Zacks Small-Cap Research

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Bellus Health, Inc. (T.BLU-TSX)

BLU: Kiacta™ Phase 3 Still on Track for Results in 2016.

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/19/2014
Current Price (03/2/15)	$1.14
Target Price	**$2.50**

UPDATE

On February 25, 2015, Bellus Health, Inc. announced financial results for the fourth quarter and full year ending December 31, 2014. For the year, the company reported $2.38 million in revenue and had a net loss of $1.97 million, or $0.04 per share. The company exited the year with approximately $12.3 million in cash, which we estimate will be enough to finance operations past the conclusion of the Kiacta Phase 3 clinical trial. More than two-thirds of the required events to complete the Kiacta™ Phase 3 study have occurred; the study remains on track to conclude in 2016. During the fourth quarter the company sold all of its asset-backed commercial paper ("ABCP Notes"), netting $0.15 million in cash and saving an equivalent amount in future interest payments.

52-Week High	**$1.61**
52-Week Low	**$0.40**
One-Year Return (%)	**65.60**
Beta	**3.01**
Average Daily Volume (sh)	**1,565**
Shares Outstanding (mil)	**47**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**10.25**
Institutional Ownership (%)	**12**
Insider Ownership (%)	**24**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of C$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	$0.5 A	$0.4 A	$0.4 A	$1.1 A	$2.4 A
2015	$0.6 E	$0.6 E	$0.6 E	$0.6 E	$2.4 E
2016					$2.5 E
2017					$2.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.01 A	-$0.02 A	$0.01 A	$0.00 A	-$0.04 A
2015	-$0.01 E	-$0.01 E	-$0.01 E	-$0.01 E	-$0.05 E
2016					-$0.08 E
2017					-$0.08 E

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WHAT'S NEW

Financial Update (in Canadian dollars)

On February 25, 2015, Bellus Health, Inc. (BLU.TO) (BLUSF) reported financial results for the fourth quarter and full year for 2014. Revenues for the fourth quarter totaled $1.06 million, compared to $0.75 million in the corresponding period of 2013, and consisted mostly of revenue recognized for accounting purposes from the asset sale and licensing agreement and the service agreement entered into with Auven Therapeutics in 2010 in relation to Kiacta™. The increase is primarily due to higher revenue recognized following an increase, during the fourth quarter of 2014, of management's estimate of Bellus' expected support and assistance to Auven Therapeutics in connection with the development plan for Kiacta™, which adjusted the expected amount receivable by the company over the life of the service agreement. For the full year 2014, the company had revenues of $2.4 million, compared to $2.3 million for 2013.

Operating expenses for the fourth quarter consisted of $0.6 million in G&A and $0.46 million in R&D. Both expenses were below our expectations, as the company remains focused on controlling costs ahead of the Phase 3 Kiacta™ data expected in mid-to-late 2016. During the fourth quarter and full year, there was a net finance gain of $0.2 million and $0.45 million, respectively, which was mainly attributable to the depreciation of the Canadian dollar versus the U.S. dollar and the decrease in the fair value of the ABCP Notes compared to the previous year. For 2014, G&A expenses were $3.15 million while R&D expenses totaled $1.7 million, compared to $4.28 million in G&A and $1.27 million in R&D for 2013. The decrease in G&A expenses in 2014 is mainly attributable to transaction costs in 2013 associated with the acquisition of Thallion. The increase in R&D expenses in 2014 was primarily attributable to expenses incurred in relation to the development of Shigamab™.

Bellus reported a net gain of $0.22 million, or $0.00 per share during the fourth quarter 2014. For 2014, the company had a net loss of $1.97 million, or $0.04 per share. As of December 31, 2014 the company had cash, cash equivalents, and short-term investments of approximately $12.3 million, compared to $15.3 million on December 31, 2013 and $12.7 million on September 30, 2014. We remind investors that the cost of the confirmatory Phase 3 study with Kiacta™ is in the area of $60 million; however, this amount is being fully funded by Bellus' partner, Auven Therapeutics. As such, we estimate Bellus current cash balance of $12.3 million is enough to finance the company's operations beyond the end of the Phase 3 study in 2016.

Kiacta™ Phase 3 Study Fully Enrolled

The Kiacta™ Phase 3 confirmatory study (NCT01215747) completed enrollment in January 2015, with a total of 261 patents participating in the study. The study had previously reached its target enrollment of 230 patients earlier in 2014; however, the enrollment was extended beyond 230 patients as eligible patients who were in the pre-screening and screening process at the time the target enrollment was reached were allowed the opportunity to enroll in the study.

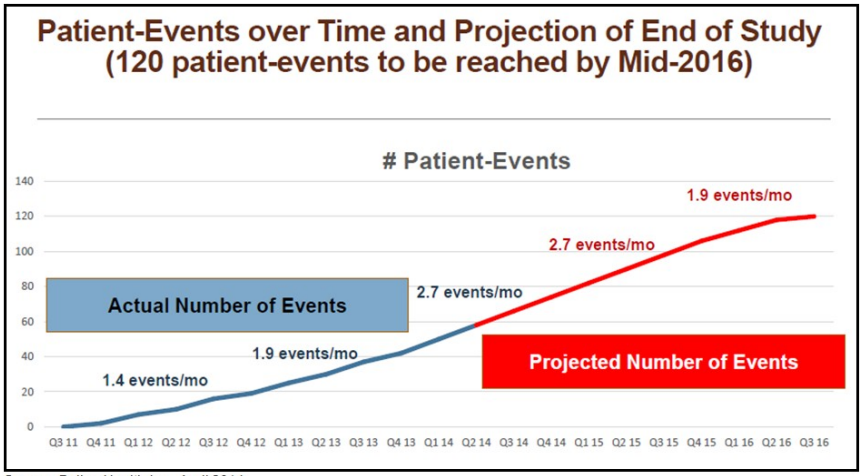
Kiacta™ (eprodisate) in an orally available small molecule intended for the treatment of Amyloid A (AA) Amyloidosis. To qualify for the study, patients must have had confirmed AA Amyloidosis demonstrated by positive biopsy using congo red staining and immuno-histochemistry or electronmicroscopy. Patients must have had persistent proteinuria greater than 1 gram and a CrCl level greater than 25 ml/min at two distinct visits over a 24-hour period. Randomization was 1:1 between Kiacta™ and the placebo. Enrollment took place at over 70 sites in 30 countries around the globe.

As a reminder, the confirmatory Phase 3 study is an event-driven trial that will end when 120 patients have experienced renal decline and for which the company has obtained a U.S. FDA Special Protocol Assessment (SPA). Renal decline, the primary endpoint of the study, is a composite assessment of persistent increase in serum creatinine ≥ 80%, persistent decrease in creatinine clearance ≥ 40%, or progression to end-stage renal disease / dialysis. The primary efficacy analysis is the 'Time to first worse event (log rank test)' stratified by baseline proteinuria (3 g/day) and eGFR (60 ml/min). Increasing the size of the study from 230 to 261 patients will help assure the 120 patient events are reached in a timely manner.

As with most other clinical trials, there are occasional meetings of the Data Safety Monitoring Board (DSMB) as part of the Phase 3 study for Kiacta™. The DSMB independently assesses the safety of Kiacta™ treatment throughout

the study. The DSMB last met in December 2014 and recommended that the study continue as per protocol.

As of late February 2015, Bellus reported that more than two-thirds of the target 120 events (~82 events) have occurred. Based on event dynamics reported in April 2014, roughly two-thirds of the patient events have more than one event, with the most common event being a ≥ 40% decrease in CrCl. In April 2014, roughly 55 events had occurred, and in the intervening 10 months almost more 30 events have occurred, meaning that trial participants have been experiencing roughly 3 events per month. Based on these numbers, we are estimating for the trial to complete in approximately April/May 2016.



Source: Bellus Health Inc., April 2014

We remind investors that Kiacta™ is partnered with the global private equity firm Auven Therapeutics. Auven is conducting the Phase 3 trial and funding 100% of the development costs, which are estimated to cost in excess of US$60 million.

Sarcoidosis Represents Upside To Kiacta™ Value

In May 2014, Bellus and Auven announced they had signed a license agreement with Mount Sinai Hospital under which Auven obtained rights to develop Kiacta™ as a treatment for chronic sarcoidosis. By obtaining the rights to utilize Kiacta™ in a second indication, Bellus and Auven could further expand the commercial potential of the drug while helping patients suffering from this sometimes debilitating chronic disease.

Sarcoidosis is a rare condition that involves the growth of tiny collections of immune cells in different parts of the body, however it most commonly occurs in the lungs and the skin. The condition affects approximately 120,000 individuals in the U.S. While most patients will go on to recover, approximately 30% of patients will go on to develop a chronic, debilitating disease, with death occurring in between 1-5% of patients.

The current plan for the development of Kiacta™ as a treatment for sarcoidosis is for Auven to conduct a Phase 2 proof-of-concept clinical trial to evaluate the safety and effectiveness of Kiacta™ as a treatment for certain medical manifestations of sarcoidosis during the first half of 2015. A study protocol should be finalized shortly. The Phase 2 trial should take approximately 18 months to complete. Just as with the confirmatory trial in AA amyloidosis, all costs related to the development of Kiacta™ in sarcoidosis will be borne by Auven. Any proceeds from potential future revenue of Kiacta™, including the rights to Kiacta™ for sarcoidosis, are subject to the proceeds sharing agreement between Bellus and Auven.

Bellus sells ABCP notes and settles credit facilities

On November 26, 2014, Bellus announced the sale of its ABCP Notes and the settlement of its credit facilities. The company sold all of its asset-backed commercial paper notes for $5.345 million, which the company in turn utilized to settle its credit facilities, which amounted to $5.193 million, which were scheduled to mature in April 2016. In the process, the company generated $0.15 million in cash. In addition, by settling the credit facilities early the company will save approximately $0.15 million in future interest payments, thus with this transaction the company eliminated the market risk associated with the assets and extended its cash runway by an additional $0.3 million.

Investor Outreach Activities

In an effort to maintain direct communications with investors and other interested parties, Bellus has established official portals on social media channels including Facebook, Twitter, LinkedIn, and Google+. The company's CEO, Roberto Bellini, is also on Twitter @rbellini. In addition, the company will be launching an official blog on their website, which the company plans to use to address important topics related to company projects, rare diseases, and industry trends.

Conclusion: Valuation & Recommendation

We believe Bellus Health is worth $2.50 per share. Bellus is developing Kiacta™ for the treatment of AA amyloidosis. Our analysis largely values the company based on the potential for Kiacta™ in AA Amyloidosis, with some minor upside over the next several quarters based on progression into new areas of indications such as sarcoidosis, or with pre-clinical monoclonal antibody candidate, Shigamab™, for the treatment of hemolytic uremic syndrome (HUS) related to Shiga toxin-producing *E. coli* infection (STEC). Bellus has been granted Orphan Drug designation for Shigamab™ in the U.S. and EU for STEC-HUS. During the third quarter 2014, Bellus reported positive mouse model data performed in collaboration with the Uniformed Services University of the United States Department of Defense. The data show Shigamab™ was able to prevent toxicity of Shiga toxin type 2 in a sHUS as measured by body weight loss, renal biomarkers, and renal histopathology.

We have constructed a model to derive a fair value for Bellus Health based upon a discounted cash flow analysis where we estimate the future revenues that Kiacta™ would likely bring in after approval if Bellus were to market the drug on their own. We use this as a guide for what an acquiring company would reasonably be expected to pay for Kiacta™. We are modeling for Kiacta™ to be priced at $200,000/year in the U.S., $150,000/year in the E.U., and have conservatively modeled peak market share of between 25-45%. We model that Bellus would receive 50% of revenues per their agreement with Auven and estimate a 50% net income rate. We apply a discount rate of between 15-25% and believe that the Phase 3 confirmatory study has a 75% chance of success.

The following tables give the net present value (NPV) per share of Bellus' future cash flows from sales of Kiacta™ based on the aforementioned assumptions as well as the price per share based on 65.7 million shares fully diluted.

Discount Rate \ Market Share	45%	40%	35%	30%	25%
25%	$2.32	$2.00	$1.66	$1.58	$1.38
23%	$2.76	$2.37	$1.97	$1.87	$1.64
20%	$3.29	$2.83	$2.36	$2.22	$1.95
18%	$3.95	$3.40	$2.83	$2.67	$2.34
15%	$4.77	$4.11	$3.43	$3.22	$2.83

Bellus' fair value per share

Based upon our model, we value Bellus at $2.50/share. This is based on a conservative 35% peak market share for Kiacta™ using a 20% discount rate. Given the current stock price, we believe that Bellus is significantly undervalued and offers investors tremendous upside at the current valuation. We reiterate the fact that Bellus and Auven have hired Lazard to facilitate the sale of Kiacta™, which we believe increases the likelihood that a larger pharmaceutical company will end up acquiring the drug.

Another caveat to our valuation is that our model does not account for Bellus signing a licensing deal instead of selling Kiacta™. We forecast Kiacta™ to have peak revenues of between $500 million and $1 billion, which would justify an upfront payment of $50 to $100 million coupled with mid-teens royalties. The upfront cash would certainly cause the market to re-price the stock appropriately, and depending upon the royalty rate could supply Bellus with a steady stream of income to deploy for development of additional products.

…Potential Risks Are Obvious…

The biggest risk to our investment thesis is if the confirmatory Phase 3 study for Kiacta™ fails. We've previously gone into detail why we believe the trial will be a success (see our last update); however, if we are wrong and the trial fails, Bellus Health stock will tumble dramatically. Besides the obvious risk to running a large Phase 3 trial, additional risks include the timing and level at which Bellus and Auven can partner Kiacta™. We believe Kiacta™

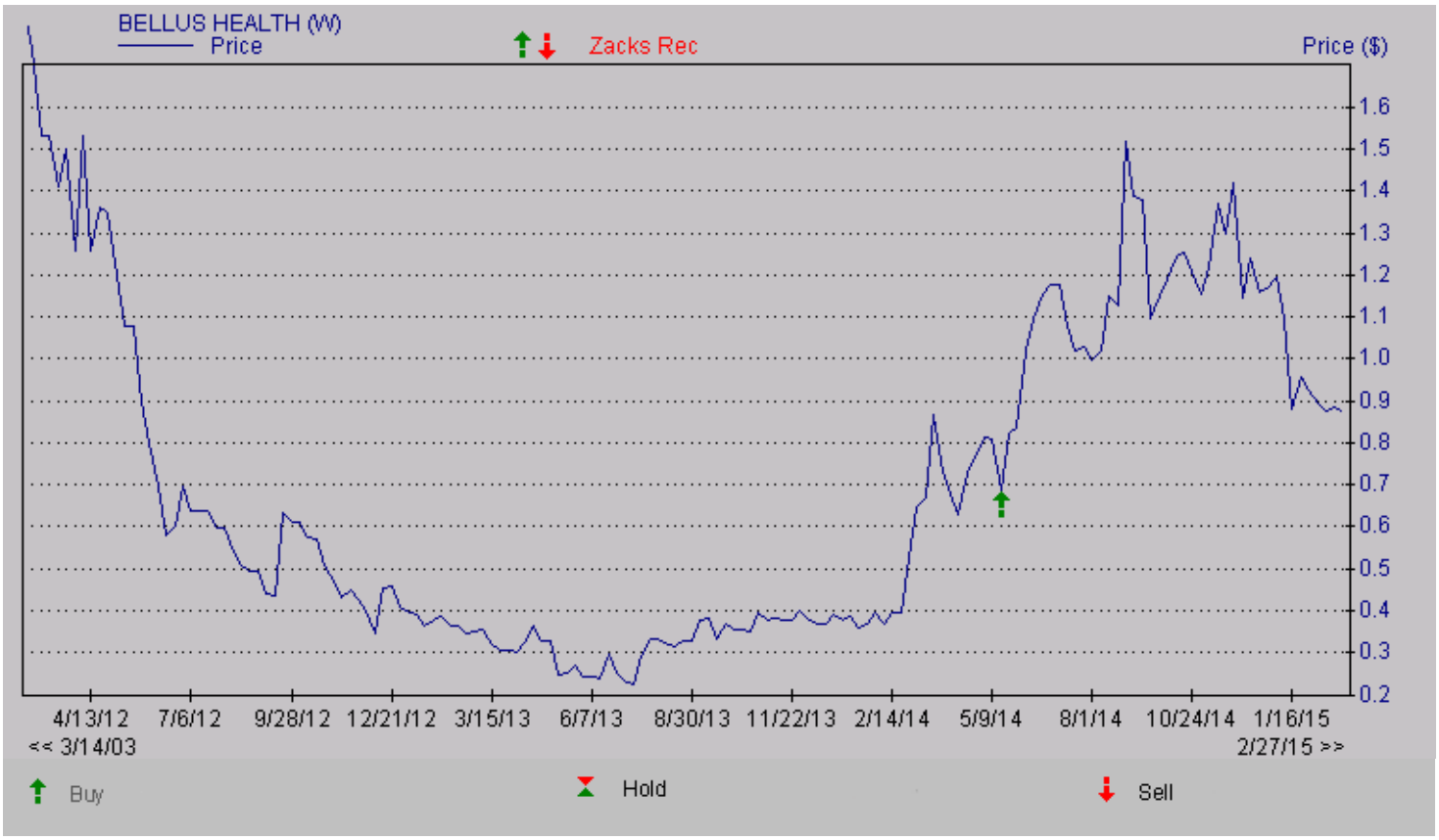
will be a highly attractive pre-NDA asset for a larger pharmaceutical company based on Orphan Disease market dynamics and limited competition. However, for investors to realize the full value of the asset Bellus and Auven need to strike a favorable partnership for commercialization. The timing and level represent risk because Bellus has enough cash to fund operations to late 2016. Thus, because we cannot guarantee a deal by that time, investors today need to be aware of financing and execution risk beyond simply clinical trial risk.

Bellus Health, Inc.
Income Statement (in Canadian dollars)

Bellus Health, Inc.	2014 A	Q1 E	Q2 E	Q3 E	Q4 E	2015 E	2016 E
Revenues	$2.376	$0.600	$0.600	$0.600	$0.600	$2.400	$2.500
YOY Growth	-					-	-
Total Revenues	$2.376	$0.600	$0.600	$0.600	$0.600	$2.400	$2.500
YOY Growth	-					-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
General & Administration	$3.150	$0.650	$0.700	$0.750	$0.800	$2.900	$5.500
Research & Development	$1.695	$0.450	$0.475	$0.500	$0.500	$1.925	$1.800
Other Operating Expenses	$0	$0	$0	$0	$0	$0	$0
Operating Income	($2.5)	($0.5)	($0.6)	($0.7)	($0.7)	($2.4)	($4.8)
Operating Margin	-					-	-
Non-Operating Expenses (Net)	$0.45	$0.03	$0.03	$0.03	$0.03	$0.12	
Pre-Tax Income	($2.017)	($0.470)	($0.545)	($0.620)	($0.670)	($2.305)	($4.800)
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($1.97)	($0.470)	($0.545)	($0.620)	($0.67)	($2.31)	($4.80)
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($0.04)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.05)**	**($0.09)**
YOY Growth	-					-	-
Basic Shares Outstanding	47.4	47.4	47.4	47.4	47.4	47.4	55.00

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

HISTORICAL ZACKS RECOMMENDATIONS



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