Zacks Small-Cap Research

November 14, 2014
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Nuo Therapeutics, Inc. (CMXI-OTCQX)

NUOT: Is 2015 Finally The Year For Nuo Therapeutics To Shine?

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	04/25/2014
Current Price (11/14/14)	$0.36
Target Price	**$1.40**

UPDATE

On November 13, 2014, Nuo Therapeutics, Inc. (NUOT) reported financial results for the third quarter ending September 30, 2014. Total revenues in the quarter were $1.69 million, down 50% from the third quarter 2013. Upon initial look, the revenue numbers ugly. But were not changing our investment thesis. We continue to believe that fundamentals are set to dramatically improve in 2015. It remains early, but all the pieces are in place for a breakout year based on a ramp in sales of both Aurix and Angel. The valuation is attractive based on our sales assumptions. We acknowledge the stock is in “show me” mode, but we believe downside is limited and upside is tremendous on the first signs of progress. We believe this will take place in May 2015 when the company reported Q1-2015 results.

SUMMARY DATA

52-Week High	**$0.65**
52-Week Low	**$0.34**
One-Year Return (%)	**-9.33**
Beta	**-1.05**
Average Daily Volume (sh)	**110,551**
Shares Outstanding (mil)	**124**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**1.62**
Institutional Ownership (%)	**22**
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)
2013	2.3 A	2.4 A	3.4 A	3.5 A	11.6 A
2014	1.9 A	2.3 A	1.7 A	2.2 E	8.0 E
2015					19.9 E
2016					40.9 E

Earnings per Share
(EPS is based on diluted shares)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.05 A	-$0.05 A	-$0.05 A	-$0.05 A	-$0.20 A
2014	-$0.05 A	-$0.09 A	-$0.04 A	-$0.04 E	-$0.21 E
2015					-$0.10 E
2016					-$0.02 E

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WHAT'S NEW

Financial & Business Update

On November 13, 2014, Nuo Therapeutics, Inc. (NUOT) reported financial results for the third quarter ending September 30, 2014. Total revenues in the quarter were $1.69 million, down 50% from the third quarter 2013. Revenues were driven by $1.20 million in product sales derived from both Angel and Aurix and $0.49 million in licensing fees, royalties, and other revenue related to the company's licensing agreement and commercial partnership with Arthrex, Inc. signed in August 2013. Product sales declined 59% from the third quarter 2013. Gross margin in the quarter was 21.1%. Below we provide a breakdown of each revenue line item:

Nuo Therapeutics, Inc.	Q3-2014	Q3-2013	YoY
Angel	$1.11	$2.81	-61%
Aurix	$0.09	$0.12	-19%
Angel Royalties	$0.33	$0.24	36%
Other Licensing & Royalites	$0.16	$0.20	-22%
TOTAL REVENUES	$1.69	$3.37	-50%

The decrease in revenues was primarily due to a $1.3 million one-time sale of existing placed Angel centrifuges to Arthrex in the year-ago period, lower Angel disposable product sales to Arthrex and transition services revenue, partially offset by an increase in royalty revenue as a result of increased sales by Arthrex.

Operating expenses in the quarter totaled $4.86 million, consisting of $0.64 million in R&D and $4.22 million in SG&A. R&D showed a significant year-over-year and sequential decline thanks to the company closing down its Aldagen facility in Durham, NC following the failure of ALD-401 in the RECOVER-Stroke trial in May 2014. Management has stated that closing down this facility will save an estimated $4 million in costs on an annualized basis. SG&A costs were flat from the same period in 2013. It is clear that Nuo is shifting the cost savings from closing down its Aldagen R&D program to the Aurix commercial operations. We discuss this in greater detail below.

Net loss in the quarter totaled $4.79 million, or $0.04 per share. Actual cash burn in the quarter was $4.86 million. Nuo has been slowly losing less and less money each quarter. Long-time investors probably do not take much comfort in that notion but the truth is that this was the lowest reported net loss in the past seven quarters for the company. We think that both reported net loss and operating burn will continue to trend down as sales of both Angel and Aurix begin to take off in 2015. As of September 30, 2014, Nuo held $20.1 million in cash and investments. At current burn rates, the company has cash to fund operations into the second half of 2015.

Upon initial look, the revenue numbers ugly; however, investors need to understand the dynamics of the new income statement at Nuo post the Arthrex, Inc. transaction in 2013. The primary reason for the significant decline in product sales in the third quarter 2014 is simple – Nuo no longer books product sales on Angel, they book the transfer price on Angel sold to Arthrex. We believe this transfer price is sold at near zero margin for Nuo and is about 60% of the original sales price that Nuo booked on Angel. That alone explains the year-over-year decline in revenues for Angel. In fact, with Angel royalties up 36% from the third quarter 2013, it is clear that growth is positive. Going forward, we expect Arthrex to grow Angel revenues significantly over the next several years. We expect this ramp to take place starting in 2015.

We are not surprised to see unimpressive Aurix sales in the third quarter 2014. Prior to obtaining CED, Aurix was annualizing at around $0.5 million per year, with sales primarily to long-term acute care hospitals and private or cash pay wound centers. Nuo has been undertaking a major re-branding of Aurix (formerly called AutoloGel). The company hired 12 new sales representatives over the past few months, bringing the current total to 17. Previous existing and all new sales representatives not only have significant experience in the wound care market, but have direct experience selling wound care products in their respective territories. This is important because with the substantial changes that have taken place in the wound care market throughout 2014, primarily with respect to packaging of services and reimbursement, the physician/rep relationship is key to future growth.

Further changes are coming to the market in 2015. For example, both MiMedx (MDXG) EpiFix® and Osiris (OSIR) Grafix® will lose pass-through status on January 1, 2015, further crowding the "high priced skin substitute" market; and we believe driving use of lower costs, equally effective products like Aurix. Nuo used the Symposium on Advanced Wound Care (SAWC) Fall session in October 2014 to kick-off the launch of Aurix. According to management, the Aurix booth (#511) at SAWC was one of the best attended exhibits at the event. Management has commended several times on how positive the feedback and response on Aurix has been since SAWC. Investors are no doubt wondering when that supposed enthusiasm will results in an increase in sales.

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 $100 million in the U.S.

Over the past several months, Nuo has been building the necessary infrastructure to prepare for the re-launch of Aurix. For example, the hiring of Dean Tozer, the previous Senior Vice President at Advanced BioHealing Inc., was a major positive in our view. Mr. Tozer was previously responsible for the acquisition and reintroduction of Dermagraft into the U.S. market. He brings more than 25 years' experience in the global healthcare industry and has an established track record of successfully launching and marketing wound care products. He is now the new Chief Commercial Officer at Nuo Therapeutics.

As far as the required clinical programs under CED, all things look to be on track to being enrollment later this year. In the next 2-3 quarters, we expect the company to have over 1,000 patients enrolled in all four programs combined. We remind investors that the four CED programs include one randomized clinical trial (RCT) seeking to enroll 280 patients with varied wounds, and then three separate registry programs each seeking to enroll up to 750 patients with diabetic foot ulcers, venous legs ulcers, and pressure ulcers, respectively. These programs should enroll and report data in 2015. Similar to any clinical program, implementing the protocol includes obtaining IRB approval at each site. The company is targeting 120 sites right now. We continue to believe by the end of 2015, Nuo will have one of the largest data sets in the entire wound care market.

As noted above, Nuo has been working on standardizing the policies and procedures under the new CMS payment rules, enrolling the CED trials, and working with PFS and HOPPS groups to iron out and kinks in the process so that things go smoothly in 2015. Given the size of the wound care market at an estimated $3.4 billion, and the fact that Aurix has an FDA approved label for all three wound types – diabetic foot ulcers, pressure ulcers, and venous leg ulcers (note: Dermagraft and Apligraf has label indication only for diabetic foot ulcers) – and the favorable economics associated with the product, nine peer-reviewed publications, massive data to be in hand in 2015, CMS clearly on the company's side with respect to low-cost / effective pricing, we see Nuo as uniquely well-positioned in this market.

Attractive 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 $100 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.

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 four CED programs that Nuo plans to enroll in 2015 should generate a few million in sales alone. Assuming modest growth in the base business, Aurix sales should eclipse $5 million in 2015. Industry analysis of previous wound care products suggest that with 20 reps, Aurix could do $15 million in revenues in 2016. Based on these forecasts, our NPV analysis pegs the valuation of Aurix at $1.05 per share.

Arthrex Inc. should be able to turn Angel into a $75 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 $75 million in peak sales and 15% economics, applying the same NPV analysis done with Aurix, Angel is worth $0.35 per share.

Summing these parts two parts together and we believe Cytomedix shares are fairly-valued right now at a market $1.40 per share. We fully understand the stock is in “show-me” mode and that the top-line probably will not take off meaningfully until 2015. 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 and are set to dramatically improve over the next 12 to 18 months.

PROJECTED FINANCIALS

Nuo Therapeutics, Inc.
Income Statement

Nuo Therapeutics, Inc.	2012 A	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
Med Product Sales	**$7.24**	**$10.50**	**$1.42**	**$1.85**	**$1.20**	**$1.62**	**$6.10**	**$16.45**	**$35.00**
YOY Growth	22.7%	45.0%	-36.8%	-21.7%	-59.0%	-45.2%	-41.9%	169.9%	112.8%
Royalties & Collabs	**$3.32**	**$1.07**	**$0.42**	**$0.48**	**$0.49**	**$0.55**	**$1.94**	**$3.46**	**$5.95**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$10.56**	**$11.57**	**$1.85**	**$2.33**	**$1.69**	**$2.17**	**$8.03**	**$19.91**	**$40.95**
YOY Growth	45.8%	9.5%	-20.3%	-4.0%	-49.7%	-37.4%	-30.6%	147.8%	105.7%
Cost of Royalties	$0.02	$0.09	$0.04	$0.04	$0.04	$0.04	$0.17	$0.14	$0.10
Cost of Sales	$3.90	$8.36	$1.41	$1.85	$1.29	$1.58	$5.61	$12.91	$24.00
Product Gross Margin	46.2%	20.3%	1.0%	-0.1%	-7.5%	2.8%	8.0%	21.5%	31.4%
R&D	$3.39	$3.80	$0.95	$0.96	$0.64	$0.65	$3.20	$3.10	$3.50
% R&D	32.1%	32.8%	51.7%	41.2%	37.6%	30.0%	39.8%	15.6%	8.5%
SG&A, Other Fees	$16.16	$17.41	$4.09	$9.29	$4.22	$4.25	$21.85	$19.50	$16.50
% G&A	152.9%	150.5%	221.5%	399.5%	249.3%	195.9%	272.0%	97.9%	40.3%
Operating Income	($12.88)	($18.10)	($4.65)	($9.82)	($4.50)	($4.35)	($22.79)	($15.74)	($3.15)
Operating Margin	-121.9%	-156.4%	-251.9%	-422.3%	-265.8%	-200.2%	-283.7%	-79.0%	-7.7%
Interest & Other Income	($6.89)	($2.13)	($0.98)	($1.49)	($0.28)	($0.30)	($3.06)	($1.20)	($1.00)
Pre-Tax Income	($19.76)	($20.23)	($5.63)	($11.32)	($4.78)	($4.65)	($25.85)	($16.94)	($4.15)
Taxes	$0.02	$0.009	$0.00	$0.00	$0.00	$0.01	$0.02	$0.02	$0.02
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%
Preferred A, B, D, E	$0.01	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($19.80)	($20.24)	($5.63)	($11.32)	($4.79)	($4.65)	($25.87)	($16.96)	($4.17)
Net Margin	-187.4%	-174.9%	-305.2%	-486.7%	-282.8%	-214.3%	-322.0%	-85.2%	-10.2%
Reported EPS	**($0.24)**	**($0.20)**	**($0.05)**	**($0.09)**	**($0.04)**	**($0.04)**	**($0.21)**	**($0.10)**	**($0.02)**
YOY Growth	217.7%	-19.2%	-6.0%	93.5%	-18.5%	-19.7%	9.9%	-54.9%	-78.5%
Weighted Ave. Shares Out	81.9	103.6	111.2	121.6	124.0	125.0	120.5	175.0	200.0

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

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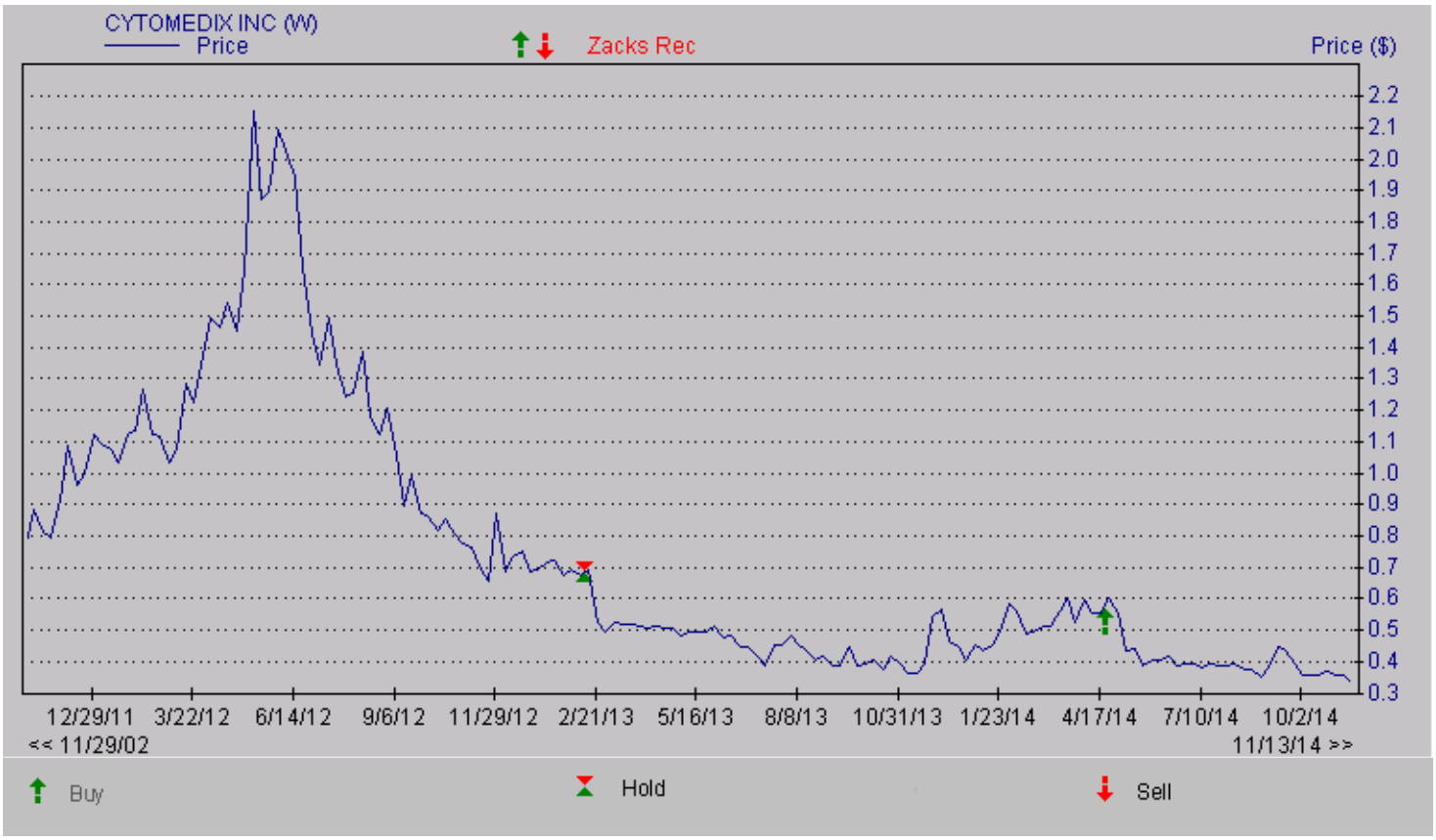

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