Zacks Small-Cap Research

May 19, 2015
Jason Napodano, CFA
David Bautz, PhD
312-265-9421 / jnapodano@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

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

BLU: Kiacta™ Phase 3 Clinical Trial 75% Completed; Results in 2016…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/19/2014
Current Price (05/19/15)	$1.23
Target Price	**$2.50**

UPDATE

On May 19, 2015, Bellus Health, Inc. announced financial results for the first quarter of 2015. The company reported $0.79 million in revenue and had a net loss of $0.007 million, or $0.00 per share. The company exited the quarter with approximately $11.5 million in cash, which we estimate will be enough to finance operations past the conclusion of the Kiacta Phase 3 clinical trial. Approximately three-quarters of the required events to complete the Kiacta™ Phase 3 study have occurred; the study remains on track to conclude in 2016. The company has plans to initiate a Phase 2 study of Kiacta™ for the treatment of sarcoidosis in the second half of 2015.

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 2015 Estimate	**N/A**
P/E using 2016 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	$0.8 A	$0.7 E	$0.7 E	$0.7 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	-$0.00 A	-$0.01 E	-$0.01 E	-$0.01 E	-$0.03 E
2016					-$0.08 E
2017					-$0.08 E

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Update (in Canadian dollars)

On May 12, 2015, Bellus Health, Inc. (BLU.TO) (BLUSF) announced financial results for the first quarter of 2015. Revenues for the quarter totaled $0.79 million, compared to $0.48 million in the corresponding period of 2013. The increase in revenue is primarily attributable to sales-based royalty revenue received in 2015 in relation to the VIVIMEND™ licensing agreement with FB Health along with higher revenue recognized for accounting purposes in 2015 in relation to the service agreement with Auven Therapeutics for Kiacta™.

Operating expenses for the quarter consisted of $0.72 million in G&A and $0.32 million in R&D, compared to $0.89 million in G&A and $0.46 million in R&D in the corresponding period the previous year. The decrease in G&A expenses was primarily due to lower expenses recognized in 2015 in relation to the company's deferred share unit and stock option plans. The decrease in R&D expenses was primarily attributable to lower expenses incurred in the development of Shigamab™ during 2015. During the first quarter there was a net finance gain of $0.24 million, which was mainly attributable to the depreciation of the U.S. dollar versus the Canadian dollar. Net loss for the quarter was $0.007 million, or $0.00 per share.

As of March 31, 2015 the company had cash, cash equivalents, and short-term investments of approximately $11.5 million. 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 $11.5 million is enough to finance the company's operations beyond the end of the Kiacta™ Phase 3 study in 2016.

Three-Quarters of Required Events Have Occurred in Kiacta™ Phase 3 Study

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.

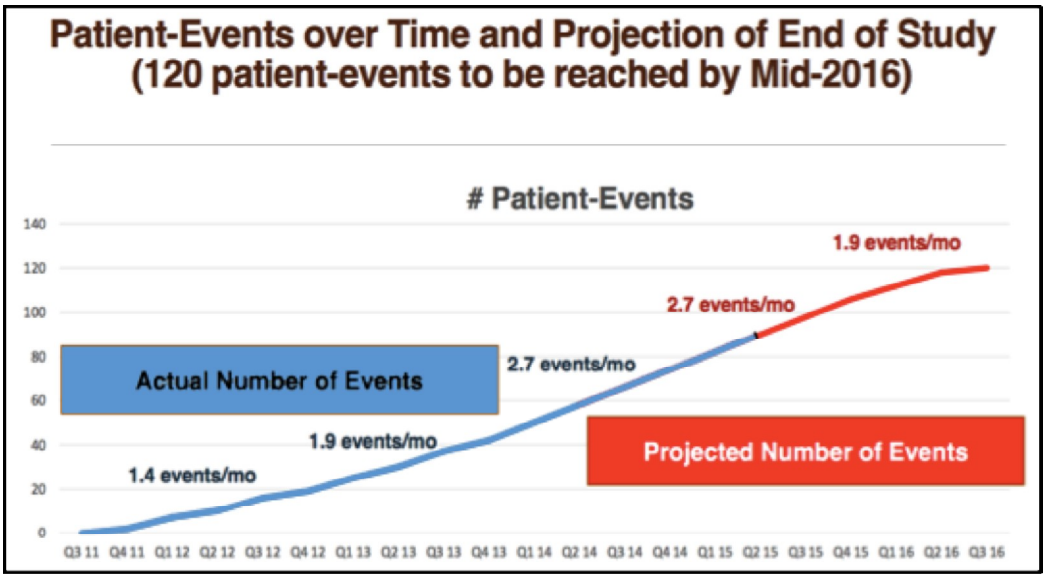
Kiacta™ (eprodisate) in an orally available small molecule intended for the treatment of Amyloid A (AA) Amyloidosis. To qualify for the study, patients must have had confirmed AA Amyloidosis demonstrated by positive biopsy using congo red staining and immuno-histochemistry or electronmicroscopy. Patients 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 mid-May 2015, Bellus reported that approximately three-quarters of the target 120 events (~89 events) have occurred. In April 2014, roughly 55 events had occurred, and in the intervening 13 months approximately 34 events have occurred, meaning that trial participants have been experiencing roughly 2.6 events per month. This is keeping in line with prior company projections, and we have updated the projection graph previously presented by the company to show that the trial is proceeding as previously anticipated.

We believe the number of events per month will decrease somewhat as the trial moves forward, due to their being a smaller number of patients from which events can occur. At this point, based on the aforementioned numbers, we are estimating for the trial to complete in approximately mid-2016.



***Source*: Bellus Health / Zacks SCR**

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 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 that will initiate in the second 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.

Shigamab™ Preclinical Studies Ongoing

Shigamab™ is a monoclonal antibody therapy being developed for the treatment of Hemolytic Uremic Syndrome caused by Shiga toxin-producing *E. coli* (sHUS), which principally affects the kidneys and often leads to acute dialysis, and in certain cases chronic kidney disease and death, primarily in children. Bellus has been granted Orphan Drug designation for Shigamab™ in the U.S. and EU for sHUS.

During 2014, in studies performed in collaboration with the Uniformed Services University of the U.S. Department of Defense, Shigamab™ was shown to reduce toxicity of Shiga toxin type 2 in a sHUS mouse model, even following delayed treatment, as measured by body weight loss, renal biomarkers and renal histopathology. Further pre-clinical studies are being conducted to evaluate Shigamab™ in the treatment of toxicity of Shiga toxin type 2.

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 has launched 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™.

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.

Market Share

Discount Rate	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 continues to be 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.

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

Bellus Health, Inc.	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E
Revenues	**$2.376**	**$0.786**	**$0.700**	**$0.700**	**$0.700**	**$2.886**	**$2.500**
YOY Growth	-					-	-
Total Revenues	**$2.376**	**$0.786**	**$0.700**	**$0.700**	**$0.700**	**$2.886**	**$2.500**
YOY Growth	-					-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
General & Administration	$3.150	$0.719	$0.750	$0.750	$0.800	$3.019	$5.500
Research & Development	$1.695	$0.323	$0.475	$0.500	$0.500	$1.798	$1.800
Other Operating Expenses	$0	$0	$0	$0	$0	$0	$0
Operating Income	($2.5)	($0.3)	($0.5)	($0.6)	($0.6)	($1.9)	($4.8)
Operating Margin	-					-	-
Non-Operating Expenses (Net)	$0.45	$0.2	$0.03	$0.03	$0.03	$0.33	
Pre-Tax Income	($2.017)	($0.012)	($0.495)	($0.520)	($0.570)	($1.597)	($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)	($0.007)	($0.495)	($0.520)	($0.57)	($1.59)	($4.80)
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($0.04)**	**($0.00)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($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

Chart by Yahoo! Finance



Initiation of Coverage: May 20, 2014 @ $0.78

Buy Hold Sell

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Jason Napodano, CFA, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1072 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.8%, Hold/Neutral- 76.4%, Sell/Underperform – 5.9%. Data is as of midnight on the business day immediately prior to this publication.