

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 (DATE OF EARLIEST EVENT REPORTED)
January 7, 2010

NOVELOS THERAPEUTICS, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN CHARTER)

DELAWARE
(STATE OR OTHER JURISDICTION
OF INCORPORATION)

333-119366
(COMMISSION
FILE NUMBER)

04-3321804
(IRS EMPLOYER
IDENTIFICATION NO.)

One Gateway Center, Suite 504, Newton, Massachusetts 02458
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (617) 244-1616

NOT APPLICABLE
(FORMER NAME OR FORMER ADDRESS, IF CHANGED SINCE LAST REPORT)

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:

- ☐ 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 January 7, 2010 announcing the occurrence of the 725th event in our pivotal phase 3 lung cancer trial is furnished as Exhibit 99.1 and is incorporated by reference in this Item.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits

Number	Title
99.1	Press Release dated January 7, 2010 entitled “Novelos Therapeutics Reaches 725 th Event in Pivotal Phase 3 Lung Cancer Trial.”

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: January 7, 2010

NOVELOS THERAPEUTICS, INC.

By: /s/ Harry S. Palmin
Harry S. Palmin
President and Chief Executive Officer

EXHIBIT INDEX

Number	Title
99.1	Press Release dated January 7, 2010 entitled “Novelos Therapeutics Reaches 725 th Event in Pivotal Phase 3 Lung Cancer Trial.”

**NOVELOS THERAPEUTICS REACHES 725th EVENT
IN PIVOTAL PHASE 3 LUNG CANCER TRIAL**

Trial Conclusion on Track for 1Q 2010

NEWTON, Mass., January 7, 2010 – **Novelos Therapeutics, Inc. (OTCBB: NVLT)**, a biopharmaceutical company focused on the development of therapeutics to treat cancer and hepatitis, today announced that the 725th event (patient death) has been reached in its pivotal Phase 3 trial in advanced non-small cell lung cancer (NSCLC) studying its lead product, NOV-002, in combination with first-line chemotherapy. The 725th event triggers the steps towards the pre-specified analysis according to the trial's Statistical Analysis Plan (SAP). Top-line trial results are expected to be available later in the first quarter.

This randomized, controlled, open-label Phase 3 trial, being conducted under a Special Protocol Assessment (SPA) and Fast Track designation, has enrolled 903 patients with Stage IIIB/IV NSCLC, which includes all histological subtypes. The trial, conducted across approximately 100 clinical sites in 12 countries, is evaluating NOV-002 in combination with first-line paclitaxel and carboplatin chemotherapy versus paclitaxel and carboplatin alone. The primary efficacy endpoint of the trial is improvement in overall survival. Enrollment commenced in November 2006 and the target enrollment was achieved in March 2008. According to the SAP, a total of 725 events are required to detect a 25% improvement in overall survival (hazard ratio of 0.8) with 85% power and a two-sided significance level of 0.05. No interim analysis was performed.

“We are on track for our pivotal Phase 3 trial to conclude this quarter,” said Harry Palmin, President and CEO of Novelos. “Should this registrational trial be positive, we will proceed with filing a New Drug Application (NDA) in 3Q 2010. Thereafter, based on our Fast Track designation, we would project FDA approval for first-line treatment of advanced NSCLC in combination with chemotherapy in 1Q 2011.”

About NSCLC

NSCLC accounts for about 87% of lung cancer, which is the leading cause of cancer death in the U.S. According to the American Cancer Society, approximately 215,000 people were expected to be diagnosed with lung cancer in 2008 in the U.S., with approximately 162,000 deaths. Approximately 1,500,000 new cases of lung cancer were expected worldwide in 2007 and approximately 1,350,000 deaths were projected from lung cancer in 2007. Only about 16% of NSCLC patients are diagnosed early enough to be eligible for surgery. Platinum-based chemotherapy regimens are standard first-line treatment for advanced NSCLC patients. Paclitaxel and carboplatin is the most common first-line treatment in the U.S., while gemcitabine / pemetrexed and cisplatin are more common in Europe. During treatment, patients are subject to serious chemotherapy-induced adverse effects. According to results of 12 Phase 3 clinical trials published from 2001-2008, the one-year survival rate for patients receiving paclitaxel and carboplatin first-line therapy was on average only about 40%, the weighted average for median survival was 9.7 months and the objective tumor response (defined as greater than 30% tumor shrinkage) rate was about 27%. Overall, fewer than 5% of advanced non-small cell lung cancer patients survive five years.

About NOV-002 for NSCLC

NOV-002 is a small molecule compound based on a proprietary formulation of oxidized glutathione that acts together with chemotherapy as a chemopotentiator and a chemoprotectant by regulating redox-sensitive cell signaling pathways. Three separate Phase 2 trials demonstrated clinical activity and safety of NOV-002 in combination with first-line chemotherapy in NSCLC. In a controlled, randomized U.S. Phase 1/2 clinical trial, advanced NSCLC patients treated with NOV-002 in combination with first-line paclitaxel and carboplatin demonstrated improved objective tumor response ($p < 0.05$) and higher tolerance of chemotherapy ($p < 0.01$) compared to the active control group. In a controlled, randomized Russian Phase 2 trial, when used in combination with cisplatin-based first-line chemotherapy, NOV-002 increased the one-year survival of advanced NSCLC patients from 17% to 63% ($p < 0.01$); median survival (i.e. 50% of patients dead) was not reached in the NOV-002 arm at 14 months compared to a median survival of 7 months in the active control. In a single arm Russian Phase 2 trial, advanced NSCLC patients treated with NOV-002 in combination with first-line cisplatin-based chemotherapy exhibited greater than 50% one-year survival. NOV-002 has an extensive safety database, and has also demonstrated improved recovery from chemotherapy toxicity in cancer patients. Importantly, NOV-002 does not appear to be chemotherapy specific or tumor specific.

About Novelos Therapeutics, Inc.

Novelos Therapeutics, Inc. is a biopharmaceutical company commercializing oxidized glutathione-based compounds for the treatment of cancer and hepatitis. NOV-002, the lead compound currently in Phase 3 development for lung cancer under an SPA and Fast Track, acts together with chemotherapy as a chemopotentiator and a chemoprotectant. NOV-002 is also in Phase 2 development for early-stage breast cancer and chemotherapy-resistant ovarian cancer. Novelos has a partnership with Mundipharma, an independent associated company of Purdue Pharma, to develop and commercialize NOV-002 in Europe and Asia (excluding China). Novelos' second compound, NOV-205, acts as a hepatoprotective agent with immunomodulating and anti-inflammatory properties. NOV-205 is in Phase 1b development for chronic hepatitis C non-responders. Both compounds have been partnered with Lee's Pharm in China. For additional information about Novelos please visit www.novelos.com

COMPANY

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This news release contains forward-looking statements. Such statements are valid only as of today, and we disclaim any obligation to update this information. These statements 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 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.

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