Zacks Small-Cap Research

May 22, 2015
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Nuvo Research, Inc. (T.NRI - TSX)

T.NRI: Nuvo Strategy Becomes Clear, Valuation Very Attractive…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/05/2014
Current Price (05/22/15)	$4.94
Target Price	**$7.00**

UPDATE

On March 5, 2015, Nuvo Research, Inc. (NRI.TO) provided investors with a business update that offered some visibility on the future direction of the cash-rich company. In short, management is splitting the company into two distinct divisions: an Immunology Group and a Topical Products and Technology (TPT) Group. Based on the success of the company's planned Phase 2 study with WF10, we believe management plans to spin-off the Immunology Group to shareholders. Below we outline the key drivers for each group and what to expect in terms of news over the next few quarters. We conclude with a valuation of the entire company, with some thoughts on what the upside might look like if WF10 succeeds. Our target is $7 per share.

SUMMARY DATA

52-Week High	**10.36**
52-Week Low	**2.50**
One-Year Return (%)	**86.30**
Beta	**N/A**
Average Daily Volume (sh)	**33,678**
Shares Outstanding (mil)	**10.8**
Market Capitalization ($mil)	**53.9**
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 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	$2.8 A	$3.9 A	$3.0 A	$3.5 A	$13.1 A
2015	$4.5 A	$3.8 E	$4.8 E	$4.9 E	$17.9 E
2016					$21.0 E
2017					$27.7 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.31 A	-$0.23 A	$4.80 A	-$0.57 A	$3.76 A
2015	-$0.02 A	-$0.10 E	$0.11 E	-$0.14 E	-$0.37 E
2016					-$0.17 E
2017					$0.27 E

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WHAT'S NEW

On March 5, 2015, Nuvo Research, Inc. (NRI.TO) provided investors with a business update that offered some visibility on the future direction of the cash-rich company. In short, management is splitting the company into two distinct divisions: an Immunology Group and a Topical Products and Technology (TPT) Group. Based on the success of the company's planned Phase 2 study with WF10, we believe management plans to spin-off the Immunology Group to shareholders. Below we outline the key drivers for each group and what to expect in terms of news over the next few quarters. We conclude with a valuation of the entire company, with some thoughts on what the upside might look like if WF10 succeeds.

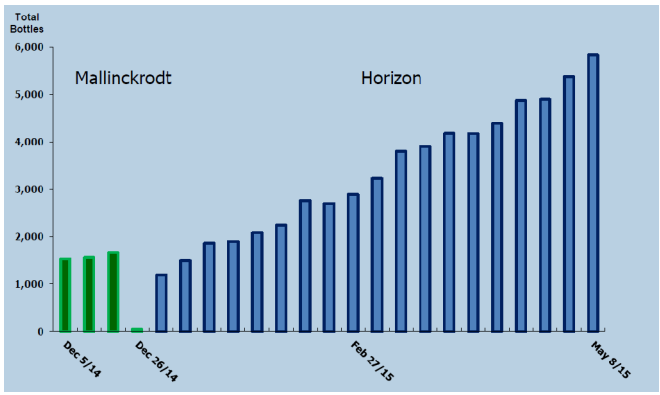
TPT Group

Nuvo's Topical Products and Technology (TPT) Group consists of several approved and revenue-generating products, including Pennsaid®, Pennsaid® 2%, Pliaglis®, and HLT Patch® (heated lidocaine / tetracaine), and Oxoferin™. Nuvo receives sales and royalties on these products on a region-by-region basis.



The primary driver of the TPT Group is Pennsaid 2%. Pennsaid 2% is FDA approved (since January 2014), and is currently being sold in the U.S. by Horizon Pharma plc (HZNP). Horizon took over promotion for Pennsaid 2% in October 2014 after Nuvo regained the rights from previous development and commercialization partner, Mallinckrodt plc (MNK). For whatever reason, Mallinckrodt was doing a rather poor job promoting Pennsaid 2% in the U.S., and Nuvo filed a lawsuit against the company claiming a breach of contract with respect to development and promotion of the product. The lawsuit was settled in September 2014, with Nuvo regaining the U.S. rights to the product, plus $10 million in cash. When we include the $45 million Nuvo received from Horizon Pharma, all-told the company walked away with $55 million in cash for Pennsaid 2%. Nicely done!

However, besides the cash, which is clearly nice and will enable Nuvo to conduct a Phase 3 trial with the drug for regulatory approval outside the U.S., Nuvo is also receiving a generous manufacturing mark-up on transfer of product to Horizon Pharma. Horizon is doing an outstanding job in promoting Pennsaid 2%. Sales in the first quarter totaled $18.2 million, about equal to what Mallinckrodt did in all of 2014. The trajectory looks fantastic, with Horizon management thinking Pennsaid 2% will do over $100 million in 2015. The product is patent protected to 2027.



Source: IMS Health

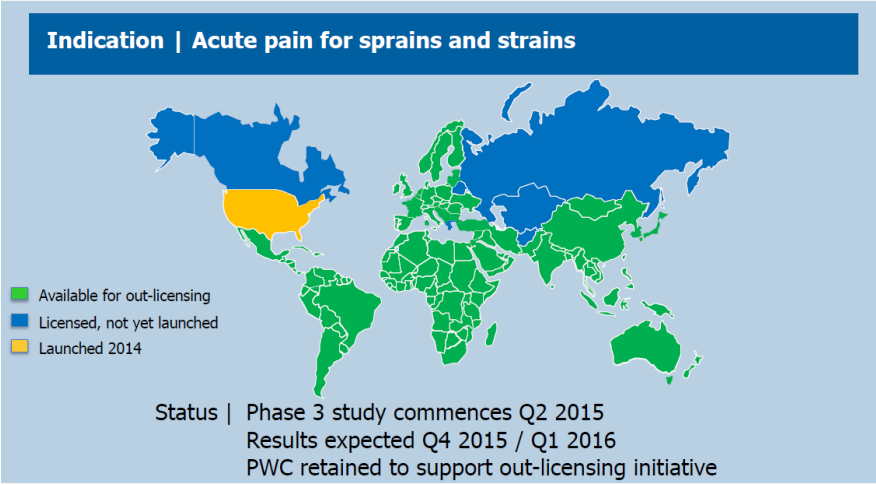
NUVO

Nuvo's goal is to continue to help Horizon by providing product as the ramp gains steam throughout 2015. The manufacturing mark-up has not been disclosed by Nuvo management, but based on the reported product sales of $2.2 million in the quarter, compared to the $18.2 million Horizon reported in end-user sales and the total $2.6 million in cost of goods versus the $3.9 million in total product sales at Nuvo during the quarter, we can begin to understand the economics here. For example, Nuvo's $2.6 million in cost of goods equates to a 34% gross margin on the $3.9 million in total product sales. If Pennsaid 2% has 90% end-user gross margin, then the mark-up for Nuvo to transfer product to Horizon is likely to be in the ~30% range.

This is not an exact science since Nuvo obviously manufactures other products besides Pennsaid 2%, including regular Pennsaid, Pliaglis, and HLT. Reported sales by Horizon do not necessarily match up in the exact quarter that Nuvo ships the product to them, but it still helps investors understand, Nuvo's manufacturing business should see solid growth in 2015 thanks to Pennsaid 2% growth; and it's already profitable on a pre-tax basis right now. In fact, during the first quarter 2015, on a segmented basis, the TPT Group incurred net income before taxes of $1.1 million.

…Expand Pennsaid 2%...

Beyond Pennsaid 2% in the U.S., Nuvo is also shipping Pennsaid to partners such as NovaMedica for distribution in Russia and some other countries, and partners like Paladin for sale in Canada, Vianex S.A. for sales in Greece, Italchimici SpA for sale in Italy, and Movianto Ltd for sale in the UK. The primary driver of upside to the current TPT Group business is expanding the approval of Pennsaid 2% outside the U.S. As a reminder, this is a product that is already approved in the U.S., with a successful registration trial conducted in 2011. The picture below shows the regions for which Pennsaid 2% is available for out-licensing and future potential sale.



To gain approval for Pennsaid 2% outside of the U.S., management plans to commence a Phase 3 clinical study of Pennsaid 2% for the treatment of acute pain. It is important to note that the U.S. label is for pain of osteoarthritis of the knee. The new Phase 3 program, to be conducted in Germany, will be a randomized, double-blind, placebo-controlled study evaluating the efficacy of Pennsaid 2% for the relief of pain associated with acute, localized muscle or joint injuries such as sprains, strains or sports-related injuries. This is a wider label indication than in the U.S., which has its pros and cons in our view. Nevertheless, this is similar to the label for Voltaren Gel, another topical diclofenac product, currently on the market and doing sales in the $100-150 million range in Europe alone.

We estimate the cost of this Phase 3 study will be approximately $1.5 million. The primary endpoint will be change in pain on movement (POM) from day 1 to day 5. It will also measure other secondary endpoints. Nuvo Research anticipates that results could be available in the fourth quarter 2015 or the first quarter 2016. In addition, NovaMedica has advised the company that they have commenced clinical studies required to obtain regulatory approval in 2015 in Russia, and the Independent States.

We believe a cost of $1.5 million to fund a Phase 3 study is extremely cheap, and could allow for the approval of Pennsaid 2%, a potential $100 million product outside the U.S. Based on the strong uptake for the drug in the U.S., we expect that Nuvo will be successful in signing new licensing and distribution deals for Pennsaid 2% for key areas such as South America, Asia, and Europe in 2015 and 2016. We believe this will allow the TPT Group, which is already profitable on a segmented basis, to generate even more cash flow.

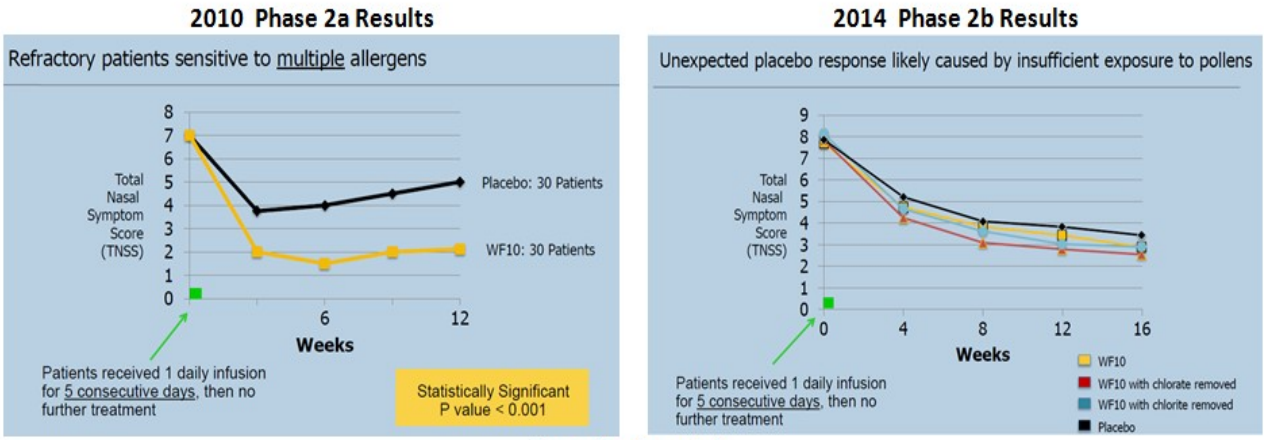
We expect management to use existing and new cash to bring in more products to develop, license, and manufacture. We note that manufacturing capacity seems adequate, with plenty of room to expand, and thus management's strategy makes excellent sense.

Immunology Group

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

As a reminder, the Phase 2b 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 2a 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 2b study, the 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 2a 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 not the case for the recent Phase 2b. The baseline TNSS score for the most recent Phase 2b study was around 8 according to the conference call held back in January 2015.



Source: Nuvo Research, Inc.

Management's contention is that the 2010 trial more accurately illustrates the efficacy of WF10 in the treatment of allergic rhinitis. They believe that the placebo group in the 2014 trial did not record as high TNSS and TOSS scores compared to the 2010 trial due to a longer enrollment period that started later in the allergy season, varying environmental conditions (a wetter spring and summer in Germany leading to lower allergic response by patients), and other factors that resulted in some patients in the 2014 trial not being exposed to a high enough concentration of the allergens that they were allergic to throughout the trial period.

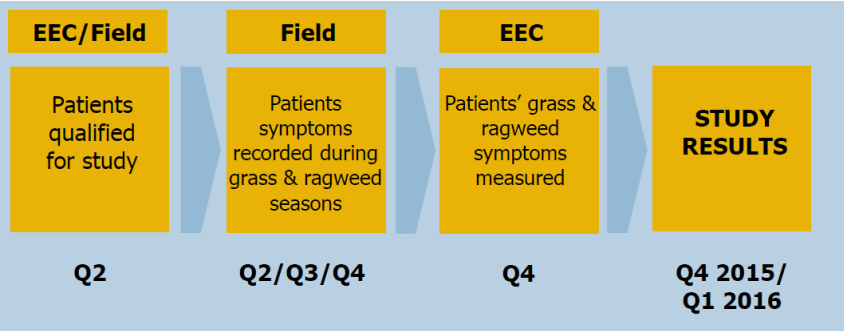
As someone who suffers from seasonal allergies, I can certainly understand the ebbs and flows of the allergy market. During some seasons, my symptoms are terrible and I find myself taking just about every OTC medication that is available. On the other hand, other seasons are more mild, highly inversely correlated to the frequency of rainfall. My allergies arrive in early May, and I suffer for approximately 4-5 weeks, with my symptoms usually disappearing by the middle of June. Therefore, it seems logical to assume that a mild allergy season in Germany in 2014 due to higher rainfall, along with enrolling patients too late in the allergy season, would have negatively impacted the study results.

According to the National Centers for Environmental Information (NOAA), in 2014, Germany recorded its warmest year on record, with average temperatures 1.4°C above the 1981-2010 average. This would seem to suggest higher pollen counts. However, total rainfall in Germany was also above normal, with the month of July 2014, right in the middle of the Nuvo Phase 2b study, reporting up to a 150% increase in rainfall from the 1981-2010 NOAA average (source: NOAA). The months of June, July, and August reported a 140% increase in precipitation compared to the 1981-2010 average. Generally speaking, increased rain means lower pollen count. As such, this would seem to suggest that Nuvo's claim of "a mild allergy season in Germany impacting results" holds some validity.

However, investors should keep in mind, the 2010 Phase 2a study that management thinks is more representative of the true efficacy of WF10 was a 60-patient, single center study. The failed 2014 Phase 2b study was a 184-patient, 15 center study. Historically speaking, results from multi-center studies are more representative of future outcomes for registration of pivotal trials, and we would be remiss to not caution investors, regardless of the weather, that it is very possible that WF10 simply may not an effective drug.

…There's Only One Way To Find Out…

During the months of January to March 2015, Nuvo management went back and analyzed the data from the 2014 Phase 2b study. In April 2015, the company announced a strategy update noting its intension to conduct another Phase 2 study with WF10 to truly determine if the product has utility for the treatment of allergic rhinitis. The new Phase 2 trial will be a randomized, double-blind, placebo-controlled, single-center trial to assess the efficacy, safety and tolerability of a regimen of five WF10 infusions. The trial will enroll patients who have a moderate to severe allergy to grass and ragweed pollen. Patients' symptoms will be recorded prior to commencement of the grass allergy season in an Environmental Exposure Chamber (EEC), in the field throughout the grass and ragweed allergy seasons and again in the EEC after completion of the ragweed season. We note the trial will be conducted in southern Ontario, Canada by Inflamax Research Inc., a full service, specialty Contract Research Organization (CRO) that specializes in allergy, respiratory and EEC studies. The 2015 WF10 Trial is expected to enroll approximately 146 patients and to be completed with topline results available in late 2015 or early 2016. Nuvo's external costs of conducting the trial will be approximately $4.5 million (CND$5.0 million). Below is a timeline of the expected trial.



If the 2015 WF10 Trial is successful, the company plans to continue WF10 development in an independently financed entity that will include the participation of Nuvo shareholders. While Nuvo's management is optimistic that the 2015 WF10 Trial will generate positive results, should the trial be unsuccessful, the company plans to discontinue WF10 development. Management has taken steps to curtail spending on a number of WF10 projects and studies planned for 2015 until results of the 2015 WF10 Trial are available.

Valuation & Recommendation

On May 12, 2015, Nuvo Research, Inc. reported financial results for the first quarter ending March 31, 2015. Total revenues in the quarter were $4.5 million, comprised of $3.9 million in product sales and transfer, $0.5 million in royalties, and $0.1 million in research contracts. For 2015, we believe revenues will grow to $17.9 million, driven primarily by increasing product sales and manufacturing transfer of Pennsaid 2% to Horizon Pharma. We also see the potential for Nuvo to sign licensing and distribution agreements for Pennsaid 2% outside the U.S., and begin shipping product to areas that would piggy-back off of the U.S. approval. In the long-run, success of the Phase 3 Pennsaid 2% study in Germany creates enormous value by allowing commercialization deals in Europe.

Nuvo Research exited the first quarter with $56.8 million in cash and short-term investments. Based on roughly 10.8 million shares outstanding as of today, this equates to $5.26 per share. The stock is currently trading at $4.95 per share, or a 6% discount to the cash on hand as of March 31, 2015. In the first quarter 2015, the company burned only $1.7 million in cash, so investors should not have great fear that the cash balance will dwindle quickly. In fact, as a reminder, on a segmented basis, the TPT Group generated $1.1 million in pre-tax income in the first quarter.

We think it make sense to value the TPT Group as a hybrid between a Contract Manufacturing Organization ("CMO") and a Contract Research Organization ("CRO"). The company clearly has manufacturing capabilities with products like Pennsaid and Pennsaid 2%. They also have research capabilities and are running the Phase 2 WF10 and Phase 3 Pennsaid 2% clinical trials. Comparables to the stock are other publicly traded CMOs and CROs such as Lonza Group, Patheon, Catalent, Parexel, Quintiles, Charles River Labs, Lab Corp of America, and ICON plc. Looking at these comparison companies, we see that Nuvo Research is vastly undervalued. As a reminder, Lab Corp purchased Covance in February 2015 for $6.1 billion in total value, which equated to roughly 2.5x revenues.

Comparables	Market Cap (Billions)	Price / Sales
Contract Research Organizations		
Parexel	$3.8	1.9
Quintiles Trans	$8.6	2.2
Charles River Labs	$3.4	2.6
Lab Corp of America	$12.1	1.4
ICON plc	$4.0	2.5
Covance	*$5.6*	*2.3*
Contract Manufacturing Organizations		
Lonza Group	$7.6	1.9
Evonik Industries	$15.7	1.3
Patheon	$1.5	1.3
Catalent, Inc.	$3.9	2.2
DaitoPharma	$0.3	1.3
Average	-	1.9

Source: Zacks SCR / Napodano, CFA

For 2015, we model total revenues of $17.9 million. If we apply the average CRO price / sales ratio of ~2x to this number, we arrive at a market capitalization of roughly $36 million. Even if we just add in half of the $56 million in cash, Nuvo could trade to a market cap of $64 million, or over $6 per share. We expect the product sales from Pennsaid 2% will accelerate in the coming years as Horizon Pharma ramps in the U.S. and deals are struck outside the U.S. for distribution in areas such as Europe and Latin America. Accordingly, we think Nuvo can post revenues of $28 million in 2017. Applying the CRO industry-average price / sales ratio with approximately half the cash balance yields a market capitalization of $88 million, or $8.50 per share.

We note that the TPT Group posted EBITDA of roughly $1.1 million in the first quarter 2015. For 2015, we think that number can approach $5 million. Applying the CRO industry average EV/EBITDA number of 12x yields a market capitalization of $62 million, or roughly $6 per share. Nuvo currently trades with negative enterprise value!

Our price target on Nuvo Research is $7 per share. That is our valuation for the TPT Group based on the above industry comps, along with expected growth from Pennsaid 2% piggy-backing on a growth from Horizon in the U.S. and a successful Phase 3 study in Germany. We believe that this will allow for expansion of the distribution footprint outside the U.S. We think investors can buy Nuvo Research today and get a very nice CMO / CRO operation with good upside.

…Upside Comes From WF10…

Nuvo Research plans to spend around $4.5 million (CND$5.0 million) to conduct the 2015 WF10 Phase 2 study. In our opinion, this is not an unreasonable amount of money to conclude if WF10 truly works or not. As noted above, the company believes the 2010 Phase 2a study is more representative of the true efficacy of the product, and thinks the 2014 Phase 2b study failed due to a rather mild spring and summer allergy season in Germany. The belief is that this did not allow for separation between WF10 and the placebo group. As such, the next Phase 2 study will be exposing patients to "environmentally relevant" allergens in an Environmental Exposure Chamber (EEC). The company should have a definitive answer by early 2016. If WF10 works, Nuvo Research will package up the asset and spin-out the Immunology Group to shareholders. If it fails, the company will discontinue it and focus solely on the TPT Group.

We know what the Phase 2 trial will cost – roughly $4.5 million. However, if it succeeds, we think the asset is worth between $40 and $50 million pre-Phase 3. We arrive at this number by doing some probability-adjusted NPV modeling on WF10 sales once approved. Firstly, according to the American College of Allergy, Asthma & Immunology, in 2014, approximately 17 million American adults and 6.7 million children had seasonal allergies. In 2014, more than 13.4 million visits to physician offices, hospital outpatient departments and emergency departments were due to allergic rhinitis.

This second statistic would seem to suggest, that despite the availability of OTC medications like diphenhydramine (Benadryl®), loratadine (Claritin®), and certirizine (Zyrtec®), a significant percent of Americans are still suffering from seasonal or perennial allergic rhinitis, and might be interested in a new and effective treatment option like WF10. We assume this to be 25%. We also assume that a product like WF10 will cost roughly $1,000 per year, which is expensive compared to OTC medications, but still very cheap in comparison to other branded pharmaceutical products. We assume approximately $25 million in funds required to gain approval of WF10 in 2019, with 5% market penetration, and a 20% discount rate on the future cash flows. If we apply a 15% probability of success of the pending Phase 2 trial, which we believe the company might argue is very low, our NPV analysis pegs the valuation of WF10 at $36 million today.

We have not added this to our $7 price target. We believe it represents 100% upside to the Nuvo Research story. As such, we think $5 million to conduct the trial is a prudent investment, because if the trial succeeds, we think the shares could easily double.

Nuvo Research, Inc.
Income Statement

Nuvo Research, Inc.	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E
Revenue from Product Sales	**$6.5**	**$3.9**	**$3.3**	**$3.9**	**$4.1**	**$15.1**	**$17.1**	**$16.1**
YOY Growth	*46.0%*	*237.6%*	*47.4%*	*156.7%*	*151.7%*	*132.7%*	*13.6%*	*-5.8%*
Royalties	**$5.5**	**$0.5**	**$0.4**	**$0.3**	**$0.2**	**$1.4**	**$0.9**	**$5.6**
YOY Growth	*-10.5%*	-	-	-	-	*-74.0%*	*-36.6%*	*522.2%*
Licensing Fees	**$0.6**	**$0**	**$0**	**$0.5**	**$0.5**	**$1.0**	**$2.5**	**$5.0**
YOY Growth	*-91.8%*	-	-	-	-	*60.3%*	*150.0%*	*100.0%*
Research and Contracts	**$0.5**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.4**	**$0.5**	**$1.0**
YOY Growth	*85.7%*	-	-	-	-	*-15.8%*	*17.6%*	*100.0%*
Total Revenues	$13.1	$4.5	$3.8	$4.8	$4.9	$17.9	$21.0	$27.7
YOY Growth	*-29.1%*	-	-	-	-	*37.1%*	*17.3%*	*31.9%*
CoGS	$5.5	$2.6	$1.9	$2.4	$2.4	$9.3	$9.5	$10.5
Gross Margin	*57.6%*	*43.7%*	*49.3%*	*49.5%*	*50.5%*	*48.3%*	*54.8%*	*62.1%*
R&D	$8.1	$2.0	$2.0	$2.7	$3.1	$9.8	$10.0	$10.0
SG&A	$13.0	$0.7	$1.0	$1.0	$1.0	$3.7	$4.0	$4.5
Other expenses	$0.5	($0.1)	$0.1	$0.1	$0.1	$0.2	$0.5	$0.5
Operating Income	($14.0)	($0.5)	($1.3)	($1.5)	($1.8)	($5.0)	($3.0)	$2.2
Operating Margin	*-107.4%*	*-11.8%*	*-33.3%*	*-30.5%*	*-36.1%*	*-27.9%*	*-14.3%*	*7.9%*
Total Other Income	$52.6	$0.3	$0.2	$0.2	$0.2	$0.9	$1.0	$1.0
Pre-Tax Income	$38.6	($0.3)	($1.1)	($1.3)	($1.6)	($4.1)	($2.0)	$3.2
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	$38.6	($0.3)	($1.1)	($1.3)	($1.6)	($4.1)	($2.0)	$3.2
Net Margin	*295.6%*	*-5.9%*	*-28.0%*	*-26.3%*	*-32.0%*	*-23.0%*	*-9.5%*	*11.6%*
Gain/Loss on trans. of foreign ops	$0.0	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)	($0.5)
Comprehensive Income	$38.6	($0.4)	($1.2)	($1.4)	($1.7)	($4.5)	($2.5)	$2.7
Reported EPS	$3.76	($0.02)	($0.10)	($0.11)	($0.14)	($0.37)	($0.17)	$0.27
YOY Growth	*#VALUE!*	-	-	-	-	*-110.0%*	*-53.6%*	*-253.3%*
Shares Outstanding	10.3	10.8	10.9	11.0	11.2	11.0	11.5	12.0

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

HISTORICAL ZACKS RECOMMENDATIONS

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

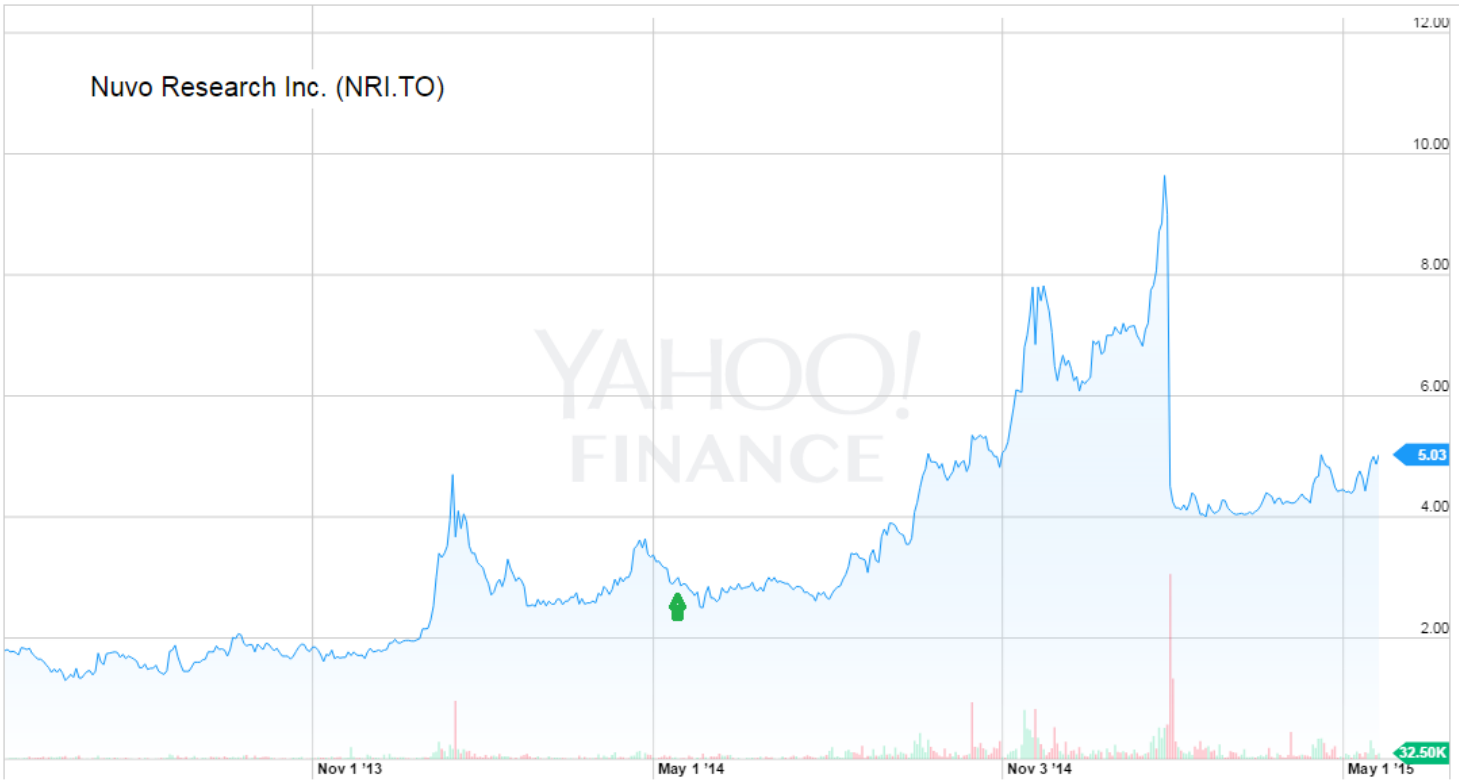


Chart By: Yahoo!, Inc.

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