

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: May 16, 2013
(Date of earliest event reported)

NOVELOS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

333-119366
(Commission
File Number)

04-3321804
(IRS Employer
Identification Number)

One Gateway Center, Suite 504
Newton, MA 02458
(Address of principal executive offices)

(617) 244-1616
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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ITEM 7.01 REGULATION FD DISCLOSURE

A copy of the press release issued by us on May 16, 2013 providing a product pipeline update, including I-124-CLR1404 (LIGHT) positron emission tomography (PET) imaging agent for solid tumor indications, I-131-CLR1404 (HOT) cancer-targeted molecular radiotherapeutic for advanced solid tumors and CLR1502 (GLOW2) optical imaging agent for intraoperative tumor margin illumination in real-time and non-invasive tumor imaging, is furnished as Exhibit 99.1 and is incorporated by reference in this Item.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

<u>Number</u>	<u>Title</u>
99.1	Press Release dated May 16, 2013 entitled "Novelos Therapeutics Provides Product Pipeline Update"

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 16, 2013

NOVELOS THERAPEUTICS, INC.

By: /s/ Harry S. Palmin

Name: Harry S. Palmin

Title: President and Chief Executive Officer

EXHIBIT INDEX

Number	Title
99.1	Press Release dated May 16, 2013 entitled “Novelos Therapeutics Provides Product Pipeline Update”



NOVELOS THERAPEUTICS PROVIDES PRODUCT PIPELINE UPDATE

*To Begin I-124-CLR1404 (LIGHT) Phase 2 Imaging Trial in Brain Cancer in Early 2014
Evaluating I-131-CLR1404 (HOT) Potential Phase 2 Indications and Trial Designs
To File CLR1502 (GLOW2) IND for Intraoperative Tumor Margin Illumination by End 2013*

MADISON, Wisc. (May 16, 2013) – **Novelos Therapeutics, Inc. (OTCQX: NVLT)**, a pharmaceutical company developing novel drugs for the treatment and diagnosis of cancer, today provided an update on its product pipeline, including I-124-CLR1404 (LIGHT) positron emission tomography (PET) imaging agent for solid tumor indications, I-131-CLR1404 (HOT) cancer-targeted molecular radiotherapeutic for advanced solid tumors and CLR1502 (GLOW2) optical imaging agent for intraoperative tumor margin illumination in real-time and non-invasive tumor imaging.

“We are excited to be advancing multiple product opportunities aimed at significant unmet needs, all based on Novelos’ proprietary cancer-targeted delivery platform,” said Harry Palmin, President and CEO of Novelos. “Our development plan is centered on advancing compounds that we expect to most rapidly achieve significant development milestones. Both LIGHT and GLOW2, subject to additional funding, are expected to reach such milestones by the end of 2014.”

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 2 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.

“In early PET imaging trials with I-124-CLR1404 (LIGHT) in primary and metastatic brain cancer patients, we have observed high tumor-to-background ratios,” said Lance Hall, M.D., Assistant Professor of Radiology at the University of Wisconsin Carbone Cancer Center, and the principal investigator for the Phase 1-2 trials in brain cancer. “These data provide a strong rationale for rapidly transitioning to a Phase 2 trial in glioma patients to compare I-124-CLR1404 PET imaging to magnetic resonance imaging (MRI), the current standard of care in this patient population, where a significant unmet medical need exists for post-treatment efficacy assessment and differentiating tumor growth from pseudoprogression.”

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 1b 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. Details of the trial design are available on www.clinicaltrials.gov ID: NCT01495663, or at www.novelos.com in the ‘Clinical Trials’ section.

“We are approaching the stated objective of the Phase 1b dose-escalation trial to determine the Maximum Tolerated Dose of I-131-CLR1404 (HOT),” said 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, and the trial’s principal investigator. “We continue to observe selective uptake of I-131-CLR1404 in a variety of tumor types where it persists in excess of 21 days.”

In parallel with the ongoing Phase 1b fourth cohort, Novelos will be evaluating a range of potential HOT Phase 2 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.

“A good example of the potential utility of CLR1502 (GLOW2) is in breast cancer surgery, where 25% of patients undergoing lumpectomy require repeat resection due to incomplete removal of the primary tumor and malignant lymph nodes,” said Lee Wilke, M.D., Associate Professor (CHS), Division of General Surgery, and Director Breast Center at the University of Wisconsin Carbone Cancer Center. “An imaging agent that enables improved surgical accuracy by better defining malignant tissues could significantly improve patient outcomes and rapidly impact medical practice.”

Mr. Palmin further noted, “Based on positive initial LIGHT imaging results in primary and metastatic brain cancer, we believe LIGHT has potential to address a significant unmet medical need for post-treatment efficacy assessment and differentiating tumor growth from pseudoprogression in brain cancer, potentially avoiding unnecessary surgeries, biopsies and other treatments. While LIGHT human imaging data is confirming the broad-spectrum potential of our cancer-targeted technology, it is also expected to guide us in selecting a therapeutic direction with HOT. Additionally, we will utilize the clinical data generated with HOT to date as we evaluate potential HOT Phase 2 indications and trial designs. With GLOW2, there is strong medical support for the need to improve outcomes of tumor surgery, including reducing repeat resections and early progression, stemming from incomplete removal of malignant tissue or lymph nodes. Each of these compounds exploits the same key attribute of our proprietary, cancer-targeted delivery platform based on phospholipid ether analogs (PLE); the enabling of selective uptake and prolonged retention in cancer cells. We look forward to advancing the development of these compounds as well as exploring additional applications of our delivery platform in the oncology space.”

About Novelos Therapeutics, Inc.

We are a pharmaceutical company developing novel drugs for the treatment and diagnosis of cancer. Our cancer-targeted compounds are selectively taken up and retained in cancer cells, including cancer stem cells, versus normal cells. I-124-CLR1404 (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. I-131-CLR1404 (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. HOT Phase 1b dose-escalation trial is ongoing in patients with advanced solid tumors. CLR1502 (GLOW2) is a preclinical, cancer-targeted, non-radioactive optical imaging agent for intraoperative tumor margin illumination and non-invasive tumor imaging. Together, we believe our compounds are able to “find, treat and follow” cancer anywhere in the body in a novel, effective and highly selective way. For additional information please visit www.novelos.com

INVESTOR CONTACTS

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This news release contains forward-looking statements. You can identify these statements by our use of words such as “may,” “expect,” “believe,” “anticipate,” “intend,” “could,” “estimate,” “continue,” “plans,” or their negatives or cognates. Such statements are valid only as of today, and we disclaim any obligation to update this information. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, our pharmaceutical collaborators’ ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2012 and in our quarterly reports on Form 10-Q. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

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