

TARGETED GENETICS CORP /WA/
Form 8-K
June 24, 2004

**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): June 22, 2004

Targeted Genetics Corporation

(Exact name of registrant as specified in charter)

| | | |
|---|-----------------------------|--------------------------------------|
| Washington | 0-23930 | 91-1549568 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |
| 1100 Olive Way, Suite 100 Seattle, Washington 98101 | | |
| (Address of principal executive offices and Zip Code) | | |
| (206) 623-7612 | | |
| (Registrant's telephone number, including area code) | | |

Not Applicable
(Former name or former address, if changed since last report)

Item 5. Other Events and Regulation FD Disclosure.

On June 23, 2004, Targeted Genetics Corporation issued a press release announcing the interim results of its Phase IIb study on its treatment for Cystic Fibrosis. A copy of the press release is furnished as Exhibit 99.1 and is incorporated into this current report by reference.

Item 7. Exhibits.

- (a) Financial statements of business acquired.

Not applicable.

- (b) Pro forma financial information.

Not applicable.

- (c) Exhibits.

| <u>Exhibit</u> <u>No.</u> | <u>Description</u> |
|------------------------------|--|
| 99.1 | Press Release of Targeted Genetics Corporation dated June 23, 2004 |
| 99.2 | Press Release of Targeted Genetics Corporation dated June 22, 2004 |

Item 9. Regulation FD Disclosure

On June 22, 2004, Targeted Genetics Corporation issued a press release announcing the sale of CellExSys, Inc., its majority-owned subsidiary, to Chromos Molecular Systems, Inc. A copy of the press release is furnished as Exhibit 99.2 and is incorporated into this current report by reference.

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

Date: June 23, 2004

By: /s/ Todd E. Simpson
Todd E. Simpson
Vice President, Finance and
Administration, Chief Financial
Officer, Secretary and Treasurer
(Principal Financial and Accounting
Officer)

EXHIBIT INDEX

Exhibit

SIGNATURES

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|------------|--|
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Exhibit 99.1

Contact:

Targeted Genetics Corporation
Courtney Self
(206) 521-7392

RESULTS FROM INTERIM ANALYSIS SUPPORT CONTINUATION OF
TARGETED GENETICS' PHASE IIB CYSTIC FIBROSIS

CLINICAL TRIAL

- Clinical Trial Remains on Track for Completion of Patient Dosing by End of 2004 -

Seattle, WA June 23, 2004 Targeted Genetics Corporation (NASDAQ: TGEN) today announced that an independent data monitoring committee (DMC) met for its scheduled interim analysis of a Phase IIB clinical trial of the Company's product candidate, tgAAVCF, to treat patients with cystic fibrosis (CF). Based upon its review, the DMC recommended continuation of the study as planned. The DMC provided its recommendation based upon an analysis of whether or not there was a chance that, upon full patient enrollment, the study could show a statistically significant positive impact on lung function measurements in patients treated with tgAAVCF compared to placebo.

Targeted Genetics' ongoing Phase IIB clinical trial has advanced further than any other CF gene therapy program to date, and we are pleased to continue this study based on the DMC's recommendation, said H. Stewart Parker, president and chief executive officer of Targeted Genetics.

This recommendation allows us to continue to generate clinical results and assess the ability of this product candidate to improve lung function in patients with CF. There remains a significant unmet need in the CF patient community for treatments that address the underlying cause of this chronic disease. We are optimistic about this trial and hope it will lead to a true advance in the treatment of CF.

This Phase IIB, double-blind, randomized, placebo-controlled study is partially funded by Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT), the drug discovery and development affiliate of the Cystic Fibrosis Foundation, and is being conducted through CFFT's Therapeutics Development Network. The trial includes bi-monthly evaluation of lung function after repeat dosing of tgAAVCF. Researchers also are assessing the impact of tgAAVCF on inflammation and biologic markers over time when compared to placebo. The study continues to monitor the safety and tolerability profile of tgAAVCF. A total of 100 patients, 12 years of age and older, are being evaluated, 50 in the treatment group and 50 in the placebo group. Study participants receive two doses of 1×10^{13} DNase resistant particles (DRP) of tgAAVCF or placebo, delivered via nebulizer at day 0 and day 30 of the study and are evaluated for efficacy every two weeks for a total of 90 days. Study participants are being monitored for safety for seven months.

The planned interim analysis was conducted after 53 patients were dosed with either the product candidate or placebo. The DMC did not raise any safety concerns and recommended continuation of the trial. In order to protect the integrity of the trial, the complete, unblinded results will not be made available to Targeted Genetics until the study is completed. The DMC is an independent group of experts that was established by CFFT to monitor the safety and efficacy data. The primary role of the DMC is to safeguard the interests of current and future patients in the trial and act in an advisory capacity to Targeted Genetics and the Cystic Fibrosis Foundation.

About Targeted Genetics

Targeted Genetics Corporation develops gene-based products for preventing and treating acquired and inherited diseases. The Company has three clinical product development programs, targeting cystic fibrosis, AIDS prophylaxis and rheumatoid arthritis. The Company also has a promising pipeline of product candidates focused on hemophilia and cancer and a broad platform of gene delivery technologies. For more information about Targeted Genetics visit its website at www.targetedgenetics.com.

This release contains forward-looking statements regarding our research programs, clinical trials, product development and potential related to tgAAVCF and other statements about our plans, objectives, intentions and expectations. These statements, involve current expectations, forecasts of future events and other statements that are not historical facts. Inaccurate assumptions and known and unknown risks and uncertainties can affect the accuracy of forward-looking statements. Factors that could affect our actual results include, but are not limited to, the timing, nature and results of our research and our clinical trials, our preclinical results with animals are not necessarily indicative of results that will be obtained in humans, our ability to obtain and maintain regulatory or institutional approvals, our ability to obtain, maintain and protect our intellectual property related to tgAAVCF, and our ability to raise capital when needed, as well as other risk factors described in the section entitled Factors Affecting Our Operating Results, Our Business and Our Stock Price in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2004. You should not rely unduly on these forward-looking statements, which apply only as of the date of this release. We undertake no duty to publicly announce or report revisions to these statements as new information becomes available that may change our expectations.

Exhibit 99.2

[GRAPHIC OMITTED]

Contact:

Targeted Genetics Corporation
Courtney Self
(206) 521-7392

CELLEXSYS ANNOUNCES MERGER AGREEMENT WITH CHROMOS

**Merger Combines Broad Intellectual Property,
Expands Product Development Opportunity**

Seattle, WA June 22, 2004 CellExSys, Inc. announced today that the Company has signed a definitive merger agreement with Chromos Molecular Systems, Inc. (TSX: CHR). Under the terms of the agreement, Chromos will acquire all of the outstanding shares of CellExSys through the merger between CellExSys and Chromos Inc., a wholly owned subsidiary of Chromos. CellExSys, based in Seattle, WA, is a majority-owned subsidiary of Targeted Genetics Corporation (NASDAQ: TGEN). The acquisition will provide Chromos with new cell therapy technology and a strong preclinical pipeline to support product development to treat infectious diseases and cancers.

On closing Chromos will issue to CellExSys shareholders 1,500,000 common shares of Chromos and a secured convertible debenture in principal amount of approximately \$2,500,000. The convertible debenture will bear interest at the rate of 2 percent per annum and the principal will be due in two installments over two years. The principal will be repayable by Chromos at its option either in cash or by the issuance of common shares of Chromos. In addition, Chromos has agreed to fund certain of CellExSys' operational costs through closing of the acquisition. The acquisition has been approved by the boards of directors of both companies and is subject to approval by the stockholders of CellExSys and other customary closing conditions. If the debenture is fully paid in common shares of Chromos, the shareholders of CellExSys would receive up to approximately 17.2 percent of Chromos, based on current shares issued and outstanding.

This transaction between CellExSys and Chromos provides an infrastructure to advance T cell therapy technology into human clinical trials, and allows Targeted Genetics, along with other shareholders of CellExSys, to benefit from the potential value that can come with the advancement of this technology, said H. Stewart Parker, president and chief executive officer of Targeted Genetics. While outside of the scope of Targeted Genetics' core focus, we believe that CellExSys has a substantial intellectual property position related to a unique approach for generating large numbers of antigen-specific T-cells rapidly while retaining the antigen specificity of these cells. This Rapid Expansion Method (REM) technology can be used to generate autologous antigen-specific cytotoxic T lymphocyte (CTL) isolates for use in adoptive immunotherapy, supporting the opportunity inherent in this combined company to develop products to treat a variety of diseases, such as cancers or infectious diseases.

This strategic acquisition combines the proprietary technology of Chromos with CellExSys' proprietary T cell therapy technology to accelerate our product development pipeline and expand our partnering opportunities, said Alistair Duncan, president and chief executive officer of Chromos. We believe this transaction creates greater long-term value for both Chromos and CellExSys shareholders because it allows us to realize the commercial potential of cell therapy through our ability to now access multiple product opportunities in a variety of disease indications. Consistent with our corporate strategy to grow Chromos into a leading cell therapy company, this acquisition enables us to make the

[GRAPHIC OMITTED]

critical transition from a platform company to a product development company, while allowing us to build on the advancements realized in our cellular protein production programs.

About CellExSys, Inc.

CellExSys, Inc. was established in late 2000 as a subsidiary of Targeted Genetics Corporation, with a focus on commercializing a robust portfolio of cell therapy assets that are outside of Targeted Genetics' core focus. The Company's patient-specific technology platform has yielded promising results in preclinical studies in a variety of viral diseases and cancers. The Company's core technology, the Rapid Expansion Method (REM), was originally developed at The Fred Hutchinson Cancer Research Center in Seattle, Washington and is licensed exclusively to CellExSys. For more information about CellExSys, please visit our website at www.cellexsys.com.

The securities to be issued to CellExSys' stockholders have not been and will not be registered under the United States Securities Act of 1933, as amended, and may not be offered or sold in the United States unless an exemption from registration is available.

Note: This press release contains forward-looking statements concerning the pending merger transaction, the anticipated benefits of the transaction to Targeted Genetics and CellExSys if it is completed, initiatives proposed by Chromos for CellExSys, expectations as to CellExSys position in the market for infectious disease and cancer treatments and Chromos' anticipated cash position. Forward-looking statements are not statements of historical fact, and actual events or results may differ materially from those anticipated by Targeted and Chromos and described in the forward-looking statements, as the result of a variety of risks, uncertainties and other factors; including, without limitation, the risk that one or more of the parties may not perform its obligations under its agreement with CellExSys and its shareholders, including Targeted Genetics; that conditions to the closing of the acquisition may not be satisfied; that one or more third parties may make competing acquisition proposals, commence litigation, or take other action to seek to delay or prevent closing of the acquisition; that planned business initiatives could be delayed or cancelled or could prove ineffective; that Chromos and CellExSys may not realize the expected benefits to their combined businesses from the acquisition due to competition, introduction by competitors of new products or technologies or pricing or initiatives, and the possible emergence of post acquisition integration problems with Chromos or that Chromos may have unanticipated costs and expenses or cost overruns that could cause its cash position to be lower than anticipated as well as the other risks identified in Targeted Genetics' periodic reports available at www.sec.gov and Chromos' periodic reports available at www.sedar.com. Neither Targeted Genetics nor Chromos assumes any obligation to update forward-looking statements to reflect future events.
