ONCOGENEX PHARMACEUTICALS, INC.

FORM 8-K
(Current report filing)

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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 13, 2016

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.)**

19820 North Creek Parkway **Bothell, Washington**	**98011**
(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 8.01 Other Events.

On October 13, 2016, OncoGenex Pharmaceuticals, Inc. (Company) announced results from the final analysis of the Phase 3 ENSPIRIT trial of custirsen in patients whose non-small cell lung cancer has progressed following initial treatments. The trial did not meet the primary endpoint of demonstrating a statistically significant improvement in overall survival for patients treated with custirsen in combination with docetaxel compared to docetaxel alone. The median overall survival for the custirsen arm was 9.0 months versus 7.9 months for the control arm with a hazard ratio of 0.915 (one-sided p=0.178). In addition, there was no survival benefit when evaluated by histology. In 2015 a futility analysis was conducted which required a hazard ratio of less than 0.87 for the trial to continue. Safety results were consistent with those observed in previous trials of custirsen in combination with chemotherapy.

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 13, 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.

ONCOGENEX PHARMACEUTICALS, INC.

Date: October 13, 2016

/s/ John Bencich

John Bencich
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by OncoGenex Pharmaceuticals, Inc. dated October 13, 2016

Exhibit 99.1

OncoGenex Announces Results from the Phase 3 ENSPIRIT Trial of Custirsen in Non-Small Cell Lung Cancer

Company to Host Conference Call Today, Thursday, October 13, 2016 at 8:00 a.m. EDT

BOTHELL Wash. And VANCOUVER, British Columbia, Oct. 13, 2016 – OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) announced today results from the final analysis of the Phase 3 ENSPIRIT trial of custirsen in patients whose non-small cell lung cancer (NSCLC) has progressed following initial treatments. The trial did not meet the primary endpoint of demonstrating a statistically significant improvement in overall survival for patients treated with custirsen in combination with docetaxel compared to docetaxel alone. The median overall survival for the custirsen arm was 9.0 months versus 7.9 months for the control arm with a hazard ratio of 0.915 (one-sided p=0.178). Safety results were consistent with those observed in previous trials of custirsen in combination with chemotherapy.

“Following the negative results of previous custirsen trials, an early final analysis of the ENSPIRIT trial was conducted in an effort to conserve capital and extend our cash runway,” said Scott Cormack, President and CEO of OncoGenex. “We will continue to take appropriate steps to realize the most value for our shareholders once we receive the results of our apatorsen Phase 2 Borealis-2 bladder cancer trial which are expected by the end of October.”

OncoGenex is continuing to work with MTS Health Partners who has been advising the company in the exploration of strategic alternatives since mid-August.

“OncoGenex is grateful to the patients who participated in the ENSPIRIT trial and their families for their support, as well as our investigators and our employees for their commitment to improving cancer care for those who need it most,” Cormack continued.

Conference Call Details

OncoGenex will host a conference call at 8:00 a.m. Eastern Time today, Thursday, October 13, 2016, to discuss today’s news. A live event will be available on the Investor Relations section of the OncoGenex website at www.OncoGenex.com . Alternatively, visitors may access the live conference call by dialing (877) 606-1416 (U.S. & Canada) or (707) 287-9313 (International). A webcast replay will be available approximately two hours after the call and will be archived on www.OncoGenex.com for 90 days.

About the Phase 3 ENSPIRIT Trial

The Phase 3 ENSPIRIT trial is an international, randomized, open-label trial designed to evaluate custirsen for the treatment of advanced or metastatic NSCLC in patients who have progressed after initial chemotherapy treatment. The trial investigated if combining custirsen with docetaxel, a standard second-line NSCLC chemotherapy, has the potential to improve survival outcomes compared to docetaxel alone in these patients. The trial enrolled 664 patients at approximately 50 sites globally.

For more information on the ENSPIRIT trial, please visit http://clinicaltrials.gov/ct2/show/NCT01630733 .

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. The trial is being coordinated by the Hoosier Cancer Research Network at 27 sites across the United States.

About OncoGenex

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. OncoGenex has a diverse oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. Apatorsen is in Phase 2 clinical development and OGX-225 is currently in pre-clinical development. 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 development of our product candidates 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 risks and uncertainties include, among others, the risk that our product candidates do not demonstrate the hypothesized or expected benefits, the risk that we cannot achieve our business strategies including the completion of strategic transactions, the risk that new developments in the rapidly evolving cancer therapy landscape require changes in our clinical trial plans or limit the potential benefits of our products 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.

Media/IR Contact

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