
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): November 12, 2015

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 November 12, 2015, OncoGenex Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter of 2015. 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 November 12, 2015

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: November 12, 2015

/s/ John Bencich

John Bencich
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.

Description

99.1 Press release of OncoGenex Pharmaceuticals, Inc. dated November 12, 2015

OncoGenex Pharmaceuticals, Inc. Reports Financial Results for Third Quarter 2015

Conference call to be held on Thursday, November 12, 2015 at 4:30 p.m. Eastern Time

BOTHELL, WA, and VANCOUVER, British Columbia, November 12, 2015– OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGX1) today announced third quarter 2015 financial results and provided a summary of clinical developments and anticipated milestones.

Clinical Developments and Anticipated Near-term MilestonesCustirsen – Phase 3 Prostate Cancer Trials

- On September 27, 2015, OncoGenex announced results from additional exploratory analyses of the Phase 3 SYNERGY trial demonstrating that custirsen treatment significantly lowered serum clusterin (sCLU) levels from baseline in men with metastatic castrate-resistant prostate cancer (mCRPC). In addition, these data presented at the 2015 European Cancer Congress (ECC 2015) in Vienna showed that sCLU reductions after custirsen treatment resulted in higher two-year survival rates in patients who were at increased risk for poor outcomes. Of those patients with lower sCLU levels, the data also showed a correlation to an overall survival benefit for custirsen-treated patients who were at increased risk for poor outcomes.
- On October 8, 2015, OncoGenex announced that the European Medicines Agency (EMA) completed its review of the proposed amendment to the company's Phase 3 AFFINITY protocol and statistical analysis plan. Both the U.S. Food and Drug Administration (FDA) and the EMA have now completed their reviews and are supportive of the proposed amendment to the AFFINITY protocol and statistical analysis plan.
- Final results from the first of two analyses of the custirsen Phase 3 AFFINITY trial are expected by the end of this year. The first of these two analyses will determine the ability of custirsen to extend survival in a subgroup of men who are at increased risk for poor outcomes. This group is comprised of men having two or more of five common clinical features, including poor performance status, elevated prostate-specific antigen (PSA), elevated **lactate dehydrogenase** (LDH), decreased hemoglobin, and the presence of liver metastasis. If the final analysis shows efficacy in this subgroup, OncoGenex would proceed with discussions with the FDA and a new drug application filing.
- At the same time as the final analysis for the subgroup, interim analyses for both futility and efficacy is scheduled to occur in the intent to treat, or entire patient population, of the AFFINITY trial. If this interim analysis shows early efficacy, OncoGenex would proceed with an NDA filing for the entire trial population. If the early efficacy interim analysis does not show a highly significant difference, the study will continue as planned with final results are expected in the second half of 2016.

Apatorsen – Phase 2 Bladder, Lung Cancer Trials

- On September 27, 2015, the company announced additional analyses from the Borealis-1™ trial for its other lead product candidate, apatorsen. The results confirmed that patients with advanced bladder cancer at increased risk for poor outcomes had increased baseline levels of both circulating tumor cells (CTC) and serum heat shock protein 27 (Hsp27). The study showed that baseline Hsp27 and CTC levels were additional risk factors for survival outcomes. These
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results were presented at ECC 2015 and have been accepted for oral presentation at the upcoming 7th European Multidisciplinary Meeting on Urological Cancers (EMUC 2015).

- On September 30, 2015, the company announced that Borealis-2™, an investigator-sponsored, randomized Phase 2 trial, met its target enrollment of 200 patients. The trial is designed to evaluate apatorsen in combination with docetaxel in patients with advanced or metastatic bladder cancer who have disease progression following first-line platinum-based chemotherapy. Borealis-2 is sponsored by Hoosier Cancer Research Network and being conducted at 27 sites across the United States. Results are expected in 2016.
- Primary progression-free survival (PFS) results from the Spruce™ trial are expected in the first quarter of 2016, with continued survival follow up expected later next year. The Spruce trial is an investigator-sponsored, randomized, placebo-controlled Phase 2 trial designed to determine if adding apatorsen to carboplatin and pemetrexed therapy can extend PFS outcome in patients with previously untreated advanced non-squamous NSCLC.

“This is a pivotal time in the company’s history with results expected by the end of this year from the first of two custirsen Phase 3 AFFINITY trial final analyses. We look forward to this important milestone,” said Scott Cormack, President and CEO of OncoGenex. “We anticipate additional milestones throughout 2016 including final survival analysis of all patients from the AFFINITY study and possible ENSPIRIT lung cancer results, as well as several upcoming Phase 2 data readouts in our apatorsen program.”

Financial Update and Results

- As of September 30, 2015, our cash, cash equivalents and short-term investments increased to \$65.9 million from \$47.1 million as of December 31, 2014.
 - Based on our current expectations, we believe that our cash, cash equivalents, and short-term investments will be sufficient to fund our currently planned operations into the first quarter of 2017, which may include:
 - announcing AFFINITY trial results, including final results of the poor prognosis subpopulation by the end of 2015 and final analysis for the ITT population in the second half of 2016, depending on timing of the event-driven final analysis;
 - announcing ENSPIRIT trial results, which could be available in the second half of 2016;
 - announcing Spruce trial results for the primary PFS endpoint in the first quarter of 2016;
 - announcing Borealis-2 trial results in 2016;
 - completing enrollment in the Pacific trial; and,
 - continuing enrollment in the Spruce-2 trial, formerly referred to as the Cedar Trial
 - Revenue for the three months ended September 30, 2015 increased to \$6.7 million from \$4.8 million for the three months ended September 30, 2014. Revenue for the nine months ended September 30, 2015 decreased to \$12.1 million from \$21.5 million for the nine months ended September 30, 2014.
 - Total operating expenses for the three and nine months ended September 30, 2015 were \$11.4 million and \$27.4 million, respectively, compared to \$12.0 million and \$44.3 million for the three and nine months ended September 30, 2014, respectively.
 - Net loss for the three and nine months ended September 30, 2015 was \$4.6 million, or \$0.16 per diluted common share, and \$15.1 million, or \$0.60 per diluted common share, respectively, compared with \$4.9 million, or \$0.23 per diluted common share, and \$20.6 million, or \$1.21 per diluted common share for the three and nine months ended September 30, 2014, respectively.
 - As of November 12, 2015, OncoGenex had 29,804,273 shares outstanding.
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Conference Call Details

OncoGenex will host a conference call at 4:30 p.m. Eastern Time today, Thursday, November 12, 2015, to provide a business update and discuss the third quarter 2015 financial results. A live event will be available on the Investor Relations section of the OncoGenex website at www.OncoGenex.com. Alternatively, you 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 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 product candidates do not demonstrate the hypothesized or expected benefits, the risk of delays in its expected clinical trials, the risk that 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 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-1™, Borealis-2™, and Spruce™ are registered trademarks of OncoGenex Pharmaceuticals, Inc.

OncoGenex Contact:

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

	<u>Three months ended Sept 30,</u>		<u>Nine months ended Sept 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Collaboration revenue	\$ 6,737	\$ 4,803	\$ 12,136	\$ 21,463
Operating expenses:				
Research and development	8,303	9,586	18,520	36,372
General and administrative	3,125	2,459	8,890	7,892
Total operating expenses	<u>11,428</u>	<u>12,045</u>	<u>27,410</u>	<u>44,264</u>
Loss from operations	(4,691)	(7,242)	(15,274)	(22,801)
Other income (expense)	141	2,335	197	2,242
Net loss	<u>\$ (4,550)</u>	<u>\$ (4,907)</u>	<u>\$ (15,077)</u>	<u>\$ (20,559)</u>
Basic and diluted net loss per share	<u>\$ (0.16)</u>	<u>\$ (0.23)</u>	<u>\$ (0.60)</u>	<u>\$ (1.21)</u>
Weighted average number of basic and diluted common shares	<u>28,538,918</u>	<u>21,079,310</u>	<u>24,914,844</u>	<u>16,952,793</u>

Consolidated Balance Sheets
(In thousands)

	<u>September 30,</u>	<u>December 31,</u>
	<u>2015</u>	<u>2014</u>
	(unaudited)	
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 66,159	\$ 47,308
Interest receivable	48	113
Amounts receivable	13	5,676
Prepaid expenses and other current assets	1,599	2,664
Property, equipment and other assets	418	530
Total assets	<u>\$ 68,237</u>	<u>\$ 56,291</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 14,168	\$ 15,730
Current portion of long-term obligations	53	236
Warrant liability	2,836	3,002
Lease termination liability	1,250	3,250
Deferred collaboration revenue	11,041	—
Long term liabilities	117	14
Stockholders' equity	38,772	34,059
Total liabilities and stockholders' equity	<u>\$ 68,237</u>	<u>\$ 56,291</u>