

---

---

**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 (Date of earliest event reported): June 24, 2009**

**ONCOGENEX PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

<hr/> <b>Delaware</b> (State or other Jurisdiction of Incorporation)	<hr/> <b>033-80623</b> (Commission File Number)	<hr/> <b>95-4343413</b> (IRS Employer Identification No.)
<hr/> <b>1522 217th Place S.E. Bothell, Washington</b> (Address of Principal Executive Offices)		<hr/> <b>98021</b> (Zip Code)

Registrant's telephone number, including area code: **(425) 686-1500**

N/A  
(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))
- 
-

**Item 7.01 Regulation FD Disclosure.**

On June 24, 2009, OncoGenex Pharmaceuticals, Inc. issued a press release entitled "OncoGenex Pharmaceuticals Completes Amendment to Phase 3 Special Protocol Assessment for Confirming Survival Benefit in Patients Receiving OGX-011 with First-Line Docetaxel for Metastatic Prostate Cancer." A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this report, including the exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated June 24, 2009

---

**SIGNATURES**

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

ONCOGENEX PHARMACEUTICALS, INC.

Date: June 24, 2009

/s/ Stephen Anderson  
Stephen Anderson  
Chief Financial Officer and Secretary

---

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated June 24, 2009



**OncoGenex Pharmaceuticals Completes Amendment to Phase 3 Special Protocol Assessment for Confirming Survival Benefit in Patients Receiving OGX-011 with First-Line Docetaxel for Metastatic Prostate Cancer**

BOTHELL, WA, and VANCOUVER – June 24, 2009 — OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today that the company has reached an agreement with the U.S. Food and Drug Administration (FDA) via the special protocol assessment process (SPA) on an amendment to the design of a Phase 3 registration trial of OGX-011, its lead product candidate targeting castrate resistant prostate cancer (CRPC). The FDA has agreed on modifications to the study population of a previously reviewed Phase 3 trial featuring survival as the primary endpoint. The study population has been modified to evaluate patients receiving first-line chemotherapy, rather than those receiving second-line chemotherapy. FDA agreed that the amended protocol adequately addresses the objectives necessary to support a regulatory submission.

“We are now ready to proceed with two Phase 3 trial designs from the FDA via the SPA process, one in first-line and one in second-line treatment of advanced prostate cancer,” said Scott Cormack, President and CEO of OncoGenex Pharmaceuticals. “The trial for first-line treatment evaluates overall survival benefit for OGX-011 while the trial for second-line treatment evaluates for a durable pain palliation benefit. Based on the robustness of the OGX-011 survival benefit observed in the randomized Phase 2 trial for first-line docetaxel treatment, we felt evaluating both of these patient populations, as well as both endpoints, in our Phase 3 trials better positions the availability of OGX-011 treatment to a larger number of men with prostate cancer.”

The Phase 3 trial has been designed in collaboration with internationally recognized experts in the treatment of patients with castrate resistant prostate cancer (CRPC) including Dr. Celestia Higano at the University of Washington and Dr. Kim Chi at the University of British Columbia. The revised trial will be a randomized, controlled, international study in 800 men with metastatic CRPC who are in need of first-line chemotherapy. Patients will be randomized to receive treatment with either OGX-011 and docetaxel/prednisone or docetaxel/prednisone alone. The primary endpoint of the study will be overall survival. It is expected that approximately 80 sites, primarily from United States and Canada, will participate in this study.

The planned initiation of this Phase 3 trial evaluating survival is supported by Phase 2 data from patients receiving OGX-011 plus docetaxel as first-line chemotherapy presented at the 2009 Annual Meeting of the American Society of Clinical Oncology (ASCO) and reported on May 30<sup>th</sup> of this year. Analyses indicated the median overall survival in patients with advanced metastatic prostate cancer who were treated with OGX-011 plus docetaxel in a randomized Phase 2 trial was 23.8 months compared to 16.9 months for patients treated with docetaxel alone — a 6.9 month observed survival advantage for the OGX-011 arm. Furthermore, the unadjusted hazard ratio (HR), a measure used to compare the death rates between treatment groups, was 0.61, representing a 39% lower rate of death for patients treated with OGX-011.

## **About OGX-011**

OGX-011 is designed to inhibit the production of clusterin, a protein that is associated with cancer treatment resistance, and has completed Phase 2 clinical trials in prostate, lung and breast cancer.

Based on clinical results to date, OncoGenex intends to conduct two Phase 3 registration trials with OGX-011 in metastatic castrate resistant prostate cancer, subject to the receipt of additional funding. The U.S. Food & Drug Administration (FDA) has now agreed on the design of both Phase 3 registration trials, via the Special Protocol Assessment (SPA) process, of OGX-011 in combination with chemotherapy. One trial design investigates overall survival as the primary endpoint in patients treated with first-line docetaxel chemotherapy; the other trial design investigates pain palliation as the primary endpoint in patients treated with second-line docetaxel chemotherapy.

OGX-011 has received Fast Track designation from the FDA for the treatment of progressive metastatic prostate cancer in combination with docetaxel.

## **About the Special Protocol Assessment and Agreement Process**

Under a Special Protocol Assessment (SPA), a company and the FDA can reach an agreement on the design and size of a clinical trial to support a regulatory submission. This agreement can be in writing and cannot be changed after the clinical trial begins except: (i) with written agreement of the company and the FDA; or (ii) if the director of the FDA reviewing division determines that "a substantial scientific issue essential to determining the safety or effectiveness of the drug" was identified after testing began.

## **About OncoGenex**

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address unmet needs in the treatment of cancer. OncoGenex has a deep oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. OGX-011, the lead candidate that has completed five Phase 2 clinical trials in prostate, lung and breast cancers, is designed to inhibit the production of a specific protein associated with treatment resistance; OGX-427 is in Phase 1 clinical development; SN2310 has completed the Phase 1 clinical trial; and CSP-9222 and OGX-225 are currently in pre-clinical development.

OGX-011, OGX-427 and OGX-225 utilize second-generation antisense technology, licensed from Isis Pharmaceuticals (NASDAQ: ISIS), to effectively target and inhibit production of specific proteins in tumor cells. OncoGenex and Isis partnered in the successful discovery of OGX-011, OGX-427 and OGX-225 and with respect to OGX-011, in its initial development. In 2008, OncoGenex and Isis amended their OGX-011 agreement to provide OncoGenex with sole rights to OGX-011 and sole responsibility for development and related costs and partnering decisions, subject to financial obligations to Isis. OncoGenex is also solely responsible for development and related costs and partnering decisions regarding OGX-427 and OGX-225. Key intellectual property related to OGX-011, OGX-427 and OGX-225 were discovered by the University of British Columbia and the Vancouver Prostate Centre, and were exclusively licensed to OncoGenex.

More information about OncoGenex is available at [www.oncogenex.com](http://www.oncogenex.com).

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements concerning the potential survival benefit of OGX-011, anticipated clinical development activities, timing of these activities, the ability of future trials to demonstrate clinical benefit and the potential for regulatory approvals. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements.

The potential risks and uncertainties associated with forward-looking statements include, among others, the possibility that any benefit in patient survival will not be maintained or will become less substantial as patient survival follow up continues, risks that clinical trials will not be successful or confirm earlier clinical trial results, including the risk that the survival benefit will not be confirmed by a Phase 3 clinical trial, risks associated with obtaining funding from third parties or completing a financing necessary to support the costs and expenses of a Phase 3 clinical trial, the timing and costs of clinical trials and regulatory approvals will be different than management currently anticipates, risks relating to the development, safety and efficacy of therapeutic drugs and potential applications for these products and the risk factors set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for fiscal year 2008. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof.

###

**OncoGenex Contact:**

Scott Cormack  
President & CEO  
(604) 736-3678  
scormack@oncogenex.com

**Media and Investor Contact:**

Jason Spark  
Porter Novelli Life Sciences  
(619) 849-6005  
jspark@pnlifesciences.com