Zacks Small-Cap Research

November 12, 2014
Jason Napodano, CFA
David Bautz, PhD
312-265-9421 / jnapodano@zacks.com

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

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

T.NRI: Sitting On A Pile Of Cash Ahead Of WF10 Data Q1-2015…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/05/2014
Current Price (11/12/14)	$5.99
Target Price	**$7.50**

UPDATE

On November 10, 2014 Nuvo Research reported results for the third quarter of 2014. Total revenue for the quarter was $3.0 million with operating expenses totaling $6.7 million. Due to the settlement with Mallinckrodt the company reported a gain of $52.3 million, which included the net cash settlement payment of $8.8 million and the non-cash portion related to the value of Pennsaid rights of $43.5 million.

Subsequently, Nuvo sold the U.S. rights to Pennsaid 2% to Horizon Pharma for $45 million. We estimate that Nuvo currently has approximately $60 million in cash and cash equivalents as of November 10, 2014. The company is already going to put some of that cash to use by initiating a Phase 3 trial for Pennsaid 2% in Germany for the treatment of acute, localized muscle or joint injuries. This data will be used to support regulatory approval in jurisdictions outside the U.S.

SUMMARY DATA

52-Week High	**5.73**
52-Week Low	**1.58**
One-Year Return (%)	**97.2**
Beta	**N/A**
Average Daily Volume (sh)	**19,658**
Shares Outstanding (mil)	**10.2**
Market Capitalization ($mil)	**33.5**
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

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Update

On November 10, 2014, Nuvo Research (TSX: T.NRI) reported financial results for the third quarter of 2014. Total revenue in the current quarter, consisting of product sales, royalties, license fee revenue, and research and other contract revenue, was $3.0 million compared to $9.1 million for the corresponding time period in 2013. The decrease in revenue was due to $4.5 million in license fee revenue related to the sale of Synera® to Galen in the U.S. market and the $2.0 million milestone payment related to the marketing approval for Pliaglis® in Brazil during the comparative period.

Total operating expenses in the current quarter increased to $6.7 million from $5.7 million for the same time period in 2013. The increase was mostly attributable to higher G&A expenses, which totaled $3.5 million for third quarter of 2014 compared to $2.3 million for the third quarter of 2013. R&D expenses for the current quarter totaled $1.9 million compared to $1.7 million for the same time period of 2013.

Other income for the current quarter was $53.4 million compared to $2.3 million for the third quarter of 2013. This was a result of the company reaching a settlement agreement with Mallinckrodt (MNK) that resulted in a cash settlement of $10 million and return of all U.S. rights to Pennsaid® and Pennsaid® 2% to Nuvo. The total gain on the litigation settlement was $52.3 million, which included the net cash settlement payment of $8.8 million and the non-cash portion related to the value of the Pennsaid® rights of $43.5 million.

Nuvo reported cash and cash equivalents of $9.7 million as of September 30, 2014. However, both the settlement with Mallinckrodt and the Pennsaid® 2% asset sale to Horizon occurred subsequent to the quarter, thus as of November 10, 2014 we estimate that Nuvo has approximately $60 million in cash and cash equivalents. We estimate this cash position should be enough to fund the company through the end of 2016.

Pennsaid® 2% U.S. Asset Sale

On October 17, 2014 Nuvo announced an asset purchase agreement with Horizon Pharma (HZNP) in which Nuvo sold the sales and marketing rights, intellectual property, and other aspects with respect to Pennsaid® 2% in the U.S. for US$45 million.

Under the terms of the agreement, Nuvo agreed to discontinue the manufacture, sale, and marketing of Pennsaid® in the U.S. In addition, Nuvo will be the exclusive supplier of Pennsaid® 2% from its Varennes, Quebec manufacturing facility. The initial term of the supply agreement expires on December 31, 2022 and, unless terminated, will automatically renew for two-year terms thereafter. Horizon will pay an agreed-upon transfer price for Pennsaid® 2%, with the transfer price subject to semi-annual adjustments based on Nuvo's raw material costs and annual adjustments based upon changes in the national manufacturing cost for pharmaceutical products.

After the announcement of the Mallinckrodt litigation we had surmised that a deal for Pennsaid® 2% was "…likely to bring in approximately $20-30 million upfront with royalties in the high teens to low-twenties…" In addition, our DCF model had Pennsaid®/Pennsaid® 2% worth approximately $45 million, thus we were quite accurate with both our valuation and our prediction for what Nuvo would receive and feel that Nuvo received a fair price for the rights to Pennsaid® 2%.

Pennsaid® 2% Phase 3 Clinical Trial

When Nuvo originally signed the development plan for Pennsaid® 2% with Mallinckrodt in 2009 the agreement called for Mallinckrodt to conduct two Phase 3 clinical trials for Pennsaid® 2%. A Phase 2 trial examining the effect of Pennsaid® 2% in knee osteoarthritis (OA) was completed in June 2011, with positive results being reported showing Pennsaid® 2% met the primary endpoint of reducing knee OA pain. Mallinckrodt decided that instead of filing a conducting the two Phase 3 trials and filing a new drug application (NDA), instead it would seek approval via a supplementary new drug application (sNDA) based on the data from the Phase 2 clinical trial. This was one of the reasons for the litigation between the two companies, as not having data from pivotal Phase 3 clinical trials would prevent Nuvo from being able to seek regulatory approval for Pennsaid® 2% outside of the U.S.

As a reminder, Nuvo has retained the rights for Pennsaid® 2% outside of the U.S. To gain approval, the company is going to commence a Phase 3 clinical study of Pennsaid® 2% for the treatment of acute pain to support regulatory approval applications in international jurisdictions. 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.

Update on WF10

Nuvo recently announced that the Phase 2 trial examining the safety and efficacy of WF10 for the treatment of refractory allergic rhinitis is fully enrolled. As a reminder, this is a 16-week randomized, double blind, placebo controlled study that is examining a regimen of once daily infusions for five consecutive days of either WF10 or its main constituents (sodium chlorite and sodium chlorate) relative to saline control in patients with multiple airborne allergies who suffer from moderate to severe allergic rhinitis. The trial will measure total nasal symptom score (TNSS) and other secondary endpoints. The trial should be completed in the fourth quarter of 2014 with topline results anticipated in the first quarter of 2015.

Nuvo recently performed a market study to investigate the commercial potential of WF10 in the U.S. The study was performed by Psscion Lifesciences Consulting and forecasts that WF10 could capture 10-15% of the U.S. refractory allergic rhinitis market with peak U.S. annual sales of $0.7 billion to $1.1 billion.

In the course of the study Psscion interviewed patients with refractory allergic rhinitis, physicians, and representatives from insurance companies and found that:

- ✓ The physicians were impressed with WF10's efficacy, long-lasting therapeutic effect, the ability to treat multiple allergens with one dosing regimen, and favorable safety profile. All of these characteristics were observed in the company's completed 60-patient Phase 2 proof-of-concept study and case studies.
- ✓ Both patients and physicians believe that WF10 would address an unmet need in the treatment of refractory allergic rhinitis.
- ✓ WF10 could be an attractive alternative to "allergy shots", which are highly specific to one particular allergen and must be dosed for months or years.
- ✓ Insurance payers rated WF10 positively and felt that it was unlikely to face significant barriers to coverage.

For our valuation model, we forecast peak sales of WF10 in the $800 million range. Thus, it appears as though our model is aligned with the findings from the Psscion study. This forecast is based on the current dosing regimen for WF10. Nuvo is planning on performing dosing studies to determine the minimum effective dose. For both Phase 2 trials, WF10 was administered as a once daily 90-minute infusion for five consecutive days at a dose of 0.5 mL/kg body weight. Obviously, getting the dose down to the smallest number possible would be optimal as visiting a doctor's office for five consecutive days could be problematic for some patients. Limiting the number of doses could also help to drive the uptake for WF10, and in turn increase its peak sales potential.

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. It appears the market is finally beginning to take notice, with the stock up almost 100% in the past three months. We believe this trend could continue as we get closer to the release of the topline results from the WF10 Phase 2 clinical trial in the first quarter of 2015.

Even with the recent rise in the stock price, we feel Nuvo is still undervalued with a fully diluted market cap of approximately $60 million. This is very close to the amount of cash that we estimate Nuvo currently holds. As we've stated previously, we believe that an investor in Nuvo today is getting a company with a solid portfolio of products with WF10 almost for free, as the market has assigned very little value to WF10. Our current sum of parts valuation for Nuvo gives us a target price of $7.50 per share, and we continue to rate the stock a 'Buy'.

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*

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



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

Chart By: Yahoo!, Inc.

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

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, 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, investment 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 in the issuers which they cover. 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 1047 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- 16.5%, Hold/Neutral- 77.7%, Sell/Underperform – 5.1%. Data is as of midnight on the business day immediately prior to this publication.