Zacks Small-Cap Research

November 9, 2012
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Novelos Therapeutics, Inc. (NVLT-OTCQX)

NVLT: Balance sheet boosted and pipeline expanded– Outperform.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	04/15/2012
Current Price (11/07/12)	$1.00
Twelve- Month Target Price	**$2.50**

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	**$0.40**
One-Year Return (%)	**25.00**
Beta	**0.61**
Average Daily Volume (sh)	**9,487**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$43**
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 E	0.00 E
2013					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 E	-$0.23 E
2013					-$0.21 E
2014					-$0.17 E

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

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WHAT'S NEW

Balance Sheet Boosted By Private Placement

Novelos Therapeutics (NVLT) filed 10-Q on November 6 for the third quarter ended September 30, 2012.

There was no revenue for the third quarter of 2012.

Net loss was $2.1 million or $0.05 per share for 3Q12 compared to $1.9 million or $0.07 per share for 3Q11.

At the end of September 2012, NVLT had cash and cash equivalents of $5.6 million.

On Nov. 5, Novelos announced the closing of a private placement of equity securities to an affiliated entity of **Renova Group** for gross proceeds to Novelos of $2 million. The securities issued and sold in the private placement consisted of 2 million shares of Novelos' common stock, a warrant to purchase up to 1 million shares of common stock at an exercise price of $1.25 per share expiring in five years and a warrant to purchase up to 2 million shares of common stock at an exercise price of $1.00 per share expiring in 90 days.

Novelos has earmarked the proceeds for the build-out of an in-house clinical-stage manufacturing facility for I-124-CLR1404 (LIGHT). The facility is expected to be completed in about one year and is expected to cost approximately $3 million. The build-out of an in-house clinical-stage manufacturing facility for LIGHT is a key strategic initiative as the Company moves toward larger Phase II and pivotal LIGHT imaging trials. NVLT already has an operational in-house clinical-stage manufacturing facility for HOT.

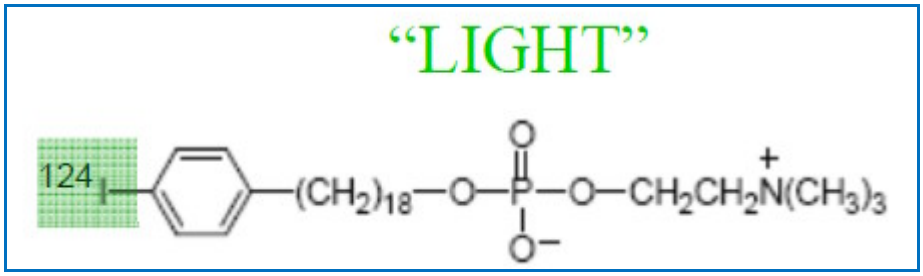
The private placement not only boosts NVLT's balance sheet immediately, but also validates its technology and clinical programs.

Novelos Continues to Advance LIGHT Phase I/II Programs in Solid Tumors

On October 25, 2012, Novelos Therapeutics (NVLT) announced that the University of Wisconsin Carbone Cancer Center (UWCCC) has enrolled the first patient in a Phase I/II positron emission tomography (PET) imaging trial of I-124-CLR1404 (LIGHT), a cancer-targeted PET imaging agent, in patients with **additional nine solid tumor types**, including triple negative breast, soft tissue sarcoma, colorectal, gastric, esophageal, prostate, ovarian, pancreatic and head & neck cancer.

Glenn Liu, M.D., Associate Professor of Medicine and Director of the Cancer Therapy Discovery and Development Program at the UWCCC, is the trial's principal investigator. Initial imaging results are expected in **1Q2013**.

LIGHT is a small-molecule **imaging agent** that has first-in-class potential for selective detection of tumors and metastases in a broad range of cancers. LIGHT is comprised of a small, non-pharmacological quantity of CLR1404 (COLD, acting as a cancer-targeted delivery and retention vehicle) labeled with the shorter-lived radioisotope, iodine-124, a new PET imaging isotope. Chemically, LIGHT is 18-(p-[I-124]iodophenyl) octadecyl phosphocholine, identical to COLD except that the iodine is the radioactive isotope, I-124, which has a radiation half-life of 4 days.



PET imaging used in conjunction with CT scanning has now become the imaging method of choice in oncology. In studies to date, LIGHT selectively illuminated malignant tumors in 52 of 54 animal models of cancer, demonstrating evidence of broad-spectrum, cancer-selective uptake and retention.

Novelos is conducting Phase I/II clinical trials to evaluate LIGHT across **multiple solid tumor types.**

An investigator-sponsored **Phase I/II** trial of LIGHT as a PET imaging agent for **lung cancer** was initiated in December 2011 at the University of Wisconsin Carbone Cancer Center (UWCCC) and first patient was enrolled in February 2012. Dr. Anne M. Traynor at UWCCC is conducting the Phase I/II trial. Novelos provides funding for the trial and the data is shared with Novelos while the study progresses and at the conclusion of the study. Up to 12 patients will be enrolled across two dose levels (3 mCi and 5 mCi) in this Phase I/II trial. Novelos already reported positive initial data in September 2012. The trial will be completed in 2012.

Another investigator-sponsored **Phase I/II** trial of LIGHT as a PET imaging agent for **brain cancer** was initiated in December 2011 at UWCCC and first patient was enrolled on March 15, 2012. Dr. Lance Hall at the UWCCC is conducting the Phase I/II trial. This trial is being funded by an Institute for Clinical and Translational Research (ICTR) grant, whereas the data is shared with Novelos while the study progresses and at the conclusion of the study. Up to 20 patients will be enrolled at a 5 mCi dose. Novelos also reported positive initial data in September 2012. The trial will be completed in early 2013.

An investigator-sponsored **Phase I/II** trial of LIGHT as a PET imaging agent for **metastatic brain cancer** was initiated in January 2012 at UWCCC. This trial is being funded by a $1.2 million grant from the National Cancer Institute.

LIGHT has the potential to supplant the current "gold standard" agent, 18-fluoro-deoxyglucose (**FDG**), due to its superior cancer-specificity and more favorable logistics of clinical use.

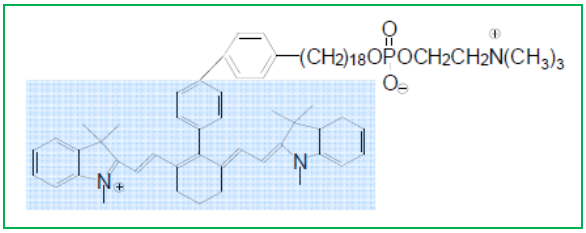
We believe positive data would establish proof-of-concept for LIGHT as a PET imaging agent for this indication, and could advance partnering discussions.

Development of CLR1502 (GLOW2) Further Expands Pipeline

On August 28, 2012, Novelos Therapeutics, Inc. (NVLT) announced that it is developing CLR1502 (GLOW2), a preclinical cancer-targeted optical imaging agent for intraoperative tumor margin illumination and non-invasive tumor imaging.

GLOW2 is expected to facilitate and enable diagnostic, staging, debulking and curative cancer surgeries intraoperatively in real time. Novelos expects to submit an Investigational New Drug Application **(IND)** to the FDA for GLOW2 in the second half of 2013 and begin clinical trials shortly thereafter, subject to additional funding.

GLOW2 is a small-molecule optical imaging agent that has first-in-class potential for intraoperative tumor margin illumination and non-invasive tumor imaging. GLOW2 is comprised of a proprietary phospholipid ether analog (PLE), acting as a cancer-targeted delivery and retention vehicle, covalently attached to a near-infrared (800nm) fluorophore.



GLOW2 Selectively Target Tumor Cells

In preclinical models, mice without intact immune systems and inoculated with human HCT-116 (colorectal carcinoma) were injected with GLOW2 24 and 96 hours prior to imaging. In vivo optical imaging showed pronounced accumulation of GLOW2 in tumors versus non-target organs and tissues.

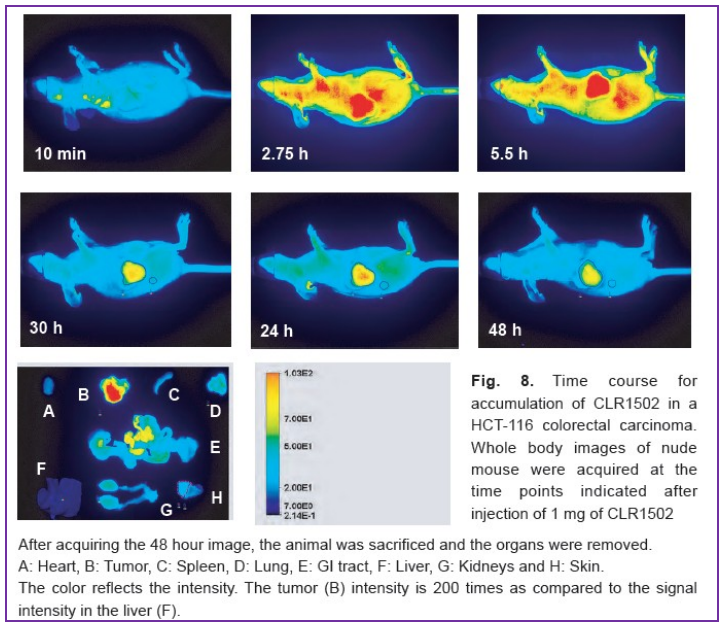


Fig. 8. Time course for accumulation of CLR1502 in a HCT-116 colorectal carcinoma. Whole body images of nude mouse were acquired at the time points indicated after injection of 1 mg of CLR1502

After acquiring the 48 hour image, the animal was sacrificed and the organs were removed.
A: Heart, B: Tumor, C: Spleen, D: Lung, E: GI tract, F: Liver, G: Kidneys and H: Skin.
The color reflects the intensity. The tumor (B) intensity is 200 times as compared to the signal intensity in the liver (F).

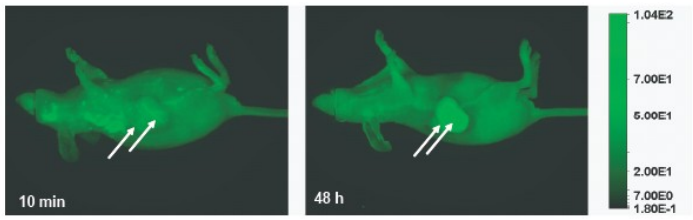


Fig. 9
Fluorescent image of nude mouse bearing HCT-116 colorectal carcinoma 10 min and 48 h post injection with 1 mg of CLR1502. The arrows show blood vessels. At 10 min, the vessels are highlighted with fluorescence while at 48 h only tumor shows fluorescence and not the blood vessel.

In addition, non-invasive imaging with GLOW2 has been demonstrated in a variety of animal solid tumor models. Thus, GLOW2 may also have utility for non-invasive imaging of relatively superficial tumor types in man (e.g., melanoma, head & neck, colon, esophageal).

Market Potential of GLOW2 is Huge

According to the American Cancer Society, most cancer patients will have some type of surgery, and approximately 1.3 million cancer patients were diagnosed with solid tumors in the U.S. alone in 2011. GLOW2 may facilitate and enable diagnostic, staging, debulking and curative cancer surgeries intraoperatively in real time by defining tumor margins and regional lymph node involvement, resulting in more accurate and successful tumor resectioning.

Current imaging modalities are extremely limited in their ability to define tumor margins, thus contributing to the unacceptably high rate of incomplete surgical removal of malignant tissue, which is associated with an increased risk of cancer recurrence. The potential for GLOW2 to provide surgeons with more accurate visualization of tumor margins during surgery could result in more complete and selective removal of tumors and significantly improve patient outcomes. Therefore, GLOWS could gain significant market share if approved by health authorities.

The GLOW2 program further expands Novelos' pipeline, which illustrates the broad spectrum cancer therapy and imaging potential of the Company's proprietary phospholipid ether analog (PLE)-based delivery and retention vehicle which is also being used to selectively target cancer cells with a PET imaging agent (I-124-CLR1404, or LIGHT) and a molecular radiotherapeutic agent (I-131-CLR1404, or HOT) in ongoing clinical trials.

NVLT is on Track to Advance I-131-CLR1404 (HOT)

On September 11, 2012, Novelos Therapeutics, Inc. (NVLT) successfully completed the second cohort in a U.S. multi-center **Phase 1b** dose-escalation trial of its cancer-targeted molecular radiotherapeutic compound I-131-CLR1404 (HOT) in cancer patients with **advanced solid tumors**.

As a reminder, Novelos initiated the above **Phase 1b** dose-escalation / MTD trial in November 2011. First patient was enrolled in Jan 2012. For each subject, the study will be conducted in two phases, dosimetric and therapy. In the **dosimetric phase**, subjects will receive one 5 mCi dose of the study drug and undergo whole body imaging on the day of infusion and on post-infusion days 1, 2, 3, and 6 for assessment of biodistribution of I-131-CLR1404. If normal and expected biodistribution are demonstrated, the subject will begin the therapy phase. In the **therapy phase**, the first cohort of subjects will receive a dose of 12.5 mCi/m2. Dose escalation in subsequent cohorts will initially be in increments of 12.5 mCi/m2. Subjects will be followed and observed for unacceptable toxicity through 56 days after the therapy dose infusion with follow-up for up to one year.

The primary objective of this Phase Ib dose-escalation trial in patients with a range of advanced solid tumors is to define the Maximum Tolerated Dose (MTD) of HOT. In addition to determining the MTD, the Phase Ib trial is intended to evaluate overall tumor response (using standard RESIST I criteria) and safety.

Novelos completed the first cohort in the **Phase Ib** dose-escalation trial of HOT in May, 2012. The first two-patient cohort was successfully dosed with approximately 20 mCi of HOT. Data from the first cohort indicates HOT was well-tolerated, without any grade 3 or 4 toxicities. HOT uptake in cancerous tumors persisted for at least 21 days.

The second two-patient cohort was successfully dosed with approximately 40 mCi of HOT, triggering enrollment into the third cohort at approximately 60 mCi. Glenn Liu, M.D., Associate Professor of Medicine and Director of the Cancer Therapy Discovery and Development (Phase I) Program at the University of Wisconsin Carbone Cancer Center, is the trial's principal investigator. Detailed trial results are expected to be presented at a scientific venue at a later date.

Data from the first two cohorts indicate that HOT was well-tolerated, without any dose-limiting or sub-dose-limiting toxicities, enabling enrollment of the third cohort as planned. Selective uptake of HOT in cancerous tumors continues to be observed where it persists for at least 21 days.

NVLT intends to combine the data from this trial with calculation of effective doses for HOT based on quantitative positron emission tomography (PET) tumor imaging data using I-124-CLR1404 (LIGHT), the Company's small-molecule cancer-targeted PET imaging agent. Together, these data will enable NVLT to commence HOT **Phase II** proof-of-concept trials in 3Q13 in cancer patients.

The Implications

Data so far from the first two cohorts suggest that HOT has a favorable safety profile and is selective in cancerous tumor uptake and retention.

Novelos expects to begin HOT Phase II proof-of-concept trials in **the third quarter of 2013** as soon as a minimal efficacious dose is established, if additional funding can be secured. We believe the data generated from the ongoing HOT Phase 1b trial combined with cancerous tumor imaging data from the ongoing I-124-CLR1404 (LIGHT) clinical trials will enable selection of indications for HOT Phase II trials and guide trial designs. The target cancer will be NSCLC, triple-negative breast cancer, brain cancer, soft tissue sarcoma, etc.

Since HOT has demonstrated synergistic efficacy when used in combination with chemotherapeutics in animal models, the Company plans to explore **HOT combination with chemotherapeutic agents** for the treatment of cancers if funds are available. A number of chemotherapeutic agents are known to be radiosensitizers and could have the potential to enhance the efficacy of HOT. Combination therapy could greatly expand HOT usage in a variety of cancers and could enhance its commercial potential as a cancer therapeutic.

We are glad that NVLT is on track to advance its clinical programs. Current valuation still does not reflect the Company's fundamentals in our view. Current valuation for NVLT is low, and the risk/return profile is biased to return at this point.

Novelos' Diapeutic Platform is Presented at the Imaging in 2020 Conference

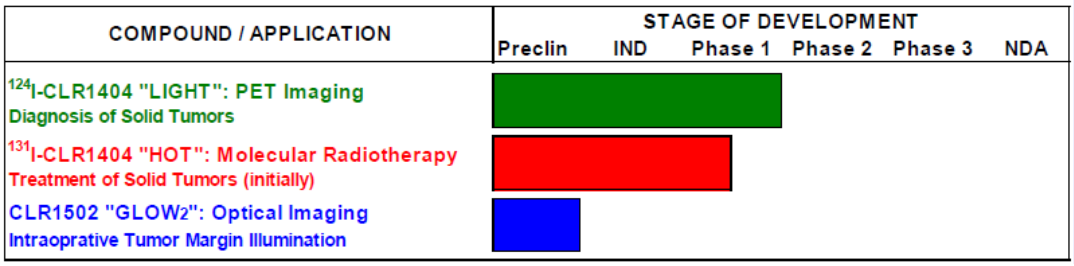
On October 3, 2012, Novelos Therapeutics announced that an oral presentation on research conducted by Jamey Weichert, Ph.D., Lance Hall, M.D., Anne M. Traynor, M.D., Glenn Liu, M.D. and their colleagues is being made by Dr. Weichert at the Imaging in 2020 Conference taking place September 30 to October 4, 2012 in Jackson Hole, Wyoming.

This presentation 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 uptake 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. Dr. Weichert is Associate Professor of Radiology, Dr. Hall is Assistant Professor of Radiology, Dr. Traynor is Associate Professor of Medicine and Dr. Liu is Associate Professor of Medicine, all in the School of Medicine and Public Health at the University of Wisconsin, Madison and all are members of the UW Carbone Cancer Center. Dr. Weichert is also the Chief Scientific Officer of Novelos and the founder of Novelos' technology.

The presentation is titled ***Molecular Diapeutics: Phospholipid Ether Analogs as Broad-Spectrum Cancer and Cancer Stem Cell Detection and Treatment***. Dr. Weichert 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 in 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 as well as selective uptake and retention in cancerous tumors in clinical trials to date. The 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. Weichert's talk also describes 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 is also being shown.

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



We believe Novelos' platform technology has great potential for cancer imaging and therapy, which can be used in various cancer types. With all these progresses made in the past few months, we believe Novelos' share price deserves further appreciation.

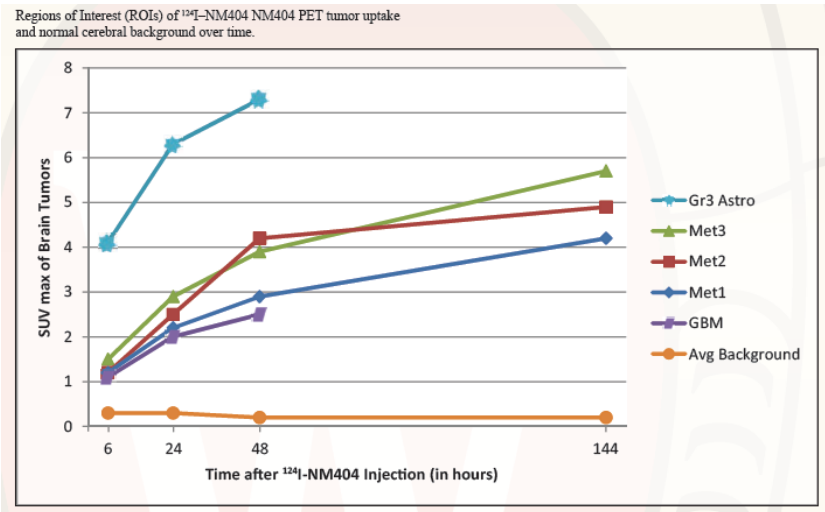
New Posters Demonstrate Efficacy of Clinical Programs

On Sept 7, Novelos announced that three clinical imaging posters based on research conducted by Lance Hall, M.D., Anne M. Traynor, M.D., Glenn Liu, M.D., Jamey Weichert, Ph.D. in the School of Medicine and Public Health at the University of Wisconsin, Madison and their colleagues are being presented at the World Molecular Imaging Congress taking place September 5-8, 2012 in Dublin, Ireland.

These presentations describe initial findings in advanced cancer patients that demonstrate selective and prolonged uptake of Novelos' PET imaging and therapeutic compounds in a range of tumor types. These three posters are:

First in Human Use of I-124-CLR1404 PET/CT in Primary and Metastatic Brain Tumors

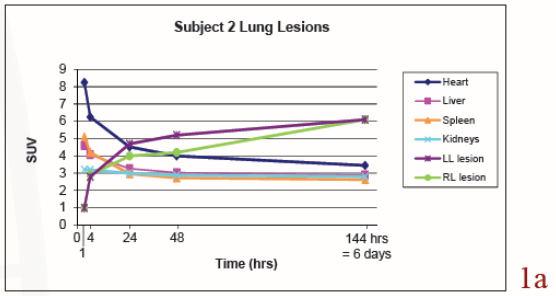
Dr. Hall and his colleagues are presenting clinical data showing that LIGHT PET/CT successfully imaged brain metastases and gliomas in humans. In doing so, the agent demonstrated a high degree of uptake and prolonged retention in tumors with no significant background uptake in normal brain tissue.



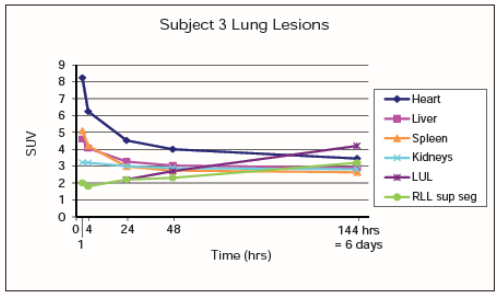
Relative Biodistribution and Tumor Uptake of I-124-CLR1404 in Humans with Non-Small Cell Lung Cancer

The second presentation by Dr. Hall and his colleagues reports clinical data demonstrating malignant tumor uptake of LIGHT with prolonged retention and an increasing tumor-to-background ratio in advanced non-small cell lung cancer patients. It also shows that the relative normal organ biodistribution of LIGHT is reproducible between patients.

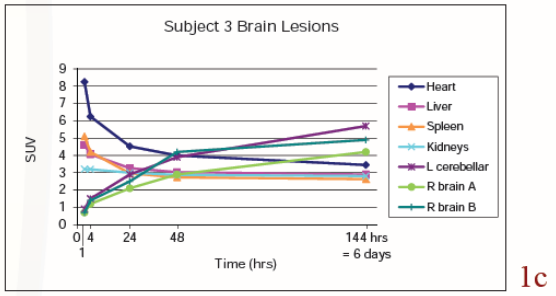
Physiologic organ 124I–NM404 uptake average (SUVav) in relationship with tumor uptake (SUVmax): LL (left lung), RL (right lung), LUL (left upper lobe), RLL sup seg (superior segment of the right upper lobe), R (right), L (left). In general, lesion SUVmax increases with time, while SUVav average of the different organs decreases with time, with the exception of the kidneys where SUVav is relatively stable over time.



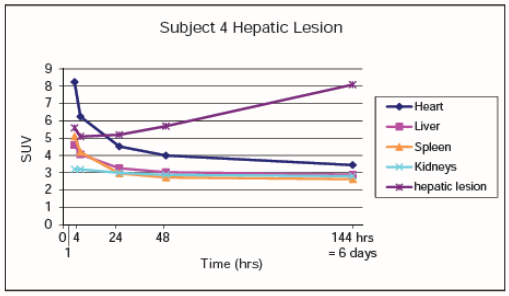
1a



1b



1c



1d

Relative Biodistribution and Tumor Uptake of I-131-CLR1404 in Human Subjects with Advanced Colon Cancer

Dr. Hall and colleagues' third presentation indicates that pre-therapy planar imaging with a low dose of HOT can be used to determine its biodistribution prior to a therapeutic treatment dose of HOT. SPECT/CT imaging, following a higher dose of HOT, successfully demonstrated selective tumor accumulation and prolonged retention in two patients with treatment-resistant metastatic colon cancer.

We are very pleased to see the initial positive LIGHT imaging data in lung and brain cancer patients, as well as the selective cancerous tumor uptake and prolonged retention of HOT in advanced colon cancer patients.

Initial Data from LIGHT Phase I/II Brain Cancer Trial Are Very Encouraging

On June 19, 2012, Novelos Therapeutics, Inc. (NVLT) announced that the University of Wisconsin Carbone Cancer Center (UWCCC) has successfully dosed three patients in a **Phase I/II** positron emission tomography (PET) imaging trial of I-124-CLR1404 (LIGHT), a cancer-targeted PET imaging agent, in patients with primary or metastatic **brain cancer**.

As a reminder, the investigator-sponsored **Phase I/II** trial of LIGHT as a PET imaging agent for **brain cancer** was initiated in December 2011 at UWCCC and first patient was enrolled on March 15, 2012.

Lance Hall, M.D., is the trial's principal investigator. This trial is being funded by the UWCCC and the Institute for Clinical and Translational Research (ICTR). Up to 20 patients will be enrolled at a 5 mCi dose.

The three glioma patients were dosed with LIGHT at 5 mCi.

- LIGHT is well tolerated, and there are no adverse safety signals are observed.
- Strong and sustained uptake of LIGHT in cancerous tumors against very low background has been observed;
- Further, LIGHT's cancerous tumor to normal tissue uptake ratio exceeded 30:1 in one tumor, which compares favorably with PET agents that are generally considered good tumor biomarkers if tumor to normal tissue uptake ratios are in the range of 3:1 and 5:1.

Detailed trial results are expected to be presented at a scientific venue at a later date. Novelos expects final results to be available in 1Q13.

We think the preliminary results from these three brain cancer patients are very encouraging. The uptake is strong and cancer-specific with no safety signals. These results begin to establish proof-of-concept for LIGHT as a PET imaging agent for brain cancer, and could be used to calculate effective doses for Phase II clinical trials of I-131-CLR1404 (HOT) in this indication.

Initial LIGHT Data from Phase I/II NSCLC Trial Are also Encouraging

On April 24, 2012, Novelos Therapeutics, Inc. (NVLT) announced that the University of Wisconsin Carbone Cancer Center has successfully completed the first cohort in a Phase I/II PET imaging trial of I-124-CLR1404 (LIGHT), a cancer-targeted PET imaging agent, in patients with advanced **non-small cell lung cancer (NSCLC)**.

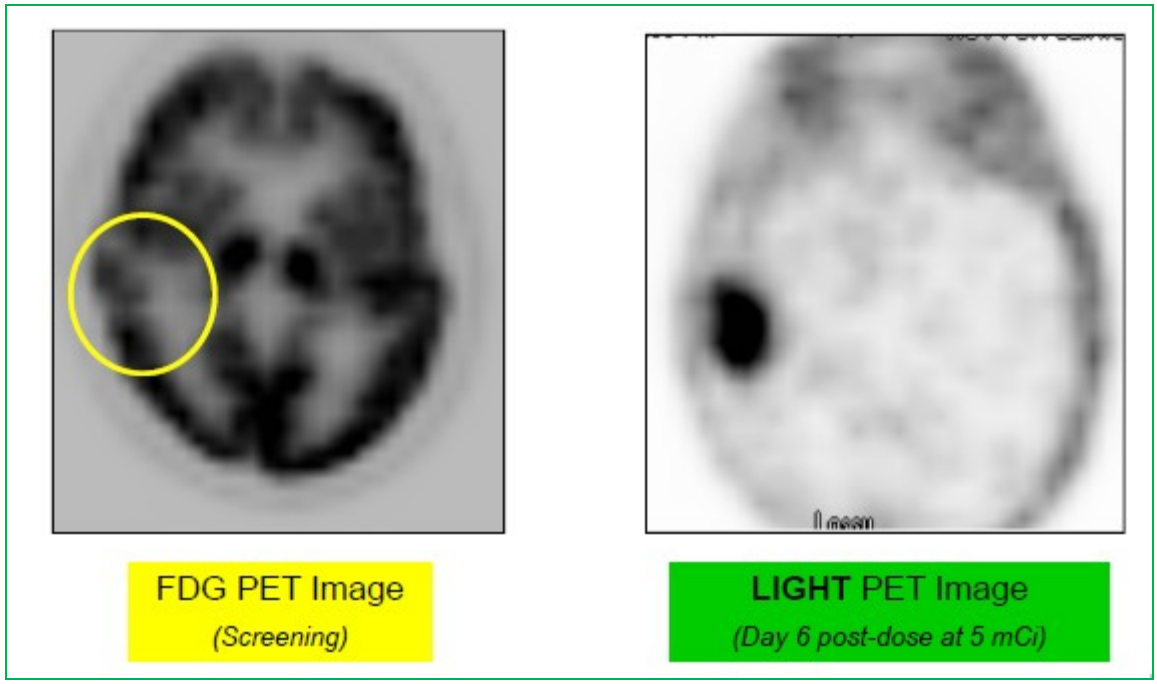
The fact:

As a reminder, an investigator-sponsored **Phase I/II** trial of LIGHT as a PET imaging agent for **lung cancer** was initiated in December 2011 at the University of Wisconsin Carbone Cancer Center (UWCCC) and first patient was enrolled in February 2012. Dr. Anne M. Traynor at UWCCC is the principal investigator. Novelos provides funding for the trial and the data is shared with Novelos while the study progresses and at the conclusion of the study. Up to 12 patients will be enrolled across two dose levels (3 mCi and 5 mCi) in this Phase I/II trial. The trial will be completed in 2012.

The first cohort comprised three patients dosed with LIGHT at 5 mCi. The first cohort has demonstrated positive initial imaging results. In fact, in one of NSCLC patients, LIGHT PET scan clearly identifies a brain metastasis that FDG missed.

- LIGHT is safe and there is no adverse safety signals;
- Strong selective uptake of LIGHT in cancerous tumors against very low background has been observed;
- LIGHT PET scan clearly identifies a brain metastasis that FDG missed in a NSCLC patient

Detailed trial results are expected to be presented at a scientific venue at a later date.



Novelos is now planning to evaluate the next dose level at 3mci in three patients as the Company seeks to identify a minimally effective dose.

Our takeaways from the initial data:

- The preliminary results from the first cohort are positive; the more tumor-selective advantage of LIGHT over FDG for one patient is especially encouraging;
- The excellent safety profile and strong efficacy data could accelerate the completion of the Phase I/II trial of LIGHT as a lung cancer PET imaging agent;
- These data begin to establish proof-of concept for LIGHT as a PET imaging agent for NSCLC; could advance Novelos' partnering discussions and could be used to calculate effective doses for Phase II clinical trials of I-131-CLR1404 (HOT);

VALUATION AND RECOMMENDATION

We maintain an Outperform rating on Novelos Therapeutics (NVLT) shares and reiterate our 12-month target price of $2.50 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.

With all these in mind, we think Novelos is undervalued at current price. Currently, Novelos shares are trading at around $0.90 per share, which values the Company at $42 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 2013. 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 $2.5 per share corresponds to a $108 million in market cap.

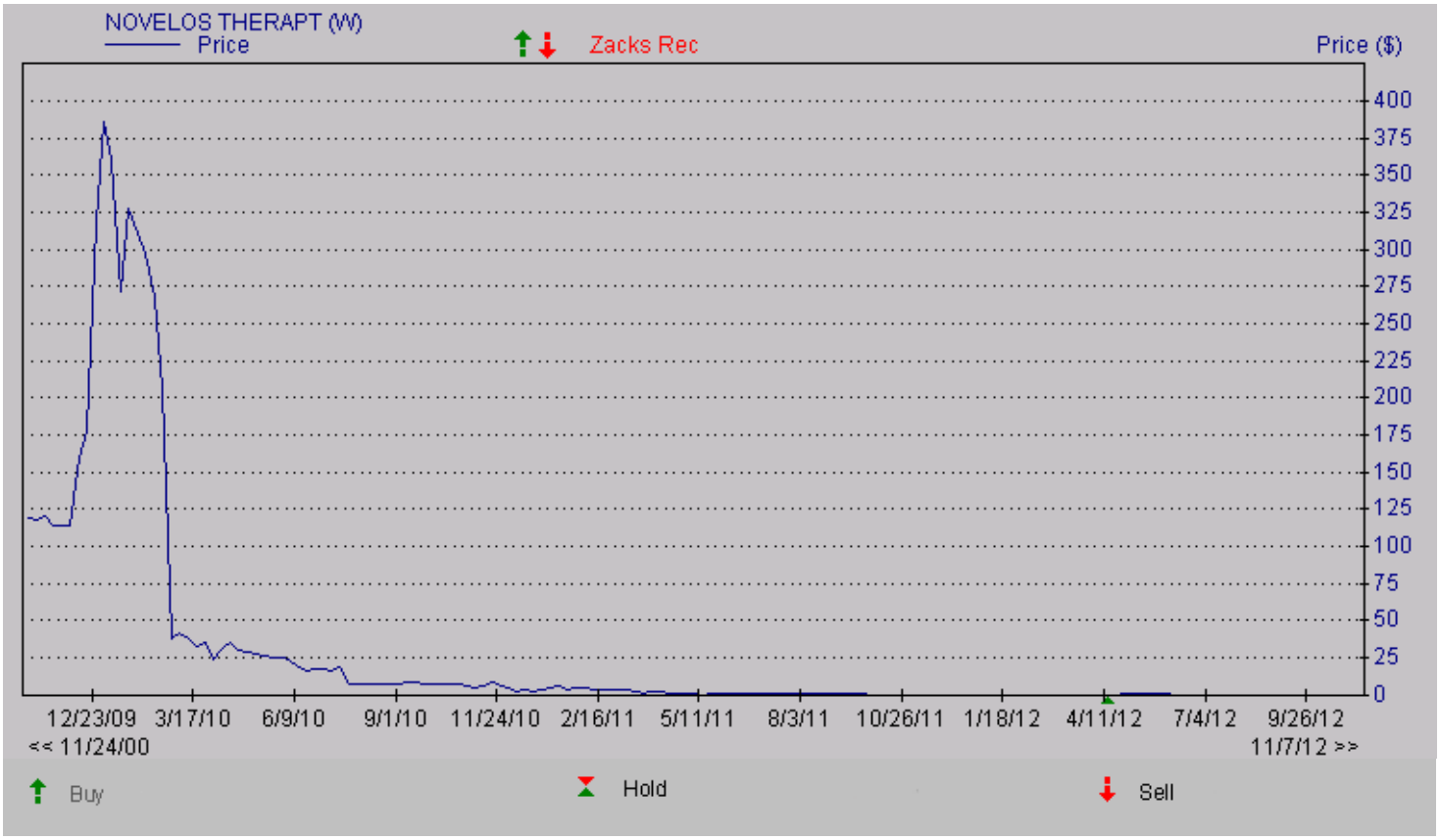
PROJECTED INCOME STATEMENT

	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)	2016E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1A	Q2A	Q3A	Q4E	FYE	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	-	-	-	-	-	-	-	-	-	-	*#DIV/0!*	*100.0%*	*100.0%*	*100.0%*
R&D	$0.47	$0.96	$1.01	$1.16	$3.60	$1.33	$1.31	$1.25	$1.50	$5.40	$6.00	$7.00	$8.50	$10.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.13	$0.80	$0.91	$0.86	$2.69	$1.00	$0.90	$0.80	$1.10	$3.80	$4.50	$5.00	$5.50	$6.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.25	$0.50	$0.00	$0.00	$0.75	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($0.9)**	**($2.3)**	**($1.9)**	**($2.0)**	**($7.0)**	**($2.3)**	**($2.2)**	**($2.1)**	**($2.6)**	**($9.2)**	**($10.5)**	**($9.5)**	**($8.0)**	**($8.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	$0.1	($0.3)	$0.0	($0.2)	($0.4)	($0.0)	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($0.7)**	**($2.6)**	**($1.9)**	**($2.2)**	**($7.4)**	**($2.4)**	**($2.2)**	**($2.1)**	**($2.6)**	**($9.2)**	**($10.5)**	**($9.5)**	**($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	**($0.7)**	**($2.6)**	**($1.9)**	**($2.2)**	**($7.4)**	**($2.4)**	**($2.2)**	**($2.1)**	**($2.6)**	**($9.2)**	**($10.5)**	**($9.5)**	**($8.0)**	**($8.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deluted Shares Out	*12.8*	*25.7*	*26.8*	*30.5*	*24.0*	*36.9*	*38.6*	*43.3*	*45.0*	*40.9*	*50.0*	*55.0*	*60.0*	*65.0*
Reported EPS	**($0.06)**	**($0.10)**	**($0.07)**	**($0.07)**	**($0.31)**	**($0.06)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.23)**	**($0.21)**	**($0.17)**	**($0.13)**	**($0.12)**
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	**($0.7)**	**($2.6)**	**($1.9)**	**($2.2)**	**($7.4)**	**($2.4)**	**($2.2)**	**($2.1)**	**($2.6)**	**($9.2)**	**($10.5)**	**($9.5)**	**($8.0)**	**($8.0)**
Non GAAP EPS	**($0.06)**	**($0.10)**	**($0.07)**	**($0.07)**	**($0.31)**	**($0.06)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.23)**	**($0.21)**	**($0.17)**	**($0.13)**	**($0.12)**

Source: Company filings and Zacks Small Cap Research

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HISTORICAL ZACKS RECOMMENDATIONS



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