\$ 227	\$ 162	\$ 2	\$ (670)	\$ -	\$ (506)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Comprehensive income (loss)	\$ 4,546	\$ (2,972)	\$ (4,238)	\$ (5,037)	\$ (3,792)	\$ (16,039)	\$ (12,588)	\$ (5,302)	\$ 683	\$ 9,991	\$ 15,818	\$ 14,760
Income (loss) per common share												
EPS (basic)	\$ 0.37	\$ (0.20)	\$ (0.26)	\$ (0.30)	\$ (0.23)	\$ (0.99)	\$ (0.61)	\$ (0.26)	\$ 0.03	\$ 0.49	\$ 0.77	\$ 0.72
EPS (diluted)	\$ 0.37	\$ (0.20)	\$ (0.26)	\$ (0.30)	\$ (0.23)	\$ (0.99)	\$ (0.61)	\$ (0.26)	\$ 0.03	\$ 0.49	\$ 0.77	\$ 0.72



<b>Statement of Cash Flow (US\$000)</b>	<b>FY2013</b>	<b>Q1A-14</b>	<b>Q2A-14</b>	<b>Q3A-14</b>	<b>Q4E-14</b>	<b>FY 2014E</b>	<b>FY 2015E</b>	<b>FY 2016E</b>	<b>FY 2017E</b>	<b>FY 2018E</b>	<b>FY 2019E</b>	<b>FY 2020E</b>
<b>Operating Activities</b>												
Net Income	\$ 4,773	\$ (3,134)	\$ (4,240)	\$ (4,367)	\$ (3,792)	\$ (15,533)	\$ (12,588)	\$ (5,302)	\$ 683	\$ 9,991	\$ 15,818	\$ 14,760
Items not affecting cash												
Amortization	\$ 649	\$ 536	\$ 564	\$ 510	\$ 500	\$ 2,110	\$ 1,899	\$ 1,709	\$ 1,538	\$ 1,384	\$ 1,246	\$ 1,121
Stock based compensation	\$ 645	\$ 226	\$ 170	\$ 370	\$ -	\$ 766	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Loss on write-down of property and equipment	\$ -	\$ -	\$ -	\$ 188	\$ -	\$ 188	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Write-down of inventory	\$ -	\$ -	\$ -	\$ 607	\$ -	\$ 607	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Gain on settlement of debt	\$ (20,834)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Unrealized FX gain	\$ (186)	\$ 56	\$ (105)	\$ (241)	\$ -	\$ (290)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Restricted cash	\$ (2,059)	\$ (25)	\$ (91)	\$ (7)	\$ -	\$ (123)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Accounts receivable	\$ 448	\$ (508)	\$ (187)	\$ (1,134)	\$ (315)	\$ (2,144)	\$ (1,664)	\$ (2,687)	\$ (1,819)	\$ (2,908)	\$ (2,562)	\$ 17
Inventories	\$ (2,816)	\$ (839)	\$ 959	\$ 297	\$ (223)	\$ 194	\$ (1,110)	\$ (1,881)	\$ (1,273)	\$ (2,035)	\$ (1,793)	\$ 12
Prepays	\$ (18)	\$ (1,154)	\$ (151)	\$ 1,321	\$ -	\$ 16	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Accounts payable and accrued liabilities	\$ 2,630	\$ (4,452)	\$ (247)	\$ 590	\$ 340	\$ (3,769)	\$ 28	\$ 346	\$ (962)	\$ (1,017)	\$ 1,137	\$ (7)
<b>Net Operating Cash Flow</b>	<b>\$ (16,768)</b>	<b>\$ (9,294)</b>	<b>\$ (3,328)</b>	<b>\$ (1,866)</b>	<b>\$ (3,490)</b>	<b>\$ (17,978)</b>	<b>\$ (13,435)</b>	<b>\$ (7,814)</b>	<b>\$ (1,833)</b>	<b>\$ 5,415</b>	<b>\$ 13,845</b>	<b>\$ 15,902</b>
<b>Investing Activities</b>												
Restricted cash paid on acquisition	\$ (1,266)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Restricted cash acquired on acquisition	\$ 1,143	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Purchase of property and equipment	\$ (39)	\$ (3)	\$ (14)	\$ (10)	\$ 20	\$ (7)	\$ 161	\$ 80	\$ 40	\$ 20	\$ 10	\$ 5
Purchase of intangible assets	\$ (147)	\$ (12)	\$ (40)	\$ (26)	\$ (100)	\$ (178)	\$ (275)	\$ (247)	\$ (223)	\$ (200)	\$ (180)	\$ (162)
<b>Net Investing Cash Flow</b>	<b>\$ (309)</b>	<b>\$ (15)</b>	<b>\$ (54)</b>	<b>\$ (36)</b>	<b>\$ (80)</b>	<b>\$ (185)</b>	<b>\$ (114)</b>	<b>\$ (167)</b>	<b>\$ (182)</b>	<b>\$ (180)</b>	<b>\$ (170)</b>	<b>\$ (157)</b>
<b>Financing Activities</b>												
Issuance of common stock	\$ 8	\$ 12,410	\$ (4)	\$ -	\$ 1	\$ 12,407	\$ 40,000	\$ 4	\$ 4	\$ 4	\$ 4	\$ 4
Proceeds from sale of property and equipment	\$ 149	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Issuance of long term debt	\$ -	\$ -	\$ -	\$ 12,000	\$ -	\$ 12,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Financing fees	\$ -	\$ -	\$ -	\$ (893)	\$ -	\$ (893)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Payment of deferred consideration	\$ -	\$ -	\$ -	\$ (723)	\$ -	\$ (723)	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (973)	\$ -
Repayment of long term debt	\$ (13,000)	\$ (871)	\$ (728)	\$ -	\$ (700)	\$ (2,299)	\$ (2,800)	\$ (2,800)	\$ (2,800)	\$ (2,214)	\$ -	\$ -
<b>Net Financing Cash Flow</b>	<b>\$ (12,843)</b>	<b>\$ 11,539</b>	<b>\$ (732)</b>	<b>\$ 10,384</b>	<b>\$ (699)</b>	<b>\$ 20,492</b>	<b>\$ 36,200</b>	<b>\$ (3,796)</b>	<b>\$ (3,796)</b>	<b>\$ (3,210)</b>	<b>\$ (969)</b>	<b>\$ 4</b>
<b>Effect of foreign exchange rate</b>	<b>\$ (99)</b>	<b>\$ 22</b>	<b>\$ 231</b>	<b>\$ (253)</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
Net Change in Cash	\$ (30,019)	\$ 2,252	\$ (3,883)	\$ 8,229	\$ (4,269)	\$ 2,329	\$ 22,651	\$ (11,777)	\$ (5,811)	\$ 2,025	\$ 12,706	\$ 15,749
Cash, beginning of period	\$ 41,003	\$ 10,984	\$ 13,236	\$ 9,353	\$ 17,582	\$ 10,984	\$ 13,313	\$ 35,963	\$ 24,186	\$ 18,375	\$ 20,400	\$ 33,106
Cash, end of period	\$ 10,984	\$ 13,236	\$ 9,353	\$ 17,582	\$ 13,313	\$ 13,313	\$ 35,963	\$ 24,186	\$ 18,375	\$ 20,400	\$ 33,106	\$ 48,855

Concordia Healthcare Corp. (TSX: CXR, OTCQX: CHEHF, C\$43.42)

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 David Martin PhD, MBA  
 Analyst  
 416-642-8865  
 dmartin@bloomburton.com

## Research Initiation - Plug and Play

Initiating coverage of Concordia Healthcare Corp. (TSX: CXR) with a target price of C\$49.50, and a rating of ACCUMULATE (AVERAGE risk). Concordia is a new (founded in December 2012, public in December 2013) integrated specialty pharmaceutical company based in Canada, with multiple divisions operating in the United States, and Barbados. In the company's short history, five acquisitions of products and companies have taken Concordia's revenues from \$0 to a forecast \$119 million in 2014 and \$208 million in 2015, assuming acquisition of new product(s) adding \$50 million to sales next year.

### Highlights

Concordia is highly profitable, needing only a small sales force since most of its products are mature with stable sales, and the majority of the company's earnings are taxed in Barbados at a low single digit rate. Concordia has also been able take very aggressive price increases for some of its products. Bloom Burton's forecasts for cash flow from operations are \$22 million (2014) and \$88 million (2015).

With this structure and strategy, the company has been agnostic to clinical specialization, being able to extract additional value from mature drugs beyond that possible by pharma domiciled in higher tax jurisdictions. Effectively, Concordia can "Plug and Play" when it finds drugs for sale that meet its criteria.

In addition to its mature (legacy) products, the company also operates an orphan drug division which includes Photofrin, and a distribution/mail-order pharmacy division which can be leveraged synergistically with Concordia's drug divisions. Growth of Photofrin is being fueled by clinical trials for new indications (cholangiocarcinoma and mesothelioma), which have the added benefit of expanding the small existing user base for current indications (lung cancer, esophageal cancer and Barrett's esophagus).

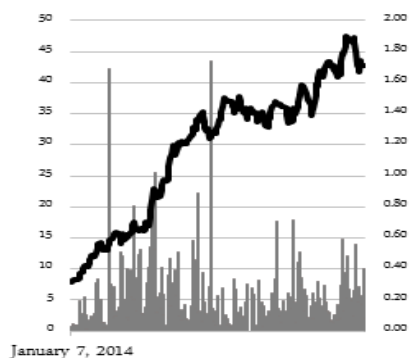
Our C\$49.50 12-month price target for CXR stock is based on the average of two valuation methodologies: 1) discounted cash flow (C\$46.15 per share; 10% discount rate; 0% terminal growth); 2) applying a 15x multiple to our 2016 adjusted EPS estimate of US\$3.04 per share (C\$52.91). Our forecasts assume acquisition of new product(s) that will add US\$50 million to 2015 revenues (paying 4x revenues and funded 50:50, equity:debt). If management executes a product acquisition matching these metrics, we would lower the discount rate to 8.7% (Concordia's WACC), and increase the P/E multiple to 16x which would increase the valuation to C\$55.00 per share. Without the assumed acquisition, the DCF value would be \$41.00 (8.7% discount rate; 0% terminal growth). Each incremental US\$10 million added to revenues impacts our valuation by approximately C\$2.80 per share.

Concordia represents a solid roll-up platform based on management's proven record of execution and the Barbados tax arbitrage opportunity. That said, CXR stock is trading at a level that we believe partially prices-in the company's next anticipated acquisition, and the return to our target price warrants an ACCUMULATE rating (AVERAGE risk) at current levels. The key risks near term are failure to execute an acquisition, and pushback by patients and payers to the aggressive price increases implement by Concordia.

Rating:	ACCUMULATE
Risk:	Average
12 month Price Target	C\$49.50

Price	C\$43.42
Implied Return	14.0%
Fiscal Year End	31-Dec
52 Week Range	C\$7.80-\$49.00
Shares Outstanding (MM)	28.86
Market Cap. (MM)	C\$1,253.1
Float (MM Shares)	14.20
Book Value/Share (latest Qtr. end)	C\$1.025
Avg. Daily Volume (MM)	0.22

	2013A	2014E	2015E	2016E
Revenues (MM)	\$40.45	\$119.13	\$207.64	\$211.36
EBITDA (MM)	\$14.00	\$43.39	\$110.04	\$111.56
EPS	\$0.38	\$0.77	\$2.27	\$2.80
EPS (adjusted)	\$1.86	\$1.58	\$2.91	\$3.04
	Q1A	Q2A	Q3A	Q4E
EPS -BASIC				
2013A	NA	NA	NA	0.38
2014E	(\$0.09)	(\$0.03)	\$0.37	\$0.57



This report is priced as of prior trading day's market close.  
 All values in US\$ unless otherwise noted.



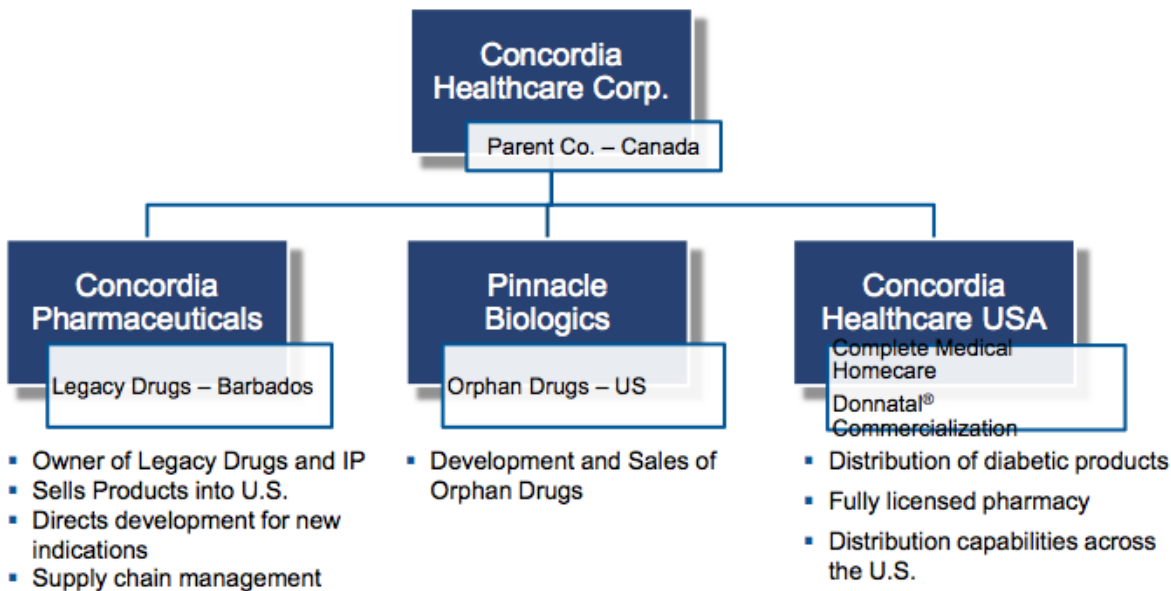
## Company Overview

Concordia Healthcare Corp. is a new, integrated specialty pharmaceutical company based in Canada, with multiple divisions operating in the United States, and Barbados. Founded in December 2012, the company, in December 2013, completed a “three-cornered” amalgamation with Mercari Acquisition Corp., a capital pool company, and Mercari SubCo Inc., a wholly-owned subsidiary of Mercari. Post-amalgamation, Concordia shareholders held 98.5% of the corporation. Mercari’s shares were delisted from the NEX board of the TSX Venture Exchange and Concordia was listed on the TSX under ticker “CXR”. Concordia’s shares were also listed on the OCTQX in the U.S under ticker “CHEHF” in January 2014.

Concordia management, led by President and CEO, Mark Thompson, has a deep history of building and operating specialty pharmaceutical companies, and has set a torrid pace in building Concordia to its current market capitalization of C\$1.2 billion. Concordia’s growth strategy has three main pillars: 1) acquiring existing legacy products with stable prescription demand; 2) developing new indications for legacy drugs (mainly qualified for orphan drug designations); and 3) expanding the Specialty Healthcare Division to support customer acquisition and the company’s growing portfolio.

The Corporation has three wholly-owned subsidiaries: 1) Concordia Pharmaceuticals Inc., a Barbados corporation; 2) Pinnacle Biologics, the orphan drug division, and 3) Concordia Healthcare (USA) Inc., a Delaware corporation (Exhibit 1).

Exhibit 1 Organizational Chart



Source: Company reports

The Legacy Pharmaceuticals division sells Donnatal, Kapvay, Orapred, Ulesfia and Zonegran. Pinnacle Biologics sells Photofrin for the treatment of lung cancer, esophageal cancer and Barrett’s esophagus, and is developing the drug for new indications. Concordia Healthcare USA includes businesses that distribute healthcare products including diabetic testing supplies, shoes, orthotic braces and other home medical equipment in the United States, as well as operating an online pharmacy.

Concordia has been built through acquisitions of products and companies. Exhibit 2 summarizes Concordia’s acquisition and financing transactions since its inception.



## Exhibit 2 Acquisitions and Financings

Date	Acquisition	Deal Amount	2015E sales	P/S (2015E)
May-13	Kapvay, Ulesfia, and Orapred from Shionogi	\$28.7M: \$27.9M cash (incl. \$2.3M inventory) + \$0.8M contingent	\$30.1M	1.0
Oct-13	SHD businesses from Global Medical Direct	\$13.2M: \$5M cash + \$5.6M vendor note + \$2.6M earn-out (shares)	\$18.8M	0.7
Dec-13	Pinnacle Biologics Inc. (Photofrin)	\$58.0M: \$32.7M cash + \$5M shares + \$20.3M delayed payments	\$12.8M	4.5
May-14	Donnatal from Revive Pharmaceuticals	\$265.3M: \$200M cash + 4,605,833 shares	\$75.6M	3.5
Sep-14	Zonegran from Eisai Inc.	\$91.5M cash (incl. \$1.5 inventory)	\$20.4M	4.5
Total		\$520.6M: \$357.1M upfront cash; \$26.7M delayed cash; \$136.8M shares		

Date	Financing	Proceeds
May-13	Senior loan @12% maturing in Oct-2015	\$19.0M
May-13	Subordinate loan @ 18% maturing in Oct-2015	\$5.15M
May-13	Private placement - 6M shares @\$1.00/share	\$6.0 M
Aug-13	Private placement - 1.67M shares @ \$3.00/share	\$3.5M
Dec-13	Private placement - 5.52M shares @ \$6.25/ share	\$34.5M
Mar-14	Bought deal of 5.75M of shares @\$11.75	Net proceeds of \$63.51M
May-14	Secured credit facility (\$170M of loan+ \$25M of operating line) at Prime/LIBOR + applicable margins, maturing in May-2019	Up to \$195M
May-14	Incremental senior credit facility (Term Loan)	Up to \$95M
Total		Up to \$421.66M

Source: Company reports, Bloom Burton & Co. estimates

The company's acquisitions have been highly accretive, and the corporate structure and strategy are optimized to extract value. For example:

- Through its Barbados domiciled subsidiary, a majority of Concordia's earnings can be taxed at the corporate rate of ~2.5%, and because of a tax treaty between Canada and Barbados, proceeds can be repatriated in the form of dividends with no further taxation.
- With robust cash flow, the company has been able to pay down earlier, high interest debt, and use lower rate facilities to finance its largest acquisition to-date, Donnatal. Overall, the company's cost of capital is attractive as a result, at 8.7%.
- Unique levers for growth have been exploited for some of Concordia's products. For example: pricing of Donnatal has been increased dramatically as competitors have exited the market; and Photofrin clinical trials in cholangiocarcinoma and mesothelioma are being used to expand the current small user base and grow sales in existing indications: non-small cell lung cancer, esophageal cancer and Barrett's esophagus.
- Synergy exists between Concordia's drug selling and drug distributing segments which will allow the corporation to capture more of the value chain.

Sales teams totaling about 100 part- and full-time representatives currently focus mainly on sales of Donnatal and Photofrin. While the company has to-date been opportunistic and not specialization-focused regarding the assets it has assembled, we believe there is potential for specialization going forward - for example, possibly in gastrointestinal disease, based on the company's current flagship product, Donnatal - which would allow Concordia to increase utilization of its salesforce.

Concordia's products generally have low to moderate generic risk either because generics are not expected or because generics have been on the market for years, and sales of the branded product have stabilized. Some of the company's products may be exposed to potential new generic competitors in the future, however, we believe we have captured this risk in our financial forecasting, with growth and cash flow expected to be strong, regardless.

Concordia has 28.9 million common shares outstanding (basic), and 1.5 million dilutive stock options and agent warrants. The cash position at September 30, 2014 was \$30.9 million, and the company had long term debt and notes payable of \$263.4 million. The company pays an annual dividend of \$0.30, distributed quarterly, and the largest shareholders include management and board (approximately 25%), AEGON Capital Management, Fidelity, Fiera Capital, Janus Capital Management, Pyramis Global Advisors,





and Visium Asset Management.

## Concordia Product Portfolio

### Concordia Pharmaceuticals - Legacy Pharmaceuticals Division

The Legacy Pharmaceuticals Division focuses on the management and acquisition of legacy pharmaceutical products, both with patent life and exclusivity remaining (pre-legacy) and products that have reached full maturity but continue on a predictable revenue path, collectively referred to as legacy pharmaceutical products. Regardless of stage of the life cycle, the targeted products have a well-established record of safety and efficacy and a history of stable, predictable prescription demand.

**Product:** Donnatal (phenobarbital and belladonna alkaloids - hyoscyamine, atropine and scopolamine)

**Indication:** Donnatal has antispasmodic and sedative effects, and was first allowed on the market in the 1940's on the basis of safety alone. The product has not been formally approved by the modern FDA which classifies the drug as "possibly effective" as an adjunctive therapy in the treatment of irritable bowel syndrome ("IBS" - irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

**Vendor:** Revive Pharmaceuticals

**Acquired/licensed:** Concordia acquired worldwide rights in May 2014

**Market:** Sales of drugs to treat IBS exceeded US\$1.2 billion in 2013, with a CAGR of 35% over the last five year. IBS has become one of the most common diseases second to cold in terms of the prevalence in the general population. IBS occurs as one of two types: IBS diarrhea and IBS constipation. The leading branded drugs for treatment include Amitiza (chloride channel activator; Sucampo Pharmaceuticals) and Linzess (guanylate cyclase-C agonist; Forest Laboratories) for treatment of IBS constipation, and Lotronex (5-HT3 antagonist; GSK), and Donnatal for treatment of IBS diarrhea. Xifaxan (antibiotic; Salix Pharmaceuticals) is used off-label to treat bacterial overgrowth in IBS patients.

**Differentiation:** Donnatal is the only remaining phenobarbital belladonna combination product on the market; has been prescribed for decades; and is generally considered effective and safe.

**Historical Sales:** In 2013, Donnatal U.S. wholesale sales were approximately \$51 million (183,000 scripts; ~\$280/script - Source: Symphony/Bloomberg). Wholesale sales in 2012 were approximately \$15 million (90,000 scripts; ~\$165/script); and in 2011, \$5 million (80,000 scripts; ~\$65/script). The rapid growth in prescriptions, pricing, and sales have been driven by removal of knockoff products from the market. In mid-2012, the FDA advised all manufacturers of anticholinergic/barbiturate combination products that it may require sponsors to participate in a hearing regarding possible clinical trials to demonstrate efficacy of the products. As a result, >15 manufacturers withdrew their products from the market, leaving only Donnatal. Scripts of Donnatal peaked in October 2013 at approximately 17,000, declining to 12,400 by October 2014.

**Outlook:** We assume price increases will moderate going forward. With sales force promotion focused on privately insured patients, we believe the rate of decline of scripts will likely slow. Donnatal scripts are currently about 12,400/month (148,800 run rate), and we expect this to drop by 15%, to an annual script total of 126,480 in 2015. Beyond 2016, we forecast that the rate of decline of scripts decreases with growth resuming by 2018. Because competing knockoff products have been removed from the market, we believe that Concordia uses minimal discounting and rebating (10% of gross sales). Our forecasts for Donnatal sales are shown in Exhibit 3.





## Exhibit 3. Donnatal Forecasts

	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Scripts (annual)	170,000						
Scripts (post-acquisition)	97,000	126,480 30%	107,508 -15%	107,508 0%	108,583 1%	111,841 3%	117,433 5%
Price/script (average)	\$ 429.41						
Price/script (average; post-acquisition)	\$ 577.32	\$ 663.92 15%	\$ 730.31 10%	\$ 796.04 9%	\$ 859.72 8%	\$ 919.90 7%	\$ 975.09 6%
Sales (\$000, gross)	\$ 73,000						
Sales (\$000, gross; post-acquisition)	\$ 56,000	\$ 83,972	\$ 78,514	\$ 85,580	\$ 93,351	\$ 102,882	\$ 114,508
Deductions	\$ 7,300						
Deductions (post-acquisition)	\$ 5,600	\$ 8,397	\$ 7,851	\$ 8,558	\$ 9,335	\$ 10,288	\$ 11,451
Sales (\$000, net)	\$ 65,700						
Sales (\$000, net; post-acquisition)	\$ 50,400	\$ 75,575	\$ 70,663	\$ 77,022	\$ 84,016	\$ 92,594	\$ 103,057

Source: Company reports; Symphony/Bloomberg; Bloom Burton & Co. estimates

Risks: Donnatal's "not approved" status creates some uncertainty, but we do not believe there is a material risk that the product will be removed from the market in the near-term. More likely, the FDA may request a clinical efficacy study(ies). Donnatal contributes \$28 to our target price, and the drug's removal from the market if efficacy studies fail, would therefore be material based on Concordia's current product portfolio.

While Donnatal enjoyed a rapid ramp in prescriptions between mid-2012 and late-2013 as knockoffs came off the market, scripts gradually declined during the first 9 months of 2014. During the same period, there has been a large drop in the overall number of patients treated with phenobarbital belladonna combination therapy (700,000 scripts/year in 2011 to 95,000 scripts in H1-2014), indicating that patients are being treated with other options - likely other antispasmodic drugs including Bentyl, Levsin, Anaspaz, or their generics and/or other anti-diarrhea drugs including Imodium, Lomotil, or their generics. With other options available, the quadrupling of Donnatal pricing since 2012 (including a 100% price increase this summer) may cause further patient and payor push-back, and further encourage migration of the user base to potentially less effective, but cheaper drugs. Our model assumes a reduced rate of erosion going forward, therefore, the risk to our valuation would be a sharp decline. Furthermore, we note that a number of competing IBS drugs have taken large price increases in the last 2-3 years, which helps to distract the payers' focus on Donnatal.

Product: Kapvay (Clonidine Hydrochloride Extended Release tablets)

Indication: Used alone or in combination with stimulant therapy for the treatment of attention deficit hyperactivity disorder (ADHD). Clonidine agonizes alpha2-adrenergic receptors in the brain.

Vendor: Shionogi Inc.

Acquired/licensed: acquired worldwide rights in May 2013

Market: ADHD affects between 5% and 7% of children and adolescents worldwide (<18 years old) and about 11% of school-age children in the U.S. The total market is \$9.7 billion, but this is dominated by stimulant drugs. Kapvay is competing in the non-stimulant ADHD drug market (~\$1.5 billion) with Strattera (Eli Lilly) and Intuniv (Shire).

Differentiation: First approved non-stimulant ADHD drug and less costly than main competing drugs.

Historical Sales: In 2013, U.S. Kapvay sales reached \$73 million (wholesale), up from \$50 million in 2012. In October 2013, Par Pharmaceuticals launched a generic to Kapvay, and quickly took 90% of the market based on scripts. Concordia disclosed that it has entered into a Supply Price Agreement with a generic manufacturer (which we believe is Par), for which Concordia receives a supply price payment (which we



believe is 30%-35% of sales). In H1-2014, wholesale sales of Kapvay were approximately \$12.6 million, and the drug is on track to sell \$20-\$21 million in 2014.

Outlook: Following the steep drop in Kapvay sales in late-2013/early-2014, the rate of decline of scripts has slowed in recent months in the range of about 3,000 per month (\$1.2 million, wholesale; ~\$400/script). We forecast 32,400 scripts for 2015 (3,000 annualized; 10% decline) followed by moderating decreases in subsequent years. Since generics are on the market, we expect Concordia to aggressively discount and rebate Kapvay (50%). In addition, we forecast that Concordia will receive \$11 million from sales of generic Kapvay. Our forecasts for revenues from Kapvay are shown in Exhibit 4.

Exhibit 4. Kapvay Forecasts

	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Scripts	58,600	32,400	29,160	27,702	26,317	25,001	23,751
		-45%	-10%	-5%	-5%	-5%	-5%
Price/script (average)	\$ 349.83	\$ 420.00	\$ 462.00	\$ 503.58	\$ 543.87	\$ 581.94	\$ 616.85
		20%	10%	9%	8%	7%	6%
Sales (\$000, gross)	\$ 20,500	\$ 13,608	\$ 13,472	\$ 13,950	\$ 14,313	\$ 14,549	\$ 14,651
Deductions	\$ 9,225	\$ 6,124	\$ 6,062	\$ 6,335	\$ 6,560	\$ 6,731	\$ 6,842
Sales (\$000, net)	\$ 11,275	\$ 7,484	\$ 7,410	\$ 7,743	\$ 8,018	\$ 8,226	\$ 8,362
Share of generic revenues (\$000)	\$ 11,000	\$ 11,330	\$ 11,670	\$ 12,020	\$ 12,381	\$ 12,752	\$ 13,135
Total Kapvay revenues (\$000)	\$ 22,275	\$ 18,814	\$ 19,079	\$ 19,763	\$ 20,398	\$ 20,978	\$ 21,497

Source: Company reports; Symphony/Bloomberg; Bloom Burton & Co. estimates

Risks: Our model does not assume market entry of another generic. We believe this is a low to moderate risk given the relatively small size of the market post the launch of Par’s generic.

Product: ZONEGRAN (Zonisamide)

Indication: Adjunctive therapy to treat partial seizure in the patients with epilepsy.

Vendor: Eisai Inc.

Acquired/licensed: acquired US rights (including Puerto Rico) in September 2014.

Market: ZONEGRAN was first approved by the U.S. Food and Drug Administration in March 2000. The key patent expired in 2006 and the drug has faced generic competition since then. Stable market share has been established for years.

Differentiation: ZONEGRAN is a sodium channel blocker, which is a very effective seizure-reducing agent with well characterized mechanism of action. It has longer half-life (~60h) than previously approved anti-epilepsy drugs with similar molecular target (e.g. Oxcarbazepine with half-life between 2h and 9h), and it might have better patient compliance.

Historical sales: U.S. wholesale sales of ZONEGRAN were \$30.1 million (49,200 scripts; ~\$610/script) in 2013. Scripts have been declining about 10% per year since 2009. Shortly after acquiring the drug in September, it appears that Concordia has raised the price of the drug ~50% without having an immediate negative impact on the script trajectory.

Outlook: Our forecasts for revenues from ZONEGRAN are shown in Exhibit 5. Following what we believe was a 50% price increase in October, we forecast that scripts will decrease by 20% in 2015, followed by a return to 10% and lower rates of decline thereafter. Deductions from gross sales are forecast at 40% based on the aggressive pricing.



## Exhibit 5. Zonegran Forecasts

	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Scripts (annual)	45,000						
Scripts (post-acquisition)	10,950	36,000 -20%	32,400 -10%	30,780 -5%	29,241 -5%	27,779 -5%	26,390 -5%
Price/script (average)	\$ 600.00						
Price/script (average; post-acquisition)	\$ 900.00	\$ 945.00 5%	\$ 1,039.50 10%	\$ 1,133.06 9%	\$ 1,223.70 8%	\$ 1,309.36 7%	\$ 1,387.92 6%
Sales (\$000, gross)	\$ 27,000						
Sales (\$000, gross; post-acquisition)	\$ 9,855	\$ 34,020	\$ 33,680	\$ 34,875	\$ 35,782	\$ 36,373	\$ 36,627
Deductions	\$ 8,100						
Deductions (post-acquisition)	\$ 3,942	\$ 13,608	\$ 13,472	\$ 13,950	\$ 14,313	\$ 14,549	\$ 14,651
Sales (\$000, net)	\$ 18,900						
Sales (\$000, net; post-acquisition)	\$ 5,913	\$ 20,412	\$ 20,208	\$ 20,925	\$ 21,469	\$ 21,824	\$ 21,976

Source: Company reports; Symphony/Bloomberg; Bloom Burton & Co. estimates

Risks: Since Zonegran has been fairly stable competing against multiple generics for nearly a decade, the key risk for this product is patient and payor reaction to Concordia's aggressive pricing strategy.

Product: Ulesfia (5% benzyl alcohol lotion)

Indication: Head Lice

Vendor: Shionogi Inc.

Acquired/licensed: acquired worldwide rights in May 2013

Market: The CDC estimates that 6-12 million people get head lice each year in the United States. The vast majority of cases (85%) are treated with over the counter agents. Prescription drugs are used when patients fail to respond to OTC products. At the time that Concordia acquired the product, its market share of prescription sales was approximately 31%, and it was the second largest prescription product based on unit volume. Other prescription products include Stromectol (Merck), Lindane (Morton Grove) and Ovide (Valeant). In January 2014, Concordia entered into an exclusive distribution agreement for Ulesfia with Lachlan Pharma Holdings who has partnered with Zylera Pharmaceuticals to market Ulesfia in the United States. Approved by FDA in 2009, patents of Ulesfia expire in 2017, 2022, and 2024.

Differentiation: Ulesfia is the only prescription head lice product that is not an insecticide. It would be difficult for competitors to genericize a topical drug such as Ulesfia.

Historical sales: 2013 sales of Ulesfia were \$18.6 million (wholesale) in the United States (135,000 scripts; \$138 per script).

Outlook: Script levels have remained relatively constant in 2014 despite a price increase to approximately \$290 per script. We are forecasting a 10% decrease in script in 2015 due to the price increase, then a resumption of low growth in later years. Because the market is competitive, we assume heavy discounting, and we model 30% of net sales paid to Lachlan/Zylera. Our forecasts for Ulesfia are shown in Exhibit 6.



## Exhibit 6. Ulesfia Forecasts

	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Scripts	122,900	110,610	112,822	115,079	117,380	119,728	122,122
		-10%	2%	2%	2%	2%	2%
Price/script (average)	\$ 240.03	\$ 336.05	\$ 369.65	\$ 402.92	\$ 435.15	\$ 465.61	\$ 493.55
		40%	10%	9%	8%	7%	6%
Sales (\$000, gross)	\$ 29,500	\$ 37,170	\$ 41,705	\$ 46,367	\$ 51,078	\$ 55,747	\$ 60,273
Deductions	\$ 20,650	\$ 26,019	\$ 29,193	\$ 32,457	\$ 35,755	\$ 39,023	\$ 42,191
Sales (\$000, net)	\$ 8,850	\$ 11,151	\$ 12,511	\$ 13,910	\$ 15,323	\$ 16,724	\$ 18,082
Paid to Lachlan/Zylera (\$000)	\$ 2,655	\$ 3,345	\$ 3,753	\$ 4,173	\$ 4,597	\$ 5,017	\$ 5,425
Total Ulesfia revenues (\$000)	\$ 6,195	\$ 7,806	\$ 8,758	\$ 9,737	\$ 10,726	\$ 11,707	\$ 12,657

Source: Company reports; Symphony/Bloomberg; Bloom Burton & Co. estimates

Risks: Since Ulesfia has been fairly stable competing against multiple less expensive OTC and Rx competitors for multiple years, the key risk for this product is patient and payer reaction to Concordia's aggressive pricing strategy. Generic risk increases in the 2017-2018 timeframe, however, there is currently no clear regulatory path for topical lotions.

Product: Orapred (prednisolone sodium phosphate)

Indication: anti-inflammatory corticosteroid for treatment of pediatric asthma, severe atopic dermatitis, and allergic rhinitis.

Vendor: Shionogi Inc.

Acquired/licensed: acquired worldwide rights in May 2013

Market: Asthma affects 7 million children in the United States. Many oral corticosteroids for treating asthma are off-patent (dexamethasone, hydrocortisone, prednisolone etc.). Despite this, Orapred ODT held 4% of the prednisolone market at the time the drug was acquired by Concordia. Orapred oral solution (OS) was approved in 2000 by FDA; Orapred orally disintegrating tablets (ODT) were approved in 2006. Patents for the ODT formulation begin to expire in 2018. Prior to the acquisition of Orapred by Concordia, Shionogi had entered into a paragraph IV settlement with Mylan Inc. (NASDAQ: MYL, unrated) which would allow for launch of a generic Orapred ODT in April 2014. Concordia intends to implement an authorized generic strategy for Orapred ODT in response.

Differentiation: unique taste-masking technology, which uses a tri-layer process that encapsulates the bitter tasted prednisolone inside the tablet, improves pediatric patients' compliance.

Historical sales: in 2013, sales of Orapred and Orapred ODT were \$24.1M (wholesale; scripts 195,000; \$123/script), representing a decrease of about 20% compared with 2012.

Outlook: Scripts are tracking to about 120,000 in 2014, impacted by higher pricing. Going forward, we are modelling a 40% script decrease in 2015 reflecting a possible Mylan generic launch. Thereafter, we forecast moderating annual script decreases and 5%-10% annual price increases. Our forecasts for this product are shown in Exhibit 7.



## Exhibit 7. Orapred Forecasts

	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Scripts	120,000	72,000	57,600	51,840	49,248	46,786	44,446
		-40%	-20%	-10%	-5%	-5%	-5%
Price/script (average)	\$ 145.83	\$ 160.42	\$ 176.46	\$ 185.28	\$ 194.55	\$ 204.27	\$ 214.49
		10%	10%	5%	5%	5%	5%
Sales (\$000, gross)	\$ 17,500	\$ 11,550	\$ 10,164	\$ 9,605	\$ 9,581	\$ 9,557	\$ 9,533
Deductions	\$ 12,250	\$ 8,085	\$ 7,115	\$ 6,723	\$ 6,707	\$ 6,690	\$ 6,673
Sales (\$000, net)	\$ 5,250	\$ 3,465	\$ 3,049	\$ 2,881	\$ 2,874	\$ 2,867	\$ 2,860

Source: Company reports; Symphony/Bloomberg; Bloom Burton & Co. estimates

Risks: Mylan may launch its generic at any time. We reflect this risk in our model, forecasting a 40% drop in scripts in 2015.

## Pinnacle Biologics – Orphan Drugs Division

The Orphan Drugs Division is intended to provide growth opportunities through the expansion into new indications for existing products or the acquisition of approved orphan drugs and further expansion within their identified markets and new indications.

**Product:** Photofrin (Porfimer sodium) Photofrin is a photosensitive agent activated by laser light and targets selectively tumor tissues when injected – a process called photodynamic therapy (PDT).

**Indications:** Photofrin is approved for treatment of patients with esophageal cancer, non-small cell lung cancer (NSCLC), and high-grade dysplasia in Barrett’s esophagus. Concordia has initiated clinical trials for new indications including cholangiocarcinoma, a rare cancer of the bile duct (phase 3; open label, randomized – 200 patients; primary endpoint survival; expected time to completion 5 years; interim analysis at 45 deaths); and adjuvant to surgery in the treatment of malignant pleural mesothelioma, an asbestos-related lung cancer (phase 2; open label, randomized – 100 patients; expected time to completion 4 years).

**Vendor:** Pinnacle Biologics Inc.

**Acquired/licensed:** acquired worldwide rights excluding Canada for Photofrin with the acquisition of Pinnacle Biologics Inc. in December, 2013

**Market:** According to the National Cancer Institute, the U.S. incidence for NSCLC is 224,000 of which we estimate approximately 5% (10,000) are unresectable due to bulky disease. Incidence of esophageal cancer is 18,000, of which we estimate about 50% (9,000) of cases are unresectable. U.S. incidence of Barrett’s esophagus is approximately 10,000 (although it is estimated that 2 million people live with the condition) – taking the total addressable market in the United States to 29,000, with about the same number of eligible patients in industrialized ex-U.S. markets. Photofrin currently has very low penetration in its approved markets, selling approximately 550 vials (\$10.1 million) in the United States in 2013 - representing 26-270 patients, depending on number of treatment sessions (typically 1-7) and number of vials/treatment (typically 2-3). This is due to availability of other options, particularly for Barrett’s (surgery, mucosal resection, cryoablation, laser ablation, RF ablation, argon plasma photocoagulation), the fact that few doctors are trained to use the activating lasers, photosensitivity of patients, cost and size of the lasers, effects of PDT may not last long so procedures might need to be repeated, and sometimes the therapy does not remove all of a tumor in one treatment, so treatments may need to be repeated.

Regarding the new indications, we believe the potential for Photofrin in palliation of unresectable bile duct cancer (cholangiocarcinoma) is more attractive, with limited options currently available.





Additionally, a number of groups have reported generally supportive data in a number of small PDT studies (reviewed in Gao et al. 2010 J. Hepatobiliary Pancreat Sci 17:125). For example, Kahaleh et al. reported that 12-month mortality was 56% among patients treated with stenting and PDT vs 82% among patients who received stenting alone (2008 Clin Gastroenterol Hepatol 6:290). Cholangiocarcinoma is a rare cancer (about 4,400 patients per year in the U.S.), of which about 2,000 are surgically unresectable. If we assume that 10 vials are used on average for each patient (2-7 treatments; 2-3 vials per treatment), the U.S. market opportunity for cholangiocarcinoma is approximately \$380 million.

According to the National Cancer Institute, approximately 3,000 new cases of mesothelioma are diagnosed each year. However, prior studies of PDT in this indication have demonstrated mixed results and less benefit than in cholangiocarcinoma (Pass et al., 1997 Annals Surg Oncol 4:628), and we view this study as a lower probability opportunity.

Differentiation: Photofrin is suitable for patients for whom surgery or radiotherapy is not indicated. In a review of 20 clinical trials, Gao et al. concluded that PDT was a safe and effective treatment for patients with unresectable cholangiocarcinoma (2010 J. Hepatobiliary Pancreat Sci. 17:125).

Historical sales: U.S. Sales of Photofrin were about US\$10M in 2013.

Outlook: Sales in the U.S. are tracking at about \$7.6 million in 2014, impacted by customer destocking in the second quarter. We estimate that an additional \$3 million will be realized from international sales.

In our opinion, the two clinical trials underway serve two purposes: they provide paths to approvals for the new indications, and they introduce more hospitals and surgeons to Photofrin therapy - management estimates that there are currently 15 key users of Photofrin in the United States, and we expect that this will increase by at least 50% as a result of the clinical program. With more physicians trained, and with more hospitals equipped with lasers, we expect that use of Photofrin for existing indications can experience renewed growth. As a result, we are forecasting 15% growth of Photofrin procedures for the next 3 years, followed by 10% growth until 2020, when we expect that Photofrin may be approved for cholangiocarcinoma. Concordia recently announced that it had entered into an exclusive product distribution agreement with Union Med. Limited for the clinically develop (if necessary), regulatory approval, distribution, marketing and selling of Photofrin throughout China, Hong Kong, Macau and Taiwan. Exhibit 8 contains our forecasts for Photofrin.

Exhibit 8. Photofrin Forecast

	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Scripts	570	655	754	867	953	1,049	1,300
		15%	15%	15%	10%	10%	24%
Price/script (average)	\$ 18,603	\$ 19,533	\$ 20,510	\$ 21,535	\$ 22,612	\$ 23,743	\$ 24,930
		5%	5%	5%	5%	5%	5%
Sales (\$000, gross)	\$ 10,600	\$ 12,800	\$ 15,455	\$ 18,662	\$ 21,555	\$ 24,896	\$ 32,409

Source: Company reports; Symphony/Bloomberg; Bloom Burton estimates

Risks: The clinical trials represent the key risks for Photofrin. We believe risk is low-to-moderate for the cholangiocarcinoma indication, and moderate-to-high in the mesothelioma indication. Because Photofrin therapy involves a drug-device combination, we believe the generic risk is low, at present, although patents on the drug have expired.

Concordia Healthcare USA - Specialty Healthcare Distribution (SHD)

Concordia Healthcare USA is a national internet and mail-order provider of diabetes testing supplies, pharmaceuticals, diabetic shoes, orthotic braces and other home medical equipment. The business is located in Lanexa Kansas, was acquired in October 2013, with an effective date of August 1, 2013. It



Prior to Concordia’s acquisition of the business of the SHD Division, Global Medical Direct and Midwest Medical Services (the predecessor companies to the Concordia SHD Division) in 2012 were investigated by the U.S. Department of Justice and the U.S. Attorney’s Offices for the Districts of Louisiana and Kansas under the anti-kickback statute and for submitting false claims for diabetic supplies. The company’s owners have settled the case, and were mandated to sell the assets of the companies and pay restitution.

On July 1, 2013, CMS implemented the Medicare Bidding Program for diabetes testing supplies. The SHD Division did not apply for a contract under the competitive bidding program, instead electing to focus on private insurance.

The SHD Division has a full-service pharmacy with the ability to fulfill orders across the United States. Concordia intends to develop the specialty pharmacy aspect of the operation, and flow additional pharmaceutical products, including its own proprietary product (potentially including Photofrin) through the SHD Division’s pharmacy.

Historical sales: Sales for the SHD businesses reached \$50 million in 2012.

Outlook: Based on changes related to the DOJ and U.S. Attorney’s investigations, and SHD’s strategic decision to not bid on the Medicare diabetes contract in order to focus on higher profit business, sales through the first 9 months of 2014 are tracking to the range of \$18-\$19 million for this year. Beyond 2014, we are forecasting modest growth of the SHD business. Exhibit 9 shows our forecasts for the SHD Division.

Exhibit 9. Specialty Healthcare Distribution Forecasts

	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Sales	18,400	18,768	19,143	19,526	19,917	20,315	20,721
		2%	2%	2%	2%	2%	2%

Source: Company reports; Bloom Burton estimates

Risks: With the legal investigations related to the previous owners settled, we are not aware of unusual risks for the SHD business outside of normal business execution risk.



## Valuation

Our C\$49.50 12-month price target for CXR stock is based on the average of two valuation methodologies: 1) discounted cash flow (C\$46.15 per share; 10% discount rate; 0% terminal growth); 2) applying a 15x multiple to our 2016 adjusted EPS estimate of US\$3.04 per share (C\$52.91). Exhibit 10 shows trading multiples of similar, acquisition-driven specialty pharmaceutical companies.

### Exhibit 10. Comparable Companies Analysis

Company	Ticker	Price	Market Cap	Enterprise Value	EV/Rev			EV/EBITDA		P/E		Net Debt/EBITDA
					LTM	2014E	2015E	2014E	2015E	2014E	2015E	
Shire	SHPG	\$215.25	\$42,161.0	\$42,543.3	7.4	7.2	6.8	15.4	14.0	20.6	18.9	0.1
Valeant Pharmaceuticals	VRX	\$140.00	\$46,993.8	\$62,421.9	7.8	7.6	6.9	16.0	13.8	16.9	14.0	3.9
Actavis	ACT	\$260.90	\$69,154.2	\$84,353.8	7.2	6.7	5.2	19.7	12.7	19.2	15.6	3.6
Mylan	MYL	\$55.26	\$20,682.2	\$28,443.6	3.8	3.7	3.0	12.2	9.0	15.5	13.6	3.3
Endo International	ENDP	\$69.59	\$10,696.7	\$14,352.8	5.4	5.0	4.5	12.4	11.2	16.4	14.7	3.1
Jazz Pharmaceuticals	JAZZ	\$166.40	\$10,065.5	\$10,830.5	10.0	9.3	7.8	16.4	13.7	20.1	16.5	1.2
<i>Average</i>					6.9	6.6	5.7	15.4	12.4	18.1	15.6	2.5
Concordia Healthcare	CHEHF	\$37.10	\$1,070.8	\$1,296.9	13.5	10.6	7.1	24.5	12.9	34.8	15.6	4.3

Source: Company reports; Bloomberg

Our forecasts assume acquisition of new product(s) that will add US\$50 million to 2015 revenues (paying 4x revenues and funded 50:50, equity:debt). If management executes a product acquisition matching these metrics, we would lower the discount rate to 8.7% (Concordia's WACC), and increase the P/E multiple to 16x which would increase the valuation to C\$55.00 per share. Excluding an acquisition, our DCF value would be \$41.00 (8.7% discount rate; 0% terminal growth). Each incremental US\$10 million added to revenues by acquisition, impacts our valuation by approximately C\$2.80 per share, assuming a similar funding structure and Concordia's current profit margins. With big pharma seemingly in a rush to shed non-strategic assets lately, the environment is currently conducive to product deals for companies like Concordia. We are uncertain how long this will last, and how many more drugs meeting Concordia's criteria will be jettisoned, so our model does not assume additional product acquisitions beyond 2015, aside from incremental M&A to replace revenues lost to genericization and new competing products.

## Financial Forecasts

Balance Sheets (US\$000 except per share data)	2013A	Q1-14A	Q2-14A	Q3-14A	Q4-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Assets</b>												
<b>Current</b>												
Cash	\$ 42,899	\$ 77,973	\$ 32,708	\$ 30,945	\$ 40,654	\$ 40,654	\$ 177,281	\$ 193,306	\$ 199,570	\$ 222,397	\$ 296,477	\$ 439,853
Accounts receivable	\$ 23,012	\$ 10,063	\$ 20,098	\$ 28,942	\$ 31,468	\$ 31,468	\$ 41,528	\$ 42,271	\$ 45,254	\$ 48,319	\$ 51,770	\$ 56,406
Inventory	\$ 4,030	\$ 3,719	\$ 5,001	\$ 6,376	\$ 7,170	\$ 7,170	\$ 10,382	\$ 10,568	\$ 11,313	\$ 12,080	\$ 12,943	\$ 14,102
Prepaid expenses and other	\$ 2,407	\$ 4,444	\$ 7,386	\$ 4,652	\$ 4,652	\$ 4,652	\$ 4,652	\$ 4,652	\$ 4,652	\$ 4,652	\$ 4,652	\$ 4,652
	\$ 72,348	\$ 96,199	\$ 65,193	\$ 70,915	\$ 83,944	\$ 83,944	\$ 233,843	\$ 250,797	\$ 260,789	\$ 287,448	\$ 365,842	\$ 515,012
Fixed assets	\$ 444	\$ 578	\$ 620	\$ 768	\$ 768	\$ 768	\$ 768	\$ 768	\$ 768	\$ 768	\$ 768	\$ 768
Intangible assets	\$ 61,700	\$ 61,120	\$ 60,540	\$ 59,818	\$ 59,818	\$ 59,818	\$ 59,818	\$ 59,818	\$ 59,818	\$ 59,818	\$ 59,818	\$ 59,818
Unallocated purchase price			\$ 327,533	\$ 419,573	\$ 419,573	\$ 419,573	\$ 419,573	\$ 419,573	\$ 419,573	\$ 419,573	\$ 419,573	\$ 419,573
Goodwill	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249	\$ 36,249
<b>Total assets</b>	<b>\$ 170,741</b>	<b>\$ 194,146</b>	<b>\$ 490,135</b>	<b>\$ 587,323</b>	<b>\$ 600,352</b>	<b>\$ 600,352</b>	<b>\$ 750,251</b>	<b>\$ 767,205</b>	<b>\$ 777,197</b>	<b>\$ 803,856</b>	<b>\$ 882,250</b>	<b>\$ 1,031,420</b>
<b>Liabilities</b>												
<b>Current</b>												
Accounts payable	\$ 21,669	\$ 3,422	\$ 18,423	\$ 11,374	\$ 11,678	\$ 11,678	\$ 15,028	\$ 15,477	\$ 16,645	\$ 17,822	\$ 19,148	\$ 21,106
Accrued liabilities	\$ 7,734	\$ 3,358	\$ 3,927	\$ 6,667	\$ 6,667	\$ 6,667	\$ 6,667	\$ 6,667	\$ 6,667	\$ 6,667	\$ 6,667	\$ 6,667
Provisions	\$ 24,208	\$ 26,918	\$ 15,010	\$ 11,910	\$ 11,910	\$ 11,910	\$ 11,910	\$ 11,910	\$ 11,910	\$ 11,910	\$ 11,910	\$ 11,910
Royalties payable	\$ 3,093	\$ 3,755	\$ 2,642	\$ 3,006	\$ 3,006	\$ 3,006	\$ 3,006	\$ 3,006	\$ 3,006	\$ 3,006	\$ 3,006	\$ 3,006
Dividend payable	\$ -	\$ -	\$ 2,138	\$ 2,165	\$ 2,165	\$ 2,165	\$ 2,165	\$ 2,165	\$ 2,165	\$ 2,165	\$ 2,165	\$ 2,165
Taxes payable	\$ 987	\$ 1,182	\$ 2,058	\$ 2,867	\$ 2,867	\$ 2,867	\$ 2,867	\$ 2,867	\$ 2,867	\$ 2,867	\$ 2,867	\$ 2,867
Senior and subordinated debt	\$ 14,966	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Current portion of notes payable	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662	\$ 662
Current portion of long-term debt	\$ -	\$ -	\$ 14,564	\$ 23,918	\$ 23,918	\$ 23,918	\$ 23,918	\$ 23,918	\$ 23,918	\$ 23,918	\$ 23,918	\$ -
Current portion of purchase consideration payable	\$ 2,786	\$ 2,751	\$ 2,271	\$ 2,314	\$ 2,314	\$ 2,314	\$ 2,314	\$ 2,314	\$ 2,314	\$ 2,314	\$ 2,314	\$ 2,314
	\$ 76,105	\$ 42,048	\$ 61,695	\$ 64,883	\$ 65,187	\$ 65,187	\$ 68,537	\$ 68,986	\$ 70,154	\$ 71,331	\$ 48,739	\$ 50,697
Long-term debt			\$ 150,130	\$ 233,128	\$ 228,553	\$ 228,553	\$ 301,254	\$ 224,957	\$ 130,116	\$ 31,826	\$ -	\$ -
Notes payable	\$ 5,104	\$ 5,297	\$ 5,500	\$ 5,690	\$ 5,690	\$ 5,690	\$ 5,028	\$ 4,028	\$ 3,028	\$ 2,028	\$ -	\$ -
Purchase consideration payable	\$ 21,599	\$ 22,277	\$ 22,990	\$ 23,711	\$ 23,711	\$ 23,711	\$ 18,969	\$ 15,175	\$ 12,140	\$ 9,712	\$ 7,770	\$ 6,216
Deferred taxes	\$ 6,391	\$ 6,408	\$ 5,695	\$ 4,902	\$ 4,902	\$ 4,902	\$ 4,902	\$ 4,902	\$ 4,902	\$ 4,902	\$ 4,902	\$ 4,902
Other liabilities	\$ 20	\$ 15	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Total liabilities</b>	<b>\$ 109,219</b>	<b>\$ 76,045</b>	<b>\$ 246,010</b>	<b>\$ 332,314</b>	<b>\$ 328,043</b>	<b>\$ 328,043</b>	<b>\$ 398,690</b>	<b>\$ 318,048</b>	<b>\$ 220,340</b>	<b>\$ 119,799</b>	<b>\$ 61,410</b>	<b>\$ 61,815</b>
<b>Shareholders' Equity</b>												
Share capital	\$ 57,521	\$ 115,511	\$ 245,000	\$ 247,035	\$ 247,035	\$ 247,035	\$ 256,035	\$ 265,035	\$ 274,035	\$ 283,035	\$ 292,035	\$ 301,035
Reserve for share based compensation	\$ 1,555	\$ 1,993	\$ 3,288	\$ 3,938	\$ 5,196	\$ 5,196	\$ 10,228	\$ 15,512	\$ 21,059	\$ 26,885	\$ 33,001	\$ 39,423
Accumulated other comprehensive income	\$ 15	\$ 2	\$ (1)	\$ (172)	\$ (172)	\$ (172)	\$ (172)	\$ (172)	\$ (172)	\$ (172)	\$ (172)	\$ (172)
Retained earnings	\$ 2,431	\$ 595	\$ (4,162)	\$ 4,208	\$ 20,249	\$ 20,249	\$ 85,470	\$ 168,782	\$ 261,934	\$ 374,310	\$ 495,975	\$ 629,319
<b>Total Shareholders' Equity</b>	<b>\$ 61,522</b>	<b>\$ 118,101</b>	<b>\$ 244,125</b>	<b>\$ 255,009</b>	<b>\$ 272,308</b>	<b>\$ 272,308</b>	<b>\$ 351,561</b>	<b>\$ 449,157</b>	<b>\$ 556,857</b>	<b>\$ 684,057</b>	<b>\$ 820,839</b>	<b>\$ 969,605</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 170,741</b>	<b>\$ 194,146</b>	<b>\$ 490,135</b>	<b>\$ 587,323</b>	<b>\$ 600,352</b>	<b>\$ 600,352</b>	<b>\$ 750,251</b>	<b>\$ 767,205</b>	<b>\$ 777,197</b>	<b>\$ 803,856</b>	<b>\$ 882,250</b>	<b>\$ 1,031,420</b>

Income Statements (US\$000 except per	2013A	Q1-14A	Q2-14A	Q3-14A	Q4-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Total Revenue</b>	\$ 40,447	\$ 16,810	\$ 26,053	\$ 36,432	\$ 39,833	\$ 119,128	\$ 207,640	\$ 211,356	\$ 226,268	\$ 241,594	\$ 258,850	\$ 282,030
Growth Y/Y			188%	147%	139%	195%	74%	2%	7%	7%	7%	9%
<b>Total cost of sales</b>	\$ 8,338	\$ 3,854	\$ 4,554	\$ 4,496	\$ 4,671	\$ 17,575	\$ 24,045	\$ 24,763	\$ 26,633	\$ 28,515	\$ 30,637	\$ 33,770
<b>Gross profit</b>	\$ 32,109	\$ 12,956	\$ 21,499	\$ 31,936	\$ 35,162	\$ 101,553	\$ 183,594	\$ 186,593	\$ 199,635	\$ 213,079	\$ 228,214	\$ 248,260
Gross margin	79%	77%	83%	88%	88%	85%	88%	88%	88%	88%	88%	88%
Expenses												
G&A	\$ 8,476	\$ 4,691	\$ 4,931	\$ 5,001	\$ 5,577	\$ 20,200	\$ 29,070	\$ 29,590	\$ 31,677	\$ 33,823	\$ 36,239	\$ 39,484
Selling and marketing	\$ 2,464	\$ 944	\$ 2,196	\$ 3,755	\$ 4,382	\$ 11,277	\$ 22,840	\$ 23,249	\$ 27,152	\$ 28,991	\$ 33,651	\$ 36,664
R&D		\$ 1,418	\$ 1,931	\$ 2,921	\$ 3,187	\$ 9,457	\$ 16,611	\$ 16,908	\$ 18,101	\$ 12,080	\$ 12,943	\$ 14,102
Depreciation	\$ 18	\$ 34	\$ 16	\$ 40	\$ 40	\$ 130	\$ 160	\$ 168	\$ 176	\$ 185	\$ 194	\$ 204
Share-based compensation	\$ 1,070	\$ 756	\$ 1,380	\$ 1,258	\$ 1,258	\$ 4,652	\$ 5,032	\$ 5,284	\$ 5,548	\$ 5,825	\$ 6,116	\$ 6,422
Acquisition related expenses	\$ 3,692	\$ 174	\$ 8,314	\$ 4,093	\$ -	\$ 12,581	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Change in FV contingent												
Other	\$ 2,404											
<b>Total operating expenses</b>	\$ 18,124	\$ 8,017	\$ 18,768	\$ 17,068	\$ 14,443	\$ 58,296	\$ 73,713	\$ 75,199	\$ 82,655	\$ 80,904	\$ 89,143	\$ 96,876
<b>Operating income</b>	\$ 13,985	\$ 4,939	\$ 2,731	\$ 14,868	\$ 20,719	\$ 43,257	\$ 109,881	\$ 111,394	\$ 116,980	\$ 132,175	\$ 139,071	\$ 151,384
EBITDA	\$ 14,003	\$ 4,973	\$ 2,747	\$ 14,908	\$ 20,759	\$ 43,387	\$ 110,041	\$ 111,562	\$ 117,156	\$ 132,360	\$ 139,265	\$ 151,588
EBITDA (adjusted)	\$ 18,765	\$ 5,903	\$ 12,441	\$ 20,259	\$ 22,017	\$ 60,620	\$ 115,073	\$ 116,846	\$ 122,704	\$ 138,185	\$ 145,382	\$ 158,011
	46%	35%	48%	56%	55%	51%	55%	55%	54%	57%	56%	56%
<b>Other (income) and expense</b>												
Interest and accretion expense	\$ 6,382	\$ 4,705	\$ 1,442	\$ 2,450	\$ 3,235	\$ 11,832	\$ 16,543	\$ 12,678	\$ 7,886	\$ 2,922	\$ -	\$ -
Change in FV of contingent consideration	\$ 4,648	\$ 567	\$ 983	\$ 579	\$ -	\$ 2,129	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Amortization of intangible assets	\$ 120	\$ 580	\$ 580	\$ 580	\$ 580	\$ 2,320	\$ 2,436	\$ 2,558	\$ 2,686	\$ 2,820	\$ 2,961	\$ 3,109
Other	\$ (150)	\$ (5)	\$ 113	\$ (16)	\$ -	\$ 92	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
FX	\$ 129	\$ 865	\$ -	\$ 73	\$ -	\$ 938	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Income (loss) before tax</b>	\$ 2,856	\$ (1,773)	\$ (387)	\$ 11,202	\$ 16,904	\$ 25,946	\$ 90,902	\$ 96,158	\$ 106,408	\$ 126,433	\$ 136,110	\$ 148,275
Income taxes	\$ 425	\$ 63	\$ 440	\$ 667	\$ 592	\$ 1,762	\$ 16,682	\$ 3,846	\$ 4,256	\$ 5,057	\$ 5,444	\$ 5,931
<b>Net income (loss)</b>	\$ 2,431	\$ (1,836)	\$ (827)	\$ 10,535	\$ 16,312	\$ 24,184	\$ 74,221	\$ 92,312	\$ 102,152	\$ 121,375	\$ 130,665	\$ 142,344
Other comprehensive income												
Exchange differences (foreign operation)	\$ 15	\$ (13)	\$ (3)	\$ (171)	\$ -	\$ (187)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Total comprehensive income for the pe</b>	\$ 2,446	\$ (1,849)	\$ (830)	\$ 10,364	\$ 16,312	\$ 23,997	\$ 74,221	\$ 92,312	\$ 102,152	\$ 121,375	\$ 130,665	\$ 142,344
EPS (basic)	\$ 0.38	\$ (0.09)	\$ (0.03)	\$ 0.37	\$ 0.57	\$ 0.81	\$ 2.38	\$ 2.93	\$ 3.22	\$ 3.79	\$ 4.05	\$ 4.38
EPS (fully diluted)	\$ 0.38	\$ (0.09)	\$ (0.03)	\$ 0.35	\$ 0.54	\$ 0.77	\$ 2.27	\$ 2.80	\$ 3.07	\$ 3.62	\$ 3.87	\$ 4.19
<b>Adjusted Income</b>												
Amortization and Depreciation	\$ 138.00	\$ 614.00	\$ 596.00	\$ 620.00	\$ 620.00	\$ 2,450.00	\$ 2,596.00	\$ 2,725.80	\$ 2,862.09	\$ 3,005.19	\$ 3,155.45	\$ 3,313.23
Share-based compensation	\$ 1,070.00	\$ 756.00	\$ 1,380.00	\$ 1,258.00	\$ 1,258.00	\$ 4,652.00	\$ 5,032.00	\$ 5,283.60	\$ 5,547.78	\$ 5,825.17	\$ 6,116.43	\$ 6,422.25
Acquisition related expenses	\$ 3,692.00	\$ 174.00	\$ 8,314.00	\$ 4,093.00	\$ -	\$ 12,581.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Change in FV contingent	\$ 4,648.00	\$ 567.00	\$ 983.00	\$ 579.00	\$ -	\$ 2,129.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	\$ 11,979.00	\$ 275.00	\$ 10,446.00	\$ 17,085.00	\$ 18,190.18	\$ 45,996.18	\$ 95,348.64	\$ 100,321.55	\$ 110,561.81	\$ 130,205.79	\$ 139,937.31	\$ 152,079.51
EPS (basic)	\$ 1.89	\$ 0.01	\$ 0.40	\$ 0.60	\$ 0.63	\$ 1.64	\$ 3.05	\$ 3.19	\$ 3.48	\$ 4.07	\$ 4.34	\$ 4.68
EPS (fully diluted)	\$ 1.86	\$ 0.01	\$ 0.40	\$ 0.57	\$ 0.60	\$ 1.58	\$ 2.91	\$ 3.04	\$ 3.33	\$ 3.89	\$ 4.15	\$ 4.47



<b>Cash Flow Statements (US\$000 except per share data)</b>	<b>2013A</b>	<b>Q1-14A</b>	<b>Q2-14A</b>	<b>Q3-14A</b>	<b>Q4-14E</b>	<b>2014E</b>	<b>2015E</b>	<b>2016E</b>	<b>2017E</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
<b>Cash flows from operating activities</b>												
Net income (loss) after tax	\$ 2,431					\$ 24,184	\$ 74,221	\$ 92,312	\$ 102,152	\$ 121,375	\$ 130,665	\$ 142,344
Adjustments												
Depreciation and amortization	\$ 138					\$ 2,450	\$ 2,596	\$ 2,726	\$ 2,862	\$ 3,005	\$ 3,155	\$ 3,313
Accretion and interest expense	\$ 6,382					\$ 11,832	\$ 16,543	\$ 12,678	\$ 7,886	\$ 2,922	\$ -	\$ -
Share based compensation expense	\$ 1,070					\$ 4,652	\$ 5,032	\$ 5,284	\$ 5,548	\$ 5,825	\$ 6,116	\$ 6,422
Share based transaction and listing expenses	\$ 4,593					\$ 12,581	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Change in fair value of contingent consideration	\$ 4,648					\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Income taxes	\$ 265					\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
	\$ 19,527					\$ 55,699	\$ 98,392	\$ 113,000	\$ 118,448	\$ 133,128	\$ 139,937	\$ 152,080
Changes in operating assets and liabilities												
Accounts receivable	\$ (19,454)					\$ (8,456)	\$ (10,060)	\$ (743)	\$ (2,982)	\$ (3,065)	\$ (3,451)	\$ (4,636)
Inventory	\$ 313					\$ (3,140)	\$ (3,212)	\$ (186)	\$ (746)	\$ (766)	\$ (863)	\$ (1,159)
Prepaid expenses and other current assets	\$ (816)					\$ (2,245)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Accounts payable	\$ 20,395					\$ (9,991)	\$ 3,350	\$ 448	\$ 1,169	\$ 1,176	\$ 1,326	\$ 1,959
Accrued liabilities	\$ 2,597					\$ (1,067)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Provisions	\$ 24,208					\$ (12,298)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Royalties payable	\$ 3,093					\$ (87)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Dividends payable	\$ -					\$ 2,165	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Taxes payable	\$ -					\$ 1,880	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Net cash provided by (used in) operating activities</b>	<b>\$ 49,863</b>					<b>\$ 22,460</b>	<b>\$ 88,470</b>	<b>\$ 112,519</b>	<b>\$ 115,889</b>	<b>\$ 130,473</b>	<b>\$ 136,949</b>	<b>\$ 148,243</b>
<b>Cash flows from investing activities</b>												
Purchase of fixed assets	\$ (107)					\$ (454)	\$ (160)	\$ (168)	\$ (176)	\$ (185)	\$ (194)	\$ (204)
Purchase consideration paid	\$ (59,259)					\$ (420,011)	\$ (2,436)	\$ (2,558)	\$ (2,686)	\$ (2,820)	\$ (2,961)	\$ (3,109)
<b>Net cash used in investing activities</b>	<b>\$ (59,366)</b>					<b>\$ (420,465)</b>	<b>\$ (2,596)</b>	<b>\$ (2,726)</b>	<b>\$ (2,862)</b>	<b>\$ (3,005)</b>	<b>\$ (3,155)</b>	<b>\$ (3,313)</b>
<b>Cash flows from financing activities</b>												
Net proceeds from issuance of common stock	\$ 39,064					\$ 187,161	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Proceeds from credit facility	\$ 3,000					\$ 2,226	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Proceeds from senior and subordinated debt	\$ 21,150					\$ 257,047	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Debt issuance costs	\$ (1,100)					\$ (8,551)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Proceeds from exercise of options	\$ -					\$ 2,353	\$ 9,000	\$ 9,000	\$ 9,000	\$ 9,000	\$ 9,000	\$ 9,000
Interest paid	\$ (1,304)					\$ (11,832)	\$ (16,543)	\$ (12,678)	\$ (7,886)	\$ (2,922)	\$ -	\$ -
Dividends paid	\$ -					\$ (4,201)	\$ (9,000)	\$ (9,000)	\$ (9,000)	\$ (9,000)	\$ (9,000)	\$ (9,000)
Repayment of credit facility	\$ (3,000)					\$ (8,902)	\$ (5,404)	\$ (4,794)	\$ (4,035)	\$ (3,428)	\$ (3,970)	\$ (1,554)
Repayment of senior and subordinated debt	\$ (5,408)					\$ (19,542)	\$ 72,701	\$ (76,297)	\$ (94,841)	\$ (98,290)	\$ (55,744)	\$ -
<b>Net cash provided by (used in) financing activities</b>	<b>\$ 52,402</b>					<b>\$ 395,759</b>	<b>\$ 50,754</b>	<b>\$ (93,769)</b>	<b>\$ (106,762)</b>	<b>\$ (104,640)</b>	<b>\$ (59,714)</b>	<b>\$ (1,554)</b>
Net change in cash	\$ 42,899	\$ 35,074	\$ (45,265)	\$ (1,763)	\$ 9,709	\$ (2,245)	\$ 136,628	\$ 16,024	\$ 6,265	\$ 22,827	\$ 74,080	\$ 143,376
Cash at beginning of period	\$ -	\$ 42,899	\$ 77,973	\$ 32,708	\$ 30,945	\$ 42,899	\$ 40,654	\$ 177,281	\$ 193,306	\$ 199,570	\$ 222,397	\$ 296,477
<b>Cash at end of period</b>	<b>\$ 42,899</b>	<b>\$ 77,973</b>	<b>\$ 32,708</b>	<b>\$ 30,945</b>	<b>\$ 40,654</b>	<b>\$ 40,654</b>	<b>\$ 177,281</b>	<b>\$ 193,306</b>	<b>\$ 199,570</b>	<b>\$ 222,397</b>	<b>\$ 296,477</b>	<b>\$ 439,853</b>

Knight Therapeutics Inc. (GUD-TSX, \$6.79)

December 18, 2014

 David Martin PhD, MBA  
 Analyst  
 416-642-8865  
 dmartin@bloomburton.com

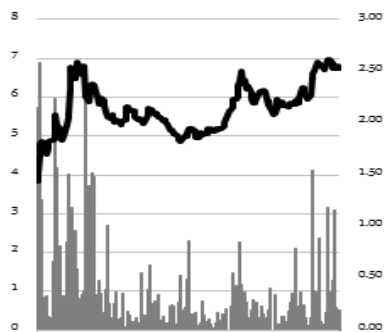
Rating:	ACCUMULATE
Risk:	Average
12 month Price Target	\$8.00

Price	\$6.79
Implied Return	17.8%
Fiscal Year End	31-Dec
52 Week Range	\$3.51-\$7.24
Shares Outstanding (MM; proforma)	92.75
Market Cap. (MM; proforma)	\$629.7
Float (MM Shares)	N/A
Book Value/Share (proforma)	\$3.81
Avg. Daily Volume (MM)	0.25

	2014E	2015E	2016E	2017E
EPS	\$1.61	\$0.12	\$0.12	\$0.15
P/E	4.3	60.0	60.1	46.1
CFPS	\$1.67	\$0.16	\$0.18	\$0.24
P/CFPS	4.2	44.4	38.9	28.8

	Q1 A	Q2A	Q3A	Q4E
EPS -BASIC				
2014E (\$0.01)	\$0.01	\$0.01	\$0.01	\$1.61



March 3, 2014

 This report is priced as of prior trading day's market close.  
 All values in C\$ unless otherwise noted.

## Research Initiation - Repeating a Successful Formula

Initiating Coverage of Knight Therapeutics (GUD: TSX) with an ACCUMULATE Rating (AVERAGE Risk); 12-month target price: \$8.00. While still early in the building stage, we believe that Knight has key foundational pieces in place (management, strategy and capital) to repeat the success of Paladin Labs. Paladin operated under the leadership of Jonathan Goodman prior to its acquisition by Endo Health Solutions (NASDAQ: ENDP; unrated) in November 2013 in a mostly stock deal valued at \$1.7 billion at the time the agreement was announced. Mr. Goodman is currently President & CEO of Knight; has invested \$69.3 million directly and indirectly in the company; and owns approximately 23% (proforma recent financing).

### Highlights

Supercharged balance sheet and a strong management track record of success. Paladin operated for 19 years prior to the Endo acquisition - over the period, raising \$180 million of equity capital, and generating a stock return of more than 9,000%. That Knight, in its first year of existence, has already raised \$342 million (\$355 if the recent bought deal over allotment is exercised) and recently sold a priority review voucher "PRV" to Gilead for US\$125 million, supports that the value-building timeline for Knight could be compressed. However, we expect management to remain patient, IRR-focused, and take the long view as it deploys the company's capital - expectations based both on the Paladin precedent, and on Knight's stated asset allocation strategy.

Product portfolio in early innings. In addition to worldwide Impavido rights which were transferred to Knight by Paladin at its inception, the company recently acquired Canadian rights to two new products, PHOTOFRIN and ATryn, and has invested in five leading life science funds. The fund investments are a departure from the Paladin model, but have become integral to Knight's strategy for several reasons: 1) with historical annual performance ranging from high single digits to low double digits, the funds are expected to appreciate at a rate matching Knight's cost of capital, 2) they provide a relative quick route to commit a sizable portion of Knight's capital, and most importantly, 3) the investments provide access and leverage for Knight to negotiate future Canadian rights to new drugs currently in development by innovative biotech companies.

With so much of Knight's value riding on potential assets not yet acquired, it is difficult to value the company. However, with more than \$4.00 cash per share (pro-forma estimate); positive cash flow from operations, and confidence that Knight's management can build value over time, we believe that downside risk in GUD is limited. The main uncertainty relates to timing and content of the asset acquisition program. As a result, we recommend GUD as a stock to ACCUMULATE on dips, for investors with a long term horizon. 12 month price target: \$8.00 based on the average of two valuation methodologies: 1) sum of the parts, 2) discounted terminal value - and applying a 20% "early pipeline" discount. As Knight tracks to deploy all capital within 2 years, we believe this discount will diminish. Additional upside may be realized if high value opportunities beyond the bandwidth of the current balance sheet are identified, funded and added to Knight's asset portfolio.



## Company Overview

Knight Therapeutics Inc. is an emerging specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian and select world markets. Headquartered in Montreal, Knight was spun-off from Paladin Labs Inc. on February 28, 2014 upon the closing of Endo Health's acquisition of Paladin, and is led by Jonathan Goodman, the co-founder and former President, CEO and chairman of Paladin. At the time of the spin off, Knight received \$1 million in cash and worldwide intellectual rights for the drug Impavido (miltefosine), a leishmaniasis treatment. The drug was issued a priority review voucher by the FDA when it was approved in the United States in March, and Knight announced on November 19, that it had sold the voucher to Gilead (NASDAQ: GILD, unrated) for US\$125 million. Knight is listed on the Toronto Stock Exchange under the ticker "GUD."

Since its inception, Knight has raised \$255.1 million in equity capital, raising \$75 million on March 19, 2014 at the price of \$3.50, and \$180.1 million on April 10, 2014 at the price of \$5.25. On December 3, the company entered into an agreement for a \$75 million bought deal of common shares at the price of \$6.75 per share, which was subsequently increased to \$87 million. If the overallotment is exercised, the total gross amount raised will be \$100 million, and the total new shares issued will be 14.8 million. Expected closing is December 22. At the end of Q3-2014 (September 30, 2014), the company had \$227.2M of cash and 77.8 million basic shares outstanding (fully diluted 79.7 million).

The company is implementing three complementary corporate strategies to support its goal of building another leading specialty pharma resembling Paladin: 1) sourcing products to be sold by Knight – which can include acquisition of products or companies with existing pharmaceutical revenues, possibly accompanied by accumulated tax losses, or in-licensing rights to late-stage innovative drugs with short, low cost and low risk development paths for Canada and/or other select international markets; 2) secured lending to other life science companies; and 3) investing in healthcare focused venture capital funds in order to realize investment gains, and enhance access to target assets.

\$130 million has been earmarked for investments into funds (\$75 million committed to date), with the remaining \$210 million (pro-forma balance of the net proceeds of the equity financings) plus the ~C\$135 million realized on the sale of the PRV (net of fees and taxes), to be used for product licensing/acquisition, and lending (which may be combined with rights to products).

## Business Transactions to-Date

On April 14, 2014, Knight entered an agreement with Medicure (TSXV: MPH), a Winnipeg based specialty pharma, to provide advisory services and receive stock options over the term of agreement.

On June 25, Knight entered into a secured debt agreement with privately-held Origin Biomed Inc. ("Origin"), a consumer health products company headquartered in Halifax, Nova Scotia, with business operations throughout the U.S., Canada and Australia. The \$850,000 asset-secured loan issued will bear interest at a rate of 15% per annum and matures on June 25, 2017. In addition, Knight was issued warrants to acquire 698,483 Origin preferred shares at \$0.0794 per share.

On June 30, Knight invested US\$13 million into the Sectoral Asset Management New Emerging Medical Opportunities Funds II, Ltd. ("NEMO II"). Sectoral's small cap strategy has done over 70 different investments since 2007 in small cap listed and late stage private equity companies in the biotech, medtech and life sciences tools industries, generating a first quartile performance as compared to a late stage private equity peer group over that time period. In exchange for Knight's investment in NEMO II, Sectoral will encourage Sectoral-invested companies to select Knight as their Canadian partner of choice and will facilitate introductions for loan agreements.

On July 3, Knight issued a US\$6.5 million secured loan to support Medicure and Signet Healthcare Partners in their acquisition of a majority position in Apicore, a process R&D and API manufacturing service provider for the worldwide pharmaceutical industry with two FDA-approved facilities – one in Somerset, NJ and the other in India. Additional debt was provided by Sanders Morris Harris, and



Signet made an equity investment – the aggregate amount of capital used for the acquisition was US\$22.5 million. The loan issued by Knight bears a 12% annual interest rate and matures on June 30, 2018. In addition, Knight has been issued warrants to acquire a beneficial interest of 8.125% of Apicore. Medicure has the right to acquire all of Knight's interests in Apicore within the next 3 years for a pre-determined cash amount.

On September 2, Knight announced its first product acquisition which was achieved by way of the acquisition of Orphan Canada Inc., a privately-held, Toronto-based specialty pharmaceutical company. Orphan held Canadian rights for PHOTOFRIN (porfimer sodium) and ATryn (recombinant human antithrombin). Also, as part of the agreement, the founders of Orphan joined the Knight leadership team bringing with them a combined 40 years of experience in the pharmaceutical industry.

On October 2, Knight invested EUR €19.5M into Forbion Capital Fund III C.V., a life science focused fund with €450M assets under management and holds positions in more than 30 life sciences companies, primarily in Europe and North America. On October 28, Knight announced that it had invested C\$30 million into Teralys Capital Innovation Fund LP. Teralys is the largest venture capital fund of funds manager dedicated to technologies and life sciences in Canada, having C\$1.3 billion in assets under management with a significant focus on the North American life sciences sector.

Combined, the three funds in which Knight has invested (Sectoral, Forbion, Teralys), have assets under management in healthcare of approximately C\$5 billion. Furthermore, each has an ability and incentives to leverage their existing relationships with key life science companies to help Knight secure Canadian product rights.

On November 19, the company announced it had sold its Impavido Priority Review Voucher to Gilead Sciences (NASDAQ: GILD, unrated) for an amount of US\$125 million in cash.

On December 2, Knight announced that it had entered into a senior secured debt agreement with CRH Medical Corporation (TSX:CRH, unrated). Knight's secured loan of USD\$30 million will bear interest at a rate of 10% per annum plus other additional consideration. Knight has been issued 3,000,000 common shares in the capital of CRH. The loan, along with US\$24.5 million of additional debt financing provided by other parties, and US\$5 million raised by CRH in a concurrent equity financing, will fund CRH's acquisition of Gastroenterology Anesthesia Associates, LLC and GAA Management, LCC, collectively a Southeast U.S.-based Anesthesia services provider.

Finally, on December 16, Knight announced that it committed to invest US\$25 million into Domain Partners IX, L.P. and US\$10 million in Sanderling Ventures VII, L.P.

## Management's History of Value Creation – The Paladin Labs Precedent

From its inception in 1995 to being acquired by Endo Health Solutions in 2013, Paladin Labs grew from a million dollar start-up to a multi-billion specialty pharma providing drugs in the areas of urology, endocrinology, and women's health. Paladin Labs owned Canadian rights for brand name drugs including Abstral, GlucaGen, Metadol, Plan B, Pennsaid, Seasonale, Testim, Twinject, Dexedrin, Tridural, and Trelstar. The company also had generic drugs and over-the-counter products in its portfolio. From 2001 to 2012, Paladin expanded its EBITDA from \$4.5 million to \$79.0 million reaching total sales of \$153.9 million. In its last reported quarter of operations, Q3-2013, the annualized run rate for revenues and EBITDA were \$284 million and \$102 million, respectively.

On the date that the Endo acquisition was announced, the C\$77.00/share deal price (\$1.16 cash + 1.6331 shares of New Endo) valued Paladin at \$1.7 billion. By the time the deal closed on February 28, 2014, Endo stock had nearly doubled, increasing the value of Paladin to \$3.1 billion or \$142 per share.





## Exhibit 1. Select Product Transactions Executed by Paladin

Product	Indication	Agreement Type	Year	Price (\$000)*	Sales (\$000)	Price/Sales
					Historical	Historical
<b>Mature Products</b>						
Dostinex, Estring, Dalacin	Various	Distribution	2002	\$8,000	\$5,000	1.6
Pennsaid	Osteoarthritis	Acquisition	2005	\$8,450	\$8,500	1.0
Metadol	Pain	Distribution	2006	\$12,000	\$3,600	3.3
Dexedrine	ADHD	Distribution	2008	\$15,227	\$14,000	1.1
<b>New Products</b>					<b>2012</b>	<b>2012</b>
Plan B	Contraceptive	Distribution	1999	\$1,100	\$9,142	0.1
Trelstar	Prostate Cancer	Marketing	2005	\$519	\$7,899	0.1
Twinject	Allergy	Commercialization	2005	\$202	NA	NA
Seasonale	Contraceptive	Distribution	2005	\$203	NA	NA
Testim	Testosterone Deficiency	Distribution	2006	\$1,500	\$5,248	0.3
Tridural	Pain	Distribution	2007	\$1,500	\$11,702	0.1

\*Estimated from Paladin Labs filings including upfront and contingent payments

Source: Paladin Labs reports; Bloom Burton & Co. estimates

Paladin realized phenomenal ROI from its business of securing rights to new products which had not yet been launched in Canada - paying, to our knowledge, some of the lowest multiples of peak sales in the industry, and investing incrementally to garner regulatory approval. Clearly, Paladin's success with this strategy provides a strong impetus for Knight to invest in life sciences funds today, with the goal of securing regional rights to products that will be launched in the future.

With respect to mature products, Paladin also paid attractive prices for products that were already on the market, and in many cases, no longer promoted or growing. Due to industry dynamics, pricing of this asset class has trended up in recent years. Big pharma remains active in the sale of non-strategic drugs, but the number of competing bidders is increasing, and Knight's business development group may need to reach higher on valuations than did Paladin.

Starting in 2008, Paladin began loaning to small biopharmaceutical companies at interest rates ranging from 8% to 16% (Exhibit 2).

## Exhibit 2.

Date	Description	Interest rate	Loan amount
Jul-08	Nuvo Research convertible note	8%	\$2.0 million
Feb-10	SpePharm convertible debenture	15%	\$5.8 million
Oct-10	Loan to Labopharm	16%	\$10.0 million
Jan-11	Loan to ProStrakan Group	10.5%	\$77.2 million
Jun-13	Loan to Bioniche Life Sciences	13.25%	US\$30.0 million
Jun-13	Loan to Nuvo Research	15%	\$4.0 million
Jul-13	Loans to undisclosed pharma	-	\$4.2 million

Source: Paladin Labs reports

Paladin also made high ROI equity investments into smaller specialty pharma companies. For example, in 2010, Paladin invested \$64.1 million to take a 45% ownership position in South African specialty pharma company, Pharmaplan Ltd. In July 2012, Pharmaplan was acquired by Litha Healthcare Group, with Paladin receiving cash and Litha shares worth a combined value of \$72.9 million for its stake. In





2011, Paladin took a position in Afexa Life Science, maker of COLD-FX, before launching a hostile bid to take over the company. Valeant Pharmaceuticals (NYSE: VRX, TSX: VRX; unrated) eventually acquired Afexa later in 2011, but not before Paladin's \$8 million position increased in value to \$13 million.

## Knight's Pharmaceutical Products

### Impavido (miltefosine)

Impavido (miltefosine, alkylphosphocholine) is the only oral leishmaniasis treatment approved by FDA. The drug was initially acquired by Paladin Labs from AETernaZentaris (TSX: AEZ, NASDAQ: AEZS; unrated) for \$9 million in 2008, at which time the drug was mainly sold in tropical countries. Rights to Impavido were transferred to Knight when it was spun out of Paladin in February, then on March 19, the FDA approved Impavido in the United States. Upon approval, Knight received a Priority Review Voucher (PRV), and the drug was given 8-year orphan drug exclusivity, although generics exist outside of the U.S.

Transmitted by sandfly, leishmaniasis is a parasitic disease, endemic in 98 tropical countries, with a yearly incidence of 2 million cases (WHO 2010). Visceral leishmaniasis (VL) infection of the liver, spleen, and bone marrow presents with fever, hepatosplenomegaly, and pancytopenia. In VL, sudden onset of fever with rigor and chills herald the onset of illness, which may subside only to reoccur. Anemia is universal and may be severe leading to weakness, fatigue and heart failure. Cutaneous leishmaniasis (CV) generally presents as a papule that enlarges to a nodule and if it ulcerates, does so over 1 to 3 months (Murray, 2005 Lancet 366:1561). CL lesions are often located at exposed areas of the skin (face, arms, legs), either as single or as multiple lesions. Leishmaniasis is increasingly treated in industrialized countries due to rising numbers of imported cases either by military personnel or travelers.

Knight's annual revenues from international sales of Impavido are expected to range between \$450,000 and \$900,000. Sales in the U.S. are expected to reach \$200,000 to \$400,000 once the drug is launched. The company intends to spend \$1 million/year (tapering over time) to fulfill post marketing requirements imposed by the FDA.

### Photofrin (Porfimer sodium)

Photofrin was developed by QLT (NASDAQ: QLTI, TSX: QLT; unrated) and received FDA approval in 1995 for the treatment of esophageal cancer, non-small cell lung cancer (NSCLC), and high-grade dysplasia in Barrett's esophagus. Knight obtained Canadian rights for Photofrin when it acquired Orphan Canada Inc. in September paying, we estimate, less than \$1 million in cash and stock. Current Canadian sales of the drug are approximately \$100,000, however, Concordia Healthcare (TSX: CXR; ACCUMULATE rating; \$53.50 target price), which owns rights to PHOTOFRIN in other global markets through its subsidiary, Pinnacle Biologics, is running clinical trials aimed at expanding the drug's label to include the treatment of cholangiocarcinoma and mesothelioma. The cholangiocarcinoma indication is expected to be significant because there are limited other treatment options, and a number of proof of concept studies have reported positive survival benefits.

### ATryn (recombinant antithrombin)

Also acquired with Orphan Canada, ATryn is a recombinant antithrombin produced by genetically engineered goats, indicated for the prevention of thromboembolic events in hereditary antithrombin deficient patients. ATryn received FDA approval in 2009 and marketing authorization by the European Commission prior to that in 2006. ATryn will be submitted shortly for approval to Health Canada. The U.S. manufacturer of ATryn, rEVO Biologics (subsidiary of LFB Biotechnologies S.A.), plans to seek additional approvals for non-hereditary antithrombin deficiency, preeclampsia and heparin resistance. Annual sales of ATryn in the U.S. are currently <\$10 million.



## Valuation

With so much of Knight's value riding on not-yet-acquired assets, it is difficult to value the company. However, we arrive at a 12 month price target of \$8.00 based on the average of two valuation methodologies: 1) sum-of-the-parts, 2) discounted terminal value; and applying a 20% "early pipeline" discount. Once Knight has established its product pipeline, we anticipate transitioning to more conventional valuation methods including discounted cash flow, and comparable EV/EBITDA and P/E analysis.

## Sum-of-the-Parts

DCF forecast operating cash flow: To date, Knight has made loans totaling approximately C\$42 million. Our model assumes that Knight will deploy its remaining capital for the acquisition of products, and that the existing loan book will pay a 12% average annual rate of interest in future periods. We forecast that approximately \$300 million will be invested in products to be sold by Knight. The model assumes that Knight will pay 4x revenues for pharmaceuticals that it acquires; that sales of these drugs will grow by 5% annually on average. We also forecast that for each dollar invested in healthcare funds (\$130 million earmarked), Knight will negotiate license rights to drugs at no further cost that yield one dollar in peak annual sales at a later point in time. Our model forecasts an initial EBITDA margin of 30%, growing to 35%, and a long term tax rate of 20%.

Using a 10.6% WACC, and 0% terminal growth, the DCF value is \$548.8 million (\$5.66 per share, diluted).

Fund Investments: In 12 months, we estimate that the value of Knight's investments in healthcare funds will be \$88.3 million, with \$48.3 million cash remaining to be deployed under this strategy. The combined value is \$136.6 million (\$1.41 per share).

Sum-of-the-parts: together, the combined value of the forecast operating cash flow and the fund investment strategy is \$685.4 million (\$7.07 per share).

## Discounted Terminal Value

Using Paladin as a precedent: Paladin achieved a \$1.41 billion valuation prior to the announced acquisition by Endo, on \$179.7 million share capital invested (7.8x) - we apply the 7.8x multiple to the pro-forma share capital invested in Knight (\$356.3 million), to arrive at a terminal valuation of \$2.8 billion.

Paladin took 19 years to realize this ROIC, however, with Knight funded with more than \$300 million today, we are assuming the terminal value can be achieved in the shorter period - we are assuming 10-years. For this calculation, we are removing the Paladin acquisition premium and the value bump realized due to the rise in Endo stock after the acquisition announcement, since we believe that inversion benefits were large drivers of the post-announcement value surge, and recent changes made by the United States Treasury Department have stifled inversion transactions. Discounting the forecast terminal value of Knight (\$2.8 billion) using a 10.6% discount rate, generates a target value of \$1.25 billion, or \$12.86 per share (fully diluted, proforma).

## Average of Two Valuation Methodologies

The average of our sum-of-the-parts valuation (\$7.07 per share) and our discounted terminal value calculation (\$12.86 per share) is \$9.97. We apply a 20% "early pipeline" discount to this amount to arrive at our target price of \$8.00 per share. We use the 20% discount due to the risk that competition for assets may have increased since the early days of Paladin, and due to the early stage of the company's product portfolio. As Knight tracks to deploy all capital within 2 years, we believe this discount will diminish. Additional upside may be realized if high value opportunities beyond the bandwidth of the current balance sheet are identified, funded and added to Knight's asset portfolio.

## Financial Forecasts

Balance Sheet (CAD\$000)	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY2020E
<b>Current Assets</b>											
Cash & Short-Term Investments	\$ 75,449.4	\$ 234,507.2	\$ 227,223.3	\$ 386,295.5	\$ 386,295.5	\$ 295,087.4	\$ 199,641.2	\$ 117,104.2	\$ 60,773.2	\$ 88,588.4	\$ 126,467.7
Short-Term Receivables	\$ 42.4	\$ 670.8	\$ 527.5	\$ 527.5	\$ 527.5	\$ 869.8	\$ 3,359.2	\$ 7,892.2	\$ 15,724.4	\$ 18,821.8	\$ 24,389.6
Other Current Assets	\$ 52.7	\$ 175.1	\$ 238.8	\$ 250.7	\$ 250.7	\$ 263.3	\$ 276.4	\$ 290.3	\$ 304.8	\$ 320.0	\$ 336.0
<b>Total current assets</b>	<b>\$ 75,544.5</b>	<b>\$ 235,353.2</b>	<b>\$ 227,989.6</b>	<b>\$ 387,073.7</b>	<b>\$ 387,073.7</b>	<b>\$ 296,220.5</b>	<b>\$ 203,276.9</b>	<b>\$ 125,286.7</b>	<b>\$ 76,802.4</b>	<b>\$ 107,730.2</b>	<b>\$ 151,193.4</b>
<b>Long-term Assets</b>											
Property, Plant & Equipment	\$ 35.5	\$ 57.5	\$ 55.3	\$ 55.3	\$ 55.3	\$ 55.3	\$ 55.3	\$ 55.3	\$ 55.3	\$ 55.3	\$ 55.3
Intangible Assets	\$ 902.7	\$ 883.7	\$ 864.7	\$ 847.4	\$ 847.4	\$ 75,875.0	\$ 151,750.0	\$ 227,625.0	\$ 303,500.0	\$ 303,500.0	\$ 303,500.0
Other Financial Assets	\$ -	\$ 14,029.5	\$ 22,704.2	\$ 92,525.0	\$ 92,525.0	\$ 129,728.1	\$ 170,651.6	\$ 202,214.2	\$ 218,295.6	\$ 235,985.2	\$ 255,443.7
Asset Held for Sale	\$ 10,000.0	\$ 10,000.0	\$ 10,000.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Total Assets</b>	<b>\$ 86,482.7</b>	<b>\$ 260,323.8</b>	<b>\$ 261,613.8</b>	<b>\$ 480,501.4</b>	<b>\$ 480,501.4</b>	<b>\$ 501,878.9</b>	<b>\$ 525,733.7</b>	<b>\$ 555,181.2</b>	<b>\$ 598,653.3</b>	<b>\$ 647,270.7</b>	<b>\$ 710,192.4</b>
<b>Liabilities and Shareholders' Equity</b>											
Accounts Payable	\$ 471.1	\$ 1,501.7	\$ 756.0	\$ 756.0	\$ 756.0	\$ 579.9	\$ 2,239.5	\$ 5,261.5	\$ 10,483.0	\$ 12,547.8	\$ 16,259.7
Deferred revenue	\$ -	\$ -	\$ 280.3	\$ 280.3	\$ 280.3	\$ 280.3	\$ 280.3	\$ 280.3	\$ 280.3	\$ 280.3	\$ 280.3
Interest Payable	\$ 18.7	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Loan Payable	\$ 2,500.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Total Current Liabilities</b>	<b>\$ 2,989.8</b>	<b>\$ 1,501.7</b>	<b>\$ 1,036.3</b>	<b>\$ 1,036.3</b>	<b>\$ 1,036.3</b>	<b>\$ 860.2</b>	<b>\$ 2,519.8</b>	<b>\$ 5,541.8</b>	<b>\$ 10,763.3</b>	<b>\$ 12,828.1</b>	<b>\$ 16,540.0</b>
Deferred income tax liability	\$ -	\$ 265.9	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Total liabilities</b>	<b>\$ 2,989.8</b>	<b>\$ 1,767.6</b>	<b>\$ 1,036.3</b>	<b>\$ 1,036.3</b>	<b>\$ 1,036.3</b>	<b>\$ 860.2</b>	<b>\$ 2,519.8</b>	<b>\$ 5,541.8</b>	<b>\$ 10,763.3</b>	<b>\$ 12,828.1</b>	<b>\$ 16,540.0</b>
<b>Shareholders' Equity</b>											
Share Capital	\$ 11,909.0	\$ 255,779.7	\$ 256,312.5	\$ 349,568.8	\$ 349,568.8	\$ 360,055.8	\$ 370,857.5	\$ 381,983.2	\$ 393,442.7	\$ 405,246.0	\$ 417,403.4
Warrants	\$ 71,167.7	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Contributed Surplus	\$ 491.9	\$ 750.3	\$ 1,501.8	\$ 1,501.8	\$ 1,501.8	\$ 1,501.8	\$ 1,501.8	\$ 1,501.8	\$ 1,501.8	\$ 1,501.8	\$ 1,501.8
Accumulated other comprehensive income	\$ -	\$ 1,711.2	\$ 1,885.9	\$ 1,885.9	\$ 1,885.9	\$ 1,885.9	\$ 1,885.9	\$ 1,885.9	\$ 1,885.9	\$ 1,885.9	\$ 1,885.9
Retained earnings	\$ (75.7)	\$ 314.9	\$ 877.4	\$ 126,508.7	\$ 126,508.7	\$ 137,575.2	\$ 148,968.8	\$ 164,268.5	\$ 191,059.7	\$ 225,808.8	\$ 272,861.3
<b>Total Shareholders' Equity</b>	<b>\$ 83,492.8</b>	<b>\$ 258,556.2</b>	<b>\$ 260,577.5</b>	<b>\$ 479,465.1</b>	<b>\$ 479,465.1</b>	<b>\$ 501,018.7</b>	<b>\$ 523,213.9</b>	<b>\$ 549,639.4</b>	<b>\$ 587,890.1</b>	<b>\$ 634,442.5</b>	<b>\$ 693,652.3</b>
<b>Total Liabilities &amp; Shareholders' Equity</b>	<b>\$ 86,482.7</b>	<b>\$ 260,323.8</b>	<b>\$ 261,613.8</b>	<b>\$ 480,501.4</b>	<b>\$ 480,501.4</b>	<b>\$ 501,878.9</b>	<b>\$ 525,733.7</b>	<b>\$ 555,181.2</b>	<b>\$ 598,653.3</b>	<b>\$ 647,270.7</b>	<b>\$ 710,192.4</b>

Income Statement (CAD\$000)	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
<b>Total Revenues</b>											
Sales	\$ 1.4	\$ 247.4	\$ 6.9	\$ 44.3	\$ 300.0	\$ 5,798.7	\$ 22,394.9	\$ 52,614.8	\$ 104,829.5	\$ 125,478.5	\$ 162,597.4
COGS	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 579.9	\$ 2,239.5	\$ 5,261.5	\$ 10,483.0	\$ 12,547.8	\$ 16,259.7
Gross Income	\$ 1.4	\$ 247.4	\$ 6.9	\$ 44.3	\$ 300.0	\$ 5,218.8	\$ 20,155.4	\$ 47,353.3	\$ 94,346.6	\$ 112,930.6	\$ 146,337.7
SG&A expense	\$ 77.3	\$ 693.4	\$ 1,227.4	\$ 2,000.0	\$ 3,998.1	\$ 650.8	\$ 10,523.6	\$ 28,568.1	\$ 57,710.4	\$ 67,084.5	\$ 86,149.6
Research & Development	\$ 15.0	\$ 112.7	\$ 686.5	\$ 686.5	\$ 1,500.8	\$ 2,828.5	\$ 2,913.3	\$ 3,000.7	\$ 3,090.7	\$ 3,183.4	\$ 3,278.9
Depreciation	\$ 0.5	\$ 6.5	\$ 7.4	\$ 7.8	\$ 22.2	\$ 24.4	\$ 26.8	\$ 29.5	\$ 32.5	\$ 35.7	\$ 39.3
Amortization	\$ 6.3	\$ 19.0	\$ 19.0	\$ 19.0	\$ 63.2	\$ 1,702.0	\$ 3,404.1	\$ 5,106.1	\$ 6,808.1	\$ 6,808.1	\$ 6,808.1
Operating Income (loss)	\$ (97.7)	\$ (584.2)	\$ (1,933.4)	\$ (2,669.0)	\$ (5,284.3)	\$ 13.2	\$ 3,287.6	\$ 10,648.8	\$ 26,704.8	\$ 35,818.8	\$ 50,061.6
EBITDA	\$ (90.9)	\$ (558.7)	\$ (1,907.1)	\$ (2,642.2)	\$ (5,198.9)	\$ 1,739.6	\$ 6,718.5	\$ 15,784.4	\$ 33,545.4	\$ 42,662.7	\$ 56,909.1
Interest Income	\$ (41.0)	\$ (878.7)	\$ (1,135.0)	\$ (2,535.0)	\$ (4,589.7)	\$ (13,819.9)	\$ (10,954.4)	\$ (8,475.9)	\$ (6,784.2)	\$ (7,617.6)	\$ (8,753.9)
Other income	\$ -	\$ (104.9)	\$ (329.3)	\$ (128,990.0)	\$ (129,424.2)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Foreign Exchange Gain	\$ -	\$ (1.2)	\$ (976.1)	\$ -	\$ (977.4)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Interest Expense	\$ 19.0	\$ 4.5	\$ -	\$ -	\$ 23.5	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Pretax Income (loss)	\$ (75.7)	\$ 396.1	\$ 507.0	\$ 128,856.0	\$ 129,683.4	\$ 13,833.1	\$ 14,242.0	\$ 19,124.7	\$ 33,489.0	\$ 43,436.4	\$ 58,815.5
Income Taxes	\$ -	\$ 5.5	\$ (1.2)	\$ 3,224.8	\$ 3,229.1	\$ 2,766.6	\$ 2,848.4	\$ 3,824.9	\$ 6,697.8	\$ 8,687.3	\$ 11,763.1
Deferred income tax recoverable			\$ (54.4)	\$ -	\$ (54.4)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Net Income	\$ (75.7)	\$ 390.6	\$ 562.6	\$ 125,631.3	\$ 126,508.7	\$ 11,066.5	\$ 11,393.6	\$ 15,299.7	\$ 26,791.2	\$ 34,749.2	\$ 47,052.4
EPS (basic)	\$ (0.01)	\$ 0.01	\$ 0.01	\$ 1.61	\$ 1.62	\$ 0.12	\$ 0.12	\$ 0.15	\$ 0.26	\$ 0.32	\$ 0.43
EPS (diluted)	\$ (0.01)	\$ 0.01	\$ 0.01	\$ 1.61	\$ 1.61	\$ 0.12	\$ 0.12	\$ 0.15	\$ 0.26	\$ 0.32	\$ 0.43

Statement of Cash Flow (CAD\$000)	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
<b>Operating Activities</b>											
Net Income (loss)	\$ (75.7)	\$ 390.6	\$ 562.6	\$ 125,631.3	\$ 126,508.7	\$ 11,066.5	\$ 11,393.6	\$ 15,299.7	\$ 26,791.2	\$ 34,749.2	\$ 47,052.4
Deferred income tax recovery			\$ (54.4)	\$ -	\$ (54.4)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Depreciation & Amortization	\$ 6.8	\$ 25.5	\$ 26.4	\$ 26.7	\$ 85.4	\$ 1,726.4	\$ 3,430.9	\$ 5,135.6	\$ 6,840.6	\$ 6,843.9	\$ 6,847.4
Stock based compensation	\$ -	\$ 258.5	\$ 751.4	\$ 3,757.6	\$ 4,767.5	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Acquisition of product rights	\$ -	\$ -	\$ 294.1	\$ -	\$ 294.1	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Other income	\$ -	\$ -	\$ (289.8)	\$ -	\$ (289.8)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Unrealized foreign exchange gain	\$ -	\$ -	\$ (988.5)	\$ -	\$ (988.5)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Changes in non-cash working capital	\$ 43.2	\$ (407.4)	\$ 48.3	\$ (11.9)	\$ (327.9)	\$ (531.0)	\$ (843.0)	\$ (1,524.8)	\$ (2,625.3)	\$ (1,047.7)	\$ (1,871.9)
<b>Net Operating Cash Flow</b>	<b>\$ (25.8)</b>	<b>\$ 267.2</b>	<b>\$ 350.1</b>	<b>\$ 129,403.7</b>	<b>\$ 129,995.2</b>	<b>\$ 12,261.9</b>	<b>\$ 13,981.5</b>	<b>\$ 18,910.5</b>	<b>\$ 31,006.6</b>	<b>\$ 40,545.3</b>	<b>\$ 52,027.9</b>
<b>Investing Activities</b>											
Capital Expenditures	\$ (36.0)	\$ (28.5)	\$ (5.2)	\$ (7.8)	\$ (77.5)	\$ (24.4)	\$ (26.8)	\$ (29.5)	\$ (32.5)	\$ (35.7)	\$ (39.3)
Loan receivable	\$ -	\$ (850.0)	\$ (6,940.7)	\$ (33,600.0)	\$ (41,390.7)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Investment in fund	\$ -	\$ (10,664.0)	\$ (538.3)	\$ (38,780.1)	\$ (49,982.4)	\$ (30,562.5)	\$ (30,562.5)	\$ (17,750.0)	\$ -	\$ -	\$ -
Unrealized investment gain	\$ -	\$ -	\$ -	\$ (1,200.0)	\$ (1,200.0)	\$ (6,640.6)	\$ (10,360.9)	\$ (13,812.7)	\$ (16,081.4)	\$ (17,689.6)	\$ (19,458.5)
Acquisition of product rights	\$ -	\$ -	\$ -	\$ -	\$ -	\$ (76,729.6)	\$ (79,279.1)	\$ (80,981.1)	\$ (82,683.1)	\$ (6,808.1)	\$ (6,808.1)
Sale of asset	\$ -	\$ -	\$ -	\$ 10,000.0	\$ 10,000.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Net Investing Cash Flow</b>	<b>\$ (36.0)</b>	<b>\$ (11,542.5)</b>	<b>\$ (7,484.2)</b>	<b>\$ (63,587.9)</b>	<b>\$ (82,650.6)</b>	<b>\$ (113,957.1)</b>	<b>\$ (120,229.3)</b>	<b>\$ (112,573.3)</b>	<b>\$ (98,797.0)</b>	<b>\$ (24,533.4)</b>	<b>\$ (26,306.0)</b>
<b>Financing Activities</b>											
Net impact of business separation	\$ 1,000.0	\$ -	\$ -	\$ -	\$ 1,000.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Net proceeds from warrants/share issuance	\$ 72,461.1	\$ 172,833.2	\$ (149.8)	\$ 93,256.3	\$ 338,400.9	\$ 10,487.1	\$ 10,801.7	\$ 11,125.7	\$ 11,459.5	\$ 11,803.3	\$ 12,157.4
Share purchase loans	\$ (450.0)	\$ -	\$ -	\$ -	\$ (450.0)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Loan from related party	\$ 2,500.0	\$ -	\$ -	\$ -	\$ 2,500.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Repayment of loan from related party		\$ (2,500.0)	\$ -	\$ -	\$ (2,500.0)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Net Financing Cash Flow</b>	<b>\$ 75,511.1</b>	<b>\$ 170,333.2</b>	<b>\$ (149.8)</b>	<b>\$ 93,256.3</b>	<b>\$ 338,950.9</b>	<b>\$ 10,487.1</b>	<b>\$ 10,801.7</b>	<b>\$ 11,125.7</b>	<b>\$ 11,459.5</b>	<b>\$ 11,803.3</b>	<b>\$ 12,157.4</b>
<b>Net Change in Cash</b>	<b>\$ 75,449.4</b>	<b>\$ 159,057.9</b>	<b>\$ (7,283.9)</b>	<b>\$ 159,072.1</b>	<b>\$ 386,295.5</b>	<b>\$ (91,208.1)</b>	<b>\$ (95,446.1)</b>	<b>\$ (82,537.0)</b>	<b>\$ (56,331.0)</b>	<b>\$ 27,815.2</b>	<b>\$ 37,879.3</b>
Cash, beginning of period	\$ 0.0	\$ 75,449.4	\$ 234,507.2	\$ 227,223.3	\$ 0.0	\$ 386,295.5	\$ 295,087.4	\$ 199,641.2	\$ 117,104.2	\$ 60,773.2	\$ 88,588.4
Cash, end of period	\$ 75,449.4	\$ 234,507.2	\$ 227,223.3	\$ 386,295.5	\$ 386,295.5	\$ 295,087.4	\$ 199,641.2	\$ 117,104.2	\$ 60,773.2	\$ 88,588.4	\$ 126,467.7



Tribute Pharmaceuticals Canada Inc. (TSX-V: TRX, C\$0.53)

December 18, 2014

David Martin PhD, MBA  
 Analyst  
 416-642-8865  
 dmartin@bloomburton.com

Rating:	Buy
Risk:	Above Average
12 month Price Target	\$1.00

Price	\$0.53
Implied Return	88.7%
Fiscal Year End	31-Dec
52 Week Range	\$0.45-\$0.98
Shares Outstanding (MM)	94.48
Market Cap. (MM)	\$50.1
Float (MM Shares)	56.34
Book Value/Share (latest Qtr. end)	\$0.33
Avg. Daily Volume (MM)	0.44

	2013A	2014E	2015E	2016E
Revenue (MM)	\$13.44	\$16.97	\$26.09	\$30.85
EBITDA (MM)	(\$3.83)	(\$2.10)	\$3.44	\$6.49
EPS (\$0.13)	(\$0.12)	(\$0.01)	\$0.02	\$0.06
CFPS (\$0.06)	(\$0.05)	\$0.02	\$0.02	\$0.06

	Q1A	Q2A	Q3A	Q4E
EPS -BASIC				
2014	(\$0.06)	(\$0.09)	\$0.03	(\$0.01)



This report is priced as of prior trading day's market close.  
 All values in C\$ unless otherwise noted.

## Research Initiation – Solid Platform to Start Growing Profitably

We are initiating research coverage of Tribute Pharmaceuticals Canada Inc. (TSX-V: TRX), with a BUY rating (ABOVE AVERAGE risk), and a target price of C\$1.00. Tribute is a specialty pharmaceutical company engaged in acquisition, licensing, regulatory development and promotion of healthcare products principally for the Canadian market. The company was founded in 2006 by former Biovail business executives, including Rob Harris, who is Tribute's President and CEO.

Tribute has undergone a recent building phase during which the sales and marketing infrastructure has been strengthened in advance of key growth drivers which are expected to shortly "kick in." The investment has already started to pay off. YTD-2014, the company's combined revenues grew by 11% (18% excluding the impact of pharmacy stocking of Cambia during the drug's launch in Q1-13) - growth coming from all of Tribute's five mature products, as well as Cambia. With the recent acquisition of four drugs from Novartis, and approval of a new drug, bilastine, expected in 2016, we think the company is well-positioned for a prolonged period of growth from its current portfolio, possibly augmented by additional acquisitions.

### Highlights

**Established Infrastructure Provides Value and Operating Leverage.** Tribute fields a sales force which includes 20 representatives who call on doctors' offices (general practitioners and specialists), and four who call on hospitals and clinics, enabling the company to add promotional value and realize operating leverage when it buys and licenses drugs from big pharma. A regulatory team is also on hand to seek approval for new drugs that may already be marketed in other countries, but not yet in Canada.

**Multiple Near-term Revenue and Margin Drivers.** Tribute recently expanded its sales force, and this investment has already made a positive impact on existing products. Based on organic trends, and with the recent acquisition of Fiorinal and Visken/Viskazine from Novartis, we are forecasting year-over-year revenue growth of 26% and 54% in 2014 and 2015, respectively; gross margin expansion to 54% and 65% (from 45% in 2013); and positive EBITDA starting immediately.

**Set for the Long-Term.** Tribute's newly expanded sales and marketing infrastructure will be leveragable in support of the launch of urticaria drug, bilastine, expected in 2016, and the sales force should also serve as a competitive advantage when pharma assets are put up for sale in the Canadian market. In our view, other opportunities include international product out-licensing, and tax optimization.

Initiating with BUY rating. Our \$1.00 12 month target price represents an average valuation based on discounted cash flow analysis (15% discount rate; 3% terminal growth rate), and applying a 15x multiple to our 2017 forecast EBITDA of \$10.9 million, and discounting 2 years at 15%. Tribute has numerous near-term revenue and margin expansion drivers and is well-structured to optimize value when it buys or licenses Canadian marketing rights to big pharma's non-strategic assets. With 65% inferred upside to our target price, we rate TRX stock BUY (ABOVE AVERAGE risk).



## Company Overview

Tribute Pharmaceuticals is a Canadian specialty pharmaceutical company engaged in acquisition, licensing, regulatory development and promotion of healthcare products principally for the Canadian market. The company fields a sales force which includes 20 representatives who call on doctors' offices (general practitioners and specialists), and four who call on hospitals and clinics. Tribute was founded in 2006 by former Biovail business executives, including Rob Harris, who is Tribute's President and CEO. Prior to serving in general management and business development roles at Biovail, Mr. Harris worked for 20 years at Wyeth Ayerst, at the time, Canada's largest specialty pharmaceutical company.

Tribute's first major transaction occurred in 2007, when the company licensed Canadian rights to distribute hypercholesterolemia drug, Bezalip, and psoriasis drug, Soriatane from Actavis plc (NYSE: ACT, not rated). Subsequently, in 2011, Tribute gained rights to develop and market Bezalip in the United States, an opportunity for which the company is currently seeking a co-development and commercial partner. In late 2011, Tribute merged with Stellar Pharmaceuticals, a London, Canada based company which had developed and sold globally, products based on polysaccharide technology: Neovisc injection for symptomatic treatment of osteoarthritis, and Uracyst for treatment of interstitial cystitis. Other commercial products licensed or acquired by Tribute for the Canadian market include Collatamp G, a resorbable, gentamicin-impregnated collagen "sponge" implanted during surgery to reduce the risk of surgical site infections, and most recently, Fiorinal and Fiorinal C for relief of tension-type headache and Visken/Viskazide for treatment of hypertension and angina pectoris.

In our opinion, generic risk is generally low across Tribute's mature product portfolio due to either patent protection, or because sales of the branded product are too low to attract interest of the generic manufacturers, or generic versions were introduced long enough in the past that sales of the branded product have stabilized. While there does not appear to be the opportunity to implement enormous price increases, some of Tribute's mature products have responded positively to increased promotion.

Tribute has also licensed rights to growth products for which it must seek Canadian regulatory approval, including acute migraine drug, Cambia (approval granted in 2012), and allergic rhinitis/urticaria drug, bilastine, for which the company is preparing a new drug submission, with expectation of launch in 2016.

Tribute has 94.5 million shares (basic); 6.1 million options and 38.7 million warrants outstanding. Total debt at June 30 was \$7.9 million, and in connection with the October 2 acquisition of Fiorinal/Fiorinal C and Visken/Viskazide from Novartis, Tribute secured a further US\$6 million of debt, with an additional US\$3 million conditionally available to be drawn down. Major shareholders include management and directors (approximately 30%), K2 Principal Fund, and Fidelity Special Situations Fund.

Revenues in 2013 were \$13.4 million (45% gross margin; \$3.8 million EBITDA loss), and we believe the pieces are in place to improve materially on these key financial metrics in 2014 and beyond. We believe Tribute will benefit from a number of key performance drivers:

- The company's sales force was doubled to 24 in early 2013 – as a result, the launch of Cambia has been well executed, and Canadian sales of the company's other major products also grew (5%-20%) in H1-2014;
- Gross margin is increasing for the company's current top sellers, Bezalip and Soriatane, based on a formula that pays Tribute a higher percentage of sales as sales increase;
- The company just acquired four high margin products from Novartis that we forecast in 2015 will generate approximately \$8.5 million in sales and \$7.6 million of gross profit, most of which will drop to the EBITDA line;
- Launch of bilastine is expected in 2016, with the differentiated second generation antihistamine expected to become a key contributor to Tribute's growth starting in its first year of sales.

Based on expected growth for only currently marketed products, our forecasts for 2014 and 2015 are: Revenues \$16.9 million (+26%) and \$26.1 million (+54%); Gross Margin 54% and 65%; EBITDA -\$2.1 million and \$3.4 million. Our financial model indicates that with the Novartis product acquisitions, operations should be cash flow positive in 2015. This opens the possibility that the company may negotiate



lower cost debt at some point in the future (Tribute currently pays an interest rate equal to Libor plus 11.5%, minimum 13.5%).

At December 31, 2013, Tribute had non-capital losses carry-forward in the amount of \$10.6 million which may be applied against future years' taxable income. We believe the company will likely implement tax strategies to extend its Canadian tax shield beyond the existing accumulated loss and for international revenues, however, our forecasts are based on full taxation at a rate of 35% starting in 2018.

## Tribute's Product Portfolio

Tribute does not disclose sales or margin breakdowns for each product. Below are descriptions of the company's products including Bloom Burton's estimates of 2013 sales and future forecasts for each.

Product: Bezalip SR (bezafibrate)

Indication: mixed dyslipidemia

Vendor: Actavis plc

Acquired/licensed: licensed Canadian sales, marketing and distribution rights in 2008; U.S. development and profit share rights in 2011

Economics: No upfront fees were paid to Actavis. Tribute currently retains approximately 35% of sales of Bezalip SR, and this is expected to increase based on a formula that pays Tribute a higher percentage of sales as sales grow. US\$5 million is payable to Actavis upon receipt of FDA approval for Bezalip and future royalties generated from sales of the drug in the United States will be shared

Historical Sales by Tribute: estimated \$5.5 million (2013), growing 3%-4% in a declining \$50 million Canadian fibrate market dominated by generic fenofibrate

Differentiation: Bezalip is the only fibrate drug that is a pan-PPAR inhibitor. As a result, Bezalip improves glucose sensitivity in addition to improving lipid levels, giving the drug diabetes prevention properties unique among fibrates (Flory et al., 2009 Diabetes Care 32:547, Tenenbaum et al., 2005 Arch Intern Med 23:1154).

Generic Risk: Currently moderate - sustained release formulation; on the market for ~25 years with sales in the current range

Target Physician: Primary care, endocrinology, internal medicine

Outlook: We are forecasting annual sales growth of 6% in the Canadian market as Tribute's larger sales force continues to promote the benefits of Bezalip for treating dyslipidemic patients at risk of diabetes and with metabolic syndrome. In the United States market, Tribute has obtained an IND for clinical studies of Bezalip, and retained transaction advisory firm, JSB-Partners to find an optimal development and commercialization partner, however, we are not including U.S. sales of Bezalip SR in our model, and would view this as upside to our current valuation

Product: Soriatane (acitretin)

Indication: severe psoriasis and other disorders of keratinization

Vendor: Actavis plc

Acquired/licensed: licensed 2008 (Canada)

Economics: No upfront fees were paid to Actavis. Tribute currently retains a distribution fee of approximately 35% of sales of Soriatane, and this is expected to increase based on a formula that pays



Tribute a higher percentage of sales as sales grow

Historical Sales by Tribute: estimated \$3.1 million (2013), growing ~15% annually in the \$200 million Canadian psoriasis market dominated by immunosuppressive drugs (methotrexate, cyclosporine) and biologics (Enbrel, Humira, Remicade, Strattera)

Differentiation: most effective and only retinoid drug indicated for treatment of psoriasis and only non-immunosuppressive oral product available

Generic Risk: Currently low – single source API; sales <\$5 million; requires a pregnancy prevention program

Target Physician: Dermatologists

Outlook: We are forecasting growth of 12% in 2014 (gradually declining in outer years) as Tribute's larger sales force continues to promote the non-immunosuppressive benefits of Soriatane for men and women who will not become pregnant

Product: Cambia (diclofenac potassium for oral solution)

Indication: acute migraine

Vendor: Nautilus Neurosciences - product subsequently acquired by Depomed (NASDAQ: DEPO, unrated)

Acquired/licensed: licensed 2010 (Canada); approved 2012; formally launched February, 2013

Economics: US\$250,000 upfront payment paid to Nautilus + up to US\$6.75 million in regulatory and sales based contingent payments; gross margin ~75%. US\$750,000 of contingent fees have been paid to Nautilus, and the remainder may be payable to Depomed if performance thresholds are met.

Historical Sales by Tribute: Estimated \$0.9 million in first full year of launch (2013); 20%+ sequential growth in scripts each quarter since Q1-2013. Canadian market for prescription migraine drugs is \$140 million, dominated by generic triptans Differentiation: Only prescription NSAID indicated for migraine and only branded migraine drug currently marketed to doctors; fast peak absorption (15 minutes vs. 75-90 minutes for other NSAIDs and triptans); central and peripheral sites of action; avoids chest tightening/chest pain induced by triptans (10%-15% of patients); recommended as first line treatment option by Canadian Neurological Society

Generic Risk: Currently low – sales <\$5 million; rapid acting buffered formulation patented until 2026

Target Physician: Primary care and neurologists

Outlook: We are forecasting growth of 90% in 2014 and a continued aggressive sales ramp to approximately \$8 million sales by 2017 based on the success to-date of Tribute's expanded sales force in the early launch of this differentiated product

Product: NeoVisc (1% sodium hyaluronate viscosupplement solution for injection)

Indication: osteoarthritis of the knee

Vendor: Stellar Pharmaceuticals

Acquired/licensed: Acquired NeoVisc (and Uracyst) by way of merging with Stellar Pharmaceuticals (December 2011); merger valued Stellar at approximately \$14 million; John Gregory, founder and former CEO of King Pharmaceuticals (sold to Pfizer in 2010) was a Director of Stellar, and is now a member of the Board of Directors of Tribute and one of Tribute's largest shareholders.

Economics: 75% gross margin





Historical Sales by Tribute: Estimated 2013 revenues - \$1.5 million from direct sales in Canada (growing 10%-15%); nominal international revenues (\$0.2 million) from sales by distributors

Differentiation: NeoVisc is the only single dose viscosupplement derived entirely from non-animal sources (fermentation). Synvisc and other competitive products are made from rooster-combs (avian source). Canadian viscosupplement market is \$25-\$35 million led by Synvisc (Sanofi-Aventis) and Durolane (Smith & Nephew)

Generic Risk: Currently low - sales <\$5 million; approved as a medical device

Target Physician: Orthopedic surgeons, sports medicine, rheumatologists

Outlook: Based on recent Canadian and international trends, we are forecasting near term overall growth of 10% for NeoVisc revenues, gradually declining in outer years. Our forecast may be conservative since Tribute has indicated that one of its goals is to expand the out-licensing of NeoVisc for international markets including the United States. To help this process along, the company hired a seasoned director of sales and marketing for its Specialty Care business who had previously served in a similar role for the Synvisc product at Genzyme prior to its acquisition by Sanofi-Aventis in 2011.

Product: Uracyst (sodium chondroitin sulfate solution for bladder instillation)

Indication: replenishment of the GAG (glycosaminoglycan) layer in the bladder of patients suffering from interstitial cystitis/painful bladder syndrome

Vendor: Stellar Pharmaceuticals

Acquired/licensed: Acquired Uracyst (and NeoVisc) by way of merging with Stellar Pharmaceuticals (December 2011); merger valued Stellar at approximately \$14 million

Economics: 75% gross margin

Historical Sales by Tribute: Estimated 2013 revenues - \$1.1 million (growing 20%) representing transfer sales to partners in international markets (product sales ~\$5 million mainly in EU); nominal direct sales (\$0.3 million) in Canada where there is low reimbursement for instillation procedures in hospitals.

Differentiation: Disease modifier with potentially faster (10 weeks vs 4 months) and more effective symptom relief (47% vs 30% response rate) vs Janssen's market leading Elmiron, although, this has not been confirmed in head-to-head testing, and is weighed against Elmiron's oral convenience. Annual sales of Elmiron are approximately US\$250 million, in a global GAG repair market estimated at US\$400 million.

Generic Risk: Low - approved as a medical device; management anticipates issuance of a patent in Europe that will expire in 2024 and currently has 4 patents in the United States that expire in 2024, plus several other territories including Canada

Target Physician: Urologists, urogynecologists

Outlook: Based on recent international and Canadian trends, we are forecasting near term overall growth of 12% for Uracyst revenues, gradually declining in outer years. Similar to NeoVisc, Tribute has indicated that one of its goals is to expand the out-licensing of Uracyst for international markets including the United States, although we believe this is a lower priority than licensing initiatives for Bezalip SR.

Product: Fiorinal/Fiorinal C (aspirin, butalbital, caffeine/+ codeine)

Indication: tension headache

Vendor: Novartis AG

Acquired/licensed: Acquired Fiorinal/Fiorinal C (and Visken/Viskazide) for \$32 million





Economics: 90% gross margin

Historical Sales: Estimated LTM revenues - \$9.7 million. Shortage of competing generic product (Teva) increased sales by about 25% in the period - normalized run-rate approximately \$7.2 million (stable)

Differentiation: brand loyalty; substitution of a combination product at the pharmacy is more difficult; synergy with Cambia promotion

Generic Risk: Currently low - generics have been on the market for many years

Target Physician: Primary care and neurologists

Outlook: We are forecasting near term overall growth of 7% for Fiorinal/Fiorinal C revenues, gradually declining in outer years. Fiorinal and Fiorinal C will be the only products for tension headache promoted to physicians, and loyalty programs may be implemented. Tribute may launch new lifecycle formulations of this product line.

Product: Visken/Viskazide (pindolol/pindolol+hydrochlorothiazide)

Indication: treatment of mild-moderate hypertension and prevention of angina pectoris (Viskazide)

Vendor: Novartis AG

Acquired/licensed: Acquired Visken/Viskazide (and Fiorinal/Fiorinal C) for \$32 million

Economics: 90% gross margin

Historical Sales: Estimated LTM revenues - \$0.7 million (stable)

Differentiation: synergy with Bezalip promotion

Generic Risk: Currently low - Visken generic has been on the market for many years; Viskazide is a single-sourced, non-generic product (approximately 80% of sales of this product pair)

Target Physician: Primary care

Outlook: We are forecasting growth of 7%, declining in outer years, for Visken/Viskazide revenues driven by renewed promotion of the product, and possibly price increases of Viskazide.

Product: Collatamp G (gentamicin impregnated collagen implant)

Indication: local haemostasis of capillary, parenchymatous and seeping haemorrhages in areas with a high risk of infection

Vendor: Theramed Corporation

Acquired/licensed: Acquired for undisclosed amount

Economics: ~55% gross margin

Historical Sales: Estimated 2013 revenues - \$0.7 million (growing 10%+)

Generic Risk: Currently low - drug device combination product; revenues < \$1 million

Target Physician: Specialty care/hospital

Outlook: We are forecasting growth of 10% for Collatamp G based on historical trends and ongoing promotion



Product: Bilastine (non-sedating H1- antihistamine)

Indication: treatment of allergic rhinitis and chronic idiopathic urticaria (hives)

Vendor: Faes Farma, S.A.

Acquired/licensed: Licensed: \$0.4 million upfront; \$3.6 million in future contingent payments

Economics: 75%-80% gross margin

Differentiation: expected to be best-in-class treatment for urticaria (effective and non-sedating), filling a gap in the Canadian market due to the absence of levocetirizine (Xyzal)

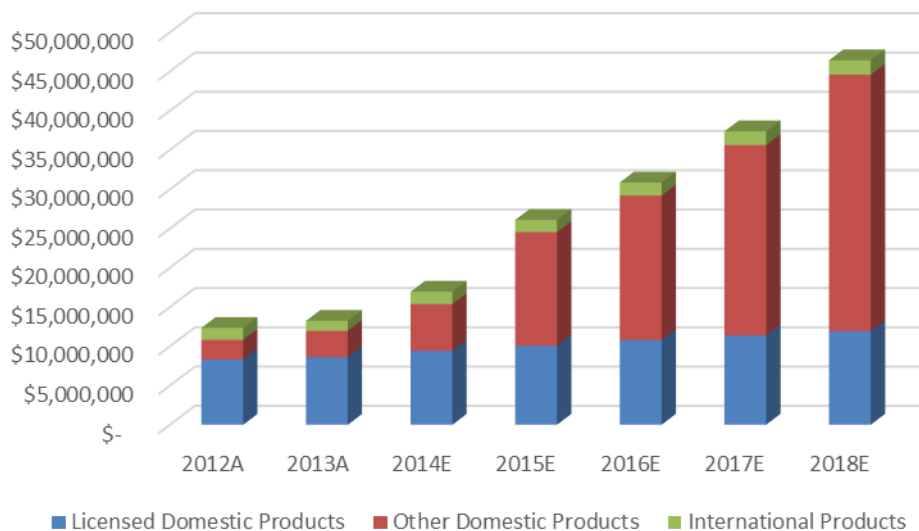
Generic Risk: Currently low - will be granted 8 years market exclusivity if approved by Health Canada (plus 6 months for pediatric indication - two formulations in development)

Target Physician: Primary care, allergists, dermatologists

Outlook: Tribute anticipates that bilastine can be launched during the 2016 allergy season. Based on differentiation of bilastine, its planned promotion to dermatologists alongside Soriatane, and the absence of other promoted prescription antihistamines, we are forecasting that the drug can achieve 5%-10% share of the \$115 million Canadian antihistamine market within 3 years.

Based on historical performance, and our outlook for Tribute’s products, our consolidated revenue forecasts for the Company are shown in Exhibit 1.

Exhibit 1. Tribute Revenue Forecasts

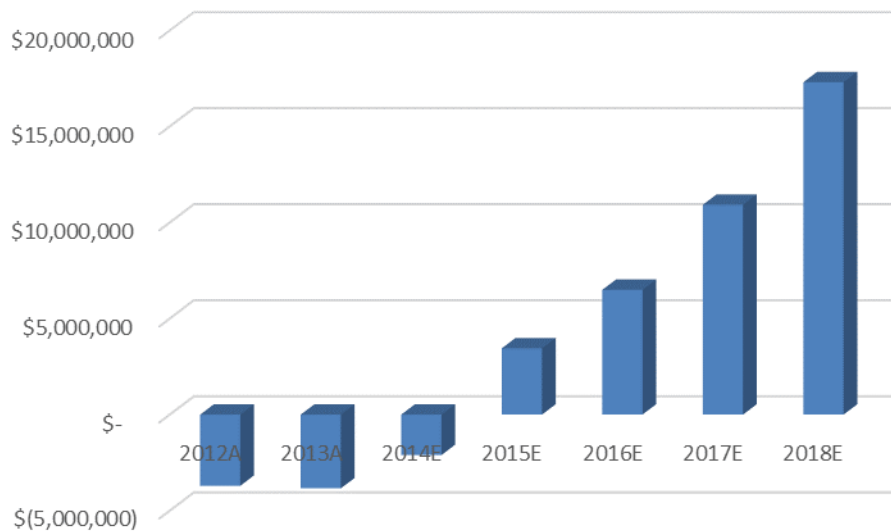


Source: Company reports; Bloom Burton & Co. estimates

With Tribute expected to increase revenues (organic growth, acquired Novartis products, anticipated bilastine launch) onto an established sales and marketing platform, we expect the company to realize good operating leverage, with much of the incremental gross profit falling to the EBITDA line. Exhibit 2 shows Bloom Burton’s estimates for Tribute’s EBITDA through to 2018.



Exhibit 2. Tribute EBITDA Forecasts



Source: Company reports; Bloom Burton & Co. estimates

## Valuation

Our \$1.00 12-month target price for TRX shares is based on two valuation methodologies: 1) discounted cash flow analysis, which generates a diluted value per share of \$1.01 (15% discount rate; 0% terminal growth rate); 2) EV/EBITDA multiple which generates a value per share of \$1.02 (15x Bloom Burton’s estimate for 2017 EBITDA, \$10.9 million; discounted 2 years at 15%). The average of the two methodologies is \$1.02, which we round down to \$1.00. Trading multiples for comparable small cap specialty pharma companies are shown in Exhibit 3.

Exhibit 3. Comparable Companies

Company	Ticker	Price	Market Cap	Enterprise Value	EV/Rev			EV/EBITDA	
					LTM	2014E	2015E	2014E	2015E
<i>U.S. dollar reporting</i>									
Pernix Therapeutics	PTX	\$9.76	\$371.31	\$388.6	4.2	3.3	1.8	na	na
Sucampo Pharmaceuticals	SCMP	\$13.42	\$594.43	\$550.3	5.5	4.6	4.2	15.3	17.4
Concordia Healthcare	CHEHF	\$37.10	\$1,059.61	\$1,287.8	13.4	9.2	6.2	24.3	12.8
<i>Average</i>					7.7	5.7	4.1	19.8	15.1
<i>Canadian dollar reporting</i>									
Merus Labs International	MSL	\$1.61	\$120.05	\$90.1	3.1	3.2	1.3	na	na
BioSynt	RX	\$9.70	\$133.87	\$127.4	11.3	na	na	na	na
<i>Average</i>					7.2	3.2	1.3		
Tribute Pharmaceuticals (basic)	TRX	\$0.53	\$50.07	\$61.5	4.2	3.6	2.1	nmf	6.6
Tribute Pharmaceuticals (fd)	TRX	\$0.53	\$70.64	\$53.0	3.6	3.1	1.8	nmf	5.7

Source: Company reports; Bloomberg; Bloom Burton & Co. estimates



With 89% upside to our target price, we rate TRX shares BUY (ABOVE AVERAGE risk). We believe that Tribute has numerous near-term revenue and margin expansion drivers and is well-structured to optimize value when it buys or licenses Canadian marketing rights to non-strategic big pharma assets. We would consider additional acquisitions as potential upside to our valuation, as we would also, possible out-licensing of Bezalip SR, NeoVisc or Uracyst, in the United States.

## Key Risks

Key risks to our valuation include: 1) generic risk, which we believe is low to moderate for Tribute's products (discussed above), and is mitigated by diversification - no single product represents more than 25% of total revenues in our 2015 forecasts; 2) license cancellation risk - Tribute does not disclose full terms of its agreements for licensed products, but based on performance trends, we believe the company should be in good standing with its licensors, and we believe that Canadian markets for the licensed products remain non-strategic for the licensors; 3) clinical/regulatory risk related to the planned Canadian new drug submission for bilastine, and possible FDA filings by U.S. partners for Bezalip SR, Uracyst and NeoVisc. Bilastine forecasts are included in our model, with material revenues beginning in 2016. Since the drug is already sold in 48 countries, we believe the probability of approval in Canada is relatively high - however, the downside scenario, failure to secure approval of bilastine, would remove \$0.25 from our \$1.00 per share target price. Currently, we do not include revenues for sales of any product in the United States in our model, and would view potential U.S. partnering as upside; 4) forecast risk - most of Tribute's products have mature sales track records and have demonstrated growth upticks due to increased promotion in recent quarters, giving us a moderate to high level of confidence in our estimates for these products. Cambia and bilastine, however, are expected to be new growth products, with less of a track record to support our forecasts; 5) liquidity risk - after the acquisition of Fiorinal/Fiorinal C and Visken/Viskazine in October for \$32 million cash, we forecast that Tribute will end 2014 with approximately \$2.0 million. The company has access to an additional US\$3 million from an existing debt facility, and we believe the company can achieve positive cash flow without drawing further debt. However, a major set-back to a key product may require an additional infusion of capital.

## Financial Forecasts

Balance Sheet (CAD\$ millions)	2014									
	FY2013	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E
<b>ASSETS</b>										
<b>Current</b>										
Cash and cash equivalents	\$2,813,472	\$3,073,341	\$2,302,033	\$28,725,849	\$2,020,120	\$2,020,120	\$4,737,605	\$30,707,278	\$36,997,513	\$53,227,381
Accounts receivable	\$591,766	\$1,656,851	\$1,947,243	\$1,922,835	\$2,504,632	\$2,504,632	\$2,935,437	\$3,470,706	\$4,204,139	\$5,222,069
Inventories	\$1,044,831	\$1,103,932	\$1,058,899	\$857,206	\$1,669,755	\$1,669,755	\$1,956,958	\$2,313,804	\$2,802,759	\$3,481,379
Taxes recoverable	\$651,791	\$122,410	\$178,713	\$47,481	\$47,481	\$47,481	\$47,481	\$47,481	\$47,481	\$47,481
Loan receivable	\$15,814	\$15,814	\$15,814	\$15,814	\$15,814	\$15,814	\$15,814	\$15,814	\$15,814	\$15,814
Prepaid expenses and other receivables	\$165,886	\$174,922	\$192,755	\$232,461	\$232,461	\$232,461	\$232,461	\$232,461	\$232,461	\$232,461
Current portion of debt issuance costs, net	\$91,100	\$119,140	\$116,522	\$135,150	\$135,150	\$135,150	\$135,150	\$135,150	\$135,150	\$135,150
<b>Total current assets</b>	<b>\$5,374,660</b>	<b>\$6,266,410</b>	<b>\$5,811,979</b>	<b>\$31,936,796</b>	<b>\$6,625,414</b>	<b>\$6,625,414</b>	<b>\$10,060,906</b>	<b>\$36,922,693</b>	<b>\$44,435,317</b>	<b>\$62,361,735</b>
<b>Property, plant and equipment, net</b>	<b>\$1,089,919</b>	<b>\$1,076,093</b>	<b>\$1,054,646</b>	<b>\$1,026,008</b>	<b>\$1,011,008</b>	<b>\$1,011,008</b>	<b>\$951,008</b>	<b>\$891,008</b>	<b>\$831,008</b>	<b>\$771,008</b>
<b>Intangible assets, net</b>	<b>\$9,717,173</b>	<b>\$9,481,581</b>	<b>\$9,622,191</b>	<b>\$9,378,881</b>	<b>\$24,291,302</b>	<b>\$24,291,302</b>	<b>\$21,207,302</b>	<b>\$18,123,302</b>	<b>\$15,039,302</b>	<b>\$11,955,302</b>
<b>Goodwill</b>	<b>\$3,599,077</b>	<b>\$3,599,077</b>	<b>\$3,599,077</b>	<b>\$3,599,077</b>	<b>\$20,299,077</b>	<b>\$20,299,077</b>	<b>\$20,299,077</b>	<b>\$20,299,077</b>	<b>\$20,299,077</b>	<b>\$20,299,077</b>
<b>Debt issuance costs, net</b>	<b>\$253,712</b>	<b>\$342,194</b>	<b>\$301,832</b>	<b>\$286,925</b>	<b>\$286,925</b>	<b>\$286,925</b>	<b>\$286,925</b>	<b>\$286,925</b>	<b>\$286,925</b>	<b>\$286,925</b>
<b>Total assets</b>	<b>\$20,034,541</b>	<b>\$20,765,355</b>	<b>\$20,389,725</b>	<b>\$46,227,687</b>	<b>\$52,513,725</b>	<b>\$52,513,725</b>	<b>\$52,805,217</b>	<b>\$76,523,005</b>	<b>\$80,891,629</b>	<b>\$95,674,047</b>
<b>LIABILITIES</b>										
<b>Current</b>										
Accounts payable and accrued liabilities	\$3,284,756	\$3,092,100	\$4,057,315	\$3,340,542	\$3,731,265	\$3,731,265	\$4,117,080	\$4,581,723	\$5,205,689	\$6,071,588
Current portion of long term debt	\$204,700	\$345,728	\$582,872	\$737,263	\$1,474,526	\$1,474,526	\$1,474,526	\$1,474,526	\$1,474,526	\$0
Warrant liability	\$2,966,714	\$4,499,402	\$7,705,377	\$3,250,811	\$3,250,811	\$3,250,811	\$3,250,811	\$3,250,811	\$3,250,811	\$3,250,811
Other current liability	\$38,156	\$103,488	\$189,430	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Total current liabilities</b>	<b>\$6,494,326</b>	<b>\$8,040,718</b>	<b>\$12,534,994</b>	<b>\$7,328,616</b>	<b>\$8,456,602</b>	<b>\$8,456,602</b>	<b>\$8,842,417</b>	<b>\$9,307,060</b>	<b>\$9,931,026</b>	<b>\$9,322,399</b>
Long term debt	\$5,640,102	\$7,849,090	\$7,366,024	\$7,645,299	\$13,662,427	\$13,662,427	\$11,982,427	\$8,482,427	\$4,282,427	\$0
Deferred tax liability	-	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Total liabilities</b>	<b>\$12,134,428</b>	<b>\$15,889,808</b>	<b>\$19,901,018</b>	<b>\$14,973,915</b>	<b>\$22,119,029</b>	<b>\$22,119,029</b>	<b>\$20,824,844</b>	<b>\$17,789,487</b>	<b>\$14,213,453</b>	<b>\$9,322,399</b>
<b>SHAREHOLDERS' EQUITY</b>										
<b>Capital Stock</b>										
Common shares	\$19,947,290	\$20,159,102	\$20,159,102	\$41,189,440	\$41,189,440	\$41,189,440	\$44,202,659	\$68,257,053	\$68,708,584	\$77,233,708
Additional paid-in capital options	\$2,286,890	\$2,404,022	\$2,503,966	\$8,994,230	\$8,994,230	\$8,994,230	\$8,994,230	\$8,994,230	\$8,994,230	\$8,994,230
Accumulated other comprehensive loss	(\$38,156)	(\$103,488)	(\$189,430)	\$13,158	\$13,158	\$13,158	\$13,158	\$13,158	\$13,158	\$13,158
<b>Deficit</b>	<b>(\$14,295,911)</b>	<b>(\$17,584,089)</b>	<b>(\$21,984,931)</b>	<b>(\$18,943,056)</b>	<b>(\$19,802,131)</b>	<b>(\$19,802,131)</b>	<b>(\$21,229,674)</b>	<b>(\$18,530,923)</b>	<b>(\$11,037,796)</b>	<b>\$110,552</b>
<b>Total shareholders' equity</b>	<b>\$7,900,113</b>	<b>\$4,875,547</b>	<b>\$488,707</b>	<b>\$31,253,772</b>	<b>\$30,394,697</b>	<b>\$30,394,697</b>	<b>\$31,980,373</b>	<b>\$58,733,518</b>	<b>\$66,678,176</b>	<b>\$86,351,648</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$20,034,541</b>	<b>\$20,765,355</b>	<b>\$20,389,725</b>	<b>\$46,227,687</b>	<b>\$52,513,725</b>	<b>\$52,513,725</b>	<b>\$52,805,217</b>	<b>\$76,523,005</b>	<b>\$80,891,629</b>	<b>\$95,674,047</b>



Income Statement (CAD\$ millions)	2014									
	FY2013	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E
<b>Revenues</b>										
Licensed domestic product net sales	\$ 8,598,385	\$ 2,276,383	\$ 2,463,309	\$ 2,381,710	\$ 2,280,250	\$ 9,401,652	\$ 10,066,414	\$ 10,764,066	\$ 11,365,639	\$ 11,912,611
	3%	20%	10%	6%	3%	9%	7%	7%	6%	5%
Other domestic product sales	\$ 3,366,374	\$ 734,779	\$ 1,220,104	\$ 991,053	\$ 3,015,600	\$ 5,961,536	\$ 14,478,773	\$ 18,428,860	\$ 24,257,423	\$ 32,679,869
	35%	-33%	67%	25%	303%	77%	143%	27%	32%	35%
International product sales	\$ 1,277,678	\$ 463,978	\$ 357,872	\$ 496,153	\$ 270,000	\$ 1,588,003	\$ 1,547,585	\$ 1,657,792	\$ 1,747,059	\$ 1,825,912
	-16%	40%	0%	43%	12%	24%	-3%	7%	5%	5%
Royalty and licensing revenues	\$ 197,924	\$ 18,414	\$ -	\$ -	\$ -	\$ 18,414	\$ -	\$ -	\$ -	\$ -
<b>Total revenues</b>	\$ 13,440,361	\$ 3,493,554	\$ 4,041,285	\$ 3,868,916	\$ 5,565,850	\$ 16,969,605	\$ 26,092,772	\$ 30,850,718	\$ 37,370,122	\$ 46,418,392
	9%	2%	21%	11%	73%	26%	54%	18%	21%	24%
<b>Cost of sales</b>										
Licensors sales and distribution fees	\$ 5,844,494	\$ 1,413,043	\$ 1,636,895	\$ 1,525,103	\$ 1,504,965	\$ 6,080,006	\$ 6,257,135	\$ 6,367,862	\$ 6,382,775	\$ 6,332,568
Cost of products sold	\$ 1,541,662	\$ 345,864	\$ 350,600	\$ 438,104	\$ 567,960	\$ 1,702,528	\$ 2,891,932	\$ 3,813,745	\$ 5,185,422	\$ 7,159,849
Write down of inventories	\$ 56,935	\$ -	\$ 13,356	\$ 25,228	\$ -	\$ 38,584	\$ -	\$ -	\$ -	\$ -
Total cost of sales	\$ 7,443,091	\$ 1,758,907	\$ 2,000,851	\$ 1,988,435	\$ 2,072,925	\$ 7,821,118	\$ 9,149,067	\$ 10,181,607	\$ 11,568,197	\$ 13,492,417
<b>Gross Profit</b>	\$ 5,997,270	\$ 1,734,647	\$ 2,040,434	\$ 1,880,481	\$ 3,492,925	\$ 9,148,487	\$ 16,943,705	\$ 20,669,110	\$ 25,801,925	\$ 32,925,975
	45%	50%	50%	49%	63%	54%	65%	67%	69%	71%
<b>Expenses</b>										
Selling, general and administrative	\$ 9,830,132	\$ 3,222,661	\$ 2,409,678	\$ 2,529,534	\$ 3,090,000	\$ 11,251,873	\$ 13,502,248	\$ 14,177,360	\$ 14,886,228	\$ 15,630,539
Amortization	\$ 1,245,846	\$ 290,352	\$ 296,574	\$ 296,723	\$ 786,000	\$ 1,669,649	\$ 3,144,000	\$ 3,144,000	\$ 3,144,000	\$ 3,144,000
<b>Profit (Loss) from operations</b>	\$ (5,078,708)	\$ (1,778,366)	\$ (665,818)	\$ (945,776)	\$ (383,075)	\$ (3,773,035)	\$ 297,458	\$ 3,347,750	\$ 7,771,697	\$ 14,151,436
EBITDA	\$ (3,832,862)	\$ (1,488,014)	\$ (369,244)	\$ (649,053)	\$ 402,925	\$ (2,103,386)	\$ 3,441,458	\$ 6,491,750	\$ 10,915,697	\$ 17,295,436
<b>Non-operating income (expenses)</b>										
Change in warrant liability	\$ (399,217)	\$ (1,411,774)	\$ (3,205,975)	\$ 4,283,610	\$ -	\$ (334,139)	\$ -	\$ -	\$ -	\$ -
Loss on disposal of intangible asset	\$ (161,200)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Loss on extinguishment of loan	\$ (620,835)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Accretion expense	\$ (103,775)	\$ (31,118)	\$ (34,409)	\$ (36,738)	\$ -	\$ (102,265)	\$ -	\$ -	\$ -	\$ -
Interest expense	\$ (527,079)	\$ (267,292)	\$ (298,006)	\$ (303,613)	\$ (476,000)	\$ (1,344,911)	\$ (1,725,000)	\$ (649,000)	\$ (369,000)	\$ (216,000)
Interest income	\$ 3,559	\$ 372	\$ 166	\$ 57,550	\$ -	\$ 58,088	\$ -	\$ -	\$ -	\$ -
<b>Income (loss) before tax</b>	\$ (6,887,255)	\$ (3,288,178)	\$ (4,400,842)	\$ 3,055,033	\$ (859,075)	\$ (5,493,062)	\$ (1,427,542)	\$ 2,698,750	\$ 7,402,697	\$ 13,935,436
Deferred income tax recovery	\$ 314,900	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Taxes	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ (90,431)	\$ 2,787,087
<b>Net income (loss) for the period</b>	\$ (6,572,355)	\$ (3,288,178)	\$ (4,400,842)	\$ 3,055,033	\$ (859,075)	\$ (5,493,062)	\$ (1,427,542)	\$ 2,698,750	\$ 7,493,127	\$ 11,148,349
<b>Loss Per Share</b>										
Basic	(\$0.13)	(\$0.06)	(\$0.09)	\$ 0.03	\$ (0.01)	\$ (0.12)	\$ (0.01)	\$ 0.02	\$ 0.06	\$ 0.08
Diluted	(\$0.13)	(\$0.06)	(\$0.09)	\$ 0.03	\$ (0.01)	\$ (0.13)	\$ (0.01)	\$ 0.02	\$ 0.05	\$ 0.08

Cash Flow Statement (CAD\$ millions)	2014									
	FY2013	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E
<b>Cash flows from (used in) operating activities</b>										
Net profit (loss)	(\$6,572,355)	(\$3,288,178)	(\$4,400,842)	\$3,055,033	(\$859,075)	(\$5,493,062)	(\$1,427,542)	\$2,698,750	\$7,493,127	\$11,148,349
Items not affecting cash:										
Deferred income tax recovery	(\$314,900)	-	\$0							
Amortization	\$1,288,509	\$295,128	\$303,661	\$296,723	\$801,000	\$1,696,512	\$3,204,000	\$3,204,000	\$3,204,000	\$3,204,000
Change in warrant liability	\$399,217	\$1,411,774	\$3,205,975	(\$4,283,610)	\$0	\$334,139	\$0	\$0	\$0	\$0
Cost of extending the warrant expiration	-	\$0	\$0							
Change in fair value of contingent consideration	-	\$0	\$0							
Stock-based compensation	\$419,167	\$117,133	\$99,943	\$25,281	\$0	\$242,357				
Accretion expense	\$103,775	\$31,118	\$34,408	\$36,738	\$0	\$102,264				
Paid in common shares for services	\$0	\$211,812	\$0	\$0	\$0	\$211,812				
Loss on disposal of intangible asset	\$161,200	\$0	\$0							
Loss of extinguishment of loan	\$620,835	\$0	\$0							
Change in non-cash operating assets and liabilities	(\$1,643,044)	(\$796,497)	\$459,058	(\$607,204)	(\$1,003,624)	(\$1,948,267)	(\$332,192)	(\$427,472)	(\$598,423)	(\$830,652)
<b>Cash flows (used in) operating activities</b>	<b>(\$5,537,596)</b>	<b>(\$2,017,710)</b>	<b>(\$297,797)</b>	<b>(\$1,477,039)</b>	<b>(\$1,061,699)</b>	<b>(\$4,854,245)</b>	<b>\$1,444,265</b>	<b>\$5,475,279</b>	<b>\$10,098,704</b>	<b>\$13,521,697</b>
<b>Cash flows (used in) investing activities</b>										
Additions to property, plant and equipment	(\$26,795)	(\$4,353)	(\$2,172)	\$0	(\$2,000)	(\$8,525)	(\$8,525)	(\$8,525)	(\$8,525)	(\$8,525)
Payment of contingent liabilities	(\$460,000)	\$0	\$0							
Increase in intangible assets	(\$33,345)	\$0	(\$222,727)	(\$53,413)	(\$15,696,421)	(\$15,972,561)	(\$51,475)	(\$51,475)	(\$51,475)	(\$51,475)
Increase in licensing agreements	-	(\$16,593)	\$16,593			\$0				
Cash cost of acquisitions	-	\$0	\$0	\$0	(\$16,700,000)	(\$16,700,000)	\$0	\$0	\$0	\$0
<b>Cash flows (used in) investing activities</b>	<b>(\$520,140)</b>	<b>(\$20,946)</b>	<b>(\$208,306)</b>	<b>(\$53,413)</b>	<b>(\$32,398,421)</b>	<b>(\$32,681,086)</b>	<b>(\$60,000)</b>	<b>(\$60,000)</b>	<b>(\$60,000)</b>	<b>(\$60,000)</b>
<b>Cash flows from (used in) financing activities</b>										
Financing costs deferred	(\$305,227)	(\$128,181)	\$0			(\$128,181)				
Long term debt repayment	(\$3,386,630)	\$0	\$0	\$433,666	\$0	\$433,666	(\$1,680,000)	(\$3,500,000)	(\$4,200,000)	(\$5,756,953)
Long term debt issued	\$6,084,437	\$2,211,000	\$0	\$0	\$6,754,391	\$8,965,391				
Units issued	\$4,713,787	\$0	\$0	\$27,520,602	\$0	\$27,520,602	\$3,013,219	\$24,054,394	\$451,531	\$8,525,124
Debt extinguishment costs	(\$348,420)	\$0	\$0			\$0				
Share issuance costs	(\$436,966)	\$0	\$0			\$0				
<b>Cash flows from financing activities</b>	<b>\$6,320,981</b>	<b>\$2,082,819</b>	<b>\$0</b>	<b>\$27,954,268</b>	<b>\$6,754,391</b>	<b>\$36,791,478</b>	<b>\$1,333,219</b>	<b>\$20,554,394</b>	<b>(\$3,748,469)</b>	<b>\$2,768,171</b>
<b>Changes in cash and cash equivalents</b>	<b>\$263,245</b>	<b>\$44,163</b>	<b>(\$506,103)</b>	<b>\$26,423,816</b>	<b>(\$26,705,729)</b>	<b>(\$743,853)</b>	<b>\$2,717,484</b>	<b>\$25,969,673</b>	<b>\$6,290,235</b>	<b>\$16,229,868</b>
<b>Change in cash due to changes in foreign exchange</b>	<b>\$266,359</b>	<b>\$215,706</b>	<b>(\$265,205)</b>			<b>(\$49,499)</b>				
<b>Cash and cash equivalents, beginning of period</b>	<b>\$2,283,868</b>	<b>\$2,813,472</b>	<b>\$3,073,341</b>	<b>\$2,302,033</b>	<b>\$28,725,849</b>	<b>\$2,813,472</b>	<b>\$2,020,120</b>	<b>\$4,737,605</b>	<b>\$30,707,278</b>	<b>\$36,997,513</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$2,813,472</b>	<b>\$3,073,341</b>	<b>\$2,302,033</b>	<b>\$28,725,849</b>	<b>\$2,020,120</b>	<b>\$2,020,120</b>	<b>\$4,737,605</b>	<b>\$30,707,278</b>	<b>\$36,997,513</b>	<b>\$53,227,381</b>

**Trillium Therapeutics Inc. (TSX: TR, \$7.56)**

December 18, 2014

 David Martin PhD, MBA  
 Analyst  
 416-642-8865  
 dmartin@bloomburton.com

## Research Initiation – Promising Early Stage Cancer Immunotherapy

Initiating coverage of Trillium Therapeutics Inc. (TSX: TR) with a BUY rating (SPECULATIVE risk), and a target price of \$20.75. There are a number of features that make Trillium a compelling company to own over the long term: 1) drugs which *unleash immune attack on cancer* are emerging as incredibly effective therapies, supporting the high potential of Trillium's lead immunology program, SIRP $\alpha$ Fc; 2) pre-clinical studies of SIRP $\alpha$ Fc have demonstrated absence of red blood cell toxicity which could materially *differentiate the drug*; 3) SIRP $\alpha$ Fc targets CD47, a molecule which is overexpressed by most cancers and cancer stem cells – as a result, the *market opportunity is large* and the drug may be adept at treating tumors which are difficult to keep in remission.

### Highlights

New blockbuster drugs validate immuno-oncology strategy. Durable tumor responses and even apparent disease eradication have become strikingly typical in patients treated with pioneering immuno-oncology drugs Yervoy (ipilimumab, Bristol-Myers Squibb NYSE: BMS; unrated) and Keytruda (pembrolizumab, Merck NYSE: MRK; unrated), both of which activate T cell attack on tumors. Peak sales estimates as high as \$6 billion reflect expectations for the profound effects of these drugs on multiple cancers.

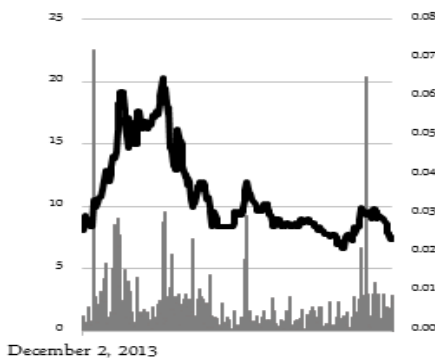
Arming a different arm of the immune system. Trillium's approach is unique - SIRP $\alpha$ Fc induces a distinct type of immune cell, the macrophage, to phagocytose (eat/consume) cancer cells. Trillium is not alone in targeting macrophages - both Trillium and a leading academic group at Stanford, have reported clear-cut anti-tumor activity in pre-clinical studies, and Celgene (NASDAQ: CELG; unrated) also has a program underway which it licensed from InhibRx (private), in a 2012 deal worth up to \$500 million.

Exciting early stage drug, attractive valuation - a good investment for those with a long view and speculative risk tolerance. With Trillium's phase 1/2 program expected to start in the second half of 2015, SIRP $\alpha$ Fc still has a long and challenging road to commercialization. However, in our opinion, TR stock has been under the radar of most investors - inexpensive relative to its 12 to 18-month potential; pre-clinical validation of SIRP $\alpha$ Fc has been positive with signs it may have safety benefits over competing programs. Our C\$20.75 target price for TR stock is based on valuations of companies that are either: 1) early leaders in the cancer immunotherapy space; or 2) small biotech companies with lead candidates either undergoing or finished phase 1/2 clinical trials. We believe that, if successful, Trillium can match these profiles, once it completes pre-clinical development and begins reporting preliminary phase 1 results for SIRP $\alpha$ Fc (estimated 12-18 months). Average enterprise value of the forward looking comparable companies is US\$379.5 million, which infers a target price of C\$41.46 per TR share. Due to the high risk of translating pre-clinical findings into humans, we discount this value by 50% to arrive at our \$20.75 target price.

Rating:	Buy
Risk:	Speculative
12 month Price Target	\$20.75

Price	\$7.56
Implied Return	174.5%
Fiscal Year End	31 -Dec
52 Week Range	\$6.30-\$22.20
Shares Outstanding (MM)	4.28
Market Cap. (MM)	\$32.4
Float (MM Shares)	NA
Book Value/Share (latest Qtr. end)	\$6.59
Avg. Daily Volume (MM)	0.03

	2013A	2014E	2015E	2016E
EPS	(\$0.11)	(\$0.75)	(\$2.76)	(\$2.80)



This report is priced as of prior trading day's market close.  
 All values in C\$ unless otherwise noted.



## Company Overview

Trillium Therapeutics, Inc. is a Toronto-based biotechnology company focused on development of novel immuno-oncology therapies. It has two preclinical programs: a CD47-binding fusion protein, SIRP $\alpha$ Fc, which was in-licensed from John Dick's laboratory at the University Health Network (Toronto) in 2012, and a CD200 monoclonal antibody (mAb), both of which target immunoregulatory pathways exploited by cancer cells to evade the host immune system.

Trillium was founded in 2003 and in 2013, went public by way of merger with Stem Cell Therapeutics Corp. (TSX: SSS). Currently, Trillium stock trades on the TSX under the symbol TR, and is listed on the OTCQX International over-the-counter marketplace with the symbol SCTPF. Following a 30:1 share consolidation in November 2014, basic shares outstanding are 4.3 million; 74.3 million preferred shares (2.5 million if converted to common at 30:1); 138.7 million warrants (4.6 million if converted to common at 30:1), 0.03 million deferred share units and 0.6 million stock options. Cash plus equivalents at September 24, 2014 were CAD\$ 30.5 million, and the monthly burn rate is approximately \$1 million. Top shareholders include Special Situations Funds, Ridgeback Capital, Merlin Nexus, Sabby Capital, venBio, Opaley Management, and HSMR Advisors.

Trillium's core-asset, TTI-621 (SIRP $\alpha$ Fc antibody-like fusion protein) is expected to enter into a phase 1 clinical program in H2-2015 in acute myeloid leukemia (AML) patients. Phase 1 trials may also be run in other hematological and solid tumors pending completion of pre-clinical studies. The company's other immuno-oncology asset is the fully human monoclonal anti-CD200 mAb, which has entered into pre-clinical development. Trillium is seeking an early stage partner for this product.

## Cancer Immunotherapy 101

### Hammers

The first hint that the immune system can fight cancer came from reports of rare cancer remissions following infections. As early as 1891, William Coley, a New York surgeon began injecting bacteria into patients' tumors to test the power of immune system to battle cancers. One hundred years later, the FDA approved the first cancer immunotherapy drug, interleukin-2 (IL-2, Proleukin), for melanoma and renal cell cancer. Although approximately 5% of patients achieved total remission (duration >10 years), the intense untargeted immune/pro-inflammatory response to IL-2 is poorly tolerated and can be toxic. Interferon-alpha was also approved for treating immunogenic cancers, but with generally the same drawbacks.

### Silver Bullets

The next wave of therapies that relied to varying degrees on "help" from the immune system were monoclonal antibody-based drugs that targeted cancer cell receptors and antigens. Some of these drugs have become the world's highest selling cancer therapies (Exhibit 1) and, due to complexities of their production, the generic industry has been delayed in its effort to develop biosimilars. Each antibody either blocks oncogenic signaling pathways or stimulates adaptive immune responses, or a mix of both, and some are used combination with immunostimulatory cytokines (e.g., GM-CSF) to enhance the efficacy of antibody therapy.



## Exhibit 1. Selected Monoclonal Antibodies Approved by FDA for Treatment of Cancers

Target	Cancer Biology	Cancer Type (function)	Generic name	Brand name	Company	2013 Sales (MM)
Her2/Neu	protein kinase erbB-2	breast cancer	Trastuzumab	Herceptin	Roche	6,079 CHF
EGFR	epidermal growth factor receptor	various	Cetuximab	Erbitux	Eli Lilly	US\$373.7
VEGF	vascular endothelial growth factor	cancer angiogenesis	Bevacizumab	Avastin	Roche	6,254 CHF
CD20	B-lymphocyte antigen CD20	B-cell lymphomas	Rituximab	Rituxan	Biogen Idec\Roche	5,760 CHF
CD52	glycoprotein on lymphocytes	certain lymphomas	Alemtuzumab	Campath \Lemtrada	Sanofi	2.0 EURO
CD33	transmembrane receptors on myeloid	AML	gemtuzumab ozogamicin	Mylotarg	Pfizer	N/A

Source: BCIQ BioCentury, company reports

## Cancer Vaccines (Can't win 'em all)

Next up came attempts to design therapeutic cancer vaccines based on the somewhat low tech assumption that swamping patients' immune systems with exogenous cancer antigens, may strengthen a pre-existing immune response or stimulate de novo reactions. At one point it seemed that anyone with a molecular biology lab could discover and produce differentially-expressed cancer antigens, turning them into "cancer vaccine candidates" ready for the clinic. Lacking the current level of understanding of tumor immunology, thousands of patients were treated with vaccines made of short peptides with overwhelmingly disappointing results. In retrospect, we now know that the failures were rooted in the lack of understanding of the role of antigen-presenting dendritic cells (DCs) in stimulating T cell responses; the fact that free peptides tend to be rapidly cleared in the blood stream before they reach DCs; and poor understanding of evasion mechanisms employed by cancer cells even if a patient is pumped full of tumor antigen. The first "cancer vaccine" that showed any real benefit was Dendreon's (NASDAQ: DNDN, unrated) Provenge (sipuleucel-T), approved by the FDA in April 2010 for metastatic castration-resistant prostate cancer. For the first time, the dendritic cell had been specifically targeted/harnessed to coordinate attack on cancer cells, and the results were positive – median survival improved (25.8 vs 21.7 months) despite having no impact on tumor shrinkage. Although successful in the clinic, Provenge has been a commercial flop – not because of lack of benefit, but because of logistical, cost and competitive realities. Provenge is not simply a drug – it is a cell therapy requiring a blood draw, dendritic cell isolation and activation at an off-site facility, then re-infusion back into the patient. Taken together, the logistical and cost issues, and more recent approvals of new prostate cancer drugs, Zytiga and Xtandi, have conspired to limit the use and commercial success of Provenge.

## eACT

A newer cell-based strategy that has demonstrated stellar tumor responses in early human testing, is engineered autologous T cell therapy or eACT. eACT is a procedure in which patient's T cells are collected, and then genetically modified to target previously undetected proteins on cancer cells before being re-infused back into the patient. Currently, there are two approaches to eACT: chimeric antigen receptor (CAR) therapy and T cell receptor (TCR) therapy. In the CAR therapy, a patient's T cells are engineered to express an artificial receptor that uses an antibody fragment to direct the T cells





against the cancer antigen. With TCR therapy, the patient's T cells are engineered to express a novel T cell receptor.

Kite Pharma (Nasdaq: KITE, unrated) and Juno Therapeutics (private) are leading the way in the eACT area with KTE-C19 CAR-T and 19-28z CAR T therapies, respectively. This summer, Kite announced a 92% Objective Response Rate (62% complete remissions) among 13 patients with advanced B cell malignancies. Earlier in the year, investigators at Memorial Sloan Kettering reported an 88% complete response rate in patients with relapsed or refractory B cell acute lymphoblastic leukemia treated with 19-28z CAR T therapy. Other players recently entering the space include Novartis (CAR-T candidate, CTL019 licensed from PennU), Collectis (OTC: CMVLF) partnered with Pfizer for \$80M upfront and up to \$185M in development milestones, with "off the shelf" T cell products, Bluebird Bio (Nasdaq: BLUE, unrated), partnered with Celgene (NASDAQ: CELG, unrated) for an upfront payment and up to \$225M in potential future milestones per therapy, and Adaptimmune (private) partnered with GSK to test a human TCR specific for the NY-ESO-1 tumor marker.

eACT has been associated with severe cytokine release leading to a syndrome of fever, hypotension, hypoxia and neurological changes. Strategies are being developed to make the toxicity more manageable. As with Provenge, the infrastructure cost, process cost, and logistics associated with eACT will be material, although this may be overlooked for end stage patients, and possibly more broadly. Ultimately though, we believe that if the immune system can be harnessed just as effectively with drugs as with cell therapy, that the drugs will be used more universally.

## The New Silver Bullets - Checkpoint Inhibitors

In contrast to the cytokines (IL-2 and interferon) and "first wave" anti-cancer antibodies both of which provide positive stimulus to the immune system to attack cancer cells, a new class of immuno-oncology drugs, the checkpoint inhibitors, interfere with cellular messages that suppress immune surveillance and attack of cancer cells.

The first checkpoint inhibitor drug to be approved, Bristol-Myer Squibb's Yervoy (ipilimumab), was designed to block a signaling molecule on T cells, CTLA-4, which normally delivers an inhibitory signal from dendritic cells to the T cells. By binding to CTLA-4, Yervoy blocks the inhibitory signal, enabling T cells to attack the cancer. In one phase 3 trial, Yervoy showed a two-fold survival benefit at 12-15 months, which was durable beyond 2.5 years (Hodi et al., 2010 N Engl J Med 363:711). In another trial, the addition of Yervoy to the standard therapy of dacarbazine was shown to improve overall survival (11.2 months versus 9.1 months) and increase the proportion of patients surviving at 3 years follow-up (20.8% vs 12.2%, Robert et al., 2011 N Engl J Med 364:2517). Antibodies targeting PD-1 and PD-L1 have recently emerged as even more potent drugs for treating advanced melanoma, by blocking direct inhibitory signals between cancer cells and T cells. In one phase 1 study of Merck's anti-PD-1 antibody, Keytruda (pembrolizumab), 26% of patients who had previously failed Yervoy therapy responded to treatment with the Merck drug (Robert et al., 2014 Lancet 384:1109).

## CD47 - A Compelling Drug Target

White blood cells called macrophages, constantly patrol the body - searching, destroying and removing pathogens, damaged cells, and cell debris. They accomplish this task by engulfing and digesting the "cellular junk" - a process called phagocytosis.

For a tumor to become established and grow, it needs to find ways to evade surveillance and attack by macrophages and other immune cells. Pioneering work at the University of Toronto and Stanford University revealed that a universal protective mechanism used by seemingly all cancers, relies on a transmembrane protein called CD47 which is produced by most cells in a tumor (Exhibit 2). The CD47 molecules on cancer cells interact with SIRP $\alpha$  (signal regulatory protein alpha) molecules on macrophages, resulting in an inhibitory "don't eat" command that prevents macrophages from



phagocytosing the cancer cells (Majeti et al., 2009 Cell 138:286 and Takenaka et al., 2007 Nature Immunol 8:1313).

## Exhibit 2. CD47 is Highly Expressed on Patient Solid Tumors

<b>Tumor Type</b>	<b>Percent of Cells Expressing CD47</b>
<b>Ovarian</b>	97%
<b>Breast</b>	97%
<b>Colon</b>	97%
<b>Bladder</b>	100%
<b>Glioblastoma multiforme</b>	95%
<b>Hepatocellular carcinoma</b>	96%
<b>Prostate</b>	99%

Source: Willingham et al., 2012 PNAS 109:6662

The CD47 signal is dominant, overwhelming other stimulatory “eat” signals that are intrinsic to cancer cells. Consequently, if CD47 function is impaired, the result is that macrophages become “unleashed” and quickly start to destroy cancer cells. The importance of this is heightened due to the fact that, in their tolerant state, macrophages exist in close proximity to tumor cells, and even promote some aspects of tumor progression (Pollard 2004 Nat Rev Cancer 4:71), which amplifies the potential impact of a drug strategy that induces macrophages to turn against cancer cells.

Additionally, targeting CD47 causes a stimulatory ripple effect on the adaptive immune system since macrophages, after “eating” cancer cells, present tumor antigens to T cells and antibody-producing B cells. Thus, a drug that blocks CD47 may trigger a multilayered immune response against cancer cells.

Another advantage of targeting CD47 is that the protein is present on cancer stem cells, tumor-forming cells which are notoriously difficult to kill with chemotherapy. As a result, CD47 blockade may be particularly effective for treating patients with cancers that are prone to relapse, such as acute myeloid leukemia (AML).

Groups independent of Trillium, also pursuing CD47 as a drug target, include the Stanford group, headed by Irving Weissman, which obtained US\$30M of non-commercial funding to move anti-CD47 antibody to phase I clinical testing. Novimmune is developing a bispecific anti-CD47/anti-CD19 antibody, NI-1701, and Celgene in-licensed a preclinical stage anti-CD47 antibody from InhibRx (private), in a deal that could pay InhibRx up to \$500 million in upfront, clinical and regulatory milestones, plus royalties.

## TT-621 (IgG1 SIRP $\alpha$ Fc) Blocks CD47

Trillium’s lead pipeline candidate, TTI-621, is a patent protected fusion protein which combines the CD47 binding region of SIRP $\alpha$  and the Fc (immune effector) region of an antibody. The SIRP $\alpha$  segment acts like a decoy - binding and preventing CD47 on cancer cells from interacting with SIRP $\alpha$  on macrophages. As a result, previously indifferent macrophages turn against, and actively start to phagocytose cancer cells. Additionally, the Fc part of SIRP $\alpha$ Fc is intended to promote antibody-dependent cell-mediated cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC), potentially providing the second of a “one-two punch” against the cancer.

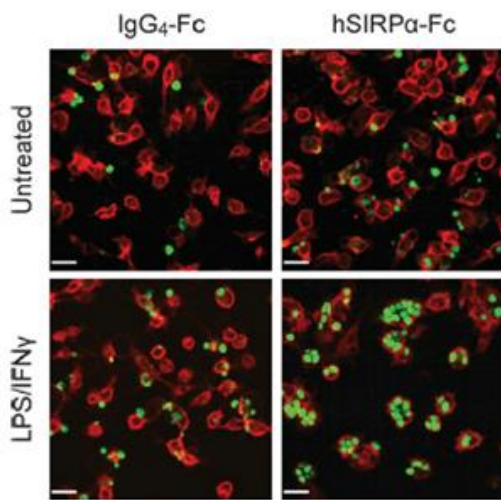
In parallel, Trillium is developing another SIRP $\alpha$ Fc fusion protein, TTI-622, which has a different Fc region with lower effector activity. While TTI-621 is intended to be a monotherapy, TTI-622 is being developed for use in combination with other targeted anti-cancer treatments, such as monoclonal antibodies.

## Pre-Clinical Results

### *SIRP $\alpha$ Fc induces phagocytosis of human AML by activated macrophages in vitro*

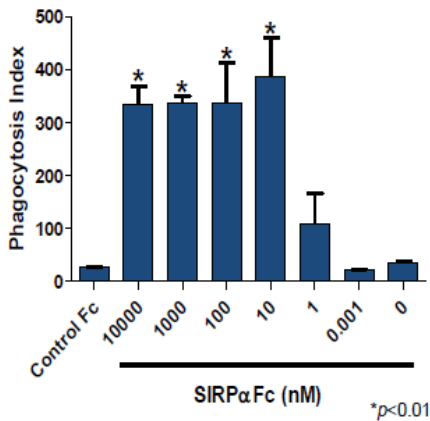
Trillium's SIRP $\alpha$ Fc lead program is based on foundational work conducted at the University Health Network. The Toronto group, headed by John Dick, demonstrated that human IgG4Fc-SIRP $\alpha$  fusion proteins are capable of inducing macrophage phagocytosis of cancerous AML or acute myeloid leukemia stem cells (Exhibit 3a). The finding was subsequently replicated by Trillium at nanomolar concentrations (Exhibit 3b).

Exhibit 3a. Engulfment of Human AML Cells by Stimulated Macrophages (lower panel) AML Cells were Treated with IgG4Fc (control), or SIRP $\alpha$ Fc. (Red stained cells are macrophages and green stained cells are AML)



Source: Theocharides et al., 2012 J Exp Med 209:1883)

Exhibit 3b. Trillium's SIRP $\alpha$ Fc Reaches Maximal Phagocytosis of AML at a Concentration of 10nM



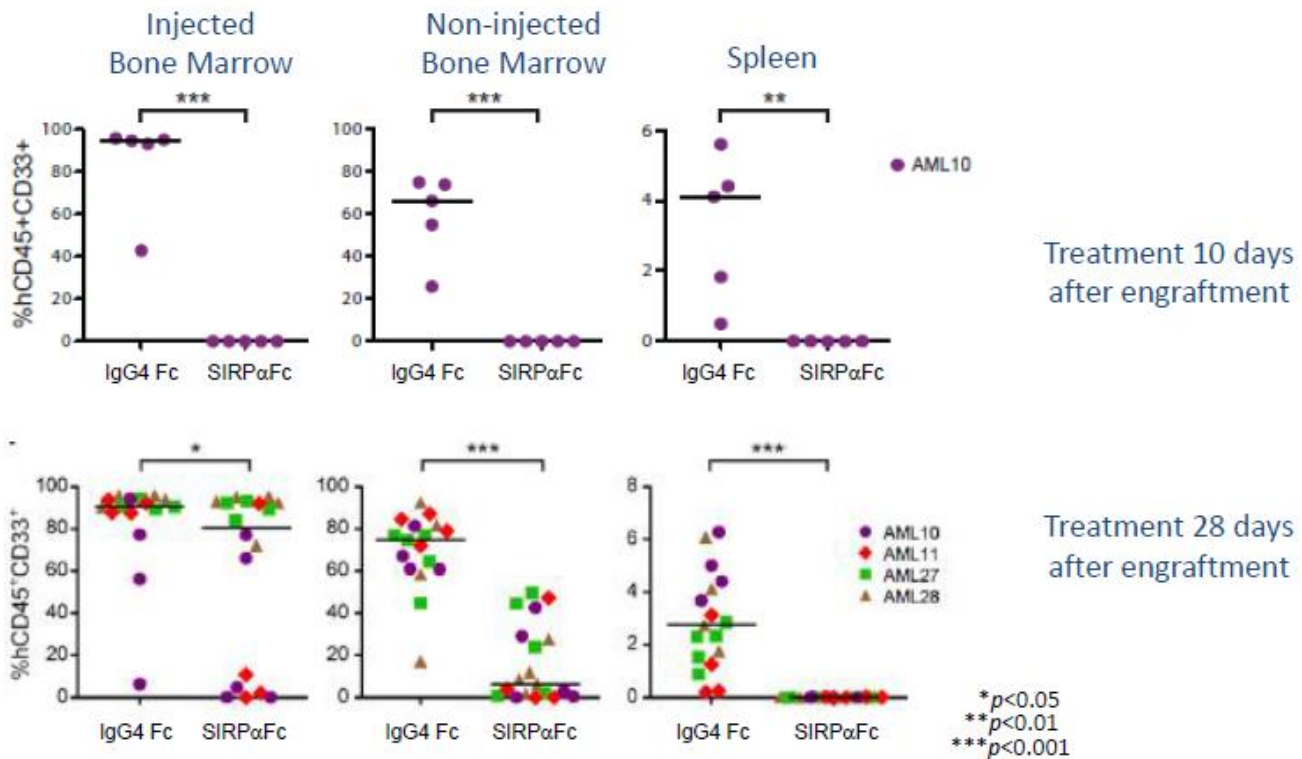
Source: Company

*SIRP $\alpha$ Fc has potent anti-leukemic activity in vivo*



The effect of SIRP $\alpha$ Fc was also tested in vivo in immuno-deficient mice bearing human AML grafts. Mice were treated either with SIRP $\alpha$ Fc or control antibody at doses of 8mg/kg three times per week for 4 weeks. Regardless of whether treatment was started 10 or 28 days after AML engraftment, mice treated SIRP $\alpha$ Fc had either complete eradication or substantially lower tumor burden by the end of the study, compared to the control group (Exhibit 4).

Exhibit 4. Human Leukemic Engraftment in Mice Treated with IgG4Fc Control or SIRP $\alpha$ Fc for 4 wk Starting 10 d and 28 d after Transplantation of Human AML Cells

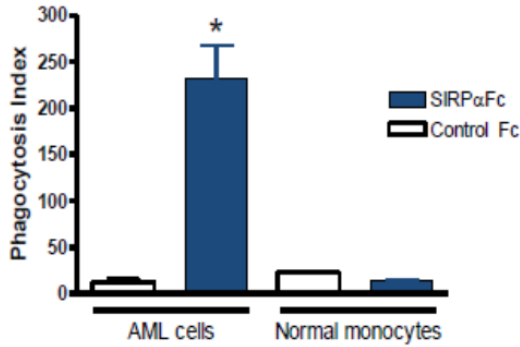


Source: Company

*SIRP $\alpha$ Fc has minimal effect on normal cells*

Importantly, the University of Toronto group and Trillium have demonstrated that while SIRP $\alpha$ Fc triggers extensive removal of AML cancer cells, the molecule does not impact levels of phagocytosis of normal blood cells in vitro (Exhibit 5), and does not affect hematopoiesis in vivo. In fact, in AML-bearing mice treated with SIRP $\alpha$ Fc, hematocrit actually increased (Uger et al., 2013 ASH poster).

**Exhibit 5 SIRP $\alpha$ Fc Blocks CD47 and Enables Macrophages to Kill only Target Cells that Express Pro-phagocytic Signals**



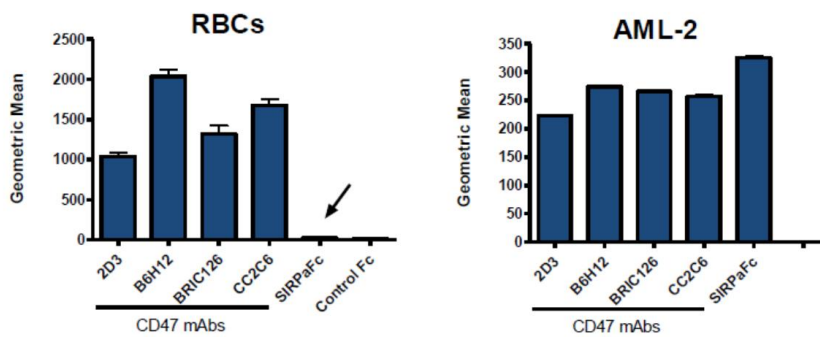
Source: Trillium Therapeutics Inc. Company presentation 2014/09/10

**Low Hematological Toxicity – A Potential Key Differentiator**

The destruction of cancerous AML cells but not normal blood cells is somewhat surprising, and potentially a key differentiator of Trillium’s SIRP $\alpha$ Fc. Normal blood cells express CD47 and one of the anticipated side-effects of CD47 blockade is depletion of RBCs. In fact, anemia effects have been reported by the Weissman lab in mouse models (Willingham et al. 2012 PNAS 109:6662).

A possible explanation for SIRP $\alpha$ Fc’s potentially differentiated effect on normal blood cells, may be related to affinity, since Trillium’s fusion protein binds very poorly to normal blood cells compared to anti-CD47 antibodies (Exhibit 6).

**Exhibit 6. SIRP $\alpha$ Fc Selectively Binds to AML-2 but not RBCs, while Commercially Available Anti-CD47Antibodies (2D3, B6H12, BRIC126, CC2C6) Bind Well to Both**



Source: Company

The benign profile of Trillium’s SIRP $\alpha$ Fc, if sustained in future testing, may become a key differentiator of the product since chemotherapy induces hematological toxicity, and cancers of the blood are themselves prone to anemia and leukopenia.

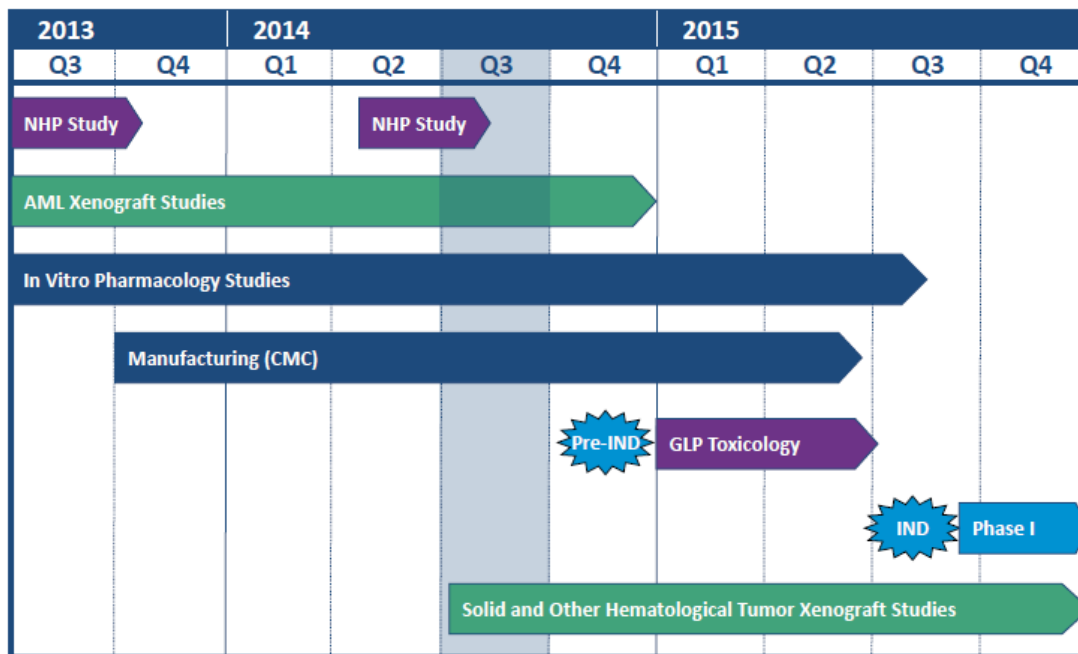




## Trillium’s TTI-621 (SIRP $\alpha$ Fc) Development Program

To date, Trillium’s pre-clinical development in cancer models, has focused mainly on acute myeloid leukemia (AML), following on the foundational work by the Dick laboratory. However, as discussed above, CD47 is also highly expressed in other cancers, and the company recently announced that it has collaborated with groups at the Lawson and Robarts Research Institutes in London, Canada, to explore the therapeutic potential of SIRP $\alpha$ Fc in a number of solid tumor models. Trillium expects to file an IND to initiate phase 1 testing of TTI-621 in AML by Q3-2015 and may expand the phase 1 program to include myelodysplastic syndromes and solid tumors, pending completion of the pre-clinical program (Exhibit 7).

Exhibit 7. Trillium’s Pipeline Development Plan



Source: Company

An ideal first-in-man AML trial would enroll patients who have achieved complete remission after first line chemotherapy, but are at high risk of relapse. In this patient group, long lasting remissions at higher doses would be encouraging from the standpoint of effectiveness, and low toxicity, in particular hematological toxicity, would be encouraging with respect to safety and differentiation. Trillium’s first phase 1 trial, however, may be limited to patients who are end-stage and who have been heavily pre-treated, likely resulting in reduced numbers of normal macrophages. In this situation, we would not expect the first phase 1 trial to elicit robust efficacy signals although pharmacokinetic and safety profiles of SIRP $\alpha$ Fc would be established.

Trillium’s second immunotherapy asset is anti-CD200 mAb. CD200 expression by human malignancies is associated with tumor progression, and CD200 is believed to act as an immunosuppressive molecule although the mechanism has not been fully elucidated. Alexion Pharmaceuticals (NYSE: ALXN; unrated) has completed a phase I clinical trial with its anti-CD200 antibody ALXN6000 (samalizumab). The drug was well tolerated by patients with advanced stage B-cell chronic lymphocytic leukemia (B-CLL) or multiple myeloma (MM), and in patients with sufficient peripheral immune cells to evaluate biological activity, 95% (19/20) showed 81% to 98% reductions in peripheral CD200+ CD4+ T cells (Kretz-Rommel et al., 2007 J Immunol 178:5595). Trillium’s anti-CD200 has entered pre-clinical development, and the company is seeking a partner before moving into human trials.



## Acute Myeloid Leukemia

AML is the second most common form of leukemia and the most frequent cause of leukemia related deaths (Bravo and Garcia-Manero 2014 Leukemia - Epub ahead of print). During 2014, it is estimated that there will be approximately 18,000 new diagnoses of AML in the United States, resulting in nearly 10,000 deaths (Siegel et al., 2014 CA Cancer J Clin 64: 9). Prognosis of AML is poor, with even worse outcomes in patients older than 65 years. In this group, median survival is 7.4 months and the 5-year survival rate is 10% (Kantarjian and O'Brien 2010 Cancer 116: 4896). First-line treatment of AML is cytarabine-based chemotherapy which has been little changed over the past 25 years. Current AML pharmacological management involves a complex mix of cytotoxic drugs, with each phase (induction, consolidation, and maintenance) utilizing chemotherapy. For example, cytarabine, methotrexate, cyclophosphamide and 6-mercaptopurine are used in the consolidation phase and monthly pulses of corticosteroids+cytarabine are used in the maintenance phase.

Different molecular mechanisms involved in AML pathogenesis have been elucidated in the past 10 years, including mutational events affecting cell cycle regulators (PIK3/PLK1), kinases (FLT3), and epigenetic regulators (DNMT). Arising from this basic research, anti-CD33, FLT3 inhibitors, Hedgehog Inhibitors, cell cycle kinase inhibitors, DNMT inhibitors, and HDAC inhibitors are all under various stages of clinical investigation with mixed success. Immunotherapy has also started to gain ground in AML. Targets for antigen-specific immunotherapy of hematological malignancies include Wilms tumor 1 (targeted by GSK with its phase 2 drug, GSK2130579), melanoma-associated antigens (MAGE), mucin-1 (MUC1) and the preferentially expressed antigen of melanoma (PRAME).

## Valuation

Our C\$20.75 target price for TR stock is based on valuations of companies that are either: 1) early leaders in the cancer immunotherapy space; or 2) small biotech companies with lead candidates either undergoing or finished phase 1/2 clinical trials. We believe that, if successful, Trillium can match these profiles, once it completes pre-clinical development and begins reporting preliminary phase 1 results for SIRPαFc (estimated 12-18 months). Exhibit 8 shows the enterprise values for comparable companies, and the inferred 12-18 month value for TR stock if initial SIRPαFc clinical testing is positive.

Exhibit 8.

Company	Ticker	Price	Shares (MM)	Market Cap (\$MM)	Cash	Debt	Enterprise Value
KITE Pharma	KITE	\$ 52.87	38.4	\$ 2,027.6	\$ 195.4	\$ -	\$ 1,832.2
OncoMed Pharmaceuticals	OMED	\$ 20.24	29.8	\$ 603.8	\$ 247.9	\$ -	\$ 355.9
Collectus	CMVLF	\$ 14.95	27.9	\$ 416.7	\$ 25.1	\$ 5.0	\$ 396.5
Five Prime Therapeutics	FPRX	\$ 22.42	21.6	\$ 483.2	\$ 130.0	\$ -	\$ 353.2
Mirati Therapeutics	MRTX	\$ 17.48	13.5	\$ 236.7	\$ 37.7	\$ -	\$ 199.0
Verastem	VSTM	\$ 8.34	25.9	\$ 215.9	\$ 93.4	\$ -	\$ 122.6
Agenus	AGEN	\$ 3.35	62.7	\$ 210.0	\$ 52.9	\$ 6.7	\$ 163.8
Affimed Therapeutics	AFMD	\$ 5.31	24.0	\$ 127.3	\$ 56.7	\$ 4.7	\$ 75.3
<b>Average (US\$)</b>				<b>\$ 482.3</b>			<b>\$ 379.5</b>
<b>Average (C\$)</b>				<b>\$ 540.2</b>			<b>\$ 425.0</b>
Trillium Therapeutics (basic)	TR	\$ 7.56	4.3	\$ 32.6	\$ 27.8	\$ 0.3	\$ 5.1
Trillium Therapeutics (f.d.; cash pro-forma exercise)	TR	\$ 7.56	12.0	\$ 90.9	\$ 73.9	\$ 0.3	\$ 17.3
Inferred TR value (C\$; f.d.)	TR	\$ 41.46	12.0	\$ 498.66	\$ 73.9	\$ 0.3	\$ 425.0
Inferred TR value (C\$; f.d.; ex-KITE)	TR	\$ 27.37	12.0	\$ 329.12	\$ 73.9	\$ 0.3	\$ 255.5

Source: Company reports, Bloomberg



Average enterprise value of the forward looking comparable companies is US\$379.5 million, which infers a target price of C\$41.46 per TR share. Due to the high risk of translating pre-clinical findings into humans, and Trillium's reliance on a single product, SIRP $\alpha$ Fc, to support the majority of value, we discount this value by 50% to arrive at our \$20.75 target price.

In summary, there is substantial upside to Trillium's current value if the company successfully progresses into a promising phase 1/2 program; the pre-clinical program thus far has been robust and results have been positive; and compelling results reported by others pursuing immuno-oncology therapies support the potential of the Trillium lead program. If Trillium's phase 1 program is successful, comparable companies' analysis suggests that TR stock could trade in the C\$25.00-\$40.00 range.



## Financial Forecasts

Balance Sheet (CAD\$000)	FY2013A	Q1A	Q2A	Q3A	Q4E	FY 2014E	FY 2015E	FY 2016E
<b>Current Assets</b>								
Cash & Short-Term Investments	\$ 32,456.5	\$ 31,864.4	\$ 30,041.0	\$ 27,754.4	\$ 24,799.0	\$ 24,799.0	\$ 12,837.1	\$ 729.2
Marketable securities	\$ 526.6	\$ 528.4	\$ 504.0	\$ 505.5	\$ 505.5	\$ 505.5	\$ 505.5	\$ 505.5
Short-Term Receivables	\$ 427.2	\$ 595.5	\$ 487.3	\$ 468.3	\$ 468.3	\$ 468.3	\$ 468.3	\$ 468.3
Other Current Assets	\$ 94.6	\$ 75.2	\$ 117.9	\$ 719.7	\$ 719.7	\$ 719.7	\$ 719.7	\$ 719.7
<b>Total current assets</b>	<b>\$ 33,504.9</b>	<b>\$ 33,063.4</b>	<b>\$ 31,150.2</b>	<b>\$ 29,447.9</b>	<b>\$ 26,492.4</b>	<b>\$ 26,492.4</b>	<b>\$ 14,530.5</b>	<b>\$ 2,422.7</b>
<b>Long-term Assets</b>								
Net Property, Plant & Equipment	\$ 109.0	\$ 112.8	\$ 228.9	\$ 221.4	\$ 221.4	\$ 221.4	\$ 221.4	\$ 221.4
Intangible Assets	\$ 1,473.5	\$ 1,252.9	\$ 602.6	\$ 517.8	\$ 517.8	\$ 517.8	\$ 517.8	\$ 517.8
<b>Total Assets</b>	<b>\$ 35,087.4</b>	<b>\$ 34,429.2</b>	<b>\$ 31,981.7</b>	<b>\$ 30,187.0</b>	<b>\$ 27,231.6</b>	<b>\$ 27,231.6</b>	<b>\$ 15,269.7</b>	<b>\$ 3,161.9</b>
<b>Liabilities and Shareholders' Equity</b>								
Accounts Payable	\$ 669.9	\$ 903.4	\$ 1,012.2	\$ 1,358.8	\$ 1,358.8	\$ 1,358.8	\$ 1,358.8	\$ 1,358.8
Other Current Liabilities	\$ 62.8	\$ 93.6	\$ 120.5	\$ 263.9	\$ 263.9	\$ 263.9	\$ 263.9	\$ 263.9
<b>Total Current Liabilities</b>	<b>\$ 732.6</b>	<b>\$ 997.0</b>	<b>\$ 1,132.7</b>	<b>\$ 1,622.6</b>	<b>\$ 1,622.6</b>	<b>\$ 1,622.6</b>	<b>\$ 1,622.6</b>	<b>\$ 1,622.6</b>
Loan payable	\$ 341.9	\$ 326.5	\$ 311.6	\$ 297.2	\$ 283.2	\$ 283.2	\$ 227.2	\$ 171.2
Other Liabilities	\$ 104.4	\$ 114.5	\$ 116.4	\$ 66.9	\$ 66.9	\$ 66.9	\$ 66.9	\$ 66.9
<b>Total Liabilities</b>	<b>\$ 1,178.9</b>	<b>\$ 1,438.0</b>	<b>\$ 1,560.7</b>	<b>\$ 1,986.7</b>	<b>\$ 1,972.7</b>	<b>\$ 1,972.7</b>	<b>\$ 1,916.7</b>	<b>\$ 1,860.7</b>
<b>Shareholders' Equity</b>								
Common Shares	\$ 47,191.3	\$ 48,266.6	\$ 48,579.4	\$ 48,807.0	\$ 48,807.0	\$ 48,807.0	\$ 48,807.0	\$ 48,807.0
Preferred Stock (Carrying Value)	\$ 11,292.5	\$ 11,292.5	\$ 11,002.6	\$ 10,774.9	\$ 10,774.9	\$ 10,774.9	\$ 10,774.9	\$ 10,774.9
Warrants	\$ 9,818.2	\$ 9,283.3	\$ 9,283.3	\$ 9,283.3	\$ 9,283.3	\$ 9,283.3	\$ 9,283.3	\$ 9,283.3
Contributed surplus	\$ 3,280.7	\$ 3,863.0	\$ 5,370.4	\$ 5,676.3	\$ 5,676.3	\$ 5,676.3	\$ 5,676.3	\$ 5,676.3
Deficit	\$(37,674.2)	\$(39,714.3)	\$(43,814.6)	\$(46,341.2)	\$(49,282.6)	\$(49,282.6)	\$(61,188.5)	\$(73,240.4)
<b>Total Shareholders' Equity</b>	<b>\$ 33,908.4</b>	<b>\$ 32,991.2</b>	<b>\$ 30,421.0</b>	<b>\$ 28,200.4</b>	<b>\$ 25,259.0</b>	<b>\$ 25,259.0</b>	<b>\$ 13,353.1</b>	<b>\$ 1,301.2</b>
<b>Total Liabilities &amp; Shareholders' Equity</b>	<b>\$ 35,087.4</b>	<b>\$ 34,429.2</b>	<b>\$ 31,981.7</b>	<b>\$ 30,187.0</b>	<b>\$ 27,231.6</b>	<b>\$ 27,231.6</b>	<b>\$ 15,269.7</b>	<b>\$ 3,161.9</b>
<b>Income Statement (CAD\$000)</b>								
	<b>FY2013</b>	<b>Q1A</b>	<b>Q2A</b>	<b>Q3A</b>	<b>Q4E</b>	<b>FY 2014E</b>	<b>FY 2015E</b>	<b>FY 2016E</b>
Research & Development	\$ 3,336.7	\$ 1,565.5	\$ 3,105.4	\$ 2,090.0	\$ 2,500.0	\$ 9,260.9	\$ 10,000.0	\$ 10,000.0
G&A	\$ 962.2	\$ 561.6	\$ 1,076.0	\$ 500.1	\$ 500.0	\$ 2,637.6	\$ 2,000.0	\$ 2,000.0
Operating Income (loss)	\$ (4,298.9)	\$ (2,127.1)	\$ (4,181.4)	\$ (2,590.0)	\$ (3,000.0)	\$(11,898.5)	\$(12,000.0)	\$(12,000.0)
Finance Income	\$ (54.0)	\$ (108.6)	\$ (102.5)	\$ (92.5)	\$ (82.6)	\$ (386.1)	\$ (170.9)	\$ (9.6)
Finance cost	\$ 44.4	\$ 21.6	\$ 21.5	\$ 29.0	\$ 24.0	\$ 96.0	\$ 76.8	\$ 61.5
<b>Net loss for period</b>	<b>\$ (4,289.3)</b>	<b>\$ (2,040.1)</b>	<b>\$ (4,100.4)</b>	<b>\$ (2,526.5)</b>	<b>\$ (2,941.4)</b>	<b>\$(11,608.4)</b>	<b>\$(11,905.9)</b>	<b>\$(12,051.9)</b>
EPS (basic and diluted)	\$ (0.11)	\$ (0.02)	\$ (0.03)	\$ (0.02)	\$ (0.68)	\$ (0.75)	\$ (2.76)	\$ (2.80)
<b>Statement of Cash Flow (CAD\$000)</b>								
	<b>FY2013</b>	<b>Q1A</b>	<b>Q2A</b>	<b>Q3A</b>	<b>Q4E</b>	<b>FY 2014E</b>	<b>FY 2015E</b>	<b>FY 2016E</b>
Net Change in Cash	\$31,081.5	\$ (592.1)	\$ (1,823.4)	\$ (2,286.6)	\$ (2,955.4)	\$ (7,657.5)	\$(11,961.9)	\$(12,107.9)
Cash beginning period	\$ 1,375.0	\$32,456.5	\$31,864.4	\$30,041.0	\$27,754.4	\$32,456.5	\$ 24,799.0	\$ 12,837.1
Cash end period	\$32,456.5	\$31,864.4	\$30,041.0	\$27,754.4	\$24,799.0	\$24,799.0	\$ 12,837.1	\$ 729.2

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Accumulate - Expected to outperform the sector average over the next 12 months or longer.

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Sell - Expected to materially underperform the sector average over the next 12 months.

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Speculative - High volatility and risk expected; potential for balance sheet concerns, low public float. Stock may be suitable for only a small subset of equity investors willing to take on the risks of a high risk investment.

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Rating	Percentage	Number
BUY	57%	4
ACCUMULATE	28.6%	2
HOLD	14%	1
SELL	0%	0
<b>Total:</b>	100%	7