

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)

February 23, 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 February 24, 2010 announcing the results of our pivotal phase 3 lung cancer trial is furnished as Exhibit 99.1 and is incorporated by reference in this Item.

ITEM 8.01 OTHER MATERIAL EVENTS

On February 23, 2010, we received a report of the top-line results of our pivotal Phase 3 clinical trial in advanced non-small cell lung cancer studying our lead product, NOV-002, in combination with first-line chemotherapy. Upon evaluation and review of the data contained in the report, we determined that the primary endpoint of improvement in overall survival was not met in the trial.

Based on a preliminary analysis of the clinical trial data, it appears that internal simulations suggesting positive trial results were inaccurate due to the deviation of certain trial data from our statistical model, the impact of censoring patterns and the survival of patients in the control arm exceeding our expectations, which had been based on historical precedents. We expect to present detailed Phase 3 lung cancer trial results at an appropriate scientific venue later this year.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(c) Exhibits

<u>Number</u>	<u>Title</u>
99.1	Press Release dated February 24, 2010 entitled “Novelos Therapeutics Pivotal Phase 3 Lung Cancer Trial Does Not Meet the Primary Survival Endpoint.”

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: February 24, 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 February 24, 2010 entitled “Novelos Therapeutics Pivotal Phase 3 Lung Cancer Trial Does Not Meet the Primary Survival Endpoint.”



FOR IMMEDIATE RELEASE

**NOVELOS THERAPEUTICS PIVOTAL PHASE 3 LUNG CANCER TRIAL
DOES NOT MEET THE PRIMARY SURVIVAL ENDPOINT**

Detailed Trial Results Expected in 2010

NEWTON, Mass., February 24, 2010 – **Novelos Therapeutics, Inc. (OTCBB: NVLT)**, a biopharmaceutical company focused on the development of therapeutics to treat cancer and hepatitis, today announced that the primary endpoint of improvement in overall survival was not met in Novelos' pivotal Phase 3 trial in advanced non-small cell lung cancer (NSCLC) studying its lead product, NOV-002, in combination with first-line chemotherapy. Detailed trial results are expected to be presented via appropriate scientific venue later this year.

This randomized, controlled, open-label Phase 3 trial, conducted under a Special Protocol Assessment (SPA) and Fast Track designation, had enrolled 903 patients with Stage IIIB/IV NSCLC, which includes all histological subtypes. The trial, conducted across approximately 100 clinical sites in 12 countries, evaluated NOV-002 in combination with first-line paclitaxel and carboplatin chemotherapy versus paclitaxel and carboplatin alone. The primary efficacy endpoint of the trial was improvement in overall survival. Enrollment commenced in November 2006, target enrollment was achieved in March 2008, and the 725 event (patient death) was announced in early January 2010. According to the trial's Statistical Analysis Plan (SAP), a total of 725 events were required to detect a 25% improvement (12.5 months versus 10 months) in overall median 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 very disappointed that our pivotal Phase 3 lung cancer trial did not meet the primary survival endpoint," said Harry Palmin, President and CEO of Novelos. "We were hopeful of a positive outcome based on our statistical model simulations and stated assumptions. In retrospect, it appears our simulations were inaccurate due to trial data deviating from our statistical model, the impact of censoring patterns, and control arm survival exceeding our expectations based on historical precedents. We will conduct a thorough analysis of all the data, and expect to present detailed Phase 3 lung cancer trial results later this year. Meanwhile, we are scheduled to present new NOV-002 preclinical data at the AACR Annual Meeting in April 2010, and we are on track for results from a NOV-002 Phase 2 breast cancer trial in 3Q 2010. We are also on track to initiate a Phase 2 hepatitis C trial shortly, with our second compound NOV-205."

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. 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. Improving on the standard of care in unselected advanced NSCLC remains challenging and elusive.



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. The pivotal Phase 3 trial of NOV-002 in 903 advanced NSCLC patients in combination with first-line chemotherapy did not meet the primary endpoint of improvement in overall survival. Previously, three separate Phase 2 trials demonstrated clinical activity and safety of NOV-002 in combination with first-line chemotherapy in NSCLC. NOV-002 has an extensive safety database, and has also demonstrated improved recovery from chemotherapy toxicity in cancer patients. 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 that completed a Phase 3 trial for lung cancer, 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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