

CYTRX CORP
Form 8-K
July 26, 2011

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): July 26, 2011

CYTRX CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware

**(State or Other Jurisdiction
of Incorporation)**

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000-15327
(Commission

58-1642740
(I.R.S. Employer

File Number)

Identification No.)

11726 San Vicente Boulevard, Suite 650

Los Angeles, California
(Address of Principal Executive Offices)

90049
(Zip Code)

(310) 826-5648

(Registrant's Telephone Number, Including Area Code)

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 Instruction 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))

ITEM 8.01 OTHER EVENTS

CytRx Corporation (we, us, our and the Company) provides the following information for the purpose of updating such information contained in previously filed reports:

OUR CLINICAL DEVELOPMENT PROGRAMS

Bafetinib

Phase I Study. In November 2008, we announced that bafetinib demonstrated clinical responses in patients with CML in a Phase I clinical trial conducted in patients with CML and other leukemias that have a certain mutation called the Philadelphia Chromosome (Ph+) and are intolerant of or resistant to Gleevec and, in some cases, second-line tyrosine kinase inhibitors such as dasatinib (Sprycel®) and nilotinib (Tasigna®). The clinical trial was designed to identify the optimal dose for possible future studies by escalating doses from 30 mg once per day to up to 480 mg twice per day in a total of 56 patients with Ph+ leukemias. Of the patients, 31 had CML in chronic phase (CML-CP), nine were in accelerated phase (CML-AP), seven were in blast phase (CML-BP), and nine had Ph+ acute lymphocytic leukemia. The clinical trial was conducted at seven clinical sites in the US, Germany, and Israel, with Hagop Kantarjian, M.D., Professor & Chairman, Department of Leukemia, The University of Texas, M.D. Anderson Cancer Center, serving as the Principal Investigator. In the 31 patients with CML-CP, a major cytogenetic response rate of 19.4% was seen.

The maximum tolerated dose was determined to be 240-360 mg given twice per day, based on evidence of increasing potential liver toxicity at higher doses. Common adverse events (observed in greater than 20% of patients in the 240 mg twice per day dose group) were gastrointestinal toxicity, swelling, and fatigue. There was no evidence of fluid accumulating around the lungs, or significant changes in a certain heart rhythm called QTc prolongation, which are serious side effects known to occur in patients treated with approved drugs for this indication. Approximately 13% of patients across all dose groups discontinued dosing due to unacceptable toxicity.

LICENSE AGREEMENTS

Tamibarotene

We have agreements with TMRC for the license of patent rights held by TMRC for North American and European development and commercialization of tamibarotene. The license is exclusive, applies to all products that may be subject to the licensed intellectual property and may be used in the treatment of APL and NSCLC. We may sublicense the intellectual property in our sole discretion. The agreement also grants us an option to include within the license the use of the drug in certain other cancers.

Under the agreement for North American rights, we must pay TMRC royalties based on net sales and make payments to TMRC in the aggregate of up to ¥ 490 million upon meeting clinical, regulatory, and sales milestones up to and including the first commercial sale of the product for the treatment of APL. Further milestone payments may become due upon certain events related to other indications.

Under the agreement for European rights, we must pay TMRC royalties based on net sales and make payments to TMRC in the aggregate of ¥ 480 million upon meeting clinical, regulatory and sales milestones up to and including the first commercial sale of the product for treatment of APL. Further milestone payments may become due upon certain events related to other indications.

Under the agreements, we must use commercially reasonable efforts to conduct the research and development activities we determine are necessary to obtain regulatory approval to market the product in those countries in North America and Europe that we determine are commercially feasible.

The agreements will expire upon the expiration of the subject patent rights, or 15 years from the date of first commercial sale of product in North America or Europe, as applicable, whichever is later. The agreement may be terminated if either party is in breach and the breach is not cured within a required amount of time. We may also terminate the agreement in the event of a material change in the safety profile of the technology that makes continued development impossible.

Item 9.01 Exhibits

(d) Exhibits

There are filed as part of this report the exhibits listed on the accompanying Index to Exhibits, which information is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 26, 2011

By: /s/ JOHN Y. CALOZ
John Y. Caloz
Chief Financial Officer

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Index to Exhibits

Exhibit No.	Description
3.1	Certificate of Amendment to Restated Certificate of Incorporation
3.2	Certificate of Amendment to Restated Certificate of Incorporation
3.3	Certificate of Increase of Shares Designated as Series A Junior Participating Preferred Stock
10.1	License Agreement dated as of August 28, 2007 between Innovive Pharmaceuticals, Inc. and TMRC Co. Ltd.*
10.2	Second Amendment to Third Amended and Restated Employment Agreement, dated May 11, 2009, between Cytrx Corporation and Steven A. Kriegsman

* Incorporated by reference to the Quarterly Report on Form 10-Q of CytRx Oncology Corp (f/k/a Innovive Pharmaceuticals, Inc.) filed on November 14, 2007.

Confidential treatment has been requested or granted for certain portions which have been blanked out in the copy of the exhibit filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission.