TARGETED GENETICS CORP /WA/
Form 8-K
January 22, 2004

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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) January 20, 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)		(Zip Code)

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

Not Applicable

(Former name or former address, if changed since last report)

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Item 5. Other Events.

Targeted Genetics Corporation (Nasdaq: TGEN) announced today that it was granted regulatory approval to begin its rheumatoid arthritis (RA) Phase I clinical trial by the U.S. Food & Drug Administration (FDA) and Health Canada. The Company plans to dose the first patient during the first quarter of 2004. The trial will be conducted in up to eight sites in the US and Canada. Dr. Philip Mease, Chief, Rheumatology Clinical Research Division of Swedish Hospital Medical Center and Head of Seattle Rheumatology Associates, and Dr. Edward Keystone, Professor of Medicine, University of Toronto, are the lead investigators in the trial.

The trial is a multi-center, randomized, double-blind, placebo-controlled, dose escalation study designed to assess safety of intra-articular delivery of tgAAC94. Other secondary parameters assessed are the efficacy of intra-articular administration of tgAAC94 in reducing pain and swelling in the injected joint and overall disease activity. The amount of local and circulating TNFR:Fc protein will also be measured. The study will enroll up to 32 adult subjects. Participants will receive a single injection of tgAAC94 directly into an affected joint and will have disease symptoms assessed at various time points after dosing. Patients will be followed for 24 weeks after receiving the first dose.

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Item 9. Regulation FD Disclosure.

The press release disclosed in Item 9 contained a typographical error in the third paragraph that stated the year as 2007 when the correct year was 2011 which has been corrected in the press release below.

TARGETED GENETICS RECEIVES APPROVAL TO BEGIN
CLINICAL TRIAL OF tgAAC94 IN RHEUMATOID ARTHRITIS

Seattle, WA January 20, 2004 Targeted Genetics Corporation (Nasdaq: TGEN) announced today that it was granted regulatory approval to begin its rheumatoid arthritis (RA) Phase I clinical trial by the U.S. Food & Drug Administration (FDA) and Health Canada. The Company plans to dose the first patient during the first quarter of 2004. The trial will be conducted in up to eight sites in the US and Canada. Dr. Philip Mease, Chief, Rheumatology Clinical Research Division of Swedish Hospital Medical Center and Head of Seattle Rheumatology Associates, and Dr. Edward Keystone, Professor of Medicine, University of Toronto, are the lead investigators in the trial.

Regulatory approval to begin our RA clinical trial represents a major development milestone for Targeted Genetics, and we are eager to proceed with this Phase I study, said H. Stewart Parker, president and chief executive officer of Targeted Genetics. Results from animal studies suggest a significant reduction in symptoms associated with RA, such as joint swelling. We believe tgAAC94 holds great promise for treating a significant portion of the patient population that continues to suffer from one or more painful joints associated with this chronic and debilitating disease.

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About tgAAC94
It is estimated that RA affects more than two million people in the U.S. TNF receptor-based products such as Enbrel®, Remicade® and Humira® have been successful in treating rheumatoid arthritis in hundreds of thousands of patients, and it is estimated that the market for anti-TNF therapies will reach $7 billion by 2011. While successful, these therapies do not provide full relief in an estimated 25 to 40 percent of patients. The goal of tgAAC94 is to express TNF receptor protein locally in arthritic joints that have not fully responded to systemically delivered therapy.

tgAAC94, Targeted Genetics product candidate for the treatment of rheumatoid arthritis, utilizes the Company s adeno-associated viral (AAV) vector technology platform to deliver the DNA sequence encoding a potent inhibitor of TNF- known as TNFR:Fc to cells within arthritic joints. AAV is a naturally occurring virus that is not associated with any disease in humans. tgAAC94 is produced by removing the AAV genes from the vector and replacing them with the sequence encoding TNFR:Fc. The product candidate is administered by direct injection into affected joints.

In preclinical studies, AAV-TNFR:Fc was delivered to the muscle or the joint of rats with experimentally induced RA. Data from these studies demonstrated that a single injection of a vector carrying the soluble TNFR gene into the ankles of arthritic rats resulted in a significant reduction in ankle and hind paw swelling as measured by arthritis index scores. Data also suggested that animals treated in a single joint experienced a reduction in swelling in both the treated joint as well as the contra-lateral joint. This was observed without accompanying elevated levels of systemic protein expression.

About the Phase I Trial

The trial is a multi-center, randomized, double-blind, placebo-controlled, dose escalation study designed to assess safety of intra-articular delivery of tgAAC94. Other secondary parameters assessed are the efficacy of intra-articular administration of tgAAC94 in reducing pain and swelling in the injected joint and overall disease activity. The amount of local and circulating TNFR:Fc protein will also be measured. The study will enroll up to 32 adult subjects. Participants will receive a single injection of tgAAC94 directly into an affected joint and will have disease symptoms assessed at various time points after dosing. Patients will be followed for 24 weeks after receiving the first dose.

About Targeted Genetics
Targeted Genetics Corp. (NASDAQ:TGEN; www.targetedgenetics.com) develops gene-based products for preventing and treating acquired and inherited diseases. The Company has two clinical product development programs, targeting cystic fibrosis and AIDS prophylaxis and expects to initiate clinical testing of its arthritis product candidate in the first quarter of 2004. The Company also has a promising pipeline of product candidates focused on hemophilia and cancer and a broad platform of gene delivery technologies as well as a promising body of technology for cellular therapy.

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This release contains forward-looking statements regarding our regulatory filings, research programs, clinical trials, product development and potential related to tgAAC94. 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

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and results of our research and our clinical trials, our ability to recruit and enroll suitable trial participants, our ability to obtain and maintain regulatory or institutional approvals, our ability to protect our intellectual property, 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 September 30, 2003. 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.

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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: January 21, 2004

By: /s/ Todd E. Simpson

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