Zacks Small-Cap Research

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# Cytomedix, Inc (CMXI-OTC)

***CMXI: Revenues Slowly Building, But The Market Remains Skeptical of ALD-401…***

| | |
|---|---|
| **Current Recommendation** | **Neutral** |
| Prior Recommendation | Outperform |
| Date of Last Change | 02/14/2013 |
| Current Price (05/10/13) | $0.49 |
| **Target Price** | **$1.50** |

## UPDATE

We currently model total revenues in 2013 at $10.9 million, comprised of $1.5 million in products sales coming from AutoloGel and $9.0 million from Angel. We model a net loss of $15.6 million for 2013, with cash burn around $12 to $14 million for the full year. We do not model upfront or licensing fees in 2013. Our rating remains 'Neutral' with a $1.50 price target. The single biggest catalyst for the shares in 2013 would be a deal for AutoloGel. If the company and strike a deal that for AutoloGel that brings in upfront cash, royalties, and backend milestones, perhaps the shares can recover from their depressed state. We suspect that Angel will keep chugging along with 2013 regardless, and that the market will continue to assign little value to the ALDH pipeline until the data from the phase 2 RECOVER-Stroke program in 2014.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$2.28** |
| **52-Week Low** | **$0.45** |
| **One-Year Return (%)** | **-75.26** |
| **Beta** | **0.26** |
| **Average Daily Volume (sh)** | **136,597** |
| **Shares Outstanding (mil)** | **104** |
| **Market Capitalization ($mil)** | **$49** |
| **Short Interest Ratio (days)** | **1.62** |
| **Institutional Ownership (%)** | **8** |
| **Insider Ownership (%)** | **16** |
| **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 2013 Estimate** | **N/A** |
| **P/E using 2014 Estimate** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Biomed/Gene** |
| **Zacks Rank in Industry** | **N/A** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | 3.0 A | 3.7 A | 1.8 A | 2.1 A | 10.6 A |
| 2013 | 2.3 A | 2.4 E | 2.8 E | 3.3 E | 10.9 E |
| 2014 | | | | | 14.4 E |
| 2015 | | | | | 17.8 E |

**Earnings per Share**
(EPS is based on diluted shares)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | -$0.07 A | -$0.09 A | -$0.04 A | -$0.04 A | -$0.24 A |
| 2013 | -$0.05 A | -$0.04 E | -$0.04 E | -$0.03 E | -$0.14 E |
| 2014 | | | | | -$0.11 E |
| 2015 | | | | | -$0.09 E |

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## WHAT'S NEW

**Financial Update**

On May 9, 2013, Cytomedix reported financial results for the first quarter 2013. Cytomedix reported $2.32 million in revenues in the quarter, down 23% from the first quarter 2012. We note the company recorded $1.33 million in revenues from the company's previous "exclusive negotiations" with a global pharmaceutical player on AutoloGel back during the first quarter 2012, so the year-over-year comparison is not truly apples-to-apples.

Product sales in the first quarter 2012 totaled only $1.69 million, so product sales in the first quarter 2013 of $2.25 million showed a solid 34% gain. The U.S. market accounted for $1.84 million (82%) of sales; however we note that international growth is outpacing U.S. growth. International sales were up 112% year-over-year. Below we provide a breakdown of the revenue line:

| Line-Item | Q1-2013 A | Q1-2013 E | Q1-2012 A | YoY |
|---|---|---|---|---|
| AutoloGel | $0.15 Mil | $0.13 Mil | $0.16 Mil | -6% |
| Angel | $2.11 Mil | $1.90 Mil | $1.52 Mil | +40% |
| **Total Product Sales** | **$2.25 Mil** | **$2.03 Mil** | **$1.69 Mil** | **+34%** |
| Royalties & Collaborative | $0.06 Mil | $0.05 Mil | $1.33 Mil | - |
| **Total Revenues** | **$2.32 Mil** | **$2.08 Mil** | **$3.02 Mil** | **-23%** |
| Gross Margin | 49.7% | 50% | 43.8% | - |

***…AutoloGel Finally Ready For Takeoff…***

AutoloGel sales were essentially in-line with our thinking, perhaps a tad higher, although with sales of only $150k its is tough forecast still. We note that the long-waited finish line for gaining CMS reimbursement on AutoloGel seems to be in sight. On March 1, 2013, CMS approved the clinical outcomes in the Coverage with Evidence Development (CED) protocols submitted by the company. This approval allowed Cytomedix to begin promoting and rolling out the protocols to physicians and patients for AutoloGel when used to treat Medicare beneficiaries. On March 18, 2013, CMS issued temporary reimbursement coding and claims payment instructions to its regional contractors for the use of AutoloGel in chronic non-healing wounds. The assignment of a Healthcare Common Procedure Coding System (HCPCS) code establishes the reimbursement mechanism for physicians and other providers submitting claims for services provided to Medicare beneficiaries. Claims processing will begin with an implementation date of July 1, 2013 for claims with dates of service after August 2, 2012.

The assigning of a reimbursement code for AutoloGel is huge for Cytomedix. The "G" code facilitates reimbursement in the hospital outpatient setting, skilled nursing facilities, rural health clinics, comprehensive outpatient rehabilitation facilities, federally qualified health centers, and critical access hospitals for three types of non-healing chronic wounds: diabetic foot ulcers, venous leg ulcers, and pressure ulcers. The market for products addressing chronic wounds in the U.S. is estimated to be $2.3 billion annually. There are over 6 million of these types of wounds treated each year in the U.S. Prior to CMS reimbursement, AutoloGel was significantly disadvantaged compared to competing products with full coverage, including Dermagraft (~$153M in sales in 2012) and Apligraf (~$125M in sales in 2011). AutoloGel is the only PRP product FDA-approved for the treatment of chronic wounds.

We estimate greater than 50% of the market is Medicare beneficiaries. But besides missing out on these patients, private payors were also disadvantaging AutoloGel. With CMS now on board, we expect private payors to follow suit. The economics around AutoloGel should be dramatically improved by the second half of 2013. For example, the company tells us it treated roughly 300 patients to generate $0.55 million of sales in 2012. That came with little marketing and promotional effort by the company. With CED now in place, the company expects to dramatically step-up the marketing effort and begin enrolling and treating patients in one of the four CMS-approved trials to collect the data necessary under the CED pathway. These four trials include one randomized efficacy program with Grade 1 or 2 diabetic foot ulcer (DFU) patients vs. a standardized (usually and customary) care and three outcome assessment studies in broader patient populations, such as DFU patients with Grade 3 and 4, venous leg ulcers, and pressure ulcers. The primary efficacy study will seek to enroll 260 patients. In total, the company plans to enroll and treat over 2,400 patients between all four studies to compile data for CMS under the CED pathway.

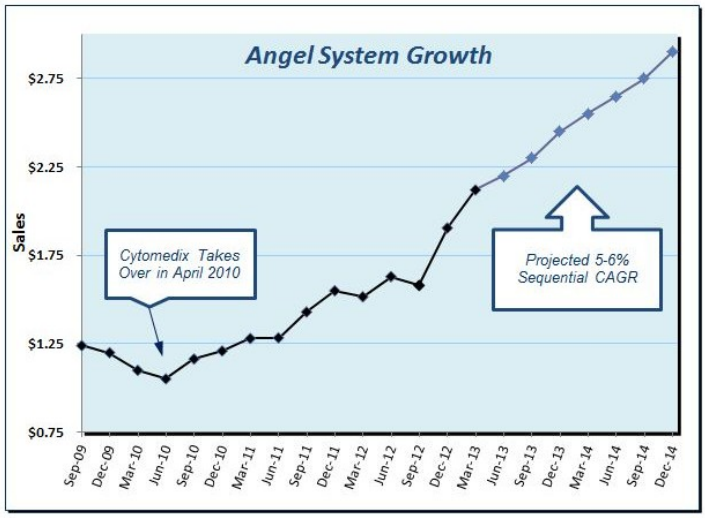
The goal for 2013 is to exit the year with over 1,000 patients enrolled. This would be a three to four fold increase in sales from 2012, or to around $1.5 million. It's been a rocky-road for AutoloGel, but the potential for significant acceleration in sales in 2013 and beyond is clearly one of the company's biggest opportunities.

The company continues to look for distribution partners for AutoloGel. After the "Big Pharma" partner walked away earlier in 2012 the company immediately began conversations with new potential partners. The timing of a deal remains a wildcard, but any transaction that provides increased sales and promotion, upfront cash, royalties on sales, and the potential for backend milestones would be a big win for management. A partnership remains another, albeit more difficult to forecast, potential opportunity for Cytomedix.

***...Angel Keeps Chugging Along…***

Angel has been the main bright spot for Cytomedix over the past year. In fact, sales have continued their impressive march upwards ever since the company acquired the product from Sorin in April 2010. Angel sales in the first quarter 2013 totaled $2.11 million, up 40% year-over-year and 11% sequentially from the fourth quarter 2012.

Cytomedix has placed over 550 units into the market, that's up nicely from the 500-525 placed at the end of 2012. We forecast Angel sales to grow to $9.0 million in 2013. Angel system growth is clearly a key strength, with much of the growth coming from orthopedics (sports medicine) and cardiovascular surgery. Cytomedix plans to increase the sales and promotion effort around Angel in 2013. The company exited the year with 8 full-time sales representatives. As of early May 2013, the number is up to 10 representatives. Management expects to increase that number to 12 shortly. The company is holding "PRP workshops" to educate and train physicians on the potential use of Angel in orthopedic and cardiovascular indications.




We expect that new markets will continue to drive growth of Angel in the near-term. On November 8, 2012, Cytomedix announced that the U.S. FDA had granted clearance for the use of Angel for processing a small sample of blood or a mixture of blood and bone marrow aspirate (BMAC). The 510(k) approval now allows for PRP produced from either blood or a mixture of bone marrow aspirate to be combined with bone graft material and used in appropriate orthopedic procedures as deemed necessary by a clinician, such as spinal fusion, healing of nonunion bone fractures and other bone grafting applications. In the U.S., approximately 400,000 spinal fusion procedures are performed each year and the application of bone marrow or bone marrow concentrates has been the historical gold standard.

Concentrated PRP produced from blood and bone marrow may be used in up to 90% of spinal fusion procedures. The U.S. biologics market associated with spinal fusion procedures is approximately $700 million annually. We think an equal opportunity exists in Europe. This is a big opportunity. Accordingly, management is talking to potential partners, some U.S. centric / some globally, on marketing Angel into these orthopedic and surgical settings. A deal could come with an upfront payment, and include backend milestones and royalties / transfer payments on sales and or distribution. This remains a key catalyst for the shares in 2013.

Net loss for the first quarter 2013 totaled $5.34 million, or $0.05 per share. We note that despite the company posting revenues higher than our model, loss was greater than expected on higher SG&A expense. The loss was driven by $0.90 million in R&D (in-line with expectations) and $5.15 million in SG&A (about $1.1 million higher than expected). On the first quarter conference call, CEO, Marty Rosendale noted a $1.0 million non-cash charge for revaluation of the Aldagen contingent consideration payment based on the enrollment pace of RECOVER-Stroke. We note that approximately 1.5 million shares were move from the enrollment goal milestone of 100 patients at May 31, 2013 into the trial success milestone. This caused SG&A to be $1.0 million higher than our model. Outside of this significant accounting change, operating costs were in-line with expected. And, despite net loss of $5.34 million in the quarter, Cytomedix burned only $4.23 million in cash from operating and investing activities.

***…Cash Secured…***

Cytomedix exited March 31, 2013 with $7.27 million in cash and investments. We project an operating burn of around $4 million per quarter for the remainder of 2013. We remind investors that the company secured up to $27.5 million in cash back in February 2013. We provide a breakdown of the terms and expenses associated with the financing below:

- Lincoln Park Transaction: Cytomedix entered into a committed equity financing – common stock purchase agreement (CPSA) with Lincoln Park Capital (LPC). The CPSA allows for up to $15 million in equity to be sold at Cytomedix' discretion for a period of 30 months. Transactions are capped to 150,000 shares per day based on the current share price, but can be increased to 200,000 or more if the stock moves above certain thresholds (one such threshold is >$1.00 per share). LPC is capped at owning 9.99% of the outstanding shares, and not obligated to buy at prices below $0.45 per share. LPC was paid a fee of 375,000 shares for entering into the transaction, and can earn another fee of 375,000 pro rata.

- Stock & Warrant Transaction: Cytomedix raised $5.0 million gross through issuing a total of 9,090,910 million shares at $0.55 per share. Participants also received 70% warrant coverage (6,363,637 million shares). The warrants are exercisable immediately at $0.75 per share for a term of five years. Burrill Securities and Barrington Research were paid a placement and expense reimbursement fee totaling $402,000. Burrill also received 136,364 million five-year warrants exercisable at $0.90 per share. We note that both Aldagen Holdings, LLC and Lincoln Park Capital Fund, as well as the State of Maryland Venture Fund, participated in the $5.0 million stock and warrant offering.

- Loan Transaction: Cytomedix entered into a $7.5 million credit and security agreement with MidCap Financial LLC. The first tranche of the loan, $4.5 million, has been received. The second $3.0 million is payable based on completion of certain performance milestones, which include raising additional cash through the LPC-CSPA noted above or a commercial partnership for Angel or AutoloGel in 2013. The loan matures on August 19, 2016 and bears interest at an annual rate of LIBOR + 8%, with a minimum LIBOR rate of 3%. MidCap received seven-year warrants to purchase 1.079 million shares of stock at $0.70 per share. There is also a prepayment penalty of 5% for the first 12 months, then 3% for the next 12 months, dropping to 1% for the final 18 months.

***…Seeking Uplisting…***

At the end of May 2013, Cytomedix plans to ask shareholders to vote on a proposed reverse split of the common stock, contingent upon seeking an uplisting to the NASDAQ-CM. We note that Cytomedix meets all other listing requirements for the NASDAQ-CM except for the stock price. If the company did a 1-for-10 reverse split, the shares would be trading around $5.00, and thus potentially be more attractive to institutional investors that are unable to buy the stock today at less than $1.00.

As of April 30, 2013, there were roughly 104.5 million basic shares outstanding, along with another 7.9 million options under the company's long-term incentive plan, 16.8 million warrants (many of them far out of the money), and 20.3 million shares issuable under the contingent milestone payments to Aldagen. The fully-diluted share count is around 151 million. We think a reverse split of 1-for-10 makes to make the capital structure appear more in-line with similar sized biotech and medical device names.

**Aldagen Pipeline: High Risk / High Reward**

Roughly a year ago, Cytomedix made the transformational decision to acquire privately-held Aldagen, and with it the company's ALDH bright cell technology. Impetuous for the deal was to boost the company's focus on regenerative medicine and create what management referred to as the "three pillars of generative medicine" – scaffolds, signals, and cells. Aldagen had candidates ALD-201 for ischemic heart failure, ALD-301 for critical limb ischemia, and ALD-401 for ischemic stroke in the clinical pipeline.

The lead program was a recently initiated phase 2 study, dubbed RECOVER-Stoke, with ALD-401. At the time of the deal (February 2012), six of the targeted 100 patients had been enrolled in the study. In May 2012, Cytomedix announced that an independent data safety monitoring board (DSMB), after reviewing the safety data from the first 10 patients, had recommended that the phase 2 trial continue as designed. Enrollment of these 10 patients took place at three clinical sites in the U.S. Safety data presented in October 2012 at the World Stoke Congress in Brazil showed procedure was safe and yielded no serious adverse events. Following the DSMB review of the first 10 patients, the trial has now been allowed to expand to the next 90 patients.

As of early May 2013, enrollment has been open to 10 sites, with an additional five planned to come online in the next few months. Unfortunately, enrollment is only up to 30 patients – four higher than when the company held its year-end call in mid-March 2013. It seems that the entry criteria for enrollment has been too strict, and that two key issues where holding patients back. The first was age of enrollment. The trial previously capped the age of subjects at 75 years. The new protocol now allows for enrollment of patients up to 83 years of age. Management believes this change will help increase the pace of enrollment by 20%. The second change is the allowance of patients with subcortical stroke. The previous entry criteria only allowed cortical stroke patients, a far more restrictive hurdle. The new protocol now allows both cortical and subcortical stroke patients to be enrolled. Management believes this change should speed enrollment by 50%.

We should have a good sense on if this is working soon. With 30 patients now enrolled, data has been sent to the DSMB for review. Assuming no safety concerns, enrollment of the next 70 patients is expected to take place at a more expeditious pace than the previous year. Management believes they can complete enrollment at 100 patients before the end of the year. We remain skeptical of that guidance. Data should follow four months after enrollment has been completed for the 3 month primary endpoint, and 15 months later for the full analysis.

Stroke is an enormous market opportunity. Each year, some 700,000 American's suffer an ischemic stroke. The RECOVER-Stroke trial is a double-blind, placebo-controlled design, with a 60/40 randomization between drug and control. ALD-401 will be administered to the patient via a single injection (3 ml) directly into the carotid artery approximately two weeks (13 to 19 days) following the stroke. Athersys is conducting a competing phase 2 trial in stroke with its MultiStem cell therapy, targeting 140 patients. Athersys is enrolling at 20+ sites and seeks to dose patients 24 to 36 hours after the stroke.

We note that Cytomedix is also in phase 1 studies with ALD-451, a formulation of the company s ALDH bright cells, designed to test the feasibility and safety when administered intravenously in World Health Organization (WHO) grade IV malignant glioma patients following surgery, radiation therapy and treatment with temozolomide. The trial is being run in collaboration with Duke University Medical Center and expected to enroll up to 12 patients in an open-label design. The primary outcome will be in looking for improvement in cognitive function in patients post treatment with ALD-451. Data from this trial may provide excellent insight into the RECOVER-Stroke trial.

Cytomedix also recently announced the signing of an agreement with the NIH to collaborate on a phase 2 clinical study in patients with intermittent claudication (IC) and ALD-301. The study is being funded by NHLBI/NIH and managed by the Cardiovascular Cell Therapy Research Network (CCTRN). The phase 2 study, called "PACE" (Patients with Intermittent Claudication Injected with ALDH Bright Cells) is expected to enroll 80 patients in a double-blind, placebo-controlled design. The primary endpoints of the study are safety and the change in peak walking time at 6 months compared to baseline. Management believes enrollment in this study should complete around the end of the year and offer data seven months later.

Between ALD-401 for stroke, ALD-451 for cognitive improvement in patients with brain cancer, and ALD-301 for intermittent claudication and potentially critical limb ischemia (CLI), Cytomedix has taken an aggressive stance with ALDH bright cells. Management is extremely optimistic on the technology.

## PROJECTED FINANCIALS

**Cytomedix, Inc.**
Income Statement

| Cytomedix, Inc. | 2011 A | 2012 A | Q1 A | Q2 E | Q3 E | Q4 E | 2013 E | 2014 E | 2015 E |
|---|---|---|---|---|---|---|---|---|---|
| AutoloGel | $0.39 | $0.55 | $0.14 | $0.16 | $0.40 | $0.80 | $1.50 | $3.00 | $5.00 |
| YOY Growth | 5.2% | 43.9% | -13.6% | -5.9% | 270.4% | 601.8% | 170.8% | 100.0% | 66.7% |
| Angel System | $5.51 | $6.63 | $2.11 | $2.20 | $2.30 | $2.45 | $9.06 | $11.00 | $12.40 |
| *YOY Growth* | 61.2% | 20.3% | 39.2% | 35.0% | 45.6% | 28.6% | 36.6% | 21.4% | 12.7% |
| Aldagen 3rd Party | *$0* | $0.06 | $0.00 | $0.02 | $0.03 | $0.04 | $0.09 | $0.10 | $0.10 |
| *YOY Growth* | - | - | - | - | - | - | 59.6% | 11.1% | 0.0% |
| **Med Product Sales** | **$5.90** | **$7.24** | **$2.25** | **$2.38** | **$2.73** | **$3.29** | **$10.65** | **$14.10** | **$17.50** |
| YOY Growth | 55.8% | 22.7% | 33.6% | 27.9% | 60.3% | 62.9% | 47.1% | 32.4% | 24.1% |
| **Drug Pipeline** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - |
| **Royalties & Collabs** | **$1.35** | **$3.32** | **$0.06** | **$0.05** | **$0.05** | **$0.05** | **$0.21** | **$0.25** | **$0.25** |
| YOY Growth | 992.9% | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$7.25** | **$10.56** | **$2.32** | **$2.43** | **$2.78** | **$3.34** | **$10.86** | **$14.35** | **$17.75** |
| YOY Growth | 85.3% | 45.8% | -23.2% | -34.1% | 58.0% | 58.8% | 2.8% | 32.1% | 23.7% |
| Cost of Sales | $2.73 | $3.90 | $1.27 | $1.21 | $1.39 | $1.65 | $5.52 | $6.77 | $8.05 |
| *Product Gross Margin* | 53.8% | 46.2% | 43.8% | 49.0% | 49.0% | 50.0% | 48.2% | 52.0% | 54.0% |
| R&D | $0.10 | $3.39 | $0.90 | $0.95 | $1.10 | $1.20 | $4.15 | $5.00 | $5.00 |
| *% R&D* | 1.4% | 32.1% | 38.9% | 39.1% | 39.6% | 35.9% | 38.2% | 34.8% | 28.2% |
| SG&A, Other Fees | $7.94 | $16.16 | $5.15 | $3.75 | $3.80 | $3.85 | $16.55 | $17.00 | $18.00 |
| *% G&A* | 109.5% | 152.9% | 222.1% | 154.3% | 136.7% | 115.3% | 152.3% | 118.5% | 101.4% |
| Operating Income | ($3.51) | ($12.88) | ($5.00) | ($3.50) | ($3.53) | ($3.38) | ($15.42) | ($14.52) | ($13.40) |
| *Operating Margin* | -48.5% | -121.9% | - | - | - | - | -141.9% | -101.2% | -75.5% |
| Interest & Other Income | $0.02 | ($6.89) | ($0.33) | ($0.20) | ($0.25) | ($0.30) | ($0.15) | $0.20 | $0.35 |
| Pre-Tax Income | ($3.49) | ($19.76) | ($5.33) | ($3.70) | ($3.78) | ($3.68) | ($15.57) | ($14.32) | ($13.05) |
| Taxes | $0.0 | $0.02 | $0.00 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0.0% | 0.0% |
| Preferred A, B, D, E | $0.35 | $0.01 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Net Income | ($3.86) | ($19.80) | ($5.34) | ($3.70) | ($3.78) | ($3.68) | ($15.57) | ($14.32) | ($13.05) |
| *Net Margin* | -53.2% | -187.4% | - | - | - | - | -143.3% | -99.8% | -73.5% |
| **Reported EPS** | **($0.08)** | **($0.24)** | **($0.05)** | **($0.04)** | **($0.04)** | **($0.03)** | **($0.14)** | **($0.11)** | **($0.09)** |
| YOY Growth | -67.4% | 217.7% | - | - | - | - | -41.5% | -19.1% | -24.0% |
| Weighted Ave. Shares Out | 50.7 | 81.9 | 99.1 | 105.0 | 107.0 | 109.0 | 110.0 | 125.0 | 150.0 |

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

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## HISTORICAL ZACKS RECOMMENDATIONS




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