

TARGETED GENETICS CORP /WA/
Form 8-K
March 03, 2009

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): February 25, 2009

Targeted Genetics Corporation

(Exact name of registrant as specified in its charter)

Washington (State or other jurisdiction of incorporation)	0-23930 (Commission File Number)	91-1549568 (IRS Employer Identification No.)
--	---	---

1100 Olive Way, Suite 100, Seattle, Washington (Address of principal executive offices)	98101 (Zip Code)
---	----------------------------

Registrant's telephone number, including area code (206) 623-7612

Not Applicable

(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 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)

Edgar Filing: TARGETED GENETICS CORP /WA/ - Form 8-K

- “ 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 1.01. Entry into a Material Definitive Agreement.

On February 25, 2009, Targeted Genetics Corporation (the Company) and Celladon Corporation (Celladon) entered into a License Agreement covering specified adeno-associated virus (AAV)-based gene therapy products, including Celladon's MYDICAL (AAV1/SERCA2a) product candidate for the treatment of congestive heart failure (the License Agreement), and a Manufacturing Agreement covering the manufacture by the Company of MYDICAL pre-bulk drug substance and the transfer of related manufacturing capability to a contract manufacturing organization (CMO) designated by Celladon (the Manufacturing Agreement), and together with the License Agreement, the New Celladon Agreements. These agreements replaced the December 31, 2004 Collaboration Agreement and the December 31, 2004 Manufacturing Agreement between the Company and Celladon (the Terminated Celladon Agreements), which were terminated as described in Item 1.02 below.

The following is a list of certain key differences between the New Celladon Agreements and the Terminated Celladon Agreements:

Increased payments to the Company in 2009 to support manufacture of MYDICAL

Transition of manufacture and control over manufacture to Celladon

Broader permitted field of use in license to Celladon

Changes to potential milestone and royalty payments

Payments to the Company upon specified strategic transactions involving Celladon
License Agreement

Under the License Agreement, the Company granted to Celladon an exclusive license under specified Company-owned and -licensed technology to develop defined AAV-delivered gene therapy products (Celladon Products). The Company also agreed to release certain manufacturing-related technology and materials to Celladon in connection with the transfer of manufacturing capability under the Manufacturing Agreement, as described below. The Company received a license from Celladon to certain improvements to the licensed technology made by Celladon, its affiliates and its sublicensees.

The Company will receive royalties on any sales of Celladon Products developed in connection with the License Agreement. The Company will also receive milestone payments upon the achievement of specified development- and regulatory-based milestones for Celladon Products, and payments in the event of partnering or other licensing transactions or merger or asset sale transactions relating to Celladon Products. In addition, Celladon is responsible for making payments due to third parties with respect to technology licensed to the Company by such third parties and sublicensed by the Company to Celladon under the License Agreement.

Celladon has the right to terminate the License Agreement with or without cause after June 30, 2009. Either party may terminate for the material breach or bankruptcy of the other party.

Manufacturing Agreement

Under the Manufacturing Agreement, the Company will manufacture MYDICAL pre-bulk drug substance for Celladon's Phase III clinical trial use, at Celladon's expense. The Company will also provide, to one or more third-party CMOs designated by Celladon, the Company's existing analytical methods and manufacturing and other technology and know-how necessary for the CMO to replicate the Company's manufacturing and testing of MYDICAL. The Company will retain the right to manufacture Company products through the same CMO(s), using the technology and know-how that was provided to the CMO. Celladon will assume responsibility for manufacturing and testing clinical and commercial Celladon products after the completion of the Phase III manufacturing campaign. The Manufacturing Agreement will terminate on the earlier of July 31, 2009 or the termination of the License Agreement. Celladon will make payments to the Company throughout the term to support the manufacturing campaign under the Manufacturing Agreement.

Item 1.02. Termination of a Material Definitive Agreement.

On February 25, 2009, the Company and Celladon terminated the Collaboration Agreement dated December 31, 2004 (the Collaboration Agreement) and the Manufacturing Agreement dated December 31, 2004 (the Original Manufacturing Agreement), which agreements covered the development of AAV-based gene therapies for the treatment of congestive heart failure. These agreements were replaced by the License Agreement and Manufacturing Agreement described above in Item 1.01.

Collaboration Agreement

Under the Collaboration Agreement, the Company funded \$2 million of the development, manufacture and preclinical development of AAV vectors, and Celladon paid for all other development costs incurred by the Company in performing activities under the Collaboration Agreement and the Original Manufacturing Agreement. The Company was entitled to receive milestone payments from Celladon for meeting certain development- and regulatory-based milestones for product candidates developed under the Collaboration Agreement, plus royalties on any net sales of products developed under the Collaboration Agreement and approved for sale and use in humans. Neither party was allowed to alone develop or commercialize certain categories of products that the parties developed together during the term of the Collaboration Agreement.

The Company incurred no early termination penalties as a result of terminating the Collaboration Agreement.

Manufacturing Agreement

Under the Manufacturing Agreement, the Company supplied clinical materials to Celladon and was responsible for the manufacture and supply of all of Celladon's product requirements under the Manufacturing Agreement for Phase I and Phase II clinical trials. Celladon was responsible for the conduct of the clinical trials for any clinical materials produced under the Manufacturing Agreement.

The Company incurred no early termination penalties as a result of terminating the Manufacturing Agreement.

SIGNATURES

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

TARGETED GENETICS CORPORATION

Dated: March 3, 2009

By: /s/ DAVID J. POSTON
David J. Poston

Vice President Finance and Chief Financial Officer