Zacks Small-Cap Research

August 26, 2013
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Novelos Therapeutics, Inc. (NVLT-OTCQX)

NVLT: reports third quarter financials, on track to advance pipeline– Outperform.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	04/15/2012
Current Price (08/23/13)	$0.44
Twelve- Month Target Price	**$1.20**

OUTLOOK

Novelos' platform technology includes three candidates with chemically identical core structure. The three candidates target cancer imaging (LIGHT), cancer radiotherapy (HOT) and cancer-targeted optical imaging (GLOW2) markets respectively.

All three candidates specifically target cancer and cancer stem cells, which offers advantages over other cancer compounds such as selectivity and broad spectrum of cancer types.

Development risk for HOT is lower than other early stage candidates due to its unique chemical structure and mechanism of action. Current valuation is low and we maintain an Outperform rating.

SUMMARY DATA

52-Week High	**$2.00**
52-Week Low	**$0.36**
One-Year Return (%)	**-64.91**
Beta	**0.66**
Average Daily Volume (sh)	**22,424**
Shares Outstanding (mil)	**57**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**61.2**
Insider Ownership (%)	**35.6**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
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)
2011	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2012	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2013	0.00 A	0.00 A	0.00 E	0.00 E	0.00 E
2014					2.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.06 A	-$0.10 A	-$0.07 A	-$0.07 A	-$0.31 A
2012	-$0.06 A	-$0.06 A	-$0.05 A	-$0.06 A	-$0.23 A
2013	-$0.07 A	-$0.04 A	-$0.05 E	-$0.05 E	-$0.19 E
2014					-$0.13 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

NVLT reports 2Q13 financials

On August 12, Novelos reported financial results for the three months ended June 30, 2013.

No revenue was reported for the three months.

Research and development expense for the three months ended June 30, 2013 was approximately $1.6 million, (comprised of $0.2 million in clinical project costs, $0.1 million of preclinical project costs, $0.2 million of manufacturing and related costs and $1.1 million in general unallocated research and development costs) compared to approximately $1.3 million (comprised of $0.2 million in clinical project costs, $0.9 million in preclinical project costs, $0.2 million in manufacturing and related costs, and $0.9 million in general unallocated research and development costs) for the three months ended June 30, 2012.

The $334,000, or 25%, increase in research and development expense resulted from increases in several categories. The $51,000 increase in clinical project costs was primarily related to increased payments to clinical sites in on-going trials. The $79,000 increase in chemistry, manufacturing and related costs was related to costs associated with the production of clinical trial materials for the ongoing Phase I/II trials for LIGHT and the Phase Ib trial for HOT, as well as costs associated with the evaluation of contract manufacturing alternatives for LIGHT. The $30,000 increase in preclinical costs was related to contract research costs to support IND-enabling activities related to GLOW2. The $174,000 increase in general unallocated research and development costs for the three months ended June 30, 2013 compared to the same period in 2012 was attributable to an increase in payroll and related costs for new employees to support our research efforts.

General and administrative expense for the three months ended June 30, 2013 was approximately $1.1 million compared to approximately $0.9 million in the three months ended June 30, 2012. The approximately $177,000, or 20%, increase is related primarily to increased consulting costs, insurance costs, and legal fees.

Novelos recorded a gain on derivative warrants of approximately $660,000 in the three months ended June 30, 2013 and a loss on derivative warrants of approximately $17,000 in the three months ended June 30, 2012. These amounts represent the change in fair value, during the respective period, of outstanding warrants which contain "down-round" anti-dilution provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise prices of the warrants.

Net loss was $2.0 million ($0.04 per share) for the three months ended June 30, 2013 compared to net loss of $2.2 million ($0.06 per share) for the three month period last year.

During the six months ended June 30, 2013, approximately $3,923,000 in cash was used in operations. As of June 30, 2013, Novelos had approximately $5,828,000 in cash and cash equivalents, which excludes approximately $1,878,000 classified as restricted cash that is contractually designated towards the construction of a clinical-stage manufacturing facility for LIGHT at Madison, WI location.

Based on Novelos' clinical development plan, current cash will last into 4Q13. Therefore, we estimate the Company may need to raise new funds by the end of 2013.

Management change will not affect operations

On July 29, 2013, Novelos announced that Harry Palmin, the company's President and CEO and a Director, will step down from his positions with the company, in order to pursue other opportunities, upon

the naming of his successor. A search process is underway to select a replacement for Mr. Palmin, during which time he will continue in his current roles to ensure an orderly transition.

In addition, Kim Hawkins, the company's Vice President of Clinical Development, has notified the Company of her resignation, effective August 9, 2013, in order to accept a position at a large pharmaceutical company.

As Novelos' clinical development activities progress, the company has expanded its clinical development team with the addition of Kevin Kozak, M.D., Ph.D., as a consultant who will serve as Chief Medical Officer, effective August 1, 2013. Dr. Kozak is the Director of Radiation Oncology, Mercy Regional Cancer Center. Between 2008 and 2013, Dr. Kozak served as an Assistant Professor of Human Oncology and Medical Physics, staff radiation oncologist and basic scientist at the University of Wisconsin Carbone Cancer Center. Dr. Kozak earned his medical and doctoral degrees from Vanderbilt University School of Medicine in 2003 then completed his residency and post-doctoral research at the Harvard Radiation Oncology Program in 2008. He has received research funding from multiple cancer research organizations including the National Institutes of Health, the Susan G. Komen Foundation, and the Damon Runyon Cancer Research Foundation. Additionally, Dr. Kozak is co-founder of Co-D Therapeutics, a company developing novel nanomedicines for cancer therapy. Dr. Kozak has numerous peer-reviewed publications, patents, book-chapters, and invited lectures to his credit.

It's our belief that management change won't affect the company's operations as the company continues to move forward with its three clinical programs.

Pipeline Updates

LIGHT is a small-molecule, broad-spectrum, cancer-targeted **PET imaging** agent. LIGHT Phase 1-2 clinical trials are ongoing across 11 solid tumor indications. These trials have demonstrated initial proof-of-concept in multiple tumor types, including primary and metastatic brain cancer.

Novelos expects to start a LIGHT **Phase II imaging trial** in brain cancer at the beginning of 2014 and, subject to additional funding, complete the trial by the end of 2014. This trial will compare LIGHT imaging of glioma with standard of care based on pathology confirmation in approximately 30 patients.

HOT is a small-molecule, broad-spectrum, **cancer-targeted molecular radiotherapeutic** that delivers cytotoxic radiation directly and selectively to cancer cells and cancer stem cells.

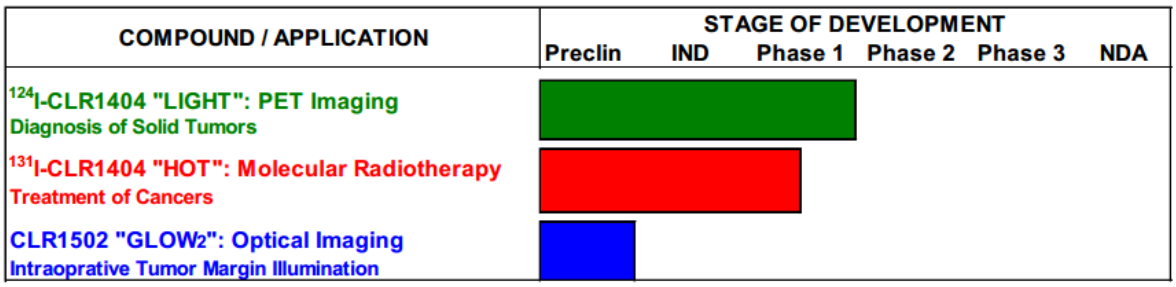
Novelos has completed the **third cohort** in a U.S. multi-center **Phase Ib** dose-escalation safety trial with HOT in cancer patients with advanced solid tumors. Data from the two-patient third cohort indicate the onset of dose-limiting hematologic toxicities with HOT, triggering enrollment into a five-patient **fourth cohort** at a dose midway between those used in the second and third cohorts, as per trial protocol. To date, three of the six patients with advanced refractory solid tumors treated with HOT had stable disease for up to four months, according to standard response evaluation criteria in solid tumors (RECIST 1.1), and confirmed by independent review.

Novelos is approaching the stated objective of the Phase Ib dose-escalation trial to determine the Maximum Tolerated Dose of HOT.

In parallel with the ongoing Phase Ib fourth cohort, Novelos will be evaluating a range of potential HOT **Phase II** indications and trial designs including incorporation of multiple dosing, as well as combination of HOT with external beam radiotherapy or with radiosensitizing therapeutics.

GLOW2 is a **preclinical**, cancer-targeted, non-radioactive **optical imaging agent** for both intraoperative tumor margin illumination and non-invasive tumor imaging. Novelos plans to file an Investigational New Drug Application (IND) for GLOW2 by the end of 2013 and, subject to additional funding, expects to

generate proof-of-concept data in cancer patients by the end of 2014. GLOW2 may address the significant unmet medical need for better definition of tumor margins and nodal involvement, potentially reducing repeat surgeries and improving patient outcomes.



Diapeutic Technology Platform Presented at EMIT: Targeted Radiotherapy Conference

On January 31, 2013, Novelos Therapeutics (NVLT) presented an oral presentation on research conducted by Novelos and its collaborators at the EMIT: Targeted Radiotherapy international conference taking place January 29 to 31, in Washington, D.C.

This presentation by invitation from EMIT describes the mechanistic foundation for Novelos' **diapeutic (diagnostic + therapeutic) technology platform** together with animal data and initial findings in advanced cancer patients that demonstrate selective and prolonged accumulation of Novelos' PET imaging I-124-CLR1404 **(LIGHT)**, therapeutic I-131-CLR1404 **(HOT)** and optical imaging CLR1502 **(GLOW2)** compounds in a range of tumor types. The presenter is Dr. Chris Pazoles, who is the Senior Vice President of Research and Development for Novelos.

NVLT's LIGHT, HOT and GLOW2 have been designed to exploit a feature shared by most, if not all cancer cells including cancer stem cells, which results in the selective uptake and prolonged accumulation of the Company's proprietary, small-molecule delivery vehicle in a wide range of malignant tumors compared with normal tissues. By incorporating a unique functional property in each – PET imaging, radiotherapy or optical imaging, NVLT has generated an array of potential therapeutic and diagnostic products that could, alone or in combinations, significantly improve the detection and treatment of cancer in multiple ways.

Novelos' diapeutic platform, which includes cancer-targeted PET Imaging, therapeutic and optical Imaging Compounds, offer broad-spectrum diagnosis and treatment for solid tumors.

The presentation is titled "Cancer-Targeted Diapeutics: Radioiodinated Phospholipid Ether Analogs for Broad-Spectrum Imaging and Therapy". Dr. Pazoles presented data showing that LIGHT, HOT and GLOW2 all share a common cancer-targeted core chemical structure. Each attaches a unique moiety to this delivery vehicle – LIGHT, a PET imaging agent (iodine-124), HOT, a radiotherapeutic agent (iodine-131) and GLOW2, an optical imaging agent (near-infrared tracer).

- Results described with LIGHT demonstrate broad-spectrum tumor PET imaging in dozens of animal tumor models, and recent human findings from ongoing **Phase I/II** clinical trials show selective uptake and retention by primary tumors and metastases in advanced non-small cell lung and brain cancer patients.

- HOT results shown include single-dose efficacy in a wide range of animal tumor models, and clinical trials to date demonstrate selective accumulation in cancerous tumors, including metastases.

- Dr. Pazoles' presentation highlights the potential diapeutic application of LIGHT and HOT, based on their chemical identity, to provide individualized treatment to cancer patients. For example, LIGHT serves as an ideal biomarker to potentially identify patients most likely to benefit from therapy with HOT.

- Dr. Pazoles' talk also described how selective uptake of GLOW2 could provide better definition of tumor margins in real time during cancer surgery, enabling more complete and selective removal of malignant tissue and potentially improving patients' prognosis. Data illustrating the potential use of GLOW2 for non-invasive detection of tumors was also featured.

We believe Novelos' platform technology has great potential for cancer imaging and therapy, which can be used in various cancer types.

NVLT is making good clinical progress with LIGHT and HOT across multiple human trials while advancing GLOW2 towards human trials. With all these progresses made in the past few months, we believe Novelos' share price deserves further appreciation.

VALUATION AND RECOMMENDATION

We maintain an Outperform rating on Novelos Therapeutics (NVLT) shares and reiterate our 12-month target price of $1.20 per share.

NVLT's platform technology is unique. All three candidates are generated from a single core chemical structure that is the foundation of the technology platform. The three candidates target three sub-cancer markets: cancer imaging (LIGHT), cancer radiotherapy (HOT) and cancer optical imaging (GLOW2).

The beauty of the Company's technology is that all three candidates specifically target cancer and cancer stem cells through interaction with **lipid rafts** which are enriched in cancer or cancer stem cells. The specific targeting of both cancer and cancer stem cells makes NVLT's HOT with the efficacy potential to target all three major drivers of mortality in cancer –**primary tumors**, **metastases** and stem cell-based **relapse**, which distinguishes HOT from all other cancer therapy modalities.

All three candidates have demonstrated excellent safety profile and efficacy in preclinical trials including animal models. The Company has moved LIGHT and HOT into the clinic with both in Phase I/II clinical trials. Preliminary data from the clinical trials have also shown excellent safety profile and efficacy activity for both LIGHT and HOT, which is in line with preclinical results.

Both LIGHT and HOT have competitive advantages over their respective competitors. LIGHT has the potential to become the new standard of care for cancer PET imaging due to its selectivity for cancer/cancer stem cells over FDG, current standard of care for cancer PET imaging. LIGHT also has the advantage of delivery range due to its four-day half-life versus F-18 labeled FDG's 110 minutes half-life.

As a new systemic radiotherapy, HOT has the advantage over existing systemic radiotherapeutic Zevalin and Bexxar. The selective interaction with lipid rafts makes HOT a **broad spectrum** cancer targeting agent since lipid rafts are overexpressed in most of cancer and cancer stem cells. Selective uptake and retention of HOT in cancer stem cells compared with normal cells also offer the prospect of **longer lasting cancer remission**.

One more important feature for HOT investors should take into account is that **development risk is relatively less for HOT** than other early stage cancer therapeutics. HOT exploits a new cancer-selective delivery and retention mechanism, but is paired with a proven and effective radioisotope (I-131) for

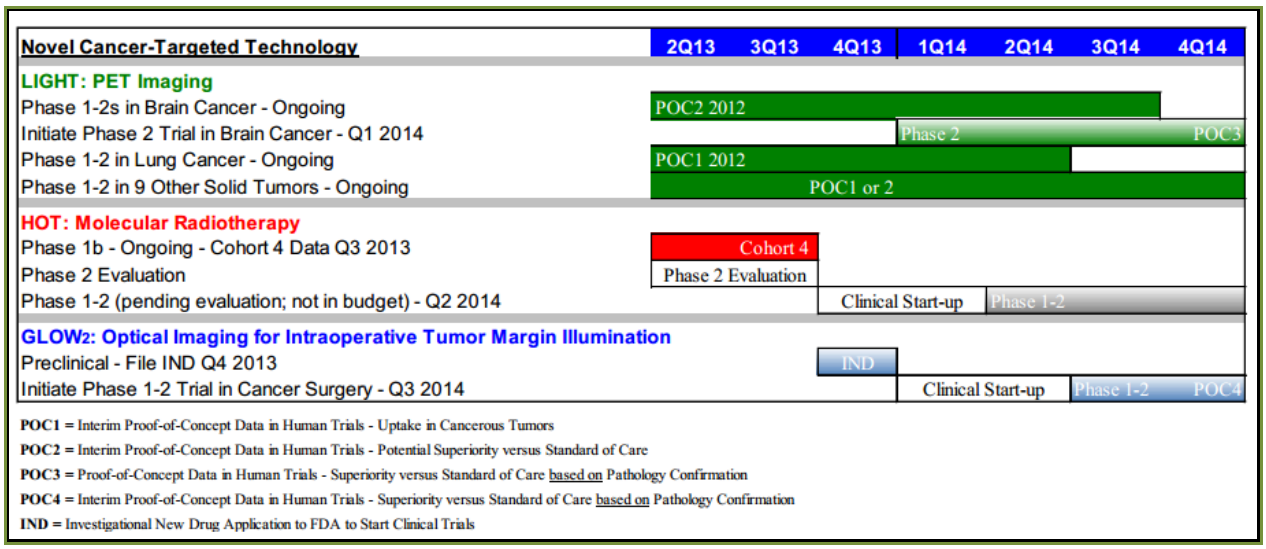
therapy. Because, to date, HOT has been shown to reliably and near-universally accumulate in cancer cells and because the therapeutic properties of the iodine-131 are well known, the risk of non-efficacy in human clinical trials is less than that of other cancer therapies at this stage of development. Furthermore, LIGHT PET imaging data is expected to predict efficacy and enable calculation of efficacious doses of HOT for Phase II trials (i.e. LIGHT serves as an ideal and personalized biomarker for HOT). This is important for investors because less development risk means that HOT has a higher probability for success in clinical trials and regulatory approval. Therefore, downside risk is reduced while upside potential remains the same.

Although GLOW2 is in preclinical development, the compound has the potential to become the best-in-class optical imaging agent.

With all these in mind, we think Novelos is undervalued at current price. Currently, Novelos shares are trading at around $0.40 per share, which values the Company at $23 million in market cap, which is a deep discount to its peers. We understand that all the Company's programs are in early stage, cash burn will accelerate in the coming quarters when the Company advances all its three programs. However, we remind investors that both LIGHT and HOT have relatively low development risks compared to other similar cancer programs. We also remind investors that Novelos plans to find a partner for LIGHT after the Phase I/II trial, which could happen as early as in 2014. Such a deal will not only validate the Company's technology, but also will boost the Company's balance sheet with non-dilutive upfront, milestone and royalty.

We are aware of that most small biotech companies of development stage are valued from $50 million to $500 million depending on how advanced the pipeline is and which indications the company is targeting. We think Novelos should be valued between $80 and $150 million at this point. Our price target of $1.20 per share corresponds to a $68 million in market cap.

Potential milestones:



PROJECTED INCOME STATEMENT

	2011 A (Dec)	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	FYA	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3E	Q4E	FYE	FYE	FYE	FYE
licensing revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$2.50	$5.00	$5.00
Product revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$1.00	$3.50
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$2.50**	**$6.00**	**$8.50**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*140.0%*	*41.7%*
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$2.50**	**$6.00**	**$8.50**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$3.60	$1.33	$1.31	$1.25	$1.23	$5.12	$1.59	$1.65	$1.75	$2.00	$6.99	$7.50	$8.50	$10.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	
SG&A	$2.69	$1.00	$0.90	$0.80	$0.94	$3.63	$1.12	$1.04	$1.15	$1.20	$4.51	$5.00	$5.50	$6.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.75	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($7.0)**	**($2.3)**	**($2.2)**	**($2.1)**	**($2.2)**	**($8.8)**	**($2.7)**	**($2.7)**	**($2.9)**	**($3.2)**	**($11.5)**	**($10.0)**	**($8.0)**	**($8.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.4)	($0.0)	($0.0)	$0.0	($0.5)	($0.6)	($0.7)	$0.7	$0.0	$0.0	($0.1)	$0.0	$0.0	$0.0
Pre-Tax Income	**($7.4)**	**($2.4)**	**($2.2)**	**($2.1)**	**($2.7)**	**($9.3)**	**($3.5)**	**($2.0)**	**($2.9)**	**($3.2)**	**($11.6)**	**($10.0)**	**($8.0)**	**($8.0)**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$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%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	-
Reported Net Income	**($7.4)**	**($2.4)**	**($2.2)**	**($2.1)**	**($2.7)**	**($9.3)**	**($3.5)**	**($2.0)**	**($2.9)**	**($3.2)**	**($11.6)**	**($10.0)**	**($8.0)**	**($8.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*24.0*	*36.9*	*38.6*	*43.3*	*45.7*	*41.1*	*51.3*	*57.4*	*60.0*	*70.0*	*59.7*	*80.0*	*90.0*	*100.0*
Reported EPS	**($0.31)**	**($0.06)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.23)**	**($0.07)**	**($0.04)**	**($0.05)**	**($0.05)**	**($0.19)**	**($0.13)**	**($0.09)**	**($0.08)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*
Non GAAP Net Income	**($7.4)**	**($2.4)**	**($2.2)**	**($2.1)**	**($2.7)**	**($9.3)**	**($3.5)**	**($2.0)**	**($2.9)**	**($3.2)**	**($11.6)**	**($10.0)**	**($8.0)**	**($8.0)**
Non GAAP EPS	**($0.31)**	**($0.06)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.23)**	**($0.07)**	**($0.04)**	**($0.05)**	**($0.05)**	**($0.19)**	**($0.13)**	**($0.09)**	**($0.08)**

Source: Company filings and Zacks Small Cap Research

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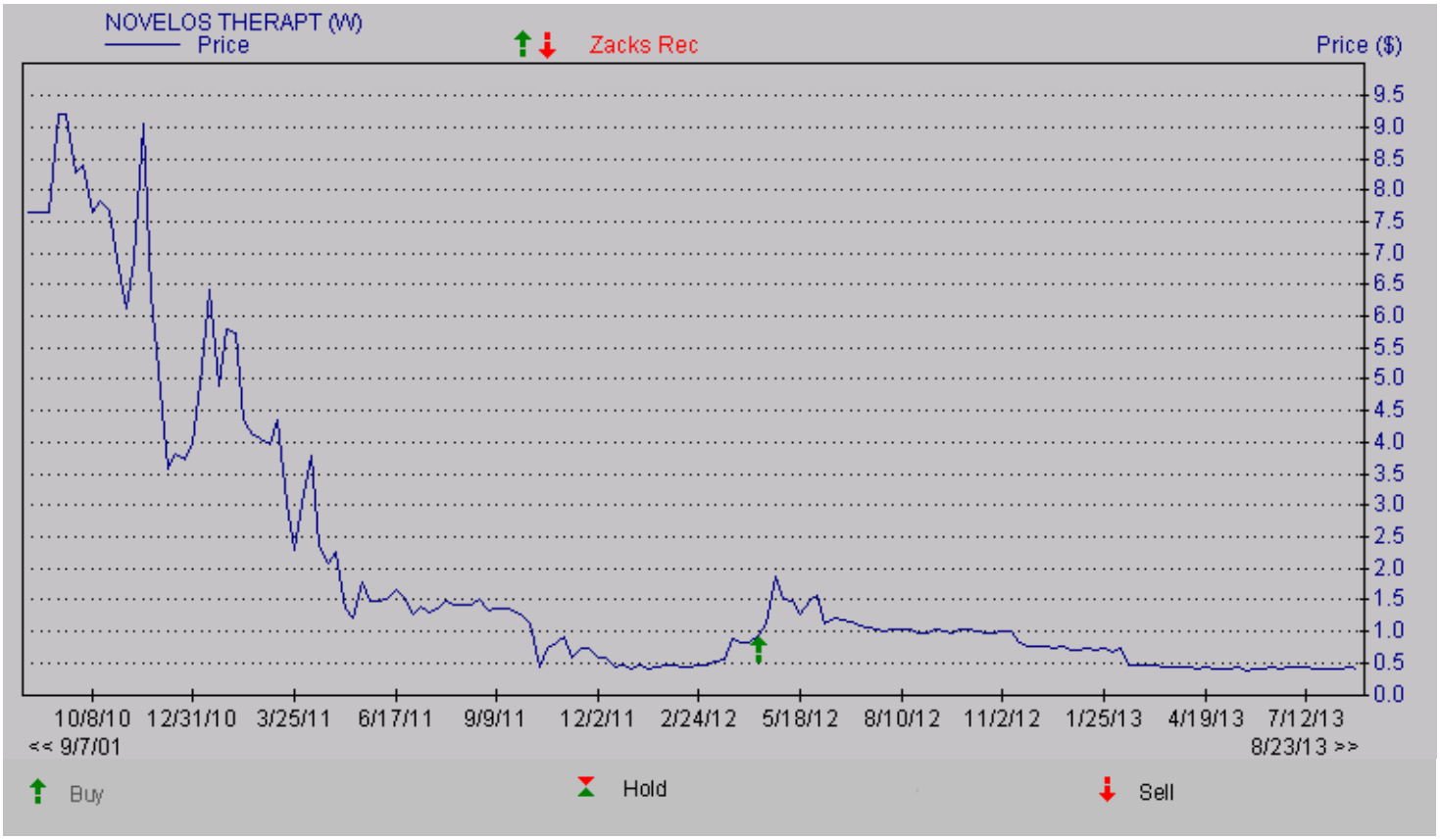
HISTORICAL ZACKS RECOMMENDATIONS



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