Zacks Small-Cap Research

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Nuo Therapeutics, Inc. (NUOT-OTCQX)

NUOT: Saying Goodbye to 2014…

UPDATE

On March 31, 2015, Nuo Therapeutics, Inc. (NUOT) reported financial results for the full year ending December 31, 2014; and for all intents and purposes, it was a horrible year! However, we think the business is a lot closer to taking off to the upside than investors would suspect based on the abysmal stock price. That's why we are sticking with the call.

We fully understand the stock is in "show-me" mode and both our target price and the stock price have done nothing buy down since we started recommending the name in April 2014. It's clearly been ugly. That being said, we believe the story remains intact and are eagerly awaiting some progress on the top-line. We are sticking to our 'Buy' rating because we believe fundamentals bottomed (we admit this is the third time I've stated this), and are set to dramatically improve over the next 6 to 12 months.

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	04/25/2014
Current Price (04/01/15)	$0.18
Target Price	**$1.00**

SUMMARY DATA

52-Week High	**$0.63**
52-Week Low	**$0.22**
One-Year Return (%)	**-52.96**
Beta	**-1.04**
Average Daily Volume (sh)	**148,988**
Shares Outstanding (mil)	**124**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**47**
Insider Ownership (%)	**14**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**21.7**
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	**High**
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	1.9 A	2.3 A	1.7 A	1.9 A	7.8 A
2015	2.1 E	2.3 E	2.7 E	3.2 E	10.2 A
2016					19.9 E
2017					36.0 E

Earnings per Share
(EPS is based on diluted shares)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.05 A	-$0.09 A	-$0.04 A	$0.02 A	-$0.16 A
2015	-$0.03 E	-$0.03 E	-$0.03 E	-$0.02 E	-$0.10 E
2016					-$0.06 E
2017					-$0.02 E

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WHAT'S NEW

Financial & Business Update

On March 31, 2015, Nuo Therapeutics, Inc. (NUOT) reported financial results for the full year ending December 31, 2014; and for all intents and purposes, it was a horrible year!

Total revenues in the fourth quarter were $1.89 million, down 45% from the fourth quarter 2013, and below our expectations of $2.17 million. Revenues were driven by $1.37 million in product sales derived from both Angel and Aurix and $0.52 million in licensing fees, royalties, and other revenue related to the company's ALDH bright cell business and licensing agreement and commercial partnership with Arthrex, Inc. Product sales consisted of $0.12 million of Aurix, down 21% from the same quarter in 2013, and $1.26 million in product transfer sales on Angel finished goods to Arthrex.

- ***What the heck happened???***

Nuo was hit by the perfect storm in the second half of 2014. Progress was being made with the re-launch of Aurix and in discussions with the U.S. Center for Medicare and Medicaid Services (CMS) on various protocol adjustments that management believed would facilitate enrollment of patients in the three approved clinical studies designed to collect data on the use of Aurix in Medicare patients. These three studies are listed below:

Status	Study
Recruiting	Effectiveness of Aurix Therapy in Diabetic Foot Ulcers **Condition:** Diabetic Foot Ulcers **Intervention:** Device: Aurix
Recruiting	Effectiveness of Aurix Therapy in Pressure Ulcers **Condition:** Pressure Ulcer **Intervention:** Device: Aurix
Recruiting	Effectiveness of Aurix Therapy in Venous Leg Ulcers **Condition:** Venous Leg Ulcers **Intervention:** Device: Aurix

Importantly, and quite perplexingly, after several months of negotiations and what management believed was an agreed upon path forward, CMS denied the protocol (referred to as the "fifth data collection protocol") in October 2014. To give investors a sense of this decision, it was essentially the equivalent of a company receiving a complete response letter from the FDA after having both a special protocol assessment and positive Advisory Committee recommendation. It was a shock, and set the Aurix story back at least six to nine months. At this point, we have no idea why CMS rejected the "fifth protocol". We suspect the decision could have been political, as Nuo has faced significant lobbying against them from several wound care competitors (or we've been watching way too much House of Cards); but, to management's credit, they fought the decision and got it reversed with a new, even better protocol, in January 2015 (more on this below).

With Angel, Nuo and commercial partner Arthrex lost essentially the entire second half of 2014 to changes in a regulatory requirement that impacted product manufacturing. We are not fully aware of the exact regulatory change that resulted in essential a wipe-out of all finished good inventory at Nuo, although on the company's fourth quarter earnings call CEO Marty Rosendale mentioned it had to do with the use of lead and other substances that apply to specific medical device products, but the change negatively impacted Nuo's inability to supply Arthrex with Angel product to sell into the market. The company took at $600,000 charge in the fourth quarter relating to the refurbishment and design improvements for existing units in circulation. So not only could Nuo not supply Arthrex with new product, existing products on the market needed to be refurbished.

As a result of the complete mess that was the fourth quarter of 2014, revenues decreased by 45%, product gross margin was -49% (yeah, negative 49%) and the company burned $4.1 million in cash. In fact, revenues for the entire second half of 2014 were down 47% and the company burned $10.0 million in cash. For the full year 2014, Nuo reported revenues of only $7.8 million, down 33% from 2013 levels. The company burned $17.8 million in cash.

- ***What is management doing about it???***

With Aurix, essentially what Nuo was trying to do was simplify the data collection process and ease the trial design criteria to facilitate enrollment in the above three studies. Specifically, the newly approved protocol now allows for patients to randomize into one of the above three trials and be treated with either "usual and customary" standard-of-care based on the physician's discretion or "usual and customary" standard-of-care based on the physician's discretion plus Aurix. The previous protocol was too restrictive and sought to tell wound care physicians what "usual and customary" standard-of-care was. Instead, now wound care physicians have discretion. As such, enrollment in the above three trials should proceed rapidly, as wound care physicians are free to treat all patients as they see it, with half also adding Aurix to the treatment paradigm. The primary endpoint is the direct comparison of the two arms at 12 weeks. Data from the above three trials is being collected under a fourth all-encompassing trial called Au Study.

The Au Study (pronounced "Gold Study") was initiated in February 2015. We believe results will be strongly in the Aurix cohort's favor, as previous clinical data with the product – specifically used to gain FDA approval and obtain CMS reimbursement codes under CED in 2014 – has all demonstrated Aurix to be a safe and highly effective product for the treatment of all three wound types. In total, the Au Study will enroll 2,200 patients. We remind investors that Medicare patients are being reimbursed for Aurix and that Nuo is booking full revenues from each patient enrolled in the study. It is the largest, randomized wound care clinical study of its kind and will we believe will position Aurix as the leading wound care product on the market once completed. There is an interim analysis planned for when the study is 50% enrolled, and if the data are strongly supportive of Aurix as a benefit to "usual and customary" standard-of-care, CMS can end the study at that time and remove the "evidence development" requirement for Aurix reimbursement.

Given that the Au Study has now started recruiting patients, we believe the corner has been turned for Nuo. We believe 1,100 patients will enroll in 2015, and that the stopping point for evidence of a clear benefit to Aurix over "usual and customary" standard-of-care will be met. This will be a major milestone for Nuo Therapeutics and what we believe proves to not only investors, but also potential licensors and/or acquires of Aurix that the business model is scalable and that significant resources behind Aurix will turn the product from $0.495 million in sales in 2014 to peak sales over $50 million (yeah, $50 million).

On the federal front, the company is working with the VA hospitals to implement use of Aurix in the VA system. Nuo has been sampling the product to select hospitals and reported on the fourth quarter conference call that they are working through the procurement process to gain access to VA patients. The company is specifically focusing on hospitals with specialized spinal cord injury units. Pressure ulcers are a major complication in patients with spinal cord injury due to immobility and one of the key differentiators of Aurix is its ability to treat such wounds. As protocols are put into place and orders start flowing in, Nuo plans to add additional sales representatives to the VA team. Nuo is also attempting to penetration the very large diabetic foot ulcer market in Japan, and signed an exclusive licensing and distribution agreement with Rohto Pharmaceutical Co, Ltd, in January 2015. The agreement netted Nuo $1.5 million in cash.

With Angel, the regulatory requirement that impacted product manufacturing and Nuo's ability to supply Arthrex seems to be resolved. All of the reasons we've stated in the past that we see the Arthrex transaction as positive for Nuo remain in place. The issue in first half of 2014 was Arthrex preparing its sales force and positioning Angel with complementary products in the suite to drive uptake. We thought the ramp would take place in the second half of last year. Unfortunately, the supply issue delayed that. We believe those issues have been resolved.

Angel is a great product. There is nothing fundamentally changed with respect to Angel or Arthrex that leads us to believe our previous forecast for Angel peak sales of $50+ million has changed. We believe a trajectory change in the sales of Angel product is coming in 2015 and that will be evidence in the royalty line by the second or third quarter of the year.

- ***Well, We Have Waited This Long…***

The past few months have no doubt been frustrating for Nuo shareholders (and analysts that cover the stock). We have been reporting that both Angel and Aurix are positioned for a "hockey stick" type ramp in sales based on dramatically improved market dynamics for both products. We summarize:

- Angel, a previous $10 million per year run-rate for Nuo Therapeutics, is now in the hands of Arthrex, Inc., one of the world's largest providers of minimally invasive orthopedic medical products. Nuo previously promoted Angel with only a handful of part-time sales representatives. The Arthrex sales force is 1,500 strong, and the product will be coupled with existing Arthrex products to help drive awareness and uptake. Arthrex also took a healthy increase in average selling price. We estimated that previous net profit margin on Angel at Nuo was around 20%. Nuo is now receiving a "low-teens" royalty on sales at Arthrex, which we believe will ultimately prove to be 6-8x what Nuo was doing by itself. In short, we expect royalties on Angel will outpace what Nuo was reporting in net margin by the end of 2015.

- Aurix is a product we always believed had fantastic efficacy and safety data. What Aurix lacked was broad-scale reimbursement and favorably economics. Prior to CMS granting CED, we believe Nuo was selling Aurix essentially at cost. The effort was primarily on long-term acute care facilities and on finding private insurance or pre-negotiated avenues for coverage. With CED, Aurix will be reimbursed at $430 per treatment in 2015 to the millions of Medicare beneficiaries that have diabetic foot ulcers, venous leg ulcers, and pressure ulcers. We believe this equates to a healthy 70% gross margin. Similar to Angel, Nuo is ramping up its sales staff and partnering with data collection companies like Net Health and Intellicure. Sales to Medicare beneficiaries prior to CED were virtual nil for Nuo. Today we think the playing field has been leveled, and Aurix is a product that can complete effectively with and even replace expensive skin-substitute products like Dermagraft, Apligraf, EpiFix, and Grafix. Ultimately, we think Aurix peak sales are $50+ million in the U.S.

- ***Cash an obvious concern…***

Nuo Therapeutics exited 2014 with $15.9 million on the books. Nuo netted $1.5 million in January 2015 thanks to the licensing agreement with Rohto. The company burned, on average, around $4.5 per quarter in 2014. We believe that number will decline in 2015 as sales of Aurix and royalties from Angel begin to ramp. Nevertheless, the existing cash position is only sufficient to fund operations into the second half of the year.

The basic share count is 125.7 million. At today's price of only $0.16 per share, the market capitalization is a puny $20 million. There are another ~120 million warrants outstanding that would net Nuo $65 million in cash if exercised. All are under-water, with the biggest chunk (mostly all in the hands of Deerfield) of 97.6 million at $0.52 per share. For example, Deerfield warrants alone would net the company $48.2 million if exercised.

Nuo is going to need another $15+ million later this year. Our guess is they go back to Deerfield and offer some sort of warrant exchange for new cash. Yes, it would be massively dilutive (potentially 75-100%) to raise this level of cash at today's price, but we believe doing it all with an existing holder like Deerfield greatly minimizes risk to current investors. After all, the Deerfield transaction in 2014 netted Nuo over $30 million in cash. We do not think they walk from the investment. The potential for Aurix and Angel is too great.

In time, Nuo needs a "White Knight" – someone to come in and take Aurix and turn it from a few million in sales to tens of millions, or scoop up the entire company. Nuo management's job between now and then is to demonstrate that Aurix is scalable and that profitability can be achieve with minimal commercial infrastructure. We do not believe this is a pipe dream. We think the business is a lot closer to taking off to the upside than investors would suspect based on the abysmal stock price. That's why we are sticking with the call.

Valuation

To value Nuo Therapeutics, we are doing a simple "sum-of-parts" valuation for the two drivers of the top-line: Aurix sales and Angel royalties. We believe Aurix is a $50+ million product for Nuo. We believe Angel is a $75 million product for Arthrex, Inc., of which Nuo gets low-teens royalty. We apply no value for ongoing clinical programs with ALD-301 in peripheral arterial disease or ALD-351 in glioblastoma. However, just for kicks we will remind investors that data from Duke University on ALD-351 will likely be presented late 2015. Data from the PACE study, which is fully funded by the NHLBI-NIH, should be available mid-2016.

The wound care market is $3.4 billion in sales, with a dramatic shift towards cheaper, easier to use, more effective products expected in 2015 thanks to a monumental CMS decision in November 2013. Aurix is a highly effective product with favorable economics to both payers and providers. The label includes approval for use in all three major wound categories, providing a distinct competitive advantage over completing products looking to crack private formularies and gain use in VA hospitals and long-term acute care facilities. The three CED programs that Nuo plans to enroll in 2015 should generate over a million in sales alone. Assuming modest growth in the base business, Aurix sales should eclipse $5 million in 2016. Industry analysis of previous wound care products suggest

that with 20 reps, Aurix could do $15 million in revenues in 2017. Based on these forecasts, our NPV analysis pegs the valuation of Aurix at $0.65 per share.

Arthrex Inc. should be able to turn Angel into a $50 million product by 2018. They will accomplish this through a combination of dramatically increasing the sale and promotional effort, raising the price of the device, and coupling Angel with other Arthrex products and developing custom kits for things like bone marrow aspiration. Nuo receives a low-teen royalty on sales of all Angel and Angel-coupled products at Arthrex, plus a small mark-up on finished goods transfer (netting around 15% all-in economics). With $50 million in peak sales and 15% economics, applying the same NPV analysis done with Aurix, Angel is worth $0.15 per share.

Summing these parts two parts together and we believe Nuo shares are fairly-valued right now at a market $0.80 per share. We fully understand the stock is in “show-me” mode and both our target price and the stock price have done nothing buy down since we started recommending the name in April 2014. It’s clearly been ugly. That being said, we believe the story remains intact and are eagerly awaiting some progress on the top-line. We are sticking to our ‘Buy’ rating because we believe fundamentals bottomed (we admit this is the third time I’ve stated this), and are set to dramatically improve over the next 6 to 12 months.

PROJECTED FINANCIALS

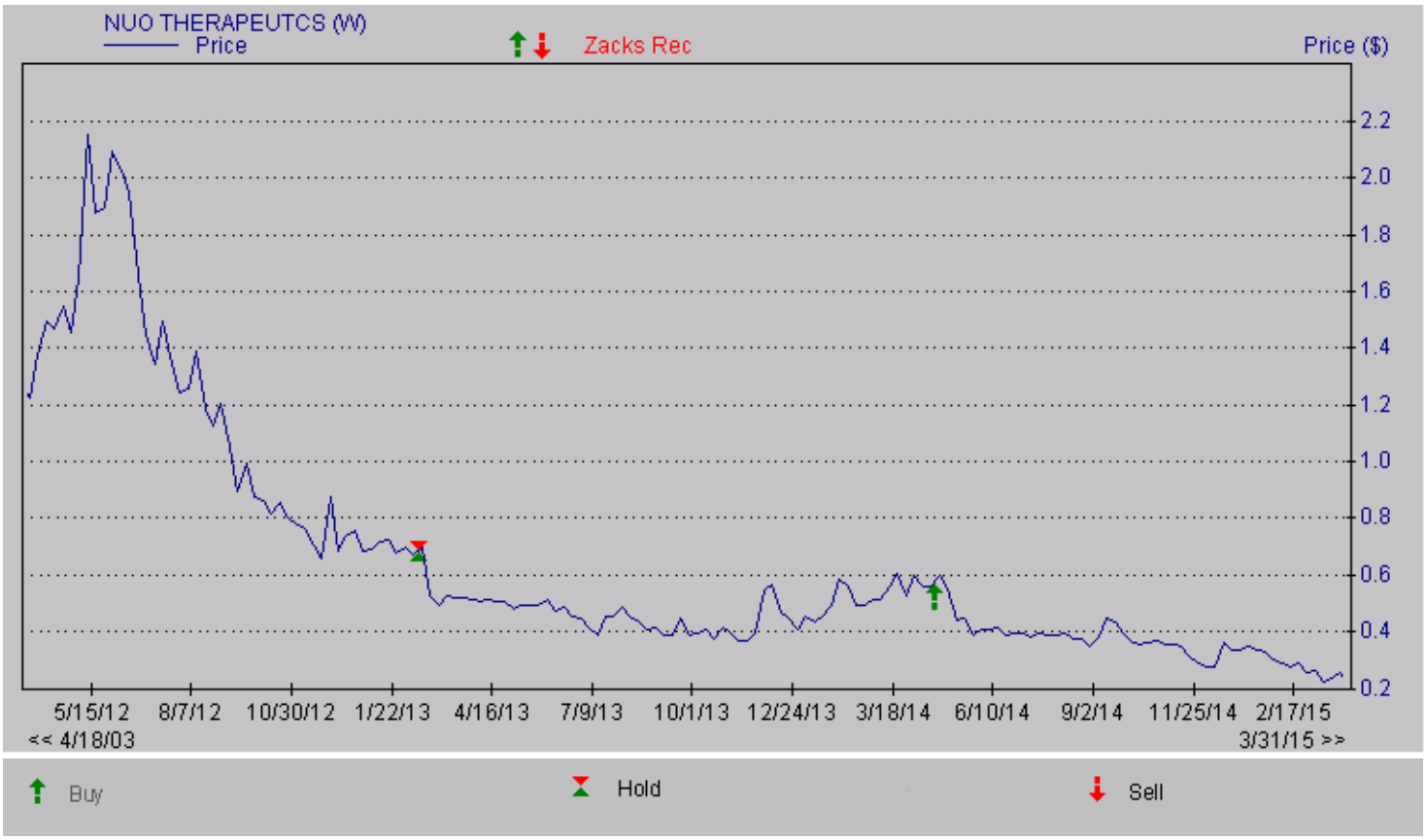
Nuo Therapeutics, Inc.
Income Statement

Nuo Therapeutics, Inc.	2013 A	Q1 A	Q2 A	Q3 A	Q4 A	2014 A	Q1 E	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 E
Med Product Sales	**$10.49**	**$1.42**	**$1.85**	**$1.20**	**$1.37**	**$5.85**	**$1.55**	**$1.75**	**$2.05**	**$2.50**	**$7.85**	**$16.50**	**$31.00**
YOY Growth	44.9%	-36.8%	-21.7%	-59.0%	-53.5%	-44.3%	8.9%	-5.5%	70.7%	81.9%	34.2%	560.0%	294.9%
Royalties & Collabs	**$1.08**	**$0.42**	**$0.48**	**$0.49**	**$0.52**	**$1.91**	**$0.55**	**$0.57**	**$0.61**	**$0.66**	**$2.39**	**$3.41**	**$5.05**
YOY Growth	-	558.7%	677.2%	11.6%	1.8%	77.6%	30.1%	20.5%	23.1%	27.8%	24.8%	416.7%	111.5%
Total Revenues	**$11.57**	**$1.85**	**$2.33**	**$1.69**	**$1.89**	**$7.76**	**$2.10**	**$2.32**	**$2.66**	**$3.16**	**$10.24**	**$19.91**	**$36.05**
YOY Growth	9.5%	-20.3%	-4.0%	-49.7%	-45.4%	-32.9%	13.8%	-0.2%	56.9%	67.1%	31.9%	530.1%	252.1%
Cost of Royalties	$0.09	$0.04	$0.04	$0.04	$0.04	$0.18	$0.04	$0.04	$0.05	$0.05	$0.18	$0.29	$0.46
Cost of Sales	$8.36	$1.41	$1.85	$1.29	$2.04	$6.59	$1.45	$1.61	$1.84	$2.15	$7.05	$11.62	$18.95
Product Gross Margin	20.3%	1.0%	-0.1%	-7.5%	-48.6%	-12.7%	6.8%	8.0%	10.2%	14.0%	10.3%	29.6%	38.9%
R&D	$3.80	$0.95	$0.96	$0.64	$0.08	$2.62	$0.45	$0.50	$0.55	$0.60	$2.10	$2.65	$2.75
SG&A, Other Fees	$17.41	$4.09	$9.29	$4.22	$4.16	$21.76	$4.10	$4.15	$4.20	$4.20	$16.65	$17.00	$17.50
Operating Income	($18.10)	($4.65)	($9.82)	($4.50)	($4.43)	($23.39)	($3.93)	($3.98)	($3.98)	($3.84)	($15.74)	($11.65)	($3.61)
Operating Margin	-156.4%	-251.9%	-422.3%	-265.8%	-234.2%	-301.4%	-187.3%	-171.4%	-149.9%	-121.6%	-153.7%	-58.5%	-10.0%
Interest & Other Income	($2.13)	($0.98)	($1.49)	($0.28)	$7.28	$4.53	($0.25)	($0.25)	($0.25)	($0.25)	($1.00)	($1.00)	($1.00)
Pre-Tax Income	($20.23)	($5.63)	($11.32)	($4.78)	$2.85	($18.86)	($4.18)	($4.23)	($4.23)	($4.09)	($16.74)	($12.65)	($4.61)
Taxes	$0.01	$0.00	$0.00	$0.00	$0.01	$0.02	$0.01	$0.01	$0.01	$0.01	$0.02	$0.02	$0.02
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Preferred A, B, D, E	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($20.24)	($5.63)	($11.32)	($4.79)	$2.85	($18.88)	($4.19)	($4.23)	($4.24)	($4.10)	($16.76)	($12.67)	($4.63)
Net Margin	-174.9%	-305.2%	-486.7%	-282.8%	150.7%	-243.3%	-199.5%	-182.3%	-159.5%	-129.7%	-163.7%	-63.6%	-12.8%
Reported EPS	**($0.20)**	**($0.05)**	**($0.09)**	**($0.04)**	**$0.02**	**($0.16)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.02)**	**($0.10)**	**($0.06)**	**($0.02)**
YOY Growth	-19.2%	-6.0%	93.5%	-18.5%	-149.1%	-19.8%	-34.9%	-64.7%	-26.9%	-202.9%	-38.9%	170.5%	-80.7%
Weighted Ave. Shares Out	103.6	111.2	121.6	124.0	125.2	120.5	127.0	129.0	150.0	175.0	175.0	200.0	250.0

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

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