Zacks Small-Cap Research

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Epirus Biopharmaceuticals, Inc. (EPRS - NASDAQ)

EPRS: Expands Biosimilar Pipeline with Acquisition of Bioceros…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	12/18/2014
Current Price (09/10/15)	$5.79
Target Price	**$15.00**

UPDATE

On September 9, 2015, Epirus Biopharmaceuticals, Inc. announced the acquisition of privately held Bioceros Holding B.V. for $14.1 million in cash and stock. The deal increases Epirus' pipeline of biosimilar products through the addition of BOW080, a biosimilar to eculizumab (Soliris®); BOW090, a biosimilar to ustekinumab (STELARA®); and BOW100, a biosimilar to golimumab (SIMPONI®). Those three reference products are estimated by EvaluatePharma to have combined sales of approximately $12 billion in 2020.

We view the deal as quite positive for Epirus. In addition to the pipeline additions, the company also gains access to a number of product development capabilities that will allow for increased in-house activities and potentially decreased overall development costs.

SUMMARY DATA

52-Week High	**$11.47**
52-Week Low	**$3.93**
One-Year Return (%)	**-30.33**
Beta	**3.00**
Average Daily Volume (sh)	**95,672**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$136**
Short Interest Ratio (days)	**4.69**
Institutional Ownership (%)	**60**
Insider Ownership (%)	**13**
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 $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2015	0.0 A	0.0 A	0.1 E	0.2 E	0.3 E
2016					0.6 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$3.83 A	-$3.81 A	-$1.28 A	-$0.80 A	-$5.90 A
2015	-$0.39 A	-$0.65 A	-$0.49 E	-$0.51 E	-$2.06 E
2016					-$1.68 E

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WHAT'S NEW

Epirus Acquires Bioceros Holdings B.V

On September 9, 2015, Epirus Biopharmaceuticals, Inc. (EPRS) announced the acquisition of Bioceros Holdings B.V., a privately held, Netherlands-based biopharmaceuticals R&D company that is focused on the development of monoclonal antibodies and the generation of cGMP cell lines.

Under the terms of the agreement, Epirus acquired Bioceros for a total of $14.1 million in cash and stock payable in installments over a one-year period. The deal is broken down as follows:

- Total cash payments of $5.1 million payable as i) $3.4 million at closing, and ii) $1.7 million on the first anniversary of closing.

- Common stock worth $9.0 million payable as i) $4.0 million in common stock at closing, based on the average closing price over the ten trading days immediately prior to closing, and ii) $5.0 million in common stock to be issued six months following closing, based on the average closing price over the ten trading days immediately prior to that date.

Based upon the company's average stock price over the previous 10 days ($5.07), we estimate that a total of approximately 0.79 million shares of common stock will be issued by Epirus upon closing the deal. Epirus had 23.6 million shares of common stock outstanding as of August 10, 2015, thus the first payment of common stock represents approximately 3.3% dilution. In addition, the company reported $58.3 million in cash and cash equivalents as of June 30, 2015, thus the deal will consume approximately 8.7% of the company's current cash holdings.

Expanded Pipeline

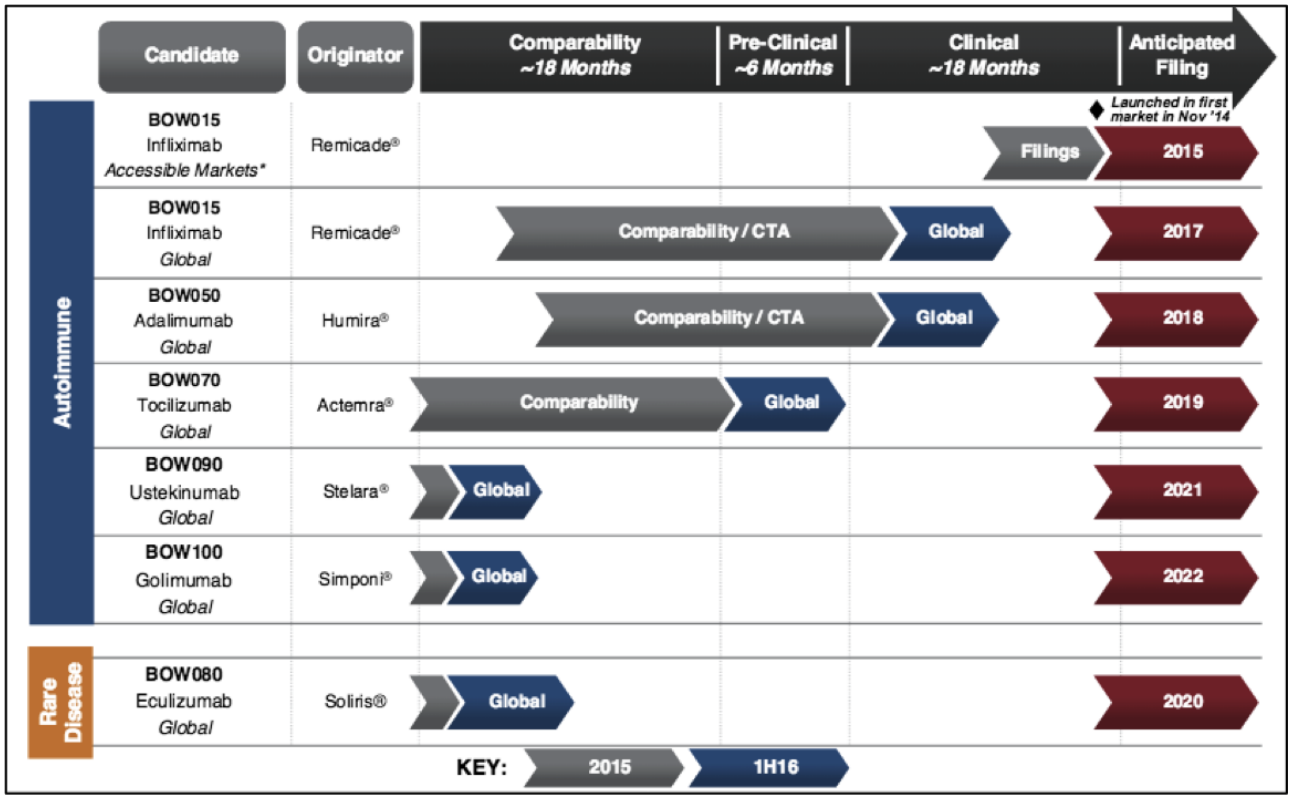
As part of the acquisition, Epirus has expanded its pipeline with an additional three biosimilar candidates: BOW080, a biosimilar to eculizumab (Soliris®); BOW090, a biosimilar to ustekinumab (STELARA®); and BOW100, a biosimilar to golimumab (SIMPONI®). According to EvaluatePharma, the three reference drugs are projected to have sales of approximately $12 billion in 2020.

STELARA® (ustekinumab): This is a fully human IgG1 monoclonal antibody that targets the p40 subunit found on both interleukin (IL)-12 and IL-23, thereby blocking the interaction between those cytokines and the receptor and inhibiting signaling, differentiation, and cytokine production found in a number of inflammatory diseases. The drug is currently approved for the treatment of plaque psoriasis and psoriatic arthritis. STELARA® is marketed by Johnson and Johnson (JNJ) and in 2014 had sales of approximately $2 billion worldwide with projected sales of $3.5 billion in 2020. The patents for ustekinumab expire in 2023 and 2024 in the U.S. and Europe, respectively.

SIMPONI® (golimumab): This is a fully human IgG1 monoclonal antibody that targets tumor necrosis factor-alpha (TNF-α), which is the same mechanism of action shared by the top selling rheumatoid arthritis (RA) drugs (Humira®, Enbrel®, and Remicade®). SIMPONI® is currently approved for the treatment of RA, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis. The drug is marketed by JNJ and Merck and in 2014 had sales of approximately $1.9 billion worldwide with projected sales of $3.4 billion in 2020. The patents for golimumab expire in 2024.

Soliris® (eculizumab): This is a humanized IgG2/4 monoclonal antibody that targets the terminal portion of the complement cascade, specifically by inhibiting the cleavage of complement protein C5 to C5a and C5b. This prevents the formation of the terminal complement complex C5b-9, which causes the complement mediated events seen in paroxysmal nocturnal hemoglobinuria (PHN) and atypical hemolytic uremic syndrome (aHUS), the two conditions for which Soliris® is approved. The drug is marketed by Alexion Pharmaceuticals (ALXN) and had sales of approximately $2.2 billion in 2014 with projected sales of $5.4 billion in 2020. The patents for eculizumab expire in 2020 and 2021 in Europe and the U.S., respectively.

The addition of ustekinumab and golimumab biosimilars adds to the company's focus on autoimmune-mediated diseases, while the eculizumab biosimilar may indicate the company is interested in expanding into the rare disease space. The updated pipeline is shown below:



Source: Epirus Biopharmaceuticals, Inc.

Strategic Rationale for Acquisition

In addition to expanding the company's pipeline, the acquisition of Bioceros will bring with it a host of other product development capabilities that will aid Epirus as it works to build a sustainable biosimilar business, including:

- ✓ A 6000 ft^2 development laboratory
- ✓ A proprietary chinese hamster ovary (CHO) cell line for expressing monoclonal antibodies
- ✓ A small scale bioreactor to allow for rapid iterations when optimizing product characteristics
- ✓ An experienced development team of approximately 20 scientists (30% w/ advanced degrees)

In the end, the acquisition of Bioceros should lead to accelerated product development timelines as the company has the capability to perform more of the necessary development activities in-house along with decreasing costs associated with each product candidate.

Conclusion and Recommendation

The acquisition of Bioceros is a clear positive for Epirus. The two companies had been collaborating for the previous 2-3 years, thus there was a real familiarity between the two entities, which likely helped lead to the deal. The product candidates added to Epirus' pipeline seem to be a natural fit, and we are intrigued by the addition of a rare disease treatment as this may be an area of focus for the company in the future. The fact that the three reference products for the three additions to the pipeline are projected to bring in approximately $12 billion in revenue in 2020 is an indication of the additional opportunity now present In Epirus' pipeline.

We have been positive on Epirus' story since we first initiated coverage in December 2014, and we remain positive after the acquisition of Bioceros. Recently, we made adjustments to our discounted cash flow model based upon the partnership agreement between PolPharma and Epirus that calls for a 51/49 split of development costs and eventual operating profits in the named regions. These adjustments resulted in slight modifications to the net present value of BOW015, BOW050, and BOW070. We have not included the three new additions to the pipeline to our model yet based on how early in development those products are. We are maintaining our recently increased price target of $15 and are reiterating our 'Buy' rating.

PROJECTED FINANCIALS

Epirus Biopharmaceuticals, Inc.
Income Statement

Epirus Biopharmaceuticals, Inc.	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E
BOW015 Royalties	$0.0	$0.0	$0.0	$0.1	$0.2	$0.3	$0.6
YOY Growth	-	-					-
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.2**	**$0.3**	**$0.6**
YOY Growth	-	-					-
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-					-
R&D	$16.3	$3.1	$8.3	$6.5	$7.5	$25.4	$25.0
SG&A	$23.0	$4.2	$6.8	$5.0	$5.5	$21.5	$24.0
Operating Income	**($39.3)**	**($7.2)**	**($15.0)**	**($11.4)**	**($12.9)**	**($46.5)**	**($48.4)**
Operating Margin	-	-	-	-	-	-	-
Interest & Other Income	($2.6)	($0.3)	($0.3)	($0.8)	($1.0)	($2.4)	($2.0)
Pre-Tax Income	($41.8)	($7.5)	($15.3)	($12.2)	($13.9)	($48.9)	($50.4)
Taxes & Other	$0.0	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($41.8)	($7.5)	($15.3)	($12.2)	($13.9)	($48.9)	($50.4)
Net Margin	-	-					-
Reported EPS	**($5.90)**	**($0.39)**	**($0.65)**	**($0.49)**	**($0.51)**	**($2.06)**	**($1.68)**
YOY Growth	-	-					-
Basic Shares Outstanding	7.1	19.3	23.5	25.0	27.0	23.7	30.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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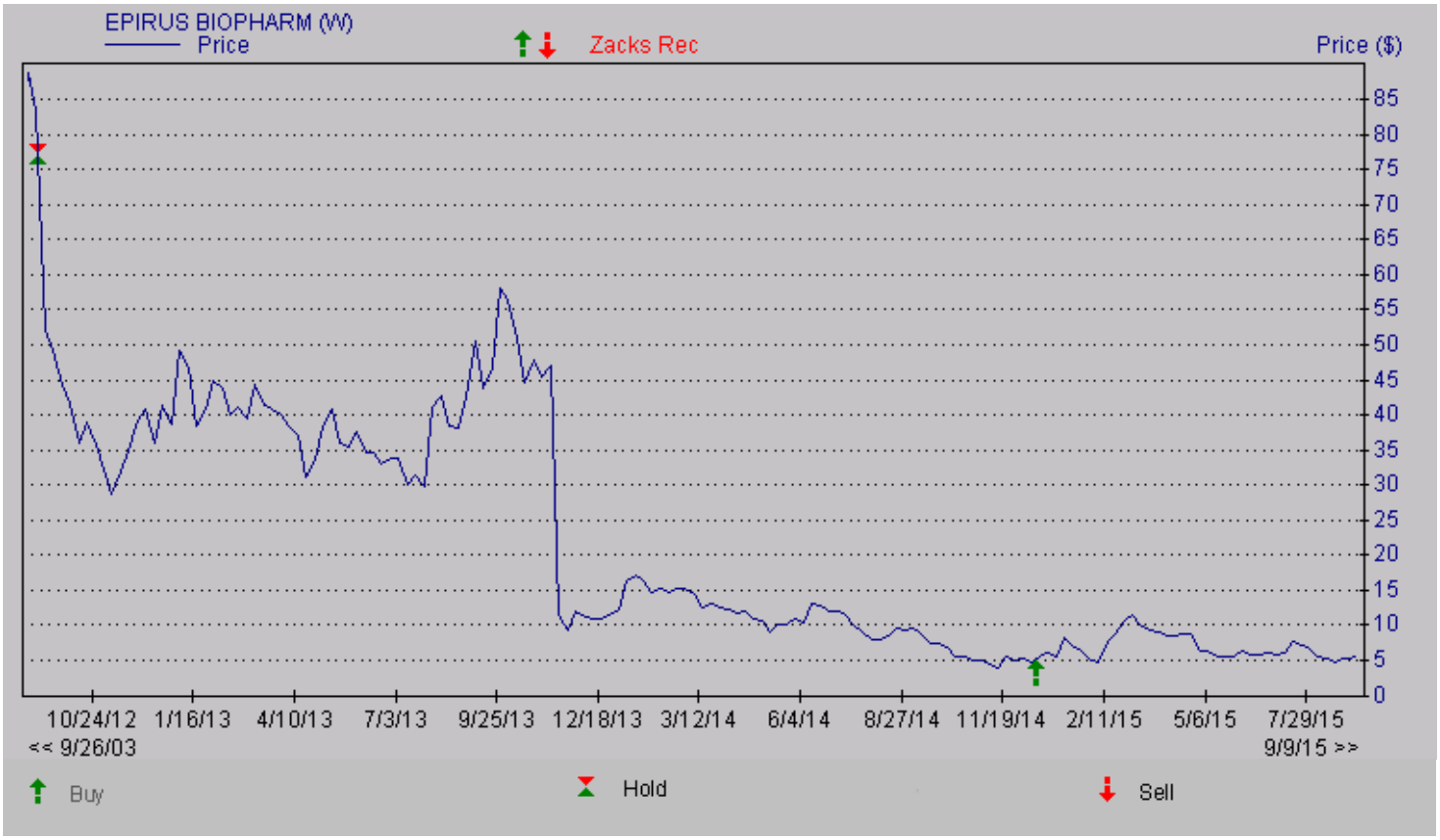

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