Zacks Small-Cap Research

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# Nuo Therapeutics, Inc. (NUOT-OTCQX)

## *NUOT: Making Progress With the VA as the Au Study Begins…*

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | Neutral |
| Date of Last Change | 04/25/2014 |
| Current Price (05/14/15) | $0.24 |
| **Target Price** | **$1.00** |

## UPDATE

On May 14, 2015, Nuo Therapeutics, Inc. reported financial results for the first quarter ending March 31, 2015. Results were generally in-line with expectations, with hints of meaningful progress on the commercial side with Aurix discussed on the conference call.

We believe Nuo shares are fairly-valued right now at a market $1 per share. We fully understand the stock is in "show-me" mode. That being said, we believe the story remains intact and are eagerly awaiting more 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 6 to 12 months.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.47** |
| **52-Week Low** | **$0.19** |
| **One-Year Return (%)** | **-41.24** |
| **Beta** | **-1.09** |
| **Average Daily Volume (sh)** | **148,060** |
| **Shares Outstanding (mil)** | **126** |
| **Market Capitalization ($mil)** | **$34** |
| **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 2015 Estimate** | **N/A** |
| **P/E using 2016 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 | 4.8 A | 2.3 E | 2.7 E | 3.2 E | 13.1 A |
| 2016 | | | | | 21.4 E |
| 2017 | | | | | 36.3 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 | -$0.04 E | -$0.03 E | -$0.03 E | -$0.06 E |
| 2016 | | | | | -$0.08 E |
| 2017 | | | | | -$0.04 E |

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## WHAT'S NEW

**Financial & Business Update**

On May 14, 2015, Nuo Therapeutics, Inc. (NUOT) reported financial results for the first quarter ending March 31, 2015. Total revenues in the quarter were $4.84 million, up 162% from the first quarter 2014, and nicely above our expectations of $2.04 million. However, we note our estimate of $2.10 million did not include a $3.00 million milestone payment from Rohto Pharmaceuticals Co. for the license and distribution agreement for Aurix in Japan, signed in January 2015. We were aware of the deal, but were unsure as to how Nuo would recognize the payment (i.e. all upfront as they did or amortized out over the life of the patents). As such, our adjusted estimate would have been $5.04 million, and thus the report $4.84 million was just shy of expectations.

As noted above, $3.00 million of the $4.84 million revenues in the quarter related to the upfront payment from Rohto for Aurix in Japan. The company had a sub-milestone payment of $1.5 million to Millennia Holdings to terminate a previous agreement in Japan, so Nuo netted $1.5 million in cash from the deal. The remaining revenues consisted of $1.31 million in product sales, broken down between $0.12 million in sales of Aurix and $1.18 million in inventory transfer of Angel to Arthrex, Inc. Neither of these are rather impressive numbers, but expectations for the quarter were low. Nuo also recognized $0.43 million in royalties on end-user sales of Angel at Arthrex. We provide a brief update on each product below:

- **Angel**

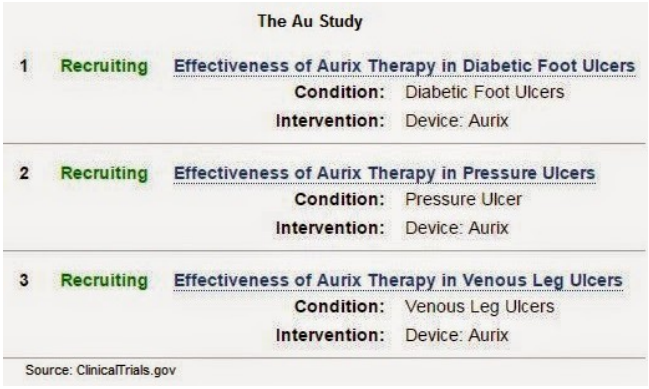
Angel, a previous $10 million per year run-rate for Nuo Therapeutics, is now in the hands of Arthrex, Inc., one of the world's largest providers of minimally invasive orthopedic medical products. Nuo previously promoted Angel with only a handful of part-time sales representatives. The Arthrex sales force 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 our last report, we outlined the regulatory challenge and manufacturing issue that negatively impacted Nuo's ability to ship product to Arthrex during the second half of 2014. As a reminder, it had to do with the use of lead and other banned substances that apply to specific medical device products, which cause Nuo to go back and not only make design improvements for new products but also go into the market and refurbishment existing units in circulation. In this regard, Nuo took a $600,000 charge in the fourth quarter 2014. That said, as of today the issue looks like it has been resolved and we believe the ramp in Angel sales is still on schedule for 2015 and beyond. Arthrex royalties on Angel sales in the first quarter 2015 were $0.43 million, up 65% from the first quarter 2014 and 19% sequentially from the fourth quarter 2014. We believe this is a clear sign of progress, and model Angel royalty payments totaling $1.89 million in 2015, growing to $4.55 million by 2017.

- **Aurix**

Nuo was hit with a curve ball from the U.S. Center for Medicare and Medicaid Services (CMS) in 2014 that essentially cause the loss of an entire year's worth of progress on obtaining data from the CED protocol studies. As a reminder, in early 2014, progress was being made with the re-launch of Aurix and in discussions with CMS on various protocol adjustments that management believed would facilitate enrollment of patients in the three approved clinical studies designed to collect "evidence" data on the use of Aurix in Medicare patients.

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 a special protocol assessment in place. 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. These three studies are listed below:




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.

As of early May 2015, Nuo management noted that three centers have been enrolled and are treading patients in the Au Study. Sales of Aurix in the first quarter 2015 were negligible at only $0.12 million. Investors may have expected more, but keep in mind that the protocol for the Au Study was only finalized in February 2015 and the three centers only became active over the past few weeks. In the next several weeks, management expects another 7-10 centers will come online. Management has stopped short of providing guidance on enrollment rates, but did say on the first quarter call that they believe they can get to the 50% mark – when an interim analysis is planned – in nine to twelve months. That would be over 1,100 patients enrolled by this time next year.

In terms of the interim analysis, if the data are strongly supportive of Aurix as a benefit to "usual and customary" standard-of-care, CMS can end the study early and remove the "evidence development" requirement for Aurix reimbursement. 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).

Aurix is a product we always believed had fantastic efficacy and safety data. In fact, Nuo just recently released data from three case studies with Aurix at the 28th Annual Symposium on Advanced Wound Care (SAWC) Spring Meeting, held in San Antonio, Texas held earlier in the month (see our analysis of that data here). 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. 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.

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.

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. On the first quarter conference call, the company noted that two VA hospitals have placed initial orders for Aurix. Another six hospitals are going through the qualification process. That's nice progress in only six weeks! The company is specifically focusing on the 24 U.S. VA 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. Once within the VA network, Nuo plans to expand to other areas of the hospital that treats things like diabetic foot ulcers and venous leg ulcers. We believe effective promotion of Aurix can be accomplished with 15-20 reps initially, and then expanded once the company gains traction to over 50.

It is for these reasons – the CED protocols enrolling and the company finally making progress with the VA – that we expect Aurix sales to ramp substantially in the next several years.

**Cash an obvious Concern**

Nuo Therapeutics exited the first quarter 2015 with $11.9 million on the books. Nuo netted $1.5 million in January 2015 thanks to the licensing agreement with Rohto, so net cash burn in the first quarter was $4.0 million. 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 $0.24 per share, the market capitalization is a puny $30 million. There are another ~116 million warrants outstanding that would net Nuo $62+ 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 30-40%) 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 $0.70 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 $0.20 per share.

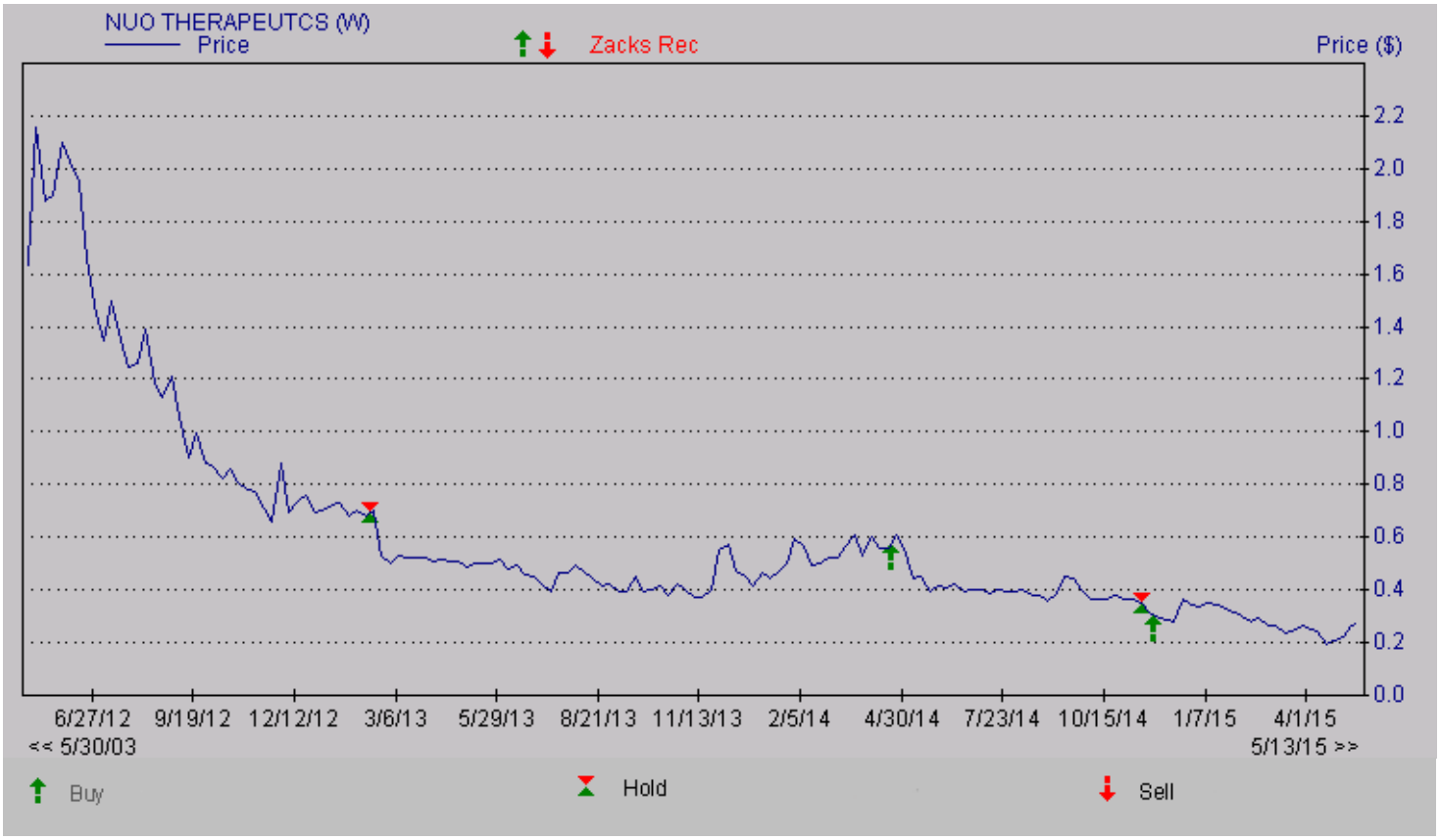
Summing these parts two parts together and we believe Nuo shares are fairly-valued right now at a market $0.90 per share. We are adding in another $0.10 for the opportunity with Aurix outside of the U.S., specifically with Rohto in Japan. We fully understand the stock is in “show-me” mode. That being said, we believe the story remains intact and are eagerly awaiting more 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 6 to 12 months.

**Nuo Therapeutics, Inc.**
Income Statement

| Nuo Therapeutics, Inc. | 2013 A | 2014 A | Q1 A | Q2 E | Q3 E | Q4 E | 2015 E | 2016 E | 2017 E |
|---|---|---|---|---|---|---|---|---|---|
| **Med Product Sales** | **$10.49** | **$5.85** | **$1.31** | **$1.76** | **$2.10** | **$2.53** | **$7.68** | **$17.75** | **$31.20** |
| *YOY Growth* | 44.3% | -44.3% | -8.3% | -5.2% | 74.9% | 83.7% | 31.3% | 131.1% | 75.8% |
| **Royalties & Collabs** | **$1.08** | **$1.91** | **$3.53** | **$0.56** | **$0.62** | **$0.69** | **$5.39** | **$3.65** | **$5.08** |
| *YOY Growth* | - | 77.6% | 735.4% | 16.8% | 26.2% | 32.6% | 181.9% | -32.3% | 39.2% |
| **Total Revenues** | **$11.57** | **$7.76** | **$4.84** | **$2.31** | **$2.72** | **$3.21** | **$13.07** | **$21.40** | **$36.28** |
| YOY Growth | 9.5% | -32.9% | 162.0% | -0.7% | 60.8% | 69.8% | 68.4% | 63.7% | 69.5% |
| Cost of Royalties & Licensing | $0.09 | $0.18 | $1.54 | $0.05 | $0.05 | $0.06 | $1.70 | $0.33 | $0.47 |
| Cost of Sales | $8.36 | $6.59 | $1.28 | $1.63 | $1.89 | $2.18 | $6.98 | $12.85 | $19.14 |
| *Product Gross Margin* | 20.3% | -12.7% | 1.9% | 7.2% | 10.0% | 13.9% | 9.2% | 27.6% | 38.7% |
| R&D | $3.80 | $2.62 | $0.73 | $0.75 | $0.80 | $0.90 | $3.18 | $3.80 | $4.25 |
| SG&A, Other Fees | $17.41 | $21.76 | $4.65 | $4.35 | $4.50 | $4.75 | $18.25 | $20.00 | $22.50 |
| Operating Income | ($18.10) | ($23.39) | ($3.37) | ($4.46) | ($4.52) | ($4.67) | ($17.03) | ($15.57) | ($10.08) |
| *Operating Margin* | -156.4% | -301.4% | -69.7% | -193.3% | -166.3% | -145.6% | -130.3% | -72.8% | -27.8% |
| Interest & Other Income | ($2.13) | $4.53 | $7.48 | ($0.25) | ($0.25) | ($0.25) | $6.73 | ($1.00) | ($1.00) |
| Pre-Tax Income | ($20.23) | ($18.86) | $4.11 | ($4.71) | ($4.77) | ($4.92) | ($10.30) | ($16.57) | ($11.08) |
| Taxes | $0.01 | $0.02 | $0.00 | $0.01 | $0.01 | $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 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Net Income | ($20.24) | ($18.88) | $4.11 | ($4.72) | ($4.78) | ($4.93) | ($10.32) | ($16.59) | ($11.10) |
| *Net Margin* | -174.9% | -243.3% | 84.9% | -204.3% | -175.6% | -153.5% | -79.0% | -77.5% | -30.6% |
| **Reported EPS** | **($0.20)** | **($0.16)** | **$0.03** | **($0.04)** | **($0.03)** | **($0.03)** | **($0.06)** | **($0.08)** | **($0.04)** |
| YOY Growth | -19.2% | -19.8% | -164.4% | -60.7% | -17.5% | -223.8% | -62.4% | 194.5% | -24.7% |
| Weighted Ave. Shares Out | 103.6 | 120.5 | 126.0 | 129.0 | 150.0 | 175.0 | 175.0 | 200.0 | 250.0 |

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

## HISTORICAL ZACKS RECOMMENDATIONS



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