

ONCOGENEX PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

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Address	19820 NORTH CREEK PARKWAY SUITE 201 BOTHELL, WA 98011
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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): August 4, 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 (see General Instructions A.2. below):

- 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 2.02 Results of Operations and Financial Condition.

On August 4, 2016, OncoGenex Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter of 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated August 4, 2016

The information in Item 2.02 of this Form 8-K and Exhibit 99.1 attached hereto is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), nor shall it 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 filing.

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: August 4, 2016

/s/ John Bencich
John Bencich
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release of OncoGenex Pharmaceuticals, Inc. dated August 4, 2016

OncoGenex Pharmaceuticals, Inc. Reports Financial Results for Second Quarter 2016*Pivotal Phase 3 Prostate Trial Results Expected in Third Quarter 2016*

BOTHELL, WA, and VANCOUVER, British Columbia, Aug. 4, 2016 – OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced its second quarter 2016 financial results and provided a summary of anticipated milestones.

Financial Results and Anticipated Near-term Milestones

As of June 30, 2016, the company's cash, cash equivalents, and short-term investments were \$39.7 million compared with \$55.2 million as of December 31, 2015.

Based on current expectations, OncoGenex believes that its cash, cash equivalents, and short-term investments will be sufficient to fund its currently planned operations into the third quarter of 2017. Depending on timing of enrollment or event-driven final analyses, the expected key milestones and activities are as follows:

- Custirsen
 - Announcing results from the AFFINITY trial, the phase 3 trial evaluating a survival benefit for custirsen in combination with cabazitaxel as second-line chemotherapy in approximately 630 patients with castrate-resistant prostate cancer. The final analysis for the intent-to-treat population is expected in the third quarter of 2016.
 - Announcing results from the ENSPIRIT trial, the phase 3 trial evaluating a survival benefit for custirsen in combination with docetaxel as second-line chemotherapy in approximately 700 patients with non-small cell lung cancer. The final survival analysis is expected by the first half of 2017.
- Apatorsen
 - Announcing results from the Borealis-2™ trial, an investigator-sponsored, randomized phase 2 trial evaluating apatorsen in combination with docetaxel treatment compared to docetaxel treatment alone in patients with advanced or metastatic bladder cancer. Final results are expected in the fourth quarter of 2016.
 - Completing a submission-ready investigational new drug application regarding apatorsen via intravesical administration in combination with Bacillus Calmette-Guerin (BCG) treatment in patients with non-muscle invasive bladder cancer.

Revenue for the three and six months ended June 30, 2016 was \$2.1 million and \$5.1 million, respectively, compared to \$4.0 million and \$5.4 million for the three and six months ended June 30, 2015, respectively. Revenue consists of recognition of deferred collaboration revenue representing our efforts in the development of custirsen. As of June 30, 2016, the full amount of the deferred collaboration revenue has been fully recognized.

Total operating expenses for the three and six months ended June 30, 2016 were \$8.5 million and \$15.9 million, respectively, compared to \$9.6 million and \$16.0 million for the three and six months ended June 30, 2015, respectively. Net loss for the three and six months ended June 30, 2016 was \$6.9 million

and \$10.6 million, respectively, compared to \$6.0 million and \$10.5 million for the three and six months ended June 30, 2015, respectively. As of Aug. 4, 2016 OncoGenex had 30,009,730 shares outstanding.

Conference Call Details

OncoGenex will host a conference call at 4:30 p.m. Eastern Time today, Thursday, Aug. 4, 2016, to provide a business update and discuss the second quarter 2016 financial results. A live event will be available on the Investor Relations section of the OncoGenex website at www.OncoGenex.com. Alternatively, the live conference call may be accessed 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 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. Custirsen is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer and in patients with advanced, unresectable non-small cell lung cancer. 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 company's anticipated product development activities, such as expected clinical trial enrollment, completion and design, statements regarding the potential benefits and potential development of its product candidates and statements regarding its expected financial results, use and adequacy of cash reserves and expected future cash requirements. 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 that the company's expected clinical trials may result in delays or may not demonstrate a clinical benefit for its product candidates, the risk that its product candidates may not receive regulatory approval or be successfully commercialized, the risk in the company's ability to complete required regulatory filings and requirements and/or future clinical trials, the risk of delayed future contractual payments and product revenue, the risk that new data from its product candidates or new developments in the rapidly evolving cancer therapy landscape require changes in its clinical trial plans or limit the potential benefits of its products, the risk that its products' market acceptance and potential size may differ materially from those projected, the risk that its cash resources are insufficient to fund its planned activities for the time period expected and the other factors described in the company's risk factors set forth in its 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.

OncoGenex Contact:

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(425) 686-1514

Consolidated Statements of Loss
(In thousands, except per share and share data)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Collaboration revenue	\$ 2,122	\$ 4,025	\$ 5,062	\$ 5,399
Operating expenses:				
Research and development	4,662	6,545	9,304	10,217
General and administrative	2,475	3,067	4,774	5,765
Restructuring costs (recovery)	(8)	-	423	-
Litigation settlement loss	1,375	-	1,375	-
Total operating expenses	<u>8,504</u>	<u>9,612</u>	<u>15,876</u>	<u>15,982</u>
Loss from operations	(6,382)	(5,587)	(10,814)	(10,583)
Other income (expense)	(507)	(423)	218	56
Net loss	<u>\$ (6,889)</u>	<u>\$ (6,010)</u>	<u>\$ (10,596)</u>	<u>\$ (10,527)</u>
Basic and diluted net loss per share	<u>\$ (0.23)</u>	<u>\$ (0.26)</u>	<u>\$ (0.35)</u>	<u>\$ (0.46)</u>
Weighted average number of basic and diluted common shares	<u>29,932,930</u>	<u>23,484,944</u>	<u>29,880,377</u>	<u>23,072,773</u>

Consolidated Balance Sheets
(In thousands)

	June 30, 2016	December 31, 2015
	(unaudited)	
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 40,000	\$ 55,458
Interest receivable	47	111
Amounts receivable	-	-
Prepaid expenses and other current assets	1,605	2,001
Property, equipment and other assets	546	639
Total assets	<u>\$ 42,198</u>	<u>\$ 58,209</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 10,212	\$ 13,217
Current portion of long-term obligations	57	52
Warrant liability	971	1,105
Lease termination liability	1,250	1,250
Litigation settlement accrual	1,375	-
Deferred collaboration revenue	-	5,040
Long term liabilities	84	105
Stockholders' equity	28,249	37,440
Total liabilities and stockholders' equity	<u>\$ 42,198</u>	<u>\$ 58,209</u>