**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): May 30, 2009**

# ONCOGENEX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **033-80623** | **95-4343413** |
|---|---|---|
| (State or other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **1522 217th Place S.E.**<br>**Bothell, Washington** | **98021** |
|---|---|
| (Address of Principal Executive Offices) | (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 May 30, 2009, OncoGenex Pharmaceuticals, Inc. issued two press releases entitled "OncoGenex Pharmaceuticals Announces OGX-011 Treatment Provides Survival Benefit in Randomized Phase 2 Trial in Advanced Metastatic Prostate Cancer" and "OncoGenex Pharmaceuticals Announces OGX-427 Treatment Demonstrates Safety, Evidence of Declines in Circulating Tumor Cells and Reductions in Tumor Markers in a Phase 1 Cancer Trial." A copy of the press releases are attached as Exhibit 99.1 and 99.2, respectively, 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

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release of OncoGenex Pharmaceuticals, Inc. dated May 30, 2009 |
| 99.2 | Press release of OncoGenex Pharmaceuticals, Inc. dated May 30, 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 2, 2009

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release of OncoGenex Pharmaceuticals, Inc. dated May 30, 2009 |
| 99.2 | Press release of OncoGenex Pharmaceuticals, Inc. dated May 30, 2009 |

**OncoGenex Pharmaceuticals Announces OGX-011 Treatment Provides Survival Benefit in Randomized Phase 2 Trial in Advanced Metastatic Prostate Cancer**

*Webcast at 7:10 p.m. Eastern Time Today*

BOTHELL, WA, and VANCOUVER, May 30, 2009 — OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced the final results of a Randomized Phase 2 Trial presented during an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. Analyses indicated a survival benefit in patients treated with OGX-011 in combination with docetaxel compared to docetaxel alone — the current standard care for patients with advanced prostate cancer:

1) 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.

2) 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.

3) A prospectively defined multivariate analysis indicated that the significant predictors of overall survival were treatment arm, performance status, and presence of metastases other than in bone or lymph nodes. Patients treated with OGX-011 had a rate of death 51% lower than patients treated with docetaxel alone (HR=0.49; p=0.012). Additional exploratory analyses found that the lower rate of death was associated with the effect of OGX-011 treatment even when varying amounts of chemotherapy were administered (i.e. OGX-011 treatment resulted in a lower rate of death when compared to the control arm for patients receiving 6 or less cycles of chemotherapy as well as for patients receiving 10 cycles of chemotherapy).

Data were presented by Dr. Kim Nguyen Chi, Principal Investigator and a medical oncologist at BC Cancer Agency — Vancouver Centre, representing the NCIC — Clinical Trials Group (NCIC-CTG). The survival curves presented by Dr. Chi are available at www.oncogenex.com.

“A 6.9 month median overall survival difference would represent a significant improvement over the current standard docetaxel therapy,” said Dr. Chi, Principal Investigator of the NCIC-CTG sponsored trial and presenter of the data at ASCO. “Docetaxel was approved in 2004 based on a 2.4 month survival advantage in advanced prostate cancer. The consistent results in favor of the OGX-011 treatment arm in this trial are a clear indication that Phase 3 trials are warranted.”

“A 39% reduction in death, consistent with the previously disclosed preliminary analysis, would be a significant advancement for treatment in this patient population,” said Scott Cormack, president and CEO of OncoGenex. “The multivariate analysis shows an even greater reduction in death rate than our preliminary data and increases our confidence that we are seeing a real and meaningful survival benefit for patients treated with OGX-011 in this Phase 2 study.”

**About the Randomized Phase 2 Trial and the Trial Results**

The trial enrolled 82 patients at 12 sites in Canada and the U.S. from September 2005 to December 2006. Patients were randomized to one of two treatment arms to receive either 640 mg per week of OGX-011 by intravenous infusion in combination with docetaxel and prednisone or docetaxel and prednisone alone. Patients in both treatment arms receive therapy until disease progression, toxicity or after receiving ten 3-week cycles of therapy. The primary endpoint of the trial was to achieve a 50% reduction in PSA from baseline in over 50% of the patients treated with OGX-011 plus docetaxel. Secondary endpoints included determining objective response and duration of response in those patients with measurable disease at baseline, determining the tolerability and toxicity of weekly OGX-011 and docetaxel when administered in combination, measuring the effect of OGX-011 plus docetaxel or docetaxel alone on serum clusterin levels and describing time to progression and overall patient survival. Baseline characteristics were well balanced between the treatment arms. In addition to the survival results presented and based on a median follow-up of 32 months, data were presented as summarized below.

- The OGX-011 plus docetaxel arm met the primary endpoint of the trial given that 58% of patients treated with OGX-011 plus docetaxel achieved confirmed PSA declines of 50% or greater.
- The median number of treatment cycles administered was 9 cycles in the OGX-011 plus docetaxel arm compared to 7 cycles in the docetaxel arm. The majority of patients either completed all 10 cycles of trial treatment (34 patients) or discontinued trial treatment based on disease progression (23 patients) or adverse events (14 patients).
- Fewer than half as many patients in the OGX-011 plus docetaxel arm (7 patients) discontinued trial treatment early for PSA progression and/or objective disease progression compared to the docetaxel arm (16 patients). Of the 9 patients in the OGX-011 arm that discontinued for adverse events, 7 of these patients experienced adverse events during the 8$^{th}$ and 9$^{th}$ treatment cycles.
- Evidence of a pharmacodynamic effect in the OGX-011 plus docetaxel arm was observed with statistically significant declines in serum clusterin levels within the first cycle of trial treatment when compared to levels in the docetaxel arm. OGX-011 has been shown to primarily target tissue clusterin levels with serum levels as an indicator of biological effect.
- Higher incidence of stable disease (20 patients in OGX-011 plus docetaxel arm versus 12 patients in docetaxel arm) with lower incidence of disease progression as best response (1 patient in OGX-011 plus docetaxel arm versus 4 patients in docetaxel arm) occurred in patients with measurable disease who were treated with OGX-011 plus docetaxel compared to the docetaxel arm; although, the incidence of overall response was comparable.

OGX-011 treatment was well tolerated in combination with docetaxel. There was an increase in incidence of mild fever, chills and creatinine levels (a laboratory measure for reduced kidney function) and a moderate to significant decrease in circulating lymphocytes in the blood (another laboratory measure) without any increase in infection rate compared to the docetaxel arm. The investigators concluded that the combination was well tolerated.

Brent Blumenstein, an independent statistician who conducted additional sensitivity analyses of the results, found that the survival benefit in the OGX-011 arm to be robust and not dependent on clinical trial sites or baseline characteristics of the patients.

“There is a clear separation of the survival curves,” said Blumenstein. “A hazard ratio of 0.61 indicates a distinct difference in survival rates and fully justifies further Phase 3 trials. It is rare for a new intervention at this stage of development to have such strong data from a randomized clinical trial.”

Cormack added, “These data clearly justify advancing to Phase 3 development, and we expect these data will be key in our partnering discussions for future clinical development and potential commercialization.”

The trial was supported by funding from the Canadian Cancer Society and was conducted by the NCIC Clinical Trials Group (NCIC CTG) based at Queen’s University in Kingston, Ontario. The trial was further supported by an unrestricted grant from Sanofi-Aventis.

**Webcast and Conference Call Today**

OncoGenex will hold a live webcast and conference call of presentations made at a Company hosted reception during the 2009 American Society of Clinical Oncology Annual Meeting (ASCO) today, May 30, 2009. The webcast will begin at 7:10 p.m. EDT.

During the reception, OncoGenex management and guest speakers will provide a comprehensive review of the final results of the randomized Phase 2 trial presented at the ASCO Annual Meeting, as well as discuss the treatment landscape and the relevance of clinical trial endpoints for prostate cancer.

To access the webcast, log on to the Investor Relations page of the OncoGenex Web site at www.oncogenex.com. Alternatively, you may access the live conference call by dialing 877-627-6544 (U.S. & Canada) or 719-325-4857 (International). A webcast replay will be available approximately two hours after the call and will be archived at www.oncogenex.com.

**About OGX-011**

OGX-011 is designed to inhibit the production of clusterin, a protein that is associated with cancer treatment resistance and is currently being evaluated in Phase 2 clinical trials in prostate, lung and breast cancer. At the 2009 American Urological Association Annual Meeting, OncoGenex reported Phase 2 data with OGX-011 in combination with second-line treatment of metastatic castrate resistant prostate cancer showing better than expected survival results, reductions in levels of clusterin, durable reductions in pain, and a decline in PSA, a protein that is often elevated in patients with prostate cancer.

Based on clinical results to date, OncoGenex intends to conduct 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 agreed on the design of two Phase 3 registration trials, via the Special Protocol Assessment (SPA) process, of OGX-011 in combination with second-line chemotherapy. One trial design investigates overall survival as the primary endpoint; the other trial design investigates pain palliation as the primary endpoint. Based on the survival benefit observed after combining OGX-011 with first-line docetaxel chemotherapy, OncoGenex has initiated discussions with the FDA regarding evaluating the overall survival benefit in patients treated with first-line chemotherapy, rather than second-line chemotherapy. OGX-011 has received Fast Track designation from the FDA for the treatment of progressive metastatic prostate cancer in combination with docetaxel.

**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 currently completing 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.

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.

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**OncoGenex Pharmaceuticals Announces OGX-427 Treatment Demonstrates Safety, Evidence of Declines in Circulating Tumor Cells and Reductions in Tumor Markers in a Phase 1 Cancer Trial**

BOTHELL, WA, and VANCOUVER, May 30, 2009 — OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced preliminary results of a Phase 1 trial presented during an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. Preliminary results as of April 2009 showed that OGX-427 was well tolerated as a monotherapy. In addition, OGX-427 demonstrated declines in circulating tumor cells at all doses evaluated as well as evidence of reduction in tumor markers. Reductions in circulating tumor cells and tumor markers both suggest single-agent activity warranting further clinical investigation.

The Phase 1 trial has evaluated 41 patients with a variety of cancers to date; enrollment is ongoing. The first phase of the study evaluated increasing doses of OGX-427 as a single agent up to 1000 mg. A maximum tolerated dose was not identified up to and including the 1000-mg dose of OGX-427 monotherapy. Subsequently, as defined by the protocol, an 800-mg dose of OGX-427 in combination with docetaxel was evaluated, to be followed by a 1000-mg dose of OGX-427 plus docetaxel. OGX-427 is administered as three loading doses within the first 9 days and then continued weekly, with three weeks defined as a treatment cycle, until disease progression or toxicity. In those groups receiving OGX-427 in combination with docetaxel, 75mg/M$^2$ docetaxel was administered on Day 1 of every 3-week cycle starting after completion of the OGX-427 loading doses.

**Safety Results**

Patients enrolled had a diagnosis of breast, ovarian, prostate or non-small cell lung cancer and most had failed multiple prior chemotherapy treatments. A median of 2 cycles (range of 1-8 cycles) was administered with the following safety results for OGX-427 as monotherapy:

- Criteria for a maximum tolerated dose were not met at the highest dose evaluated as monotherapy (1000 mg).
- No evidence of altered cardiac activity was observed.
- Majority of adverse events were mild and mainly occurred during the loading doses. Adverse events consisted of chills, itching and fatigue in over a third of patients.
- There was a trend for increasing incidence of some mild adverse events with escalating OGX-427 doses. For example, 33% of patients at the 200-mg dose compared to 67% of patients at the 1000-mg dose had mild adverse events during the loading doses.
- The half-life of OGX-427 in the blood remained constant, although there appeared to be an increase in maximum blood levels and a corresponding decease in blood clearance of OGX-427 as doses were escalated.

The combination of 800 mg OGX-427 with docetaxel was also well tolerated and escalation to 1000 mg OGX-427 with docetaxel will be evaluated next.

**Circulating Tumor Cell and Tumor Marker Results**

Circulating tumor cells (CTCs), an emerging metric to assess treatment effect, was evaluated at baseline before treatment and during treatment. Both total and Hsp27-positive CTCs were evaluated. Declines of 50% or greater in both total and Hsp27-positive CTCs were observed in over half of the patients in each cohort and in each cancer category. Declines in Hsp27 CTCs to 5 or less cells occurred in 27% of patients who had greater than 5 CTCs at baseline.

Reduction in tumor markers defined as declines of PSA levels in prostate cancer or CA-125 levels in ovarian cancer were also observed. A reduction in PSA level was observed in 7 of 20 patients (35%) with prostate cancer and a reduction in CA-125 levels was observed in 3 of 5 patients (60%) with ovarian cancer.

“CTCs are emerging as an exciting surrogate of anti-cancer activity. The frequent decreases in total and Hsp-27 positive CTC counts, coupled with decreases in serum PSA and CA-125 levels in patients with prostate and ovarian cancer, markers that strongly suggest single agent anti-cancer activity for OGX-427,” said Dr. Sebastien Hotte, Principal Investigator and a medical oncologist at Juravinski Cancer Centre, Hamilton, Ontario.

“We are very satisfied with the safety profile of OGX-427 to date in this trial and the early, strong indicators of anti-tumor and biological activity,” said Scott Cormack, president and CEO of OncoGenex Pharmaceuticals.

**About OGX-427**

OGX-427 is designed to reduce production of Hsp27, a protein that is over-produced in response to many cancer treatments including hormone ablation therapy, chemotherapy and radiation therapy. Hsp27 production has been shown to inhibit cell death in tumor cells through a variety of mechanisms. OGX-427 is being evaluated in a Phase 1 clinical trial for the treatment of solid tumors including prostate, non-small cell lung, breast, ovarian, and bladder cancers. Like OGX-011, this product candidate has potential as a treatment in a broad number of cancers.

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