Zacks Small-Cap Research

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

BLU.TO: Results From Kiacta™ Phase 3 Clinical Trial Expected in mid-2016; Bellus Reports Third Quarter Financials…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	08/21/2015
Current Price (11/17/15)	$0.82
Target Price	**$2.50**

UPDATE

On November 12, 2015, Bellus Health, Inc. announced financial results for the third quarter of 2015. The company reported $0.59 million in revenue and had a net loss of $0.18 million, or $0.01 per share. The company exited the quarter with approximately $10.7 million in cash and cash equivalents, which we estimate will be enough to finance operations past the conclusion of the Kiacta Phase 3 clinical trial.

Approximately 85% of the required events to complete the Kiacta™ Phase 3 study have occurred; the study remains on track to conclude in the first quarter of 2016, with top-line data expected in mid-2016. The company has plans to file an IND for conducting a Phase 2/3 study of Kiacta™ for the treatment of sarcoidosis before the end of 2015.

52-Week High	**$1.59**
52-Week Low	**$0.76**
One-Year Return (%)	**-9.6**
Beta	**3.61**
Average Daily Volume (sh)	**15,995**
Shares Outstanding (mil)	**47**
Market Capitalization ($mil)	**$39**
Short Interest Ratio (days)	**10.25**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**18**
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	$0.6 A	$0.6 A	$0.7 E	$2.6 E
2016					$2.7 E
2017					$2.8 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 A	-$0.00 A	-$0.01 E	-$0.02 E
2016					-$0.05 E
2017					-$0.02 E

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WHAT'S NEW

BLO.TO: Third Quarter Financial Results

On November 12, 2015 Bellus Health (BLU.TO) (BLUSF) reported its financial and operating results for the third quarter ending September 30, 2015.

Bellus Health's pipeline of rare disease projects includes KIACTA™ in Phase 3 for AA amyloidosis, KIACTA™ for sarcoidosis, clinical stage Shigamab™ for Hemolytic Uremic Syndrome caused by Shiga toxin-producing E. coli (sHUS) and a research-stage project for AL amyloidosis.

In April 2010, Auven Therapeutics acquired the worldwide rights to KIACTA ™ for an upfront payment of $10 million to Bellus. Third quarter 2015 revenues came in at $593,000 compared to $420,000 in the same period the prior year. Most of the $593,000 is from the $10 million payment from Auven, amortized over the estimated period of KIACTA™'s development. In addition, Auven agreed to fund 100% of the development costs associated with the confirmatory Phase 3 study. The plan is to sell or license the rights to KIACTA ™ to a commercial entity before or right after conclusion of the confirmatory Phase 3 study.

In September, management met with the Scientific Advisory Board (SAB) to discuss the design of the Phase 2 clinical study protocol involving Shigamab™ in the treatment of sHUS. The company intends to meet with regulatory authorities in 2016 to present its clinical development plan. Consequently, as there were no on-going trials associated with Shigamab™, R & D expenses decreased ($340,000) during this period as compared to Q3 2014 ($406,000). G & A expenses amounted to $622,000 and were lower as compared to $810,000 in Q3 2014. Actual figures came in lower than our expectations as the company remains focused on controlling costs until the Phase 3 KIACTA™ data comes in which is expected in mid-to-late 2016. Due to the appreciation of the U.S. dollar vs the Canadian dollar in 2015, the company realized a gain of $174,000 for this reporting period. Bellus' net monetary assets are denominated in U.S. dollars. The company's net loss was $0.18 million or $0.004/share.

BLU.TO exited third quarter 2015 with roughly $10 million in cash. Since the cost of the confirmatory Phase 3 study with KIACTA™ is roughly $60 million and fully funded by Auven Therapeutics, we think the financial resources provides substantial flexibility to support the company's operations even after the study concludes. Top line results from the KIACTA™ Phase 3 Confirmatory Study are expected in 2016.

Update on Kiacta™ Phase 3 Clinical Trial

Bellus' lead compound is Kiacta™, a drug candidate currently in a confirmatory Phase 3 trial for the treatment of AA Amyloidosis, an orphan disease arising from the improper extracellular deposition of serum amyloid A (SAA) protein fragments. The condition leads to renal dysfunction and typically progresses quickly to end-stage renal disease and death. There is currently no cure for AA Amyloidosis.

Amyloid A Amyloidosis

Amyloidosis comprises a generic term for a heterogeneous group of diseases that are characterized by the deposition of normally soluble proteins in the extracellular space in the form of insoluble fibrils. Amyloid A (AA) amyloidosis is the most common form of systemic amyloidosis. Also called secondary amyloidosis, it is most commonly associated with rheumatic diseases (such as rheumatoid arthritis) in developed countries, while in developing countries the most common cause is chronic infection. The fibrilar deposits are composed of fragments of the acute phase protein serum amyloid A (SAA), which is produced in high quantities during the inflammatory response. The kidney, liver, and spleen are the major sites of involvement. The disease is typically not diagnosed until overt kidney damage is detected in the form of proteinuria, nephrotic syndrome, or other failure in renal function. We estimate there are approximately 12,300 AA amyloidosis patients eligible to receive Kiacta™ in the world, with approximately 6,800 in the U.S., 3,500 in the E.U., and an additional 2,000 in the rest of the world.

Brief Background on Kiacta™

Kiacta™ (eprodisate) is a small, negatively charged molecule that shares certain structural similarities with heparin sulfate and is known to bind to A-SAA (Manetti *et al*., 2008). Kiacta™ binds to the glycosaminoglycan (GAG) binding site of A-SAA and competes with naturally occurring GAGs, thus inhibiting amyloid fibril polymerization and deposition in tissues (Ancsin *et al*., 1999).

Kiacta™ was previously evaluated for the treatment of AA amyloidosis in patients with renal involvement in a Phase 2/3 trial that was conducted from 2001 to 2004 (Dember *et al*., 2007). Treatment with Kiacta™ was associated with a 42% reduction in the risk of worsening renal disease (hazard ratio, 0.58; 95% confidence interval [CI], 0.37 to 0.93; *P* = 0.025). Even after adjusting for potentially important baseline variables (e.g., renal function, underlying disease, etc.) and for SAA concentration the risk reduction was still maintained. There was no effect on urinary protein excretion, with the benefit of Kiacta™ on the primary composite end point being due to its effect on progression of renal disease. In addition, there was no significant difference between the two groups in the risk of death.

Kiacta™ Phase 3 Confirmatory Study

The Kiacta™ Phase 3 confirmatory study (NCT01215747) completed enrollment in January 2015, with a total of 261 AA amyloidosis 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.

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.

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).

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 July 2015 and recommended that the study continue as per protocol.

As of mid-November 2015, the company reported that approximately 95% of the required 120 events to complete the study have occurred. We now anticipate that the study will conclude before the end of the first quarter of 2016, and that top-line data will be available by mid-2016.

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.

IND for Sarcoidosis Clinical Trial to be Filed in 2016

Bellus and Auven previously announced the signing of a license agreement with Mount Sinai Hospital under which Auven obtained the rights to develop Kiacta™ as a treatment for chronic sarcoidosis.

Sarcoidosis is a multisystem inflammatory disease that is characterized by the presence of granulomas, which are a collection of immune cells that form when the immune system attempts to isolate substances it deems as foreign but can't eliminate. Approximately 120,000 people in the U.S. have the condition, and while most patients go on to recover approximately 30% will develop a chronic, debilitating disease. The disease is responsible for killing 1-5% of patients in which it occurs. Corticosteroids are the current first line treatment for sarcoidosis patients, however nonsteroidal immunosuppressants such as methotrexate and azathioprine are also utilized.

The current plan for the development of Kiacta™ as a treatment for sarcoidosis is for Auven to conduct a Phase 2/3 clinical trial to evaluate the drug's safety and effectiveness. We anticipate the study protocol being finalized shortly and the filing of an Investigational New Drug (IND) application to in 1H 2016. 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.

BELLUS Health held its first Shigamab™ SAB meeting to discuss the design of the Phase 2 clinical trial protocol. Management intends to meet with regulatory authorities in 2016 to present its clinical development plan for Shigamab™ in the treatment of sHUS.

Conclusion: Valuation & Recommendation

We are valuing the company based on the potential for Kiacta™ in AA Amyloidosis. There is the potential for upside to our valuation based on moving Kiacta™ into new areas such as sarcoidosis and with pre-clinical monoclonal antibody candidate Shigamab™, as neither of those indications are currently in our model.

Orphan drugs, which Kiacta™ is considered since it is targeting a population of approximately 12,000 worldwide, typically command premium pricing, which is shown in the following chart.

	U.S. Pt. Pop. Size	Description	U.S. Price	E.U. Price
Vyndaqel (tafamidis)	1,500	1st treatment for transthyretin familial amyloid polyneuropathy (TTR-FAP)	-	$200K
Gattex (teduglutide rDNA)	9.500	Treatment of Short Bowel Syndrome	$295K	-
Kalydeco (ivacaftor)	1,350	Treatment of Cystic Fibrosis subpopulation with specific mutations to CFTR gene	$307K	$368K
Procysbi (cysteamide)	500	Management of nephropathic cystinosis	$250K	-
Juxtapid/Lojuxta (lomitapide)	3,000	Homozygous familial hypercholesterolemia (HoFH)	$250K	-
Jakafi/Jakavi (ruxolitinib)	1,500	One of first treatments for myelofibrosis; treats splenomegaly associated with myelofibrosis	$93K	$70K

Source: Bellus Health/Zacks SCR

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 peak market share of 30%. Based upon these values, we forecast Kiacta™ to have peak revenues of between $500 and $750 million. Applying a discount rate of 20%, free cash flow as 65% of revenues, and a 75% probability of success for the Kiacta™ Phase 3 clinical trial gives us a target price of $2.50. Given the current stock price, we believe that Bellus continues to be significantly undervalued and offers investors tremendous upside at the current valuation. As a reminder, 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 most likely after results from the Phase 3 trial are announced.

PROJECTED FINANCIALS

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

Bellus Health, Inc.	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E
Revenues	**$2.376**	**$0.786**	**$0.592**	**$0.593**	**$0.700**	**$2.671**	**$2.700**
YOY Growth	-					-	-
Total Revenues	**$2.376**	**$0.786**	**$0.592**	**$0.593**	**$0.700**	**$2.671**	**$2.700**
YOY Growth	-					-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
General & Administration	$3.150	$0.719	$0.864	$0.622	$0.700	$2.905	$3.500
Research & Development	$1.695	$0.323	$0.169	$0.340	$0.300	$1.132	$1.800
Other Operating Expenses	$0	$0	$0	$0	$0	$0	$0
Operating Income	($2.5)	($0.3)	($0.4)	($0.4)	($0.3)	($1.4)	($2.6)
Operating Margin	-					-	-
Non-Operating Expenses (Net)	$0.45	$0.2	$0.00	$0.17	$0.03	$0.45	$0.00
Pre-Tax Income	($2.017)	($0.012)	($0.441)	($0.195)	($0.270)	($0.918)	($2.600)
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)	($0.433)	($0.178)	($0.27)	($0.89)	($2.60)
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($0.04)**	**($0.00)**	**($0.01)**	**($0.00)**	**($0.01)**	**($0.02)**	**($0.05)**
YOY Growth	-					-	-
Basic Shares Outstanding	47.4	47.4	47.4	47.4	47.4	47.4	50.00

Source: Zacks Investment Research, Inc. *Anita Dushyanth, PhD*

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HISTORICAL ZACKS RECOMMENDATIONS

Chart by Yahoo! Finance



Initiation of Coverage: May 20, 2014 @ $0.78

Buy Hold Sell

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The current distribution is as follows: Buy/Outperform- 27.4%, Hold/Neutral- 56.0%, Sell/Underperform – 13.6%. Data is as of midnight on the business day immediately prior to this publication.

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