Zacks Small-Cap Research

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Nuvo Research, Inc. (T.NRI - TSX)

T.NRI: WF10 Trial Fails For Allergic Rhinitis, But Cash Supports Valuation…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/05/2014
Current Price (01/30/15)	$5.48
Target Price	**$6.50**

UPDATE

On January 30, 2015, Nuvo Research Inc. announced results of its Phase 2 allergic rhinitis study in Germany failed to demonstrate statistically significant separation of WF10 vs. placebo. We are disappointed with the results given the previous Phase 2 data with WF10 that had showed very nice separation between the WF10 and placebo group on both per protocol and intent-to-treat analysis. Although we are disappointed with the failure of WF10 in allergic rhinitis, the current valuation is supported entirely by the $58 million cash balance as of December 31, 2014. We think odds are high of success for the planned European Phase 3 trial with Pennsaid 2% and that the potential to partner the drug for Europe is significant once the data has been generated. Our target is $6.50 per share.

SUMMARY DATA

52-Week High	**10.36**
52-Week Low	**2.40**
One-Year Return (%)	**184.8**
Beta	**N/A**
Average Daily Volume (sh)	**120.9**
Shares Outstanding (mil)	**10.4**
Market Capitalization ($mil)	**57**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	$2.3 A	$3.3 A	$9.1 A	$3.7 A	$18.4 A
2014	$2.8 A	$3.9 A	$3.0 A	$3.4 E	$13.0 E
2015					$3.5 E
2016					$5.0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.39 A	-$0.25 A	-$0.34 A	-$0.22 A	-$1.18 A
2014	-$0.31 A	-$0.23 A	$4.80 A	-$0.30 E	$4.13 E
2015					-$1.84 E
2016					-$1.61 E

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WHAT'S NEW

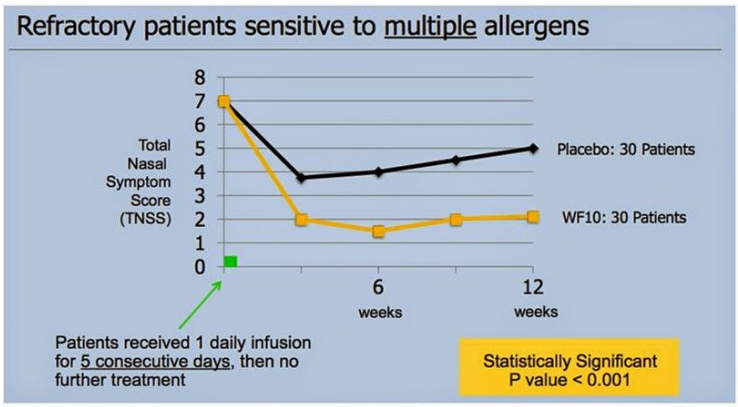
WF10 Fails Phase 2 Allergic Rhinitis Study

On January 30, 2015, Nuvo Research Inc. announced results of its Phase 2 allergic rhinitis study in Germany failed to demonstrate statistically significant separation of WF10 vs. placebo. We are disappointed with the results given the previous Phase 2 data with WF10 that had showed very nice separation between the WF10 and placebo group on both per protocol and intent-to-treat analysis.

As a reminder, the Phase 2 trial examined the safety and efficacy of WF10 for the treatment of refractory allergic rhinitis in 184 patients (179 completed). The trial commenced in March 2014 at 15 sites entirely in Germany. This was a 16-week, randomized, double-blind, placebo-controlled study to assess the efficacy, safety and tolerability of a regimen of five infusions of either WF10 or its main constituents (sodium chlorite and sodium chlorate) relative to saline control (sodium chloride) in patients who suffer from refractory allergic rhinitis with positive skin test to at least one allergen. Endpoints included assessment of total nasal symptom score (TNSS), total ocular symptom score (TOSS), and other secondary endpoints.

Topline findings from the study showed that the WF10 arm demonstrated a reduction in TNSS over the course of the observation period similar to the reduction in TNSS demonstrated in the WF10 arm in the company's previous 2010 Phase 2 proof-of-concept study. We remind investors that in this study, the baseline TNSS score was around 7 (entry criteria ≥ 6) and pooled patient data showed a reduction to ~2 at 3, 6, and 12 weeks. However, in the recent Phase 2 study, placebo arm demonstrated a reduction in TNSS over the course of the observation period that was significantly greater than demonstrated in the placebo arm of the company's 2010 Phase 2 study. In the 2010 study, the placebo group saw a meaningful decline by week 3, but patients got worse as time went on, exiting the 12th week with a TNSS score at around 5. This was on the case for the recent Phase 2. The baseline TNSS score for the most recent Phase 2 study was around 8 according to the conference call held this morning.

2010 Phase 2 Results



Data from a Phase 2 study showing a statistically significant decrease in Total Nasal Symptom Score (TNSS) for WF10 treated patients compared to placebo treated patients. *Source*: Nuvo Research, Inc.

Nuvo management is continuing to do analysis of the Phase 2 results. The press release noted that each of the active arms demonstrated a greater reduction in TNSS than placebo; however, (i) the difference between the WF10 arm and the placebo arm did not achieve statistical significance 3 weeks after commencement of the study which was the study's primary endpoint and (ii) the difference between the active arms and the placebo arm did not achieve statistical significance at measured time points over the course of the observation period.

Possible Explanation

According to management, WF10 performed as expected in the Phase 2 trial, it was the placebo group that did surprisingly better than expected. Henrich Guntermann, Nuvo's President, Europe and Immunology Group, noted that the weather in Germany during the trial was unseasonably cool and wet. The trial started in March 2014 and completed enrollment in September 2014. A cooler, wetter spring and summer in Germany during 2014 may have led to TNSS symptoms improving in all patients over the course of the trial.

Nuvo will be examining things like pollen count and temperature / rainfall during the trial vs. historical conditions in Germany, including conditions during the 2010 Phase 2 study. At this point, it remains to be seen if they will find anything that saves the WF10 program. For a financial modeling standpoint, we are assuming WF10 is shelved for the treatment of allergic rhinitis.

Luckily, Nuvo is in a Solid Financial Position

Thanks to the Pennsaid 2% asset purchase agreement with Horizon Pharma in October 2014, Nuvo Research exited 2014 with approximately $58 million in cash on hand. That's almost identical to the market capitalization right now (stock at $5.47 per share).

Even though U.S. rights to Pennsaid 2% are now with Horizon, Nuvo has retained the rights for Pennsaid / Pennsaid® 2% outside of the U.S., which includes royalties on commercial sales in Canada and the opportunity to gain approval in large markets like Europe. However, to gain approval in Europe the company must first complete a Phase 3 study. This is already in planning. The study will be conducted in Germany and will assess the efficacy of Pennsaid® 2% for the relief of pain associated with acute, localized muscle or joint injuries such as sprains, strains or sports injuries. The study is expected to begin in the second quarter of 2015 with results expected in the fourth quarter of 2015. In addition to supporting regulatory approval in locations outside the U.S., such as the European Union, the Phase 3 data will be integral to forging a partnership for marketing Pennsaid® 2% internationally. The total cost of the trial is estimated to be $1.5 million. We believe positive data will be a significant valuation inflection for the company.

Conclusion and Recommendation

Nuvo has done an excellent job in regards to extracting the full value from the Pennsaid® 2% franchise through both the litigation settlement and subsequent U.S. rights asset sale to Horizon Pharma. Although we are disappointed with the failure of WF10 in allergic rhinitis, the current valuation is supported entirely by the $58 million cash balance as of December 31, 2014. We think odds are high of success for the planned European Phase 3 trial with Pennsaid 2% and that the potential to partner the drug for Europe is significant once the data has been generated. We expect continued progress extracting value from the topical franchises and Pennsaid out-licensing opportunities throughout 2015. We have adjusted our target to $6.50 per share, which includes an estimated $55+ million in cash as of March 31, 2015 and residual manufacturing and partnering opportunities for Pennsaid 2%. The biggest catalyst for the shares in the near-term will be the Pennsaid 2% European Phase 3 data late 2015.

PROJECTED FINANCIALS

Nuvo Research, Inc.
Income Statement

Nuvo Research, Inc.	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
Revenue from Product Sales	**$4.4**	**$1.2**	**$2.2**	**$1.5**	**$1.5**	**$6.4**	**$0.5**	**$1.0**
YOY Growth	*-50.4%*	-	-	-	-	*43.5%*	*-92.1%*	*100.0%*
Royalties	**$6.1**	**$1.4**	**$1.5**	**$1.4**	**$1.5**	**$5.7**	**$1.5**	**$2.0**
YOY Growth	*-26.4%*	-	-	-	-	*-6.0%*	*-73.8%*	*33.3%*
Licensing Fees	**$7.6**	**$0.1**	**$0.2**	**$0.0**	**$0.3**	**$0.5**	**$1.0**	**$1.5**
YOY Growth	*4.9%*	-	-	-	-	*-92.9%*	*86.2%*	*50.0%*
Research and Contracts	**$0.3**	**$0.1**	**$0.0**	**$0.1**	**$0.1**	**$0.4**	**$0.5**	**$0.5**
YOY Growth	*52.8%*	-	-	-	-	*38.6%*	*32.6%*	*0.0%*
Total Revenues	**$18.4**	**$2.8**	**$3.9**	**$3.0**	**$3.4**	**$13.0**	**$3.5**	**$5.0**
YOY Growth	*-25.3%*	-	-	-	-	*-29.3%*	*-73.1%*	*42.9%*
CoGS	$4.8	$1.2	$1.5	$1.2	$1.5	$5.4	$4.0	$2.0
Gross Income	$13.6	$1.5	$2.4	$1.8	$1.9	$7.6	($0.5)	$3.0
Product Gross Margin	*74.1%*	*56.1%*	*61.2%*	*59.2%*	*55.9%*	*58.2%*	*-14.3%*	*60.0%*
R&D	$7.0	$1.9	$1.5	$1.9	$2.0	$7.3	$9.0	$11.0
% R&D	*38.2%*	*68.4%*	*38.6%*	*62.7%*	*58.8%*	*55.9%*	*257.1%*	*220.0%*
SG&A	$10.1	$2.4	$2.9	$3.5	$2.6	$11.3	$13.0	$15.0
% SG&A	*55.0%*	*86.1%*	*75.0%*	*114.7%*	*76.5%*	*87.1%*	*371.4%*	*300.0%*
Other expenses	$0.6	$0.0	$0.3	$0.1	$0.5	$0.9	$0.5	$0.5
% Payment	*3.1%*	*0.4%*	*6.6%*	*4.6%*	*14.7%*	*6.9%*	*14.3%*	*10.0%*
Operating Income	($4.1)	($2.7)	($2.3)	($3.7)	($3.2)	($11.9)	($23.0)	($23.5)
Operating Margin	*-22.1%*	*-98.7%*	*-59.0%*	*-122.8%*	*-94.1%*	*-91.6%*	*-657.1%*	*-470.0%*
Total Other Income	($6.2)	$0.0	$0.0	$53.4	$0.0	$53.4	$1.0	$1.0
Pre-Tax Income	($10.3)	($2.7)	($2.3)	$49.7	($3.2)	$41.5	($22.0)	($22.5)
Taxes & Other	$0.1	$0.0	$0.0	$0.1	$0.0	$0.1	$0.1	$0.1
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Divs. Of Preferred	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($10.4)	($2.7)	($2.3)	$49.8	($3.2)	$41.4	($22.1)	($22.6)
Net Margin	*-56.4%*	*-99.5%*	*-59.7%*	*1653.9%*	*-95.0%*	*318.3%*	*-631.4%*	*-452.0%*
Gain/Loss on trans. of foreign ops	$0.0	$0.1	($0.1)	$0.0	$0.1	$0.1	$0.2	$0.2
Comprehensive Income	($10.4)	($2.7)	($2.4)	$49.8	($3.1)	$41.5	($21.9)	($22.4)
Reported EPS	**($1.18)**	**($0.31)**	**($0.23)**	**$4.80**	**($0.30)**	**$4.13**	**($1.84)**	**($1.61)**
YOY Growth	*-23.6%*	-	-	-	-	*-450.7%*	*-144.6%*	*-12.3%*
Shares Outstanding	8.8	8.9	10.2	10.4	10.6	10.0	12.0	14.0

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

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HISTORICAL ZACKS RECOMMENDATIONS

Initiations of Coverage – May 5, 2014 @ $3.26 per share



Chart By: Yahoo!, Inc.

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