Zacks Small-Cap Research

November 14, 2013
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Novelos Therapeutics, Inc. (NVLT-OTCQX)

NVLT: New management leads the strategic transition, exited third quarter with reasonable cash position, on track to advance pipeline– Outperform.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	04/15/2012
Current Price (11/13/13)	$0.31
Twelve- Month Target Price	**$1.20**

OUTLOOK

Novelos' platform technology includes three candidates with chemically similar 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	**$0.90**
52-Week Low	**$0.30**
One-Year Return (%)	**-65.33**
Beta	**0.28**
Average Daily Volume (sh)	**37,990**
Shares Outstanding (mil)	**57**
Market Capitalization ($mil)	**$18**
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)
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 A	0.00 E	0.00 E
2014					2.50 E
2015					5.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
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 A	-$0.04 E	-$0.19 E
2014					-$0.13 E
2015					-$0.11 E

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

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WHAT'S NEW

NVLT Exits 3Q13 With Reasonable Cash Balance

On November 13, Novelos filed 10-Q for the third quarter ending September 30, 2013.

No revenue was reported for the three months.

Research and development expense for the three months ended September 30, 2013 was approximately $2,067,000 compared to approximately $1,253,000 for the three months ended September 30, 2012.

The increase in research and development expense resulted primarily from increase in preclinical costs and increase in general unallocated research and development costs.

General and administrative expense for the three months ended September 30, 2013 was approximately $844,000, representing an increase of about $43,000, or 5%, compared to approximately $801,000 for the three months ended September 30, 2012.

Novelos recorded a gain on derivative warrants of approximately $1,597,372 in the three months ended September 30, 2013 and a gain on derivative warrants of approximately $4,000 in the three months ended September 30, 2012.

Net loss was $1.3 million ($0.02 per share) for the three months ended September 30, 2013 compared to net loss of $2.1 million ($0.05 per share) for the three month period last year.

As of September 30, 2013, Novelos had approximately $5.2 million in cash and cash equivalents.

Based on Novelos' clinical development plan, current cash will last into 2Q14.

New Management Leads the Transition

On October 9, 2013, Novelos appointed **Dr. Simon Pedder** as Acting Chief Executive Officer and elected him a Director, replacing Harry Palmin, to complete a previously announced leadership transition. Effective as of April 1, 2014, Mr. Pedder will serve as President and CEO of the Company.

Dr. Pedder brings over 25 years of industry experience to the role, having served most recently as President and Chief Executive Officer of Chelsea Therapeutics. Prior to his time at Chelsea, Simon held senior leadership positions at Hoffmann La Roche, including serving as an Officer and Vice President of Pharma Business Oncology.

On November 13 following the appointment of Dr. Simon Pedder as Acting Chief Executive Officer last month, the Board of Directors has restructured the board both by appointing a new independent member, Paul L. Berns, and by reducing the overall size of the board from nine to five members. These changes are intended to align the board's size and composition with Novelos' current business and to support the transitions underway.

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 I-II** 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** in 4Q13 or 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.

The Phase II brain cancer trial will be a multi-site trial in ~30 glioma patients. The overall goal is to determine the optimal dose and imaging time points for a pivotal trial.

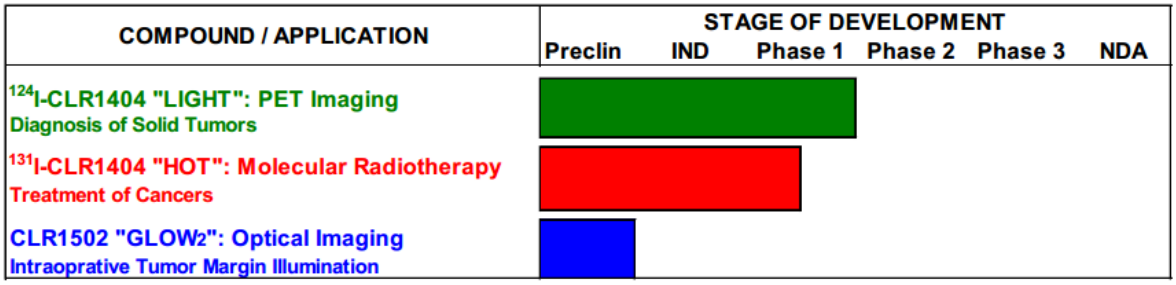
HOT is a small-molecule, broad-spectrum, **cancer-targeted molecular radiotherapeutic** that delivers cytotoxic radiation directly and selectively to cancer cells and cancer stem cells.

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 in 1Q14 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.



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 $0.30 per share, which values the Company at $19 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.

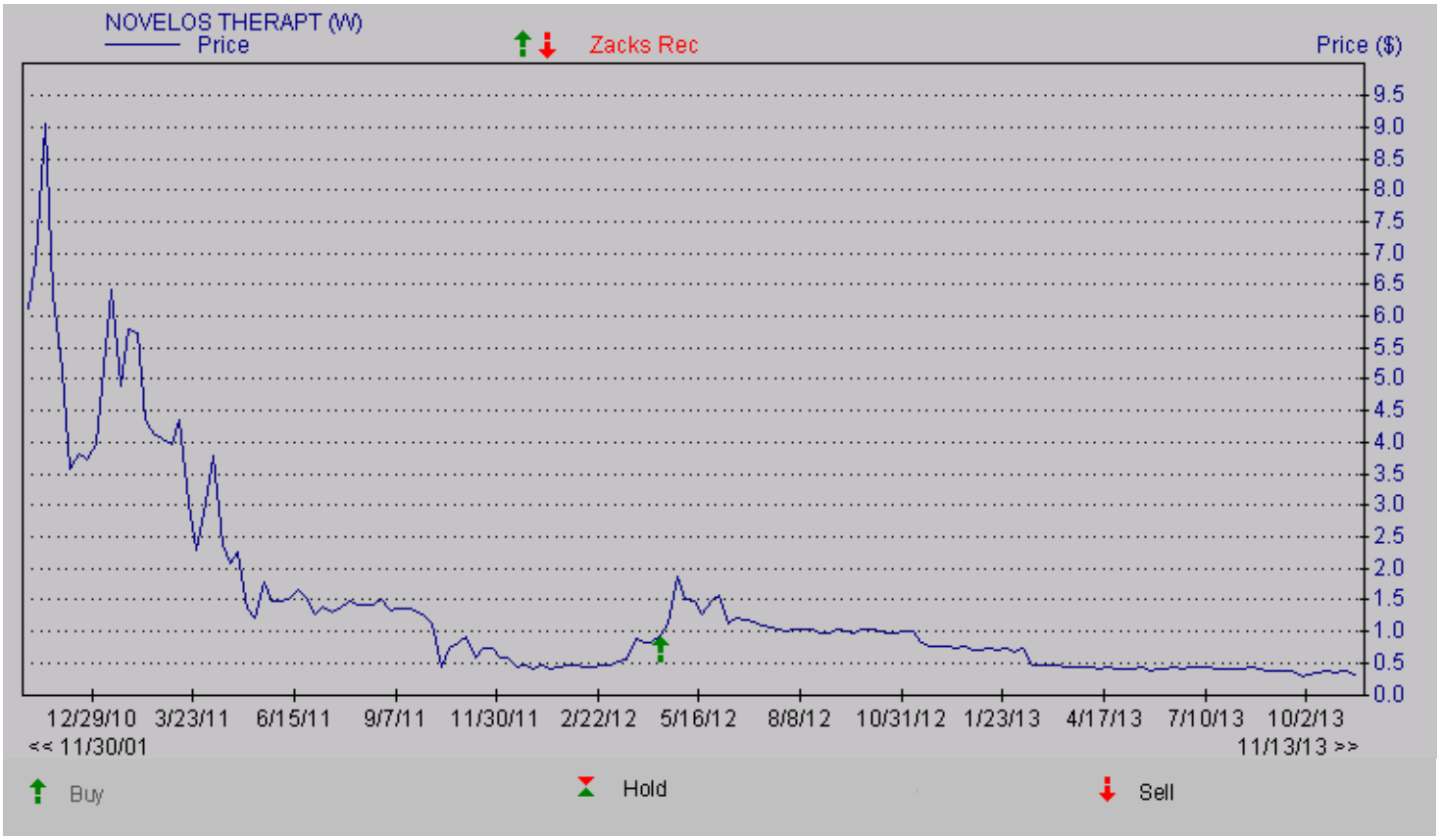
PROJECTED INCOME STATEMENT

	2011A	2012A (Dec)					2013E (Dec)					2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	FYA	Q1A	Q2A	Q3A	Q4A	FYA	Q1A	Q2A	Q3A	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	$2.07	$2.10	$7.41	$8.50	$10.00	$12.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	
SG&A	$2.69	$1.00	$0.90	$0.80	$0.94	$3.63	$1.12	$1.04	$0.84	$1.00	$4.00	$4.50	$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)**	**($3.1)**	**($11.4)**	**($10.5)**	**($9.5)**	**($10.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.4)	($0.0)	($0.0)	$0.0	($0.5)	($0.6)	($0.7)	$0.7	$1.6	$0.0	$1.5	$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)**	**($1.3)**	**($3.1)**	**($9.9)**	**($10.5)**	**($9.5)**	**($10.0)**
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)**	**($1.3)**	**($3.1)**	**($9.9)**	**($10.5)**	**($9.5)**	**($10.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*24.0*	*36.9*	*38.6*	*43.3*	*45.7*	*41.1*	*51.3*	*57.4*	*57.4*	*70.0*	*59.0*	*80.0*	*90.0*	*100.0*
Reported EPS	**($0.31)**	**($0.06)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.23)**	**($0.07)**	**($0.04)**	**($0.02)**	**($0.04)**	**($0.17)**	**($0.13)**	**($0.11)**	**($0.10)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*(1.60)*	*0.00*	*(1.60)*	*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)**	**($3.1)**	**($11.5)**	**($10.5)**	**($9.5)**	**($10.0)**
Non GAAP EPS	**($0.31)**	**($0.06)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.23)**	**($0.07)**	**($0.04)**	**($0.05)**	**($0.04)**	**($0.19)**	**($0.13)**	**($0.11)**	**($0.10)**

Source: Company filings and Zacks Small Cap Research

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