

ONCOGENEX PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

Filed 10/25/16 for the Period Ending 10/25/16

Address	19820 NORTH CREEK PARKWAY SUITE 201 BOTHELL, WA 98011
Telephone	425-686-1500
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**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 25, 2016**

ONCOGENEX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction of
Incorporation)

033-80623
(Commission File Number)

95-4343413
(IRS Employer Identification No.)

19820 North Creek Parkway
Bothell, Washington
(Address of Principal Executive Offices)

98011
(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))
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Item 8.01 Other Events.

On October 25, 2016, OncoGenex Pharmaceuticals, Inc. (Company) announced positive survival results from the final analysis of the Phase 2 Borealis-2 trial of apatersen in combination with docetaxel treatment that enrolled 200 patients with metastatic bladder cancer whose disease had progressed following first-line platinum-based chemotherapy. Patients who received apatersen treatment experienced a 20% reduction in risk of death, compared to patients receiving docetaxel alone (HR=.80; 95% CI: 0.65-0.98; p=0.078). The primary analysis was a superiority test of overall survival, performed at a one-sided 0.10 significance level using a stratified log-rank test. The trial was conducted by the Hoosier Cancer Research Network at 28 sites across the United States.

A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number**Description**

99.1

Press Release issued by OncoGenex Pharmaceuticals, Inc. dated October 25, 2016

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.

Date: October 25, 2016

ONCOGENEX PHARMACEUTICALS, INC.

/s/ John Bencich

John Bencich
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number

Description

99.1

Press Release issued by OncoGenex Pharmaceuticals, Inc. dated October 25, 2016

**OncoGenex Announces Positive Survival Results from Apatorsen Phase 2
Borealis-2™ Trial in Metastatic Bladder Cancer**

Randomized Trial of 200 Patients Meets Primary Endpoint of Overall Survival

BOTHELL, Wash. and VANCOUVER, British Columbia, Oct. 25, 2016 — OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today positive survival results from the final analysis of the Phase 2 Borealis-2™ trial of apatorsen in combination with docetaxel treatment that enrolled 200 patients with metastatic bladder cancer whose disease had progressed following first-line platinum-based chemotherapy. Patients who received apatorsen treatment experienced a 20% reduction in risk of death, compared to patients receiving docetaxel alone (HR=.80; 95% CI: 0.65-0.98; p=0.078). The primary analysis was a superiority test of overall survival, performed at a one-sided 0.10 significance level using a stratified log-rank test. The trial was conducted by the Hoosier Cancer Research Network at 28 sites across the United States.

Safety results in patients treated with apatorsen and docetaxel were similar to those observed in patients treated with docetaxel alone.

“People living with advanced bladder cancer who have failed initial therapies have few treatment options available to them. While research across different treatment modalities is underway, there continues to be a high unmet therapeutic need,” said one of the principal investigators, Jonathan Rosenberg, MD of Memorial Sloan Kettering Cancer Center. “The totality of the data evaluating apatorsen across first- and second-line chemotherapy treatment for bladder cancer suggests that it may provide clinical benefits in this highly aggressive disease.”

Apatorsen is designed to inhibit production of heat shock protein 27 (Hsp27) to disable cancer cells’ defenses and overcome treatment resistance. Hsp27 is an intracellular protein that protects cancer cells by helping them survive, leading to resistance and more aggressive cancer phenotypes.

“We are encouraged by these data that further support Hsp27 as a therapeutic target and add an additional level of evidence to previously completed trials of apatorsen in patients with bladder cancer,” said Scott Cormack, President and CEO of OncoGenex. “We look forward to completing the full data analysis from Borealis-2 and considering these data in our continuing work with MTS Health Partners in the exploration of strategic alternatives as announced in mid-August.”

About the Borealis-2 Trial

Borealis-2 is an investigator-sponsored, randomized Phase 2 trial evaluating a survival benefit with apatorsen in combination with docetaxel treatment compared to docetaxel treatment alone in approximately 200 patients with metastatic bladder cancer who have disease progression following first-line platinum-based chemotherapy.

About OncoGenex and Apatorsen

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. The company’s lead compound, apatorsen (OGX-427), is designed to inhibit production of Hsp27, disable cancer cells’ defenses and overcome treatment resistance. Hsp27 is an intracellular protein that protects cancer cells by helping them survive, leading to resistance and more aggressive cancer phenotypes. Both the potential single-

agent activity and synergistic activity of apatosen with cancer treatments may increase the overall benefit of existing therapies and augment the durability of treatment outcomes, which could lead to increased patient survival. More information is available at www.OncoGenex.com and at the company's Twitter account: https://twitter.com/OncoGenex_IR.

OncoGenex' Forward Looking Statements

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, but not limited to, statements regarding the potential benefits and potential development of our product candidates, clinical development plans and business strategies. 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. Such forward-looking statements are subject to risks and uncertainties, including, among others, the risk of failure or delays in our ongoing and future clinical trials, the risk that new developments in the rapidly evolving cancer therapy landscape require changes in our business strategy or clinical trial plans, or limit the potential benefits of our product candidates, the risk that we are unable to raise on acceptable terms the capital needed to complete our clinical trials, the risk that our product candidates do not demonstrate the hypothesized or expected benefits and the other factors described in our risk factors set forth in our filings with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

Borealis-2™ is a registered trademark of OncoGenex Pharmaceuticals, Inc.