TARGETED GENETICS CORP /WA/
Form 10-Q
November 05, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER: 0-23930

TARGETED GENETICS CORPORATION

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Washington	91-1549568
(State of Incorporation)	(I.R.S. Employer Identification No.)

1100 Olive Way, Suite 100 Seattle, WA 98101

(Address of principal executive offices)(Zip Code)

(206) 623-7612

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for at least the past 90 days. Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer o Accelerated filer o

Non-accelerated filer o	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes x No

Shares of Common Stock, par value $0.01 per share, outstanding as of November 4, 2008: 20,003,865

TARGETED GENETICS CORPORATION
Quarterly Report on Form 10-Q
For the quarter ended September 30, 2008

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PART I FINANCIAL INFORMATION

Item 1. ***Unaudited Financial Statements***

TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,183,000	$ 16,442,000
Accounts receivable	368,000	2,611,000
Prepaid expenses and other	215,000	243,000
Total current assets	9,766,000	19,296,000
Property and equipment, net	1,292,000	1,052,000
Goodwill	7,926,000	7,926,000
Other assets	200,000	200,000
Total assets	$ 19,184,000	$ 28,474,000
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,144,000	$ 2,161,000
Accrued employee expenses	512,000	1,507,000
Accrued restructure charges	619,000	574,000
Deferred revenue	1,865,000	79,000
Current portion of long-term obligations	—	336,000
Total current liabilities	5,140,000	4,657,000
Accrued restructure charges	7,099,000	7,569,000
Deferred rent	4,000	8,000
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $0.01 par value, 10,000,000 shares authorized: Series A preferred stock, 180,000 shares designated, none issued and outstanding	—	—
Common stock, $0.01 par value, 45,000,000 shares authorized, 20,003,198 shares issued and outstanding at September 30, 2008 and 19,814,161 shares issued and outstanding at December 31, 2007	200,000	198,000
Additional paid-in capital	316,766,000	316,196,000
Accumulated deficit	(310,025,000)	(300,154,000)
Total shareholders' equity	6,941,000	16,240,000
Total liabilities and shareholders' equity	$ 19,184,000	$ 28,474,000

See accompanying notes to condensed consolidated financial statements

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TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2008	**2007**	**2008**	**2007**
Revenue:				
Collaborative revenue	$ 1,742,000	$ 1,943,000	$ 6,478,000	$ 6,612,000
Licensing revenue	—	500,000	—	500,000
Total revenue	1,742,000	2,443,000	6,478,000	7,112,000
Operating expenses:				
Research and development	3,192,000	3,874,000	11,294,000	12,840,000
General and administrative	1,224,000	1,694,000	4,865,000	4,821,000
Restructure charges	196,000	183,000	597,000	809,000
Total operating expenses	4,612,000	5,751,000	16,756,000	18,470,000
Loss from operations	(2,870,000)	(3,308,000)	(10,278,000)	(11,358,000)
Investment income	53,000	277,000	251,000	305,000
Other income	79,000	—	79,000	—
Gain on debt restructure	77,000	—	77,000	—
Interest expense	—	—	—	(1,000)
Net loss	$ (2,661,000)	$ (3,031,000)	$ (9,871,000)	$ (11,054,000)
Net loss per common share (basic and diluted)	$ (0.13)	$ (0.15)	$ (0.50)	$ (0.72)
Shares used in computation of basic and diluted net loss per common share	20,002,000	19,814,000	19,906,000	15,388,000

See accompanying notes to condensed consolidated financial statements

TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended September 30,	
	2008	**2007**
Operating activities:		
Net loss	$ (9,871,000)	$ (11,054,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	399,000	447,000
Stock-based compensation	582,000	514,000
Loss on investments	—	251,000
Gain on sale of property and equipment	(76,000)	(22,000)
Gain on debt restructure	(77,000)	—
Other	(10,000)	—
Changes in assets and liabilities:		
Change in accounts receivable	2,243,000	(46,000)
Change in prepaid expenses and other	28,000	(12,000)
Change in other assets	—	6,000
Change in current liabilities	(1,012,000)	(1,000)
Change in deferred revenue	1,786,000	(33,000)
Change in deferred rent	(5,000)	(2,000)
Change in accrued restructure charges	(424,000)	(228,000)
Net cash used in operating activities	(6,437,000)	(10,180,000)
Investing activities:		
Purchases of property and equipment	(639,000)	(333,000)
Proceeds from the sale of equipment	76,000	22,000
Proceeds from sale of investments	—	16,000
Net cash used in investing activities	(563,000)	(295,000)
Financing activities:		
Net proceeds from sales of capital stock (and warrants)	—	25,956,000
Proceeds from the exercise of stock options	—	39,000
Payments under debt and equipment financing arrangements	(259,000)	(1,195,000)
Net cash (used in) provided by financing activities	(259,000)	24,800,000
Net (decrease) increase in cash and cash equivalents	(7,259,000)	14,325,000
Cash and cash equivalents, beginning of period	16,442,000	6,206,000
Cash and cash equivalents, end of period	$ 9,183,000	$ 20,531,000

See accompanying notes to condensed consolidated financial statements

TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements included in this quarterly report have been prepared by Targeted Genetics Corporation, or Targeted Genetics, according to the rules and regulations of the Securities and Exchange Commission, or SEC, and according to accounting principles generally accepted in the United States of America, or GAAP, for interim financial statements. The accompanying balance sheet information as of December 31, 2007 is derived from our audited consolidated financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been omitted in accordance with the SEC's rules and regulations. Our condensed consolidated financial statements include the accounts of Targeted Genetics and our inactive, wholly owned subsidiaries, Genovo, Inc. and TGCF Manufacturing Corporation. All significant intercompany transactions have been eliminated in consolidation. The condensed consolidated financial statements reflect, in the opinion of management, all adjustments, which consist solely of normal recurring adjustments necessary to present fairly our financial position and results of operations as of and for the periods indicated.

We do not believe that our results of operations for the three and nine months ended September 30, 2008 are necessarily indicative of the results to be expected for the full year.

The condensed consolidated financial statements included in this quarterly report should be read in conjunction with our audited consolidated financial statements and related footnotes included in our annual report on Form 10-K for the year ended December 31, 2007.

Our combined cash and cash equivalents totaled $9.2 million at September 30, 2008. We believe that our current resources and the cash we expect to receive from our collaborative partners are only sufficient to fund our planned operations into the first quarter of 2009. This estimate is based on our ability to perform planned research and development activities and the receipt of planned funding from our collaborators and actual results could differ from our estimates. We intend to seek additional financing in order to fund our operations through 2009; however, we cannot provide assurances that we will be successful in obtaining additional financing when and as needed in the future. If we do not raise additional funds, we would be forced to preserve our cash position through a combination of cost reduction measures, which may include a reduction in workforce, termination of our product development programs, monetization of technology assets or intellectual property, sales of assets, likely at values significantly below their potential worth, or the pursuit of alternative financing transactions that would likely be on terms disadvantageous to us and dilutive to our shareholders. We have prepared the accompanying condensed consolidated financial statements assuming that we will continue as a going concern notwithstanding the fact that there is no assurance that we will be able to secure the financial resources we require in the near term to continue as a going concern and our condensed consolidated financial statements do not reflect adjustments that may impact the amount and classifications of assets or liabilities that may result from these liquidity uncertainties.

Recently Issued Accounting Standards

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 157, *"Fair Value Measurements,"* or SFAS No. 157. SFAS No. 157 provides guidance for using fair value to measure assets and liabilities and requires expanded information about the extent to which

companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS No. 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. SFAS No. 157 does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS No. 157 did not have an effect on our financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities—including an amendment of FASB Statement No. 115,"* or SFAS No. 159. SFAS No. 159 permits entities to choose to measure certain financial assets and liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS No. 159 did not have an effect on our financial position or results of operations.

In July 2007, FASB's Emerging Issues Task Force, or EITF, reached a consensus on Issue No. 07-3, *"Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities,"* or EITF 07-3. The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for fiscal years beginning after December 15, 2007 and early adoption was not permitted. The adoption of EITF 07-3 changed our policy on nonrefundable prepayments for research and development services whereby such costs will be deferred and recognized as the services are rendered as compared to the existing policy whereby such payments are charged to research and development expense as paid. This change did not have a material impact on the three or nine months ended September 30, 2008.

In December 2007, FASB's EITF reached a consensus on Issue No. 07-1,*"Accounting for Collaborative Arrangements,"* or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. It also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. EITF 07-1 is effective for all of our collaborations in place after January 1, 2009. We are in the process of evaluating the effect of the adoption of EITF 07-1.

In April 2008, the FASB issued Staff Position No. 142-3, *"Determination of the Useful Life of Intangible Assets,"* or SFAS No. 142-3. This standard amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *"Goodwill and Other Intangible Assets*." SFAS No. 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. We are in the process of evaluating the effect of the adoption of SFAS No. 142-3.

2. Accrued Restructure Charges

We apply the provisions of SFAS No. 146, *"Accounting for Costs Associated with Exit or Disposal Activities,"* or SFAS No. 146, as it relates to our facility in Bothell, Washington and record restructure charges on the operating lease for the facility as a result of our 2003 decision to discontinue use of the facility. Accrued restructure charges represent our best estimate of the fair value of the liability as determined under SFAS No. 146 and are computed as the fair value of the difference between the remaining lease payments, net of any assumed sublease income and expense. In 2007, based on a number of factors, including continued high vacancy rates in the Bothell market and an increase in available office space in the competing downtown real estate markets, we concluded that we would most likely not be able to successfully sublease the facility. Therefore, we assume no sublease income and related tenant improvement costs in our restructuring accrual calculation. We record accretion expense based upon changes in the accrued liability that results from the passage of time at an assumed discount rate of 10%. Accretion expense is recorded on an ongoing basis through the end of the lease term in September 2015 and is reflected as a restructuring charge in the accompanying condensed consolidated statements of operations.

The table below presents a reconciliation of the accrued restructure liability for the nine month period ended September 30, 2008:

	Restructure Liability
December 31, 2007 accrued liability	$ 8,143,000
Adjustments to the liability (accretion)	597,000

Amount paid	(1,022,000)
September 30, 2008 accrued liability	$ 7,718,000

Adjustments to the accrued restructure liability include accretion expense of $196,000 for the three months ended September 30, 2008 and $597,000 for the nine months ended September 30, 2008.

Through September 30, 2008, we have recorded restructure charges totaling $12.7 million for our Bothell facility. We expect to incur an additional $3.2 million in accretion expense through the expiration of the Bothell lease in September 2015.

We periodically evaluate our restructuring estimates and assumptions and record restructure charges as necessary. Because restructure charges are estimates based upon assumptions regarding the timing and amounts of future events, significant adjustments to the accrual may be necessary in the future based on the actual outcome of events and as we become aware of new facts and circumstances.

3. Equity

Stock Compensation

The following table summarizes stock-based compensation expense related to employee stock options and restricted stock units under SFAS No. 123(R), *"Share-Based Payment,"* for the three and nine months ended September 30, 2008 and 2007:

	Three months ended September 30,		Nine months ended September 30,	
	2008	**2007**	**2008**	**2007**
Stock options:				
Research and development expense	$ 6,000	$ 1,000	$ 99,000	$ 195,000
General and administrative expense	6,000	7,000	41,000	157,000
Restricted stock units:				
Research and development expense	71,000	38,000	231,000	55,000
General and administrative expense	54,000	73,000	211,000	107,000
Total stock-based compensation expense	$ 137,000	$ 119,000	$ 582,000	$ 514,000

We determine the fair value of each restricted stock unit on the date of the grant using the closing market price of our traded securities. We estimate the fair value of each stock option award on the date of the grant using the Black-Scholes-Merton option pricing model. There were no stock options granted in the nine months ended September 30, 2008. The weighted average assumptions for stock options granted in the nine months ended September 30, 2007 were:

a) expected dividend rate of zero,
b) expected stock price volatility ranged from 1.047 to 1.114,
c) risk free interest rate ranged from 4.54% to 4.58%,
d) expected life of options ranged from 4 to 5 years.

Expected Dividend: We do not anticipate paying any dividends.

Expected Life: Expected life represents the period that our stock-based awards are expected to be outstanding based on historical experience and vesting schedules of similar awards.

Expected Volatility: Expected volatility represents the weighted average historical volatility of the shares of our common stock for the most recent four-year and five-year periods.

Risk-Free Interest Rate: We base the risk-free interest rate used on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term. Where the expected term of our stock-based awards does not correspond with the terms for which interest rates are quoted, we perform a straight-line interpolation to determine the rate from the available term maturities.

Forfeiture Rate: We apply an estimated forfeiture rate that we derived from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, we may record additional adjustments to compensation expense in future periods.

4. Investments

Effective January 1, 2008, we implemented SFAS No. 157 for our financial assets and other items that are recognized or disclosed at fair value on a recurring basis. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair-value measurements. SFAS No. 157 requires that fair value measurements be classified and disclosed in one of the following three categories in the fair value hierarchy:

Level 1. Observable inputs such as quoted prices in active markets;

Level 2. Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; or

Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

As of September 30, 2008, we held approximately 2.4 million shares of Chromos Molecular Systems Inc., or Chromos, a publicly traded company whose common stock was listed on the Toronto Stock Exchange. The Chromos securities were delisted from the Toronto Stock Exchange at the close of the market on May 8, 2008, and as a result there is not an active market for the stock. In October 2008, Chromos entered into a restructure agreement under which all assets, liabilities and equity are now controlled by a newly formed company, Calyx Bio-ventures. We are currently waiting for information regarding the conversion of our existing Chromos shares to determine the value of our investment in the newly formed company. Through December 31, 2007, we recorded our common stock investment in Chromos at fair market value and recorded changes in the fair market value of the Chromos stock in accumulated other comprehensive loss. We also periodically evaluated our Chromos stock for signs of impairment that may be other-than-temporary, which would necessitate a reduction in the carrying value of the investment and charge to expense. During 2007, we determined that our investment was other-than-temporarily impaired and the fair value of our investment was zero due to the declining market value of the Chromos stock and a decline in Chromos' financial position. Accordingly, we wrote the asset down to the fair market value of the Chromos stock on both March 31, 2007 and June 30, 2007 and recognized a realized loss of $208,000 in the first quarter of 2007 and an additional realized loss of $44,000 in the second quarter of 2007. This investment is classified as a Level 3 on the fair value hierarchy and there were no changes to the balance during the three and nine month periods ended September 30, 2008.

Our cash equivalents are recorded at cost, which approximates fair market value, and consist primarily of money market investments. Our money market investments are classified as Level 1 on the fair value hierarchy.

Item 2. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include statements about our product development and commercialization goals and expectations, potential market opportunities, our plans for and anticipated results of our clinical development activities and the potential advantage of our product candidates, our future cash requirements and the sufficiency of our cash and cash equivalents to meet these requirements, our ability to raise capital when needed and other statements that are not historical facts. Words such as "may," "will," "believes," "estimates," "expects," "anticipates," "plans" and "intends," or st concerning "potential" or "opportunity" and other words of similar meaning or the negative thereof, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. In making these statements, we rely on a number of assumptions and make predictions about the future. Our actual results could differ materially from those stated in, or implied by, forward-looking statements for a number of reasons, including the risks described in the section "Risk Factors" in Part II, Item 1A of this quarterly report.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this quarterly report. We undertake no obligation to publicly revise any forward-looking statement after the date of this quarterly report to reflect circumstances or events occurring after the date of this quarterly report or to conform the statement to actual results or changes in our expectations. You should, however, review the risk factors and other information we provide in the reports we file from time to time with the SEC.

BUSINESS OVERVIEW

We are a clinical-stage therapeutic biotechnology company. We are at the forefront of developing, with the goal of commercializing, a new class of therapeutic products called gene therapeutics. We believe that a wide range of diseases may potentially be treated or prevented with gene therapeutics. In addition to treating diseases for which there is no treatment, we believe that there is a significant opportunity to use gene therapeutics to more effectively treat diseases that are currently treated using other therapeutic classes of drugs such as protein-based drugs,

monoclonal antibodies or small molecule drugs.

Gene therapeutics consist of a delivery vehicle, called a vector, and genetic material. The role of the vector is to carry the genetic material into a target cell. Once delivered into the cell, the gene can express or direct production of the specific proteins encoded by the gene. Gene therapeutics may be used to treat disease facilitating the normal protein production or gene regulation capabilities of cells. Gene therapeutics may be used to enable cells to produce more of a certain protein or different proteins than they normally produce, thereby treating a disease state. Vectors can also be used to deliver specific sequences that once delivered and expressed as interfering RNA, or RNAi, can shut down or interfere with messenger RNA production of disease specific genes.

From time to time we have evaluated a range of opportunities that include strategic combinations and product diversification with a particular focus on product candidates to which we can apply our significant development expertise. For example, in the third quarter of 2008 the U.S. Department of Defense, or DOD, Amyotrophic Lateral Sclerosis Research Program awarded us up to $2.4 million of grant funding to be applied toward preclinical development of new therapies for amyotrophic lateral sclerosis, or ALS. Under this program, we are developing a small-molecule based on the observations by our collaborator, Dr. John Engelhardt, at the University of Iowa, that over-activation of nicotinamide adenine dinucleotide phosphate, or NADPH oxidase is associated with pathogenesis of ALS. Further, inhibition of NADPH oxidase activity significantly increases survival of mice with ALS. The work under this grant includes formulation development and preclinical pharmacokinetic and safety studies.

We and our partners, Celladon Corporation, or Celladon, the National Institute of Allergy and Infectious Diseases, or NIAID, the International AIDS Vaccine Initiative, or IAVI, the Children's Hospital of Philadelphia, or CHOP, and The Research Institute at Nationwide Children's Hospital (formerly known as the Columbus Children's Research Institute), or NCH, are primarily focused on the following adeno-associated viral vectors, or AAV, based product development programs:

Description	Indication	Funding Partners	Development Status
AAV delivery of TNF-alpha inhibitor	Inflammatory Arthritis	None	Phase I/II
AAV delivery of HIV antigens	HIV/AIDS	IAVI, CHOP and NCH	Phase II
AAV delivery of SERCA2a	Heart Failure	Celladon	Phase I
AAV delivery of HIV antigens	HIV/AIDS	CHOP, NCH and NIAID	Preclinical
AAV expression of htt shRNA (RNAi)	Huntington's disease, or HD	None	Preclinical
AAV delivery of RPE 65	Leber's congenital amaurosis, or LCA	None	Phase I/II

Our now complete Phase I/II clinical trial of our tgAAC94 product candidate for inflammatory arthritis evaluated multiple doses of tgAAC94 administered directly to affected joints with or without concurrent systemic TNF antagonist therapies. The study achieved its primary endpoint of safety and tolerability. In addition, we reported encouraging data on improvement of the injected joint based on patient-reported outcome measures considered a gauge of efficacy. These data suggests further study is warranted. Robin Ali, our collaborator at the University of College London plans to expand the current ongoing LCA clinical trial to include younger patients and a higher dose cohort. We and our HIV/AIDS vaccine collaborators are supporting the NIAID as it prepares to initiate a Phase I clinical trial of our AAV1-based vaccine product candidate currently anticipated for the first half of 2009. Our HD program academic collaborator, Bev Davidson, Ph.D., is conducting the necessary mice studies that are required prior to the initiation of safety studies in a large animal model. We, with our collaborator, Dr. John Engelhardt at the University of Iowa, are moving forward with planned activities to implement the ALS program plan.

Most of our expenses are related to our research and development programs, the conduct of preclinical studies and clinical trials and general and administrative support for these activities. We have financed the company primarily through proceeds from public and private sales of our equity securities, through cash payments received from our collaborative partners for product development and manufacturing activities, and through proceeds from the issuance of debt and loan funding under equipment financing arrangements.

As of September 30, 2008, our accumulated deficit totaled $310.0 million. We expect to generate substantial additional losses for the foreseeable future, primarily due to the costs associated with funding our product development programs, developing and maintaining our manufacturing capabilities and developing our intellectual

property assets.

We will require access to significantly higher amounts of capital than we currently have in order to successfully develop our product candidates or our partnered product candidates. We may be unable to obtain required funding when needed or on acceptable terms, obtain or maintain corporate partnerships, or complete acquisition transactions necessary or desirable to complete the development of our product candidates and, as a result, we may be required to delay or terminate some or all of our development programs.

CRITICAL ACCOUNTING POLICIES, ESTIMATES AND ASSUMPTIONS

There have been no material changes from the critical accounting policies, estimates and assumptions as disclosed in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our annual report on Form 10-K for the year ended December 31, 2007.

RESULTS OF OPERATIONS

Revenue

Revenue decreased to $1.7 million for the three months ended September 30, 2008 as compared to $2.4 million for the same period in 2007. Revenue decreased to $6.5 million for the nine months ended September 30, 2008 as compared to $7.1 million for the same period in 2007. The decrease in revenue reflects a decrease in research and development and manufacturing activities under the NIAID-funded HIV/AIDS vaccine project in collaboration with CHOP and NCH and decreased licensing revenue from a milestone payment received in the third quarter of 2007. This is partially offset by higher research and development activities under our collaboration with Celladon. Based upon the terms specified in our collaboration agreements, we receive advance payments from some of our collaboration partners before the project work has been performed. These payments are deferred and recognized as revenue when the costs are incurred. We expect that our revenue for the remainder of 2008 will consist primarily of research and development revenue earned from our collaboration with Celladon and the NIAID-funded HIV/AIDS subcontract with CHOP and NCH. We expect that our revenue for 2008 will decrease from 2007 as our partnered programs emphasize clinical development in 2008 which results in fewer resources devoted to the manufacturing aspects of development. We expect our 2008 revenue generated from our Celladon collaboration to be higher than in 2007. Our HIV/AIDS vaccine development revenue from the IAVI and NIAID-funded projects fluctuates year to year depending upon the scope of development efforts underway within each separate but complementary program. For 2008, our HIV/AIDS efforts are focused on advancing the NIAID-funded HIV/AIDS vaccine efforts. Accordingly, we expect no activity within the IAVI-funded portion of our HIV/AIDS development work and we expect revenue under our NIAID-funded HIV/AIDS vaccine collaboration to decrease compared to 2007 due to less development and manufacturing activity in 2008, as the project is focused primarily on preparing for the initiation of an National Institutes of Health, or NIH, sponsored clinical study in 2009.

Operating Expenses

Research and Development Expenses. Research and development expenses decreased to $3.2 million for the three months ended September 30, 2008 compared to $3.9 million for the same period in 2007. Research and development expenses decreased to $11.3 million for the nine months ended September 30, 2008 compared to $12.8 million for the same period in 2007. This decrease reflects lower clinical trial costs for our inflammatory arthritis program as we have completed our Phase I/II clinical trial. This decrease was partially offset by increased activity on our partnered heart failure product candidate during 2008.

The following is an allocation of our total research and development costs between our programs that are in clinical development and those that are in research or preclinical stages of development:

	Three months ended September 30,		Nine months ended September 30,	
	2008	**2007**	**2008**	**2007**
Programs in clinical development:				
Inflammatory arthritis	$ 269,000	$ 1,091,000	$ 1,157,000	$ 2,948,000
Heart failure [1]	833,000	170,000	2,298,000	373,000
IAVI HIV/AIDS vaccine	—	33,000	—	202,000
Indirect costs and other	1,212,000	631,000	3,531,000	2,161,000
Total clinical development program expense	2,314,000	1,925,000	6,986,000	5,684,000
Research and preclinical development program expense	878,000	1,949,000	4,308,000	7,156,000
	$ 3,192,000	$ 3,874,000	$ 11,294,000	$ 12,840,000

Total research and development expense	

(1) Includes costs incurred after the trial was initiated in May 2007. Costs incurred prior to that are included as research and preclinical development program expense.

Research and development costs attributable to programs in clinical development include the costs of salaries and benefits, clinical trial costs, outside services, materials and supplies incurred to support the clinical programs. Indirect costs allocated to clinical programs include facility and occupancy costs, research and development administrative costs, and license and royalty payments. These costs are further allocated between clinical and preclinical programs based on relative levels of program activity. Celladon separately manages and funds the clinical trial costs of the heart failure program and IAVI separately managed and funds the clinical trial costs of the HIV/AIDS vaccine program for the developing world. As a result, we do not include those costs in our research and development expenses.

Costs attributed to research and preclinical programs represent our earlier-stage development activities and include costs incurred for development activities for the NIAID-funded HIV/AIDS vaccine under a subcontract with CHOP and NCH and the heart failure programs, as well as other programs prior to their transition into clinical trials. Research and preclinical program expense also includes costs that are not allocable to a clinical development program, such as unallocated manufacturing infrastructure costs. Because we conduct multiple research projects and utilize resources across several programs, our research and preclinical development costs are not directly assigned to individual programs.

For purposes of reimbursement from our collaboration partners, we capture the level of effort expended on a program through our project management system, which is based primarily on human resource time allocated to each program, supplemented by an allocation of indirect costs and other specifically identifiable costs, if any. As a result, the costs allocated to programs identified in the table above reflect the relative costs of the program.

General and Administrative Expenses. General and administrative expenses decreased to $1.2 million for the three months ended September 30, 2008 from $1.7 million for the same period in 2007. This decrease reflects lower intellectual property charges for the quarter related to the timing of patent issuances in Europe, lower shareholder costs and decreased use of external consultants. General and administrative expense increased to $4.9 million for the nine months ended September 30, 2008 compared to $4.8 million for the same period in 2007. This increase reflects higher intellectual property charges related to patent costs and higher legal fees as compared to the first nine months of 2007.

Restructure Charges. Restructure charges increased to $196,000 for the three months ended September 30, 2008 compared to $183,000 for the same period in 2007and consists entirely of accretion expense. Restructure charges decreased to $597,000 for the nine months ended September 30, 2008 compared to $809,000 for the same period in 2007. Restructure charges include accretion expense of $597,000 for the nine months ended September 30, 2008 and $549,000 for the nine months ended September 30, 2007. Restructuring charges in 2007 also includes $260,000 related to changes in our estimates of the anticipated lead time to sublease the Bothell facility.

Other Income and Expense

Investment Income. Investment income reflects interest income earned on our short term investments and realized gains or losses on our investment in Chromos. Investment income decreased to $53,000 for the three months ended September 30, 2008 compared to $277,000 for the same period in 2007. Investment income decreased to $251,000 for the nine months ended September 30, 2008 compared to $305,000 for the same period in 2007. Investment income has decreased due to lower average cash balances and lower interest rates compared to the prior year. For the nine month period ended September 30, 2007, investment income reflects a $251,000 realized loss related to an other-than-temporary impairment loss on our investment in Chromos due to the declining market value of the Chromos securities combined with a decline in Chromos' financial condition.

Other Income. Other income reflects proceeds from the sale of obsolete capital assets.

Gain on debt restructure. In 2006, we signed an agreement to restructure $8.15 million of debt payable to Biogen Idec. Under the agreement, we exchanged $5.65 million of debt for one million shares of our common stock with a fair value of $2.9 million with Biogen Idec. Inherent in our determination of the gain on debt restructure is an estimate of the amounts and timing of future principal and interest payments. To the extent that changes in our estimates result in decreases in estimated future interest payments such gain was deferred until realized. In August 2008, we made our final principal and interest payment to Biogen Idec. The difference between the final principal and interest payment and the estimated liability established in 2006 was recognized as a realized gain of $77,000.

Liquidity and Capital Resources

We had cash and cash equivalents balances of $9.2 million at September 30, 2008 compared to $16.4 million at December 31, 2007. Our cash and cash equivalents decreased $7.3 million in the nine months ended September 30, 2008 primarily reflecting cash used in operations of $6.4 million, capital purchases of $639,000 and payments under debt arrangements of $259,000 primarily related to the final principal and interest payment of the Biogen Idec note.

Our primary sources of capital are proceeds from public and private sales of our equity securities and through cash payments received from our collaborative partners and through proceeds from the issuance of debt. To a lesser degree, we have also financed our operations through interest earned on our cash and loan funding under equipment leasing agreements and in the last two years from licensing revenue. These financing sources have historically allowed us to maintain adequate levels of cash and cash equivalents but, particularly in the current market environment, they may not continue to do so.

Our primary expenses are related to the development of our research and development programs, the conduct of preclinical studies and clinical trials and general and administrative support for these activities. We will require substantial additional financial resources to fund the development and commercialization of our clinical stage and other pre-clinical product candidates. We currently fund all costs of these programs from our working capital, although our strategy is to ultimately seek a partner to fund later-stage development of some of our self-funded programs.

In addition to the funding necessary to advance our product development and fund our ongoing operating costs, we also have lease commitments that draw on our cash resources. Our most significant obligations are approximately $10.9 million of remaining lease payments on our Bothell facility, which we are obligated to pay at $1.4 million to $1.6 million per year until the year 2015.

We expect the level of our future operating expenses to be driven by the needs of our product development programs and our lease obligations. The size, scope and pace of our product development activities depend on the availability of the sources of capital described above. Our future cash requirements will depend on many factors, including:

- whether we decide to continue to pursue all or a portion of our research and development programs;
- the timing, costs and scope of, and our success in, conducting clinical trials, obtaining regulatory approvals and maintaining and expanding our patent portfolio;
- the rate and extent of scientific progress in our research and development programs;
- the availability and success of development collaborations with third parties;
- competing technological and market developments;
- the existence and outcome of any litigation or administrative proceedings, including those involving product liability or intellectual property; and
- the timing and costs of, and our success in, any product commercialization activities and facility expansions, if and as required.

We have financed our product development activities and general corporate functions primarily through proceeds from public and private sales of our equity securities, through cash payments received from our collaborative partners and proceeds from the issuance of debt. To a lesser degree, we have also financed our operations through interest earned on cash and cash equivalents and loan funding under equipment financing agreements and, in the last two years, from license revenue. The size, scope and pace of our product development activities depend on the availability of these resources. These financing sources have historically allowed us to maintain adequate levels of cash and cash equivalents but, particularly in the current market environment, they may not continue to do so.

Our development collaborations have typically provided us with funding in several forms, including purchases of our equity securities, loans, payments for reimbursement of research and development costs and milestone fees and payments. We and our partners typically agree on a target disease and create a development plan for the product candidate, which generally spans several years and is subject to termination or extension. For example, when the Celladon collaboration was initiated in 2005, it originally had a research and development work plan that was established and funded based on quarterly costs. In March 2008, we and Celladon agreed to a research and development work plan extending through January 2010. Also, in 2005, we extended the scope of our IAVI-funded HIV/AIDS vaccine program activities to the developed world via our collaboration with CHOP and NCH through a subcontract with NIAID. To date we have received $9.7 million under this subcontract and our portion of the

remaining total project funding of up to $8.5 million depends on annual renewal of government funding and the scope of product development work plans agreed upon by us, CHOP, NCH and the NIAID. The funding is awarded to us in annual installments based on an approved work plan and achievement of milestones. In August 2008, we were officially awarded $3.9 million in additional funding for the fourth plan year covering the time period from August 31, 2008 through August 30, 2009. For 2008, this program comprises substantially all of our current HIV/AIDS product development activities.

The funding from each of our collaborative partners fully offsets our incremental program costs incurred by each collaboration and our overhead and fixed costs. Our revenue from collaborative agreements and licenses totaled $10.3 million in 2007 and, assuming that we complete all of the planned development activities for each of these funded projects, we expect revenue from our collaborative partners of approximately $8.5 million to $9.0 million in 2008. Our revenue plan for 2008 includes the expectation that we accomplish our current Celladon heart failure and NIAID-funded HIV/AIDS vaccine work plans.

The terms of each of our collaborations include provisions that allow our partners the right to terminate both the underlying collaboration and the obligation to provide research funding at any time with as little as 90 days' notice. As an example, in 2008 Sirna, a wholly-owned subsidiary of Merck & Co., Inc., decided not to continue its collaboration with us on our HD program and instead we acquired the rights necessary to continue that program on our own. If we were to lose the collaborative funding expected from the Celladon collaboration or the NIAID subcontract and were unable to obtain alternative sources of funding, we would be unable to continue our research and development program for that product candidate and/or we would not have sufficient resources available to fund our ongoing operations for as long as currently expected.

Our financing strategy is focused around the advancement of our programs in clinical development, the advancement of our LCA program, RNAi initiatives such as our HD program, new product development and broader RNAi initiatives, leveraging our intellectual property assets and capabilities into additional capital raising opportunities, including through potential strategic transactions, and accessing the public and private capital markets. Our ability to raise capital depends in part on product development success and how the public capital markets perceive the promise of our products and platform. There is a low percentage of success in biopharmaceutical product development of all types, and current capital markets have tended to discount the value of biopharmaceutical companies with early-stage products.

We are currently focusing on additional sources of financing that could involve one or more of the following:

- mergers and acquisitions;
- selling or licensing our technology, product candidates or other assets;
- entering into additional product development or manufacturing collaborations;
- issuing equity in the public or private markets;
- extending or expanding our current collaborations;
- borrowing under loan or equipment financing arrangements; and/or
- issuing debt.

Additional funding may not be available to us on reasonable terms, if at all. The capital markets have been experiencing extreme volatility and disruption for more than 12 months. In recent weeks, the volatility and disruption have reached unprecedented levels. The scope and extent of this disruption in the capital markets could make it difficult or impossible to raise additional capital in public or private capital markets until conditions stabilize and conditions may not stabilize before we reach the end of our financial resources and are forced to go out of business.

We expect that our total cash requirements for the fiscal year ending December 31, 2008 will range from $11.5 million to $12.5 million and that our cash and cash equivalents at September 30, 2008, plus the anticipated funding from our product development collaborations and contracts will only be sufficient to fund our current level of operations into the first quarter of 2009. This estimate is based on our ability to perform, and success of, planned research and development activities and the receipt of planned funding from our collaborators and actual results could differ from our estimates.

Depending on our ability to successfully access additional funding, we may be forced to implement cost reduction measures, which could include a reduction in workforce, suspension or termination of our product development programs, sales of assets, technologies or programs likely at values significantly below their potential worth, or the pursuit of alternative financing transactions that would likely be on terms disadvantageous to us and/or dilutive to our shareholders.

Item 4T. ***Controls and Procedures***

Evaluation of disclosure controls and procedures. Based on our management's evaluation, with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this quarterly report, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective in ensuring that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is properly recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms.

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting that occurred during the period covered by this quarterly report that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

In July 2007, we were notified that a patient experienced a serious adverse event, or SAE, while enrolled in the clinical trial of tgAAC94, our product candidate to treat arthritis. Although the patient subsequently died, as a result of a review of the SAE, both the National Institutes of Health Recombinant DNA Advisory Committee, or RAC, and the trial's independent data safety monitoring board, or Safety Board, concluded that the patient's death was not caused by the tgAAC94 product, as described in our Form 8-K filed on December 6, 2007. In addition, after the U.S. Food and Drug Administration, or FDA reviewed the safety data on all 127 patients in the trial and data from the SAE, the hold originally put on the clinical trial was removed, permitting the clinical trial to resume. In September 2008, we were made aware, although we have not been formally served notice, that we, among others, were named in a lawsuit filed by the patient's spouse. The complaint relating to the lawsuit alleges that the named parties' negligence was the proximate cause of the patient's death and seeks unspecified damages in excess of $50,000.

Item 1A. ***Risk Factors.***

In addition to the other information contained in this quarterly report and our annual report on Form 10-K for the year ended December 31, 2007, you should carefully read and consider the following risk factors. If any of these risks actually occur, our business, operating results or financial condition could be harmed. This could cause the trading price of our stock to decline, and you could lose all or part of your investment.

Risks Related to Our Business

If we are unable to raise additional capital or secure additional sources of funding in the near term, we will be unable to conduct our operations and develop our potential products.

Because our internally generated cash flow will not fund development and commercialization of our product candidates, we will require substantial additional financial resources. Our future capital requirements will depend on many factors, including:

- whether we decide to continue to pursue all or a portion of our research and development programs;
- the timing, costs and scope of, and our success in, conducting clinical trials, obtaining regulatory approvals and maintaining and expanding our patent portfolio;
- the rate and extent of scientific progress in our research and development programs;
- the availability and success of development collaborations with third parties;
- competing technological and market developments;
- the existence and outcome of any litigation or administrative proceedings involving intellectual property; and
- the timing and costs of, and our success in, any product commercialization activities and facility expansions, if and as required.

We currently expect that our existing financial resources will only be sufficient to fund our current level of operations into the first quarter of 2009 and actual results could differ from this estimate. Additional sources of financing could involve one or more of the following:

- mergers and acquisitions;
- selling or licensing our technology or product candidates;
- entering into additional product development or manufacturing collaborations;
- issuing equity in the public or private markets;

- extending or expanding our current collaborations;
- borrowing under loan or equipment financing arrangements; and
- issuing debt.

Additional funding may not be available to us on reasonable terms, if at all. The capital markets have been experiencing extreme volatility and disruption for more than 12 months. In recent weeks, the volatility and disruption have reached unprecedented levels. The scope and extent of this disruption in the capital markets could make it difficult or impossible to raise additional capital in public or private capital markets until conditions stabilize and conditions may not stabilize before we reach then end of our financial resources and are forced to go out of business.

The perceived risk associated with the possible sale of a large number of shares of our common stock could cause some of our shareholders to sell their stock, thus causing the price of our stock to decline. In addition, actual or anticipated downward pressure on our stock price due to actual or anticipated sales of stock could cause some institutions or individuals to engage in short sales of our common stock, which may itself cause the price of our stock to decline.

If our stock price continues to decline, or does not increase sufficiently, we may be unable to raise additional capital. As our existing financial resources are only expected to be sufficient to fund our current level of operations into the first quarter of 2009, an inability to raise capital in the near term could force us to go out of business. Additional declines in the price of our common stock, or a failure of the price of our common stock to increase sufficiently, could also impair our ability to attract and retain qualified employees, reduce the liquidity of our common stock and result in the delisting of our common stock from the NASDAQ Capital Market. Debt financing, if available, may require that we pledge our assets, including our intellectual property, or may require restrictive covenants that would restrict our business activities.

The funding that we expect to receive from our collaborations depends on continued scientific progress under the collaborations and our collaborators' ability and willingness to continue or extend the collaboration. If we are unable to successfully access sufficient additional capital, we may need to scale back, delay or terminate one or more of our development programs, curtail capital expenditures or reduce other operating activities or workforce. We may also be required to sell or relinquish some rights to our technology or product candidates or grant or take licenses on unfavorable terms, either of which would reduce the ultimate value to us of our technology or product candidates.

We expect to continue to operate at a loss and may never become profitable.

Substantially all of our revenue since 2005 has been derived from collaborative research and development agreements in connection with the development of our potential product candidates including our collaborations with Celladon and IAVI and our NIAID-funded subcontract with NCH and CHOP. We have incurred, and will continue to incur for the foreseeable future, significant expense to develop our research and development programs, conduct preclinical studies and clinical trials, seek regulatory approval for our product candidates and provide general and administrative support for these activities. As a result, we have incurred significant net losses since inception, and we expect to continue to incur substantial additional losses in the future.

As of September 30, 2008, we had an accumulated deficit of $310.0 million. We may never be able to commercialize our products or generate profits and, if we do become profitable, we may be unable to sustain or increase profitability.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, institutional review boards or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials can be delayed for a variety of reasons, including:

- the placement of a clinical hold on a trial, such as the four month clinical hold placed on our Phase I/II clinical trial of tgAAC94, our inflammatory arthritis product candidate, in 2007 after a patient participating in the clinical trial experienced a serious adverse event, or SAE, and subsequently died;

- the occurrence of drug-related side effects or adverse events experienced by participants in our clinical trials;

- discussions with the U.S. Food and Drug Administration, or FDA, or comparable foreign authorities regarding the scope or design of our clinical trials;

- delays or the inability to obtain required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;

- delays in enrolling patients into clinical trials;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, poorly executed testing or unacceptable design;
- an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval; or
- an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation.

If our clinical trials are delayed, we may be unable to develop our product candidates on a timely basis, which may increase our development costs and could delay the potential commercialization of our products and the subsequent receipt of revenue from sales, if any.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, or CROs, and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Any delays in completing our clinical trials may increase our development costs, slow down our product development and approval process, delay our receipt of product revenue and make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate, which would seriously harm our business. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may seriously harm our business.

All of our product candidates are in early-stage clinical trials or preclinical development, and if we and our partners are unable to successfully develop and commercialize our product candidates we will be unable to generate sufficient capital to maintain our business.

As of September 30, 2008, our partnered heart failure product candidate in collaboration with Celladon is in a Phase I clinical trial, we have completed a Phase I/II trial of our inflammatory arthritis candidate, our HIV/AIDS product candidate in collaboration with IAVI completed both a Phase I and Phase II trial and we have no product candidates in

Phase III trials. Of the product candidates that we are currently developing, we will not generate any product revenue, commercial manufacturing revenue, revenue sharing or royalties for at least several years, and then only if we and/or our partners can successfully commercialize our product candidates. Commercializing our potential products depends on successful completion of additional research and development and testing, in both preclinical development and clinical trials. Clinical trials may take several years or more to complete. The commencement, cost and rate of completion of our clinical trials may vary or be delayed for many reasons. If we are unable to successfully complete preclinical and clinical development of some or all of our product candidates in a timely manner, we may be unable to generate sufficient product revenue to maintain our business.

Even if our potential products succeed in clinical trials and are approved for marketing, these products may never achieve market acceptance. If we are unsuccessful in marketing or commercializing our product candidates for any reason, including greater effectiveness or economic feasibility of competing products or treatments, the failure of the medical community or the public to accept or use any products based on gene delivery, inadequate marketing and distribution capabilities or other reasons discussed elsewhere in this section, we will be unable to generate sufficient product revenue to maintain our business.

Litigation involving intellectual property, product liability or other claims and product recalls could strain our resources, subject us to significant liability, damage our reputation or result in the invalidation of our proprietary rights.

As our product development efforts progress, most particularly in potentially significant markets such as HIV/AIDS, heart failure or inflammatory arthritis therapies, the risk increases that others may claim that our processes and product candidates infringe on their intellectual property rights. In addition, administrative proceedings, litigation or both may be necessary to enforce our intellectual property rights or determine the rights of others. Defending or pursuing these claims, regardless of their merit, would be costly and would likely divert management's attention and resources away from our operations. If there were to be an adverse outcome in litigation or an interference proceeding, we could face potential liability for significant damages or be required to obtain a license to the patented process or technology at issue, or both. If we are unable to obtain a license on acceptable terms, or to develop or obtain alternative technology or processes, we may be unable to manufacture or market any product or potential product that uses the affected process or technology.

Clinical trials and the marketing of any potential products may expose us to liability claims resulting from the testing or use of our products. Gene therapy treatments are new and unproven, and potential known and unknown side effects of gene therapy may be serious and potentially life-threatening. Product liability claims may be made by clinical trial participants, consumers, healthcare providers or other sellers or users of our products. For example, a patient in one of our clinical trials experienced an SAE and subsequently died, and the spouse of that patient filed a lawsuit alleging that various named parties' negligence, including ours, was the proximate cause of the patient's death. Although we currently maintain liability insurance, the costs of product liability and other claims against us may exceed our insurance coverage. In addition, we may require increased liability coverage as additional product candidates are used in clinical trials or commercialized. Liability insurance is expensive and may not continue to be available on acceptable terms. A product liability or other claim or product recall not covered by or exceeding our insurance coverage could significantly harm our financial condition. In addition, adverse publicity resulting from a product recall or a liability claim against us, one of our partners or another gene therapy company could significantly harm our reputation and make it more difficult to obtain the funding and collaborative partnerships necessary to maintain our business.

Failure to recruit subjects could delay or prevent clinical trials of our potential products, which could delay or prevent the development of potential products.

Identifying and qualifying subjects to participate in clinical trials of our potential products is critically important to our success. The timing of our clinical trials depends on the speed at which we can recruit subjects to participate in testing our product candidates. We have experienced delays in some of our clinical trials, and we may experience similar delays in the future. If subjects are unwilling to participate in our gene therapy trials because of negative publicity from or concerns about the death of a subject in one of our trials who suffered an SAE, even though it was subsequently determined to be unrelated to our drug, or adverse events in the biotechnology or gene therapy industries in general or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting subjects, conducting trials and obtaining regulatory approval of potential products will be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether which could seriously harm our business.

Because our product candidates involve new and unproven technologies, the regulatory approval process may proceed more slowly compared to clinical trials involving new candidates in already proven drug classes.

No gene therapy products have received regulatory approval for marketing from the FDA. Because our product candidates involve new and unproven technologies, we believe that the regulatory approval process may proceed more slowly compared to clinical trials involving new candidates in already proven drug classes. The FDA and applicable state and foreign regulators must conclude at each stage of clinical testing that our clinical data suggest acceptable levels of safety in order for us to proceed to the next stage of clinical trials. In addition, gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the National Institutes of Health, or NIH, are subject to review by the NIH's Office of Biotechnology (OBA) Recombinant DNA Advisory Committee, or RAC. Although the RAC does not have regulatory status, the RAC review process can impede the initiation of the trial, because no research participant can be enrolled until the RAC review process has been completed and Institutional Biosafety Committee approval (from the clinical trial site) has been obtained, even if the FDA has reviewed and approved the protocol and initiation of clinical trial.

The regulatory approval process for our product candidates is costly, time-consuming and subject to unpredictable changes and delays, and our product candidates may never receive regulatory approval or be found safe and effective.

Both before and after approval of our product candidates, we, our product candidates and our suppliers are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: warning letters; fines and other monetary penalties; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution. We or the FDA may suspend or terminate human clinical trials at any time on various grounds. The hold on our Phase I/II clinical trial of tgAAC94 was lifted in November 2007 after several months of in depth review of data by the FDA. Although the SAE was not considered to be related to our product, completion of the trial was delayed by approximately six months because of the hold.

All of our product candidates are in development, and will have to be approved by the FDA before they can be marketed in the United States. The FDA has not approved any of our product candidates for sale in the United States and no company has sought FDA approval of a gene therapy based product. The clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use of the potential products. In addition, regulatory requirements governing gene therapy products have changed frequently and may change in the future. Obtaining FDA approval requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and we can not assure you that any approval will be granted on a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our product candidates and may require additional preclinical, clinical or other studies. As we develop our product candidates, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate for regulatory approval, if we are unable to successfully complete our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may be delayed in obtaining marketing approval for our product candidates, or may never be able to obtain marketing approval. Should this occur, we may have to delay or discontinue development of the product candidate, and the partner, if any, that supports development of such product candidate may terminate its support. Even a product candidate that appears promising at an early stage of research or development may not result in a commercially successful product. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market will decrease our ability to generate sufficient product revenue to maintain our business.

Even if regulatory approval of a product candidate is obtained, such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional clinical trials. These regulatory requirements may, among other things, limit the size of the market for the product. Even after approval, discovery of previously unknown problems with a product, manufacturer or facility, such as previously undiscovered side effects, may result in restrictions on any product, manufacturer or facility, including, among other things, a possible withdrawal of approval of the product, which would seriously harm our business.

If we are unable to obtain or maintain licenses for necessary third-party technology on acceptable terms or to develop alternative technology, we may be unable to develop and commercialize our product candidates.

We have entered into exclusive and nonexclusive license agreements that give us and our partners rights to use technologies owned or licensed by commercial and academic organizations in the research, development and commercialization of our potential products. We believe that we will need to obtain additional licenses to use patents and unpatented technology owned or licensed by others for use, compositions, methods, processes to manufacture compositions, processes to manufacture and purify gene therapeutics candidates and other technologies and processes for our present and potential product candidates. If we are unable to maintain our current licenses for third-party technology or obtain additional licenses on acceptable terms, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates. In addition, the license agreements for technology for which we hold exclusive licenses typically contain provisions that require us to meet minimum development milestones in order to maintain the license on an exclusive basis for some or all fields of the license. We also have license agreements for some of our technologies that may require us to sublicense certain of our rights. If we do not meet these requirements, our licensor may convert all or a portion of the license to a nonexclusive license or, in some cases, terminate the license.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could seriously harm our business.

If we lose our collaborative partners, we may be unable to develop our potential products.

A portion of our operating expenses are funded through our collaborative agreements with third parties. Our HIV/AIDS vaccine collaboration with CHOP and NCH is funded through a subcontract with NIAID, which is a U.S. government agency. We also have contracts with a biotechnology company, Celladon, and one public health organization, IAVI. Each of these collaborations provides for funding, collaborative development, intellectual property rights or expertise to develop certain of our product candidates. With limited exceptions, each collaborator has the right to terminate its obligation to provide research funding at any time for scientific or business reasons. For example, Sirna, a wholly-owned subsidiary of Merck & Co., Inc., recently ceased collaborating with us on our HD program and instead transferred the rights necessary to conduct the program to us. In addition, to the extent that funding is provided by a collaborator for non-program-specific uses, the loss of significant amounts of collaborative funding could result in the delay, reduction or termination of additional research and development programs, a reduction in capital expenditures or business development and other operating activities, or any combination of these measures, which could seriously harm our business.

If we do not attract and retain qualified personnel, we may be unable to develop and commercialize some of our potential products.

Our future success depends in large part on our ability to attract and retain key technical and management personnel. All of our employees, including our executive officers, can terminate their employment with us at any time. We have programs in place designed to retain personnel, including competitive compensation packages and programs to create a positive work environment. Other companies, research and academic institutions and other organizations in our field compete intensely for employees, however, and we may be unable to retain our existing personnel or attract additional qualified employees and consultants. If we experience significant turnover or difficulty in recruiting new personnel, our research and development of product candidates could be delayed and we could experience difficulty in generating sufficient revenue to maintain our business.

If our partners or scientific consultants terminate, reduce or delay our relationships with them, we may be unable to develop our potential products.

Our partners provide funding, manage regulatory filings, aid and augment our internal research and development efforts and provide access to important intellectual property and know-how. Their activities include, for example, support in processing the regulatory filings of our product candidates and funding clinical trials. Our outside scientific consultants and contractors perform research, develop technology and processes to advance and augment our internal efforts and provide access to important intellectual property and know-how. Their activities include, for example, clinical evaluation of our product candidates, product development activities performed under our research collaborations, research under sponsored research agreements and contract manufacturing services. Collaborations with established pharmaceutical and biotechnology companies and academic, research and public health organizations often provide a measure of validation of our product development efforts in the eyes of securities analysts, investors and the medical community. The development of certain of our potential products, and therefore the success of our business, depends on the performance of our partners, consultants and contractors. If they do not dedicate sufficient time, regulatory or other technical resources to the research and development programs for our product candidates or if they do not perform their obligations as expected, we may experience delays in, and may be unable to continue, the preclinical or clinical development of those product candidates. Each of our collaborations and scientific consulting relationships concludes at the end of the term specified in the applicable agreement unless we and our partners agree to extend the relationship. Any of our partners may decline to extend the collaboration, or may be willing to extend the collaboration only with a significantly reduced scope. Competition for scientific consultants and partners in gene therapy is intense. We may be unable to successfully maintain our existing relationships or establish additional relationships necessary for the development of our product candidates on acceptable terms, if at all. If we are unable to do so, our research and development programs may be delayed or we may lose access to important intellectual property or know-how.

We rely on third parties to conduct our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on third parties, such as CROs and research institutions, to conduct a portion of our preclinical research. We also rely on third parties, such as medical institutions, clinical investigators and CROs, to assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research is conducted in accordance with applicable regulations, and that our clinical trials are conducted in accordance with applicable regulations, the relevant protocol and within the context of approvals by an institutional review board. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to ensure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

We may not be able to obtain and maintain the additional third party relationships that are necessary to develop, commercialize and manufacture some or all of our product candidates or to expand our pipeline by adding new candidates.

We expect to depend on collaborators, partners, licensees, CROs, manufacturers and other third parties and strategic partners to support our discovery efforts, to formulate product candidates, to conduct clinical trials for some or all of our product candidates, to manufacture clinical and commercial scale quantities of our product candidates and products and to market, sell, and distribute any products we successfully develop.

We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, manufacturers and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts of our expenditures will be paid to third parties in these relationships. We can not, however, control the amount or timing of resources our contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all.

Any success of our clinical trials and preclinical studies may not be indicative of results in a large number of subjects of either safety or efficacy.

The successful results of our technology in preclinical studies using animal models may not be predictive of the results that we will see in our clinical trials with human subjects. In addition, results in early-stage clinical trials generally test for drug safety rather than efficacy and are based on limited numbers of subjects. Drug development involves a high degree of risk and our reported progress and results from our early phases of clinical testing of our product candidates may not be indicative of progress or results that will be achieved from larger populations, which could be less favorable. Moreover, we do not know if any favorable results we achieve in clinical trials will have a lasting or repeatable effect. If a larger group of subjects does not experience positive results or if any favorable results

do not demonstrate a beneficial effect, our product candidates that we advance to clinical trials may not receive approval from the FDA for further clinical trials or commercialization. For example, in March 2005, we discontinued the development of tgAAVCF, our product candidate for the treatment of cystic fibrosis, following the analysis of Phase II clinical trial data in which tgAAVCF failed to achieve the efficacy endpoints of the trial.

We may be unable to adequately protect our proprietary rights domestically or overseas, which may limit our ability to successfully market any product candidates.

Our success depends substantially on our ability to protect our proprietary rights and operate without infringing on the proprietary rights of others. We own or license patents and patent applications and will need to license additional patents for genes, processes, practices and techniques critical to our present and potential product candidates. If we fail to obtain and maintain patent or other intellectual property protection for this technology, our competitors could market competing products using those genes, processes, practices and techniques. The patent process takes several years and involves considerable expense. In addition, patent applications and patent positions in the field of biotechnology are highly uncertain and involve complex legal, scientific and factual questions. Our patent applications may not result in issued patents and the scope of any patent may be reduced both before and after the patent is issued. Even if we secure a patent, the patent may not provide significant protection and may be circumvented or invalidated.

We also rely on unpatented proprietary technology and technology that we have licensed on a nonexclusive basis. While we take precautions to protect our proprietary unpatented technology, we may be unable to meaningfully protect this technology from unauthorized use or misappropriation by a third party. Our competitors could also obtain rights to our nonexclusively licensed proprietary technology. In any event, other companies may independently develop equivalent proprietary information and techniques. If our competitors develop and market competing products using our unpatented or nonexclusively licensed proprietary technology or substantially similar technology, our products, if successfully developed, could suffer a reduction in sales or be forced out of the market.

If we do not develop adequate development, manufacturing, sales, marketing and distribution capabilities, either alone or with our business partners, we will be unable to generate sufficient product revenue to maintain our business.

Our potential products require significant development of new processes and design for the advancement of the product candidate through manufacture, preclinical and clinical testing. We may be unable to continue development or meet critical milestones with our partners due to technical or scientific issues related to manufacturing or development. We currently do not have the physical capacity to manufacture large-scale quantities of our potential products. This could limit our ability to conduct large clinical trials of a product candidate and to commercially launch a successful product candidate. In order to manufacture product at such scale, we will need to expand or improve our current facilities and staff or supplement them through the use of contract providers. If we are unable to obtain and maintain the necessary manufacturing capabilities, either alone or through third parties, we will be unable to manufacture our potential products in quantities sufficient to sustain our business. Moreover, we are unlikely to become profitable if we, or our contract providers, are unable to manufacture our potential products in a cost-effective manner.

In addition, we have no experience in sales, marketing and distribution. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. We intend to enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing and distribution agreements on favorable terms, if at all. If our current or future collaborative partners do not commit sufficient resources to timely marketing and distributing our future products, if any, and we are unable to develop the necessary marketing and distribution capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business.

Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.

Even if we obtain regulatory approvals for the commercial sale of our product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing

products and treatments. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

· the prevalence of adverse side effects;

· availability, relative cost, and relative efficacy of alternative and competing treatments;

· the effectiveness of our marketing and distribution strategy;

· publicity concerning our products or competing products and treatments; and

· our ability to obtain sufficient third-party insurance coverage or reimbursement.

If our product candidates do not become widely accepted by physicians, patients, third-party payors, and other members of the medical community, we would be unable to generate sufficient revenue to sustain our business.

Post-approval manufacturing or product problems or failure to satisfy applicable regulatory requirements could prevent or limit our ability to market our products.

Commercialization of any products will require continued compliance with the FDA and other federal, state and local regulations. For example, our current manufacturing facility, which is designed for manufacturing our AAV vectors for clinical and development purposes, is subject to the Good Manufacturing Practices requirements and other regulations of the FDA, as well as to other federal, state and local regulations such as the Occupational Health and Safety Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and the Environmental Protection Act. Any future manufacturing facility that we may construct for large-scale commercial production will also be subject to regulation. We may be unable to obtain regulatory approval for or maintain in operation this or any other manufacturing facility. In addition, we may be unable to attain or maintain compliance with current or future regulations relating to manufacture, safety, handling, storage, record keeping or marketing of potential products. If we fail to comply with applicable regulatory requirements or discover previously unknown manufacturing, contamination, product side effects or other problems after we receive regulatory approval for a potential product, we may suffer restrictions on our ability to market the product or be required to withdraw the product from the market.

We rely on single third-party suppliers for some of our raw materials; if these third parties fail to supply these items, development of affected product candidates may be delayed or discontinued.

Certain raw materials necessary for the manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials to us for any reason, including:

· regulatory requirements or action by the FDA or others;

· adverse financial developments at or affecting the supplier;

· unexpected demand for or shortage of raw materials;

· labor disputes or shortages; and

· failure to comply with our quality standards, which results in quality failures, product contamination and/or recall.

For example, we have experienced issues in the past with obtaining certain raw materials we use for vector production due to quality problems at the suppliers. These events could adversely affect our ability to continue development on affected product candidates, which could seriously harm our business.

Risks Related to Our Industry

Adverse events in the field of gene therapy could damage public perception of our potential products and negatively affect governmental approval and regulation.

Public perception of our product candidates could be harmed by negative events in the field of gene transfer. For example, in 2003, 14 subjects in a French academic clinical trial being treated for x-linked severe combined immunodeficiency in a gene therapy trial using a retroviral vector showed correction of the disease, although three of the subjects subsequently developed leukemia. A subject in one of our trials died in 2007 after suffering a serious adverse event that ultimately was attributed to an invasive fungal infection. Adverse events in our clinical trials, such as happened in 2007, even if not ultimately attributable to our drug candidates, and the resulting publicity, as well as any other adverse events in the field of gene therapy that may occur in the future, could result in a decrease in demand for any products that we may develop. The commercial success of our product candidates will depend in part on public acceptance of the use of gene therapy for preventing or treating human diseases. If public perception is influenced by claims that gene therapy is unsafe, our product candidates may not be accepted by the general public or the medical community, which may conclude that our technology is unsafe.

Future adverse events in gene therapy or the biotechnology industry could also result in greater governmental regulation, unfavorable public perception, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials.

Our use of hazardous materials exposes us to liability risks and regulatory limitations on their use, either of which could reduce our ability to generate product revenue.

Our research and development activities involve the controlled use of hazardous materials, including chemicals, biological materials and radioactive compounds. Our safety procedures for handling, storing and disposing of these materials must comply with federal, state and local laws and regulations, including, among others, those relating to solid and hazardous waste management, biohazard material handling, radiation and air pollution control. We may be required to incur significant costs in the future to comply with environmental or other applicable laws and regulations. In addition, we cannot eliminate the risk of accidental contamination or injury from hazardous materials. If a hazardous material accident were to occur, we could be held liable for any resulting damages, and this liability could exceed our insurance and financial resources. Accidents unrelated to our operations could cause federal, state or local regulatory agencies to restrict our access to hazardous materials needed in our research and development efforts, which could result in delays in our research and development programs. Paying damages or experiencing delays caused by restricted access could reduce our ability to generate revenue and make it more difficult to fund our operations.

The intense competition and rapid technological change in our market may result in failure of our potential products to achieve market acceptance.

We face increasingly intense competition from a number of commercial entities and institutions that are developing gene therapy technologies. Our competitors include early-stage and more established gene delivery companies, other biotechnology companies, pharmaceutical companies, universities, research institutions and government agencies developing gene therapy products or other biotechnology-based therapies designed to treat the diseases on which we focus. We also face competition from companies using more traditional approaches to treating human diseases, such as surgery, medical devices and pharmaceutical products. If our product candidates become commercial gene therapy products, they may affect commercial markets of the analogous protein or traditional pharmaceutical therapy. This may result in lawsuits, demands, threats or patent challenges by others in an effort to reduce our ability to compete. In addition, we compete with other companies to acquire products or technology from research institutions or universities. Many of our competitors have substantially more resources, including research and development personnel, capital and infrastructure, than we do. Many of our competitors also have greater experience and capabilities than we do in:

· research and development;

· clinical trials;

· obtaining FDA and other regulatory approvals;

· manufacturing; and

· marketing and distribution.

In addition, the competitive positions of other companies, institutions and organizations, including smaller competitors, may be strengthened through collaborative relationships. Consequently, our competitors may be able to develop, obtain patent protection for, obtain regulatory approval for, or commercialize new products more rapidly

than we do, or manufacture and market competitive products more successfully than we do. This could limit the prices we could charge for the products that we are able to market or result in our products failing to achieve market acceptance.

Gene therapy is a rapidly evolving field and is expected to continue to undergo significant and rapid technological change and competition. Rapid technological development by our competitors, including development of technologies, products or processes that are more effective or more economically feasible than those we have developed, could result in our actual and proposed technologies, products or processes losing market share or becoming obsolete.

Healthcare reform measures and the unwillingness of third-party payors to provide adequate reimbursement for the cost of our products could impair our ability to successfully commercialize our potential products and become profitable.

Sales of medical products and treatments, both domestically and abroad, substantially depend on the availability of reimbursement to the consumer from third-party payors. Our potential products may not be considered cost-effective by third-party payors, who may not provide coverage at the price set for our products, if at all. If purchasers or users of our products are unable to obtain adequate reimbursement, they may forego or reduce their use of our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing to realize a sufficient return on our investment.

Increasing efforts by governmental and third-party payors, such as Medicare, private insurance plans and managed care organizations, to cap or reduce healthcare costs will affect our ability to commercialize our product candidates and become profitable. We believe that third-party payors will attempt to reduce healthcare costs by limiting both coverage and level of reimbursement for new products approved by the FDA. There have been and will continue to be a number of federal and state proposals to implement government controls on pricing, the adoption of which could affect our ability to successfully commercialize our product candidates. Even if the government does not adopt any such proposals or reforms, their announcement could impair our ability to raise capital.

Risks Related to Our Common Stock

If we are unable to comply with the minimum requirements for quotation on the NASDAQ Capital Market and are delisted from the NASDAQ Capital Market, the liquidity and market price of our common stock would decline.

Our stock is listed on the NASDAQ Capital Market. In order to continue to be listed on the NASDAQ Capital Market, we must meet specific quantitative standards, including maintaining a minimum bid price of $1.00 for our common stock. On April 23, 2008, we received a staff deficiency notice from the NASDAQ Stock Market informing us that for 30 consecutive business days the bid price of our common stock had closed below the minimum $1.00 per share requirement for continued inclusion under Marketplace Rule 4310(c)(4).

The letter stated that under Marketplace Rule 4310(c)(8)(d), we will be provided with 180 calendar days, or until October 20, 2008, to regain compliance with Marketplace Rule 4310(c)(4). On October 22, 2008, the NASDAQ Stock Market notified us that it had suspended enforcement of the bid price and market value of publicly held shares requirements effective October 16, 2008 through January 16, 2009, and that we have until January 26, 2009 to regain compliance. To regain compliance, the bid price of our common stock must close at $1.00 or more per share for a minimum of 10 business days. If, on January 26, 2009, we meet The NASDAQ Capital Market initial inclusion criteria set forth in Marketplace Rule 4310(c), but have not regained bid price compliance, we may be provided with an additional 180 calendar day compliance period to demonstrate compliance. If we are not eligible for the additional compliance period at that time, NASDAQ Staff will provide written notification that Targeted Genetics' securities will be delisted. Upon such notice, we may appeal the NASDAQ Staff’s Determination to a Listing Qualifications Panel, pursuant to the procedures set forth in the NASDAQ Marketplace Rule 4800 Series. There can be no assurance that if we were to appeal such a determination that such appeal would be successful.

If we were to be delisted from the NASDAQ Capital Market, trading, if any, in our shares may continue to be conducted on the Over the Counter Bulletin Board or in a non-NASDAQ over-the-counter market, such as the “pink sheets.” Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could restrict investors’ interest in our securities. Also, a delisting could have a material adverse effect on the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than $5.00 per share, our shares could be subject to Rule 15g-9 under the Securities Exchange Act of 1934, as amended, which, among

other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a "penny stock" under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities and our ability to raise additional capital in an already challenging capital market.

If we sell additional shares, our stock price may decline as a result of the dilution that will occur to existing shareholders.

Until we are profitable, we will need significant additional funds to develop our business and sustain our operations. Any additional sales of shares of our common stock are likely to have a dilutive effect on our then-existing shareholders. Subsequent sales of these shares in the open market could also have the effect of lowering our stock price, thereby increasing the number of shares we may need to issue in the future to raise the same dollar amount and consequently further diluting our outstanding shares. These future sales could also have an adverse effect on the market price of our shares and could result in additional dilution to the holders of our shares.

The perceived risk associated with the possible sale of a large number of shares could cause some of our shareholders to sell their stock, thus causing the price of our stock to decline. In addition, actual or anticipated downward pressure on our stock price due to actual or anticipated sales of stock could cause some institutions or individuals to engage in short sales of our common stock, which may itself cause the price of our stock to decline.

If our stock price declines, we may be unable to raise additional capital. As our existing financial resources are only expected to be sufficient to fund our current level of operations into the first quarter of 2009, an inability to raise capital could force us to go out of business. Significant declines in the price of our common stock could also impair our ability to attract and retain qualified employees, reduce the liquidity of our common stock and result in the delisting of our common stock from the NASDAQ Capital Market.

Concentration of ownership of our common stock may give certain shareholders significant influence over our business and may result in certain decisions that are contrary to your interests.

A small number of investors own a significant number of shares of our common stock. As of September 30, 2008, Special Situations held approximately 2.5 million shares, Biogen Idec held approximately 2.2 million shares, OrbiMed Advisors LLC, or OrbiMed held approximately 1.3 million shares and Elan International services, Ltd., or Elan, held approximately 1.2 million shares, of our common stock. Together these holdings represent approximately 36% of our common shares outstanding as of September 30, 2008. This concentration of stock ownership may allow these shareholders to exercise significant control over our strategic decisions and block, delay or substantially influence all matters requiring shareholder approval, such as:

- approval of significant corporate transactions, such as a change of control of us;
- election of directors; or
- amendment of our charter documents.

The interests of these shareholders may conflict with your interests or the interests of other holders of our common stock with regard to such matters. Furthermore, this concentration of ownership of our common stock could allow these shareholders to delay, deter or prevent a third party from acquiring control of us at a premium over the then-current market price of our common stock, which could result in a decrease in our stock price and a reduction in the value of your investment.

Special Situations, Biogen Idec, OrbiMed and Elan have all sold shares of our common stock and may continue to do so. Sales of significant value of stock by these investors may introduce increased volatility to the market price of our common stock. In accordance with the termination agreement that we entered into with Elan in March 2004, Elan is only permitted to sell quantities of our stock equal to 175% of the volume limitation set forth in Rule 144(e)(1) promulgated under the Securities Act of 1933, as amended, subject to certain exceptions.

Market fluctuations or volatility could cause the market price of our common stock to decline and limit our ability to raise capital or cause impairment issues.

The stock market in general and the market for biotechnology-related companies in particular have experienced extreme price and volume fluctuations, often unrelated to the operating performance of the affected companies. The market price of the securities of biotechnology companies, particularly companies such as ours without earnings and product revenue, has been highly volatile and is likely to remain so in the future. Any report of clinical trial results that are below the expectations of financial analysts or investors could result in a decline in our stock price. We believe that in the past, similar levels of volatility have contributed to the decline in the market price of our common stock, and may do so again in the future. Trading volumes of our common stock can increase dramatically, resulting in

a volatile market price for our common stock. The trading price of our common stock could decline significantly as a result of sales of a substantial number of shares of our common stock, or the perception that significant sales could occur. In addition, the sale of significant quantities of stock by Special Situations, Biogen Idec, OrbiMed, Elan, or other holders of significant amounts of shares of our stock, could adversely impact the price of our common stock.

Item 2. Unregistered Sales of Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

Item 6. Exhibits

See the Index to Exhibits included in this quarterly report.

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 thereunto duly authorized.

TARGETED GENETICS CORPORATION

Date: November 5, 2008	By:	/s/ H. STEWART PARKER **H. Stewart Parker,** **President, Chief Executive Officer and Director** **(Principal Executive Officer)**
Date: November 5, 2008	By:	/s/ DAVID J. POSTON **David J. Poston,** **Vice President, Finance and Chief Financial Officer** **(Principal Financial and Accounting Officer)**

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Form	Date of First Filing	Exhibit Number	Filed Herewith
3.1	Restated Articles of Incorporation	8-K	1/30/08	3.1	
3.2	Amended and Restated Bylaws.	8-K	12/28/07	3.1	
4.1	Registration Rights Agreement among Targeted Genetics Corporation and certain investors dated as of January 8, 2007.	8-K	1/8/07	10.2	
4.2	Registration Rights Agreement among Targeted Genetics Corporation and certain purchasers dated as of June 22, 2007.	8-K	6/25/07	10.2	
10.2	Amended and Restated Senior Management Employment Agreement, dated as of March 11, 2008, between Targeted Genetics Corporation and Barrie J. Carter	8-K	3/12/08	10.2	
10.3	Amended and Restated Senior Management Employment Agreement, dated as of March 11, 2008, between Targeted Genetics Corporation and David J. Poston	8-K	3/12/08	10.3	
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934.				X
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934.				X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X