# **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): October 13, 2008

## ONCOGENEX PHARMACEUTICALS, INC.

(Exact name of small business issuer as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

0-21243 (Commission File Number)

95-4343413 (IRS Employer Identification No.)

1522 217th Place S.E. **Bothell, Washington 98021** (Address of Principal Executive Offices) (Zip Code)

> (425) 487-9500 (Registrant's telephone number)

(Former name, former address and former fiscal year, 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-4c)) Item 8.01 Other Events. On October 13, 2008, OncoGenex Pharmaceuticals, Inc. issued a press release, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Item 9.01 Financial Statements and Exhibits. (d) Exhibits. Exhibit Number Description Press Release dated October 13, 2008 99.1 2

#### 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.

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

Date: October 14 2008

### EXHIBIT INDEX

Exhibit No.	Description			
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated October 13, 2008.			
	4			



#### OncoGenex Achieves Key Regulatory Milestone for Lead Product Candidate, OGX-011

FDA confirms appropriateness of durable pain palliation as a primary endpoint for product marketing approval

Milestone achievement results in release of escrowed shares

**BOTHELL, WA and VANCOUVER, Oct. 13/PRNewswire-FirstCall/** -OncoGenex Pharmaceuticals Inc. (NASDAQ: OGXI) today announced that it concluded a meeting with the U.S. Food and Drug Administration (FDA) on October 7, 2008, and that the FDA agreed that "durable pain palliation is an acceptable and desirable study endpoint" to support a product marketing approval for OGX-011 as a treatment for hormone refractory prostate cancer (HRPC). In addition, OncoGenex reported that the FDA provided guidance on the submitted protocol including recommendations on study endpoints, the appropriate patient population, entry criteria and study conduct. The company plans to revise and submit the protocol for completing a Special Protocol Assessment with the FDA prior to initiating the registration trial.

Based on the results of this meeting, the Board of Directors of OncoGenex Pharmaceuticals has approved the release of 25% §47,207) of the shares held in escrow pursuant to agreements related to Sonus Pharmaceuticals' merger with OncoGenex Technologies described in its Proxy Statement filed with the SEC on July 3, 2008. The escrow agreements provided for the release of 25% of the shares held in escrow following the occurrence of a meeting with the FDA to confirm that pain palliation is an appropriate primary endpoint to support a product marketing approval in prostate cancer. A total of 694,431 milestone shares remain in escrow.

"Our data combining OGX-011 with second line chemotherapy in patients with HRPC has shown potential improvement in both pain palliation and survival. On July 14, 2008, OncoGenex announced that the company successfully completed an SPA with the FDA on the design of another Phase 3 registration trial of OGX-011 targeting overall survival as a primary endpoint for the treatment of HRPC," said Scott Cormack, President and CEO of OncoGenex Pharmaceuticals. "Obtaining FDA's agreement that pain palliation is an appropriate primary endpoint to support product approval in prostate cancer and receiving FDA's guidance on trial designs is essential to our plans to pursue development of OGX-011 using appropriate primary endpoints such as pain palliation and survival."

This planned registration trial to evaluate pain palliation is based on encouraging preliminary data from a Phase 2 study in HRPC indicating that OGX-011 treatment may result in durable pain palliation. These Phase 2 data were presented at the 2008 annual meeting of the American Society of Clinical Oncology (ASCO) and reported in a

1

previous press release on June 2, 2008. In summary, the Phase 2 study included 42 patients with HRPC who had received first-line docetaxel therapy and required second-line chemotherapy. While follow up on surviving patients is still ongoing, preliminary findings related to pain palliation reported reductions in pain or analgesic use in approximately 50% of evaluable patients treated with either mitoxantrone plus OGX-011 or retreated with docetaxel plus OGX-011. These data are better than expected when compared to the 22-35% of patients receiving first-line chemotherapy who reported a reduction in pain in the primary Phase 3 study resulting in the approval of docetaxel (TAX 327 study) that was published in the October 7<sup>th</sup>, 2004 issue of the New England Journal of Medicine.

#### About OGX-011

OGX-011, also known as custirsen sodium, is designed to block production of clusterin, a cell survival protein that is over-produced in several cancer indications and in response to many cancer treatments, including hormone ablation therapy, chemotherapy and radiation therapy. Increased clusterin production is observed in many human cancers, including prostate, non-small cell lung, breast, ovarian, bladder, renal, pancreatic, anaplastic large cell lymphoma and colon cancers and melanoma. Increased clusterin production is linked to faster rates of cancer progression, treatment resistance and shorter survival duration. OGX-011 is being evaluated in five Phase 2 clinical trials, each of which has completed patient enrollment. Interim study results have previously been presented for each of the five clinical trials.

### **About OncoGenex Pharmaceuticals**

OncoGenex Pharmaceuticals is a biopharmaceutical company committed to the development and commercialization of new cancer 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 studies in prostate, lung and breast cancers, is designed to inhibit the production of a specific protein associated with treatment resistance; OGX-427 and SN2310 are in Phase 1 clinical development; and CSP-9222 and OGX-225 are currently in pre-clinical development. More information is available at www.oncogenex.com.

SOURCE: OncoGenex Pharmaceuticals, Inc.

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 agreements with the FDA regarding endpoints and clinical trial design and anticipated clinical and other product development activities and timing of these activities. 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. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. For example, statements of the Company's ability to gain FDA agreement on protocol design and time frames to do so, the strength of the combined oncology product pipeline, the timing of clinical trials and development efforts and the results of clinical and pre-clinical studies are all forward-looking statements. The potential risks and

2

uncertainties include, among others, the possibility that an agreement with FDA cannot be reached regarding a clinical trial using pain as the primary endpoint for OGX-011, the timing and costs of clinical trials and regulatory approvals, risks that clinical trials will not be successful or confirm earlier clinical trial results, risks associated with obtaining funding from third parties or completing a financing necessary to support the costs and expenses of clinical studies as well as research and development activities, as well as other risks relating to the development, safety and efficacy of therapeutic drugs and potential applications for these products. A more complete discussion of risks and uncertainties that may affect forward-looking statements is included in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for fiscal year 2007, and its Quarterly Report on Form 10-Q for the second quarter of 2008. No assurances can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do so, what impact they will have on the results of operations or financial condition of the Company. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof.