TARGETED GENETICS CORP /WA/
Form 10-Q
August 12, 2009
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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 JUNE 30, 2009

¨ **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 ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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 ¨ Accelerated filer ¨ Non-accelerated filer ¨ 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). ¨ Yes x No

Shares of Common Stock, par value $0.01 per share, outstanding as of August 6, 2009: 20,652,530

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TARGETED GENETICS CORPORATION

Quarterly Report on Form 10-Q

For the quarter ended June 30, 2009

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PART I FINANCIAL INFORMATION

Item 1. *Unaudited Financial Statements*

TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	June 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,469,000	$ 5,216,000
Accounts receivable	129,000	317,000
Prepaid expenses and other	394,000	132,000
Total current assets	2,992,000	5,665,000
Property and equipment, net	1,085,000	1,285,000
Other assets		200,000
Total assets	$ 4,077,000	$ 7,150,000
LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 957,000	$ 1,735,000
Accrued employee expenses	295,000	368,000
Current portion of accrued restructure charges	454,000	656,000
Deferred revenue	302,000	1,227,000
Total current liabilities	2,008,000	3,986,000
Accrued restructure charges	25,000	6,934,000
Deferred rent	66,000	2,000
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, 445,000,000 shares authorized, 20,651,863 shares issued and outstanding at June 30, 2009 and 20,238,865 shares issued and outstanding at December 31, 2008	207,000	202,000
Additional paid-in capital	317,119,000	316,900,000
Accumulated deficit	(315,348,000)	(320,874,000)
Total shareholders equity (deficit)	1,978,000	(3,772,000)
Total liabilities and shareholders equity	$ 4,077,000	$ 7,150,000

See accompanying notes to condensed consolidated financial statements

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TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Revenue under collaborative agreements	$ 3,362,000	$ 2,237,000	$ 5,383,000	$ 4,736,000
Operating expenses:				
Research and development	1,891,000	4,156,000	4,011,000	8,102,000
General and administrative	1,036,000	1,752,000	2,397,000	3,641,000
Restructure charge (credit)	(6,873,000)	199,000	(6,539,000)	401,000
Total operating expenses	(3,946,000)	6,107,000	(131,000)	12,144,000
Income (loss) from operations	7,308,000	(3,870,000)	5,514,000	(7,408,000)
Investment income	2,000	73,000	12,000	198,000
Net income (loss)	$ 7,310,000	$ (3,797,000)	$ 5,526,000	$ (7,210,000)
Net income (loss) per common share (basic and diluted)	$ 0.36	$ (0.19)	$ 0.27	$ (0.36)
Shares used in computation of basic and diluted net income (loss) per common share	20,545,000	19,902,000	20,475,000	19,858,000

See accompanying notes to condensed consolidated financial statements

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TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six months ended June 30,	
	2009	**2008**
Operating activities:		
Net income (loss)	$ 5,526,000	$ (7,210,000)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	211,000	278,000
Stock-based compensation	230,000	445,000
Other	(6,000)	(10,000)
Changes in assets and liabilities:		
Accounts receivable	188,000	2,356,000
Prepaid expenses and other	(262,000)	(84,000)
Current liabilities	(851,000)	(296,000)
Deferred revenue	(925,000)	1,594,000
Deferred rent	64,000	(2,000)
Accrued restructure charges	(7,111,000)	(281,000)
Other non-current assets	200,000	
Net cash used in operating activities	(2,736,000)	(3,210,000)
Investing activities:		
Purchases of property and equipment	(11,000)	(530,000)
Net cash used in investing activities	(11,000)	(530,000)
Financing activities:		
Payments under leasehold improvements and equipment financing arrangements		(1,000)
Net cash used in financing activities		(1,000)
Net decrease in cash and cash equivalents	(2,747,000)	(3,741,000)
Cash and cash equivalents, beginning of period	5,216,000	16,442,000
Cash and cash equivalents, end of period	$ 2,469,000	$ 12,701,000

See accompanying notes to condensed consolidated financial statements

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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, 2008 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. There were no intercompany transactions for any of the periods included in this report. 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 six months ended June 30, 2009 are necessarily indicative of the results to be expected for the full year or any other period.

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, 2008.

We have prepared the accompanying financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business.

Our combined cash and cash equivalents totaled $2.5 million at June 30, 2009. We believe that our current financial resources and the cash we expect to receive from our collaborative partners, grants and other business activities will only be sufficient to fund our operations until mid-to-late August 2009. This estimate is based on our ability to successfully perform planned activities and to successfully manage our operating costs, and actual results could differ from our estimates. Unless we raise sufficient additional capital by the end of August 2009, we expect to begin the process of ceasing operations or otherwise winding up our business.

Fair Value

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.

Earnings Per Share

Basic and diluted net income (loss) per share have been computed based on net income (loss) and the weighted-average number of common shares outstanding during the applicable period. We have excluded certain options to purchase common stock, restricted stock units and warrants to purchase common stock, as the potentially issuable shares covered by these securities are antidilutive. The following table presents the securities not included in net income (loss) per share for the three- and six-month periods ended June 30, 2009 and 2008:

	Three and six months ended June 30,	
	2009	**2008**
Options to purchase common stock	1,742,000	731,000

Restricted stock units	277,000	808,000
Warrants to purchase common stock	7,914,000	7,914,000
Total securities excluded in net income (loss) per share	9,933,000	9,453,000

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Recently Issued Accounting Standards

In December 2007, the Emerging Issues Task Force, or EITF, of the Financial Accounting Standard Board, or FASB, 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 existing collaborations in place after January 1, 2009. The adoption of EITF 07-1 did not have an effect on our financial position or results of operations for the three or six months ended June 30, 2009. See Footnote 4 for further information.

During the quarter ended June 30, 2009, we adopted Statement of Financial Accounting Standards, or SFAS, Statement No. 165, *Subsequent Events,* or SFAS No. 165, on a prospective basis. SFAS No. 165 establishes general standards of accounting and disclosure for events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The adoption of SFAS No. 165 did not have any impact on our results of operations, cash flows or financial position. We have evaluated subsequent events through the time that we filed our financial statements.

In June 2009, the FASB issued SFAS Statement No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162,* or SFAS No. 168. SFAS No. 168 confirmed that the FASB Accounting Standards Codification, or Codification, will become the single official source of authoritative U.S. GAAP other than guidance issued by the SEC, superseding existing FASB, American Institute of Certified Public Accountants, EITF and related literature. After that date, only one level of authoritative U.S. GAAP will exist. All other literature will be considered non-authoritative. The Codification, which changes the referencing of financial standards but does not change U.S. GAAP, becomes effective for interim and annual periods ending on or after September 15, 2009. We will apply the Codification beginning in the third quarter of fiscal 2009. As the Codification does not change or alter existing GAAP, it will not have any impact on our consolidated financial statements.

2. Accrued Restructure Charges

Restructure charges primarily include contract termination costs related to building lease activity and employee termination costs. We have historically applied the provisions of Statement of Financial Accounting Standards, or 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 recorded restructure charges on the operating lease for the facility as a result of our 2003 decision to discontinue use of the facility.

On February 3, 2009, we surrendered the Bothell facility to the landlord and ceased making rent payments for the facility, actions that constituted a default under the lease. In March 2009, we forfeited our $200,000 security deposit and on June 29, 2009, we entered into an agreement to terminate the Bothell facility lease. Upon execution of the lease termination agreement, or Agreement, we were released from all obligations under the lease other than certain indemnification obligations. As consideration for the Agreement and for the discharge of our obligations under the lease, which obligations included up to $12 million in estimated payment obligations that would have been owed through September 2015, we agreed to pay a termination fee of $500,000. The termination fee will be paid in installments beginning with the execution of the Agreement and continuing through July 2010. Under the terms of the Agreement, $100,000 of the termination fee balance will be accelerated in the event that we receive a specified product development milestone payment from a collaborator and any remaining unpaid balance of the termination fee will be accelerated in the event that we receive a specified minimum amount in net proceeds from equity and/or debt financing. As a result of the termination of our Bothell facility lease obligations, we recorded a $7.2 million reversal to the accrued restructure liability, which is reflected as a benefit in our second quarter and year-to-date results.

Following the rules of SFAS No. 146, we record employee termination benefit costs associated with restructuring our business or reductions in force as restructure charges. Employee termination benefit costs include one-time termination benefits that are not part of an existing benefit arrangement, including severance payments, stock-based compensation charges related to modified stock awards and payments for post-employment medical coverage.

The table below presents a reconciliation of our accrued restructure liability for the six-month period ended June 30, 2009:

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	Restructure Costs
December 31, 2008 accrued liability	$ 7,590,000
Charges related to employee termination benefits	350,000
Accretion charge	311,000
Reversal of accrued restructure liability	(7,201,000)
Cash payments	(571,000)
June 30, 2009 accrued liability	$ 479,000

Adjustments to the accrued restructure liability for the six months ended June 30, 2009 include $350,000 of employee termination benefits, accretion expenses of $311,000 and a credit of $7.2 million to reflect the reversal of previously accrued Bothell facility restructure charges. The total of these charges and adjustments to the liability are reflected as restructure charges in the accompanying condensed consolidated statement of operations. Through June 30, 2009, we have recorded a cumulative amount of $516,000 in employee termination benefits related to our restructuring to reduce expenses and realign and narrow our product development priorities, which we announced in November 2008.

3. Equity

Stock Compensation

Our share-based compensation programs consist of share-based awards granted to employees including stock options and restricted stock units. We follow SFAS No. 123R, *Share-Based Payments,* which requires us to expense the fair value of share-based payments granted over the vesting period.

In the first quarter of 2009 we modified some outstanding restricted stock units. Under the revised restricted stock unit agreements the outstanding awards were not canceled upon termination of service and were immediately vested in full. Under SFAS No. 123R, these modified awards were revalued on the effective date of the modification and the entire stock-based compensation charge was recognized in full during the first quarter of 2009 as there is no longer a service requirement. We recorded no expense relating to these awards for the three-month period ended June 30, 2009 or the three- or six-month periods ended June 30, 2008 and we recorded expense of $58,000 in the first quarter of 2009. This expense is reflected as restructure charges in the accompanying consolidated statement of operations. For the three-month period ending June 30, 2009, we recorded a credit amount of $103,000 in stock option expense as a result of staff reductions and the resulting forfeiture of stock options by former employees.

The following table summarizes stock-based compensation expense and credits to expense related to employee stock options and restricted stock units under SFAS No. 123(R) for the three and six months ended June 30, 2009 and 2008:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Stock options:				
Research and development	$ (4,000)	$ 64,000	$ 1,000	$ 93,000
General and administrative	(5,000)	21,000	(5,000)	35,000
Restricted stock units:				
Research and development	42,000	97,000	97,000	160,000
General and administrative	45,000	69,000	79,000	157,000
Restructure			58,000	
Total stock-based compensation expense	$ 78,000	$ 251,000	$ 230,000	$ 445,000

We estimate 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. We granted options for 1.3 million shares of common stock during the three months ended June 30, 2009. We granted no stock options during 2008. We apply an estimated forfeiture rate that we derive from historical forfeited shares.

The weighted average assumptions for stock options granted in the three and six months ended June 30, 2009 were:

a) Expected dividend rate of zero,

b) Expected stock price volatility ranged from 1.249 to 1.455,

c) Risk free interest rate ranged from 0.58% to 2.68%, and

d) Expected life of options ranged from 2 to 4 years.

Expected Dividend: We do not anticipate paying any dividends.

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Expected Life: Expected life represents the period that we expect our stock-based awards to be outstanding based on historical experience, vesting schedules of similar awards and current business conditions.

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

We have entered into various product development relationships and license arrangements with pharmaceutical and biotechnology companies and non-profit organizations. Under these partnerships, we typically are reimbursed for research and development and manufacturing activities we perform. As part of these agreements we have received milestone and upfront payments and may receive additional milestone payments. Additionally, we may receive payments upon the occurrence of certain transactions involving covered products as well as royalties from product sales after commercialization.

EITF No. 07-01, which we implemented in the first quarter of 2009, prescribes that certain transactions between collaborators be recorded in the income statement on either a gross or net basis, depending on the characteristics of the collaborative relationship, and provides for enhanced disclosure of collaborative relationships. In accordance with EITF 07-01, we evaluated our collaborative agreements for proper income statement classification based on the nature of the underlying activity. Amounts earned from our collaborative partners related to development activities are generally reflected as collaborative revenue and the costs incurred are reflected as research and development expense. We currently do not have any collaborations involving commercialized products. The adoption of EITF 07-01 did not affect our financial position or results of operations.

Revenues earned for the three and six months ending June 30, 2009 and 2008 under our research and development collaborations and license agreements are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Celladon	$ 2,998,000	$ 1,403,000	$ 4,546,000	$ 2,201,000
NIAID	354,000	834,000	684,000	2,535,000
Department of Defense	10,000		153,000	
Total Collaborative Revenue	$ 3,362,000	$ 2,237,000	$ 5,383,000	$ 4,736,000

Celladon

In 2004, we entered into a collaboration agreement and manufacturing agreement with Celladon Corporation focused on the development of AAV-based drugs for the treatment of heart failure. In February 2009, we and Celladon agreed to replace the prior collaboration and manufacturing agreements with a license agreement and new manufacturing agreement. Under the terms of the modified agreements, we granted Celladon exclusive use of certain proprietary AAV vector technology in a specified field relating to heart failure, agreed to manufacture Celladon s MYDICAR® product candidate for phase III clinical studies, at Celladon s expense, and agreed to transfer technology to enable Celladon to manufacture MYDICAR® in the future through contract manufacturing organizations or a commercial partner. In addition, Celladon agreed to a new milestone payment and royalty structure covering development and commercialization of products in the permitted field, and Celladon also agreed to make payments to us in the event of specified strategic transactions involving Celladon. Celladon separately manages and funds the clinical trial costs of the heart failure program. In June 2009, we completed the manufacture of Celladon s MYDICAR® product

candidate and our work plan with Celladon concluded on July 31, 2009.

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National Institute of Allergy and Infectious Diseases

In 2005, we extended the scope of our HIV/AIDS vaccine program to include the developed world via a contract awarded by the National Institute of Allergy and Infectious Disease, or NIAID, to Nationwide Children s Hospital, or NCH, in collaboration with Children s Hospital of Philadelphia, or CHOP, and us. Under the original award, the NIAID established a $22.0 million budget for the overall collaboration, of which they identified a subcontract budget of up to $18.2 million of funding over five years for our efforts for the development, manufacture and preclinical testing of vaccine candidates. Since 2005, investigators at CHOP and NCH completed the design of the vaccine candidates and we have completed toxicology studies and manufactured the vectors for the clinical trials that are planned to be conducted in the U.S. The direct costs of any clinical trials will be borne by the NIAID and are not part of the contract. The NIAID awards funding under this program in annual installments. Total cumulative potential funding available to earn under our subcontract is $15.8 million for the performance period through August 30, 2009, and we have recognized cumulative revenues of $11.3 million through June 30, 2009. In early 2009 we began to terminate our HIV/AIDS subcontract with CHOP and NCH. As a result, we expect modest amounts of HIV/AIDS vaccine program revenue during the remainder of 2009 as we wind down our portion of the development efforts and terminate our involvement in the program.

U.S. Department of Defense

In 2008, we entered into an agreement to develop a small-molecule based product candidate to treat amyotrophic lateral sclerosis, or ALS, in collaboration with John Engelhardt, Ph.D., at the University of Iowa, or UI, and funded by a grant from the U.S. Department of Defense, or DOD. Under the award, the DOD has approved grant funding of up to $2.4 million for the reimbursement of research and development costs we incur during 2009. Since the inception of the agreement, we have recognized $260,000 of revenue in this program, including $153,000 recognized in the six months ended June 30, 2009. In June 2009, our option to a license to certain UI technology for this program expired. In light of our current cash constraints, the expiration of the technology option, the amount of preclinical progress made so far in the program, and the estimated timeline and funding requirements for future development, we are in the process of evaluating our continued involvement in the ALS program going forward.

5. Subsequent Events

On July 20, 2009, we and Ironwood Apartments, Inc., the owner of the facility we use for our headquarters offices and our primary research and development activities, entered into the eighth amendment to our lease, or the Ironwood Amendment. The Ironwood Amendment provides for reduced rent for the months of June, July and August 2009 and provides that we may either terminate the lease and our remaining obligations under the lease, effective August 31, 2009, or exercise an option to continue the lease and our occupancy of the facility. Under the terms of the Ironwood Amendment, if we elect to terminate the lease, we must pay a $45,000 termination fee in addition to the rent due for June, July and August 2009 (as reduced by the Ironwood Amendment), which payments would release us from up to approximately $4 million in estimated payment obligations and other liabilities under the lease. If we elect to continue the lease, we must notify the landlord by August 15, 2009, pay $45,000 as additional base rent for the months of June, July and August 2009 and, if the landlord so requests before August 31, 2009, provide reasonable assurance of our ability or the ability of a potential assignee to perform our ongoing obligations under the lease (which assurances may include, without limitation, having cash and cash equivalents sufficient to fund our ongoing operations for at least twelve months). If we are unable to provide this credit assurance upon landlord s timely request, the landlord has the right to terminate the lease effective October 31, 2009.

On August 10, 2009, we and Metropolitan Park West IV, LLC, the landlord of the facility we use for our administrative office space, entered into a Ninth Amendment to Lease Agreement and Conditional Termination of Lease, or the MPW Amendment. On the effective date of the MPW Amendment, we paid the landlord rent for the months of August and September 2009 and an additional fee of $10,000. The MPW Amendment provides for the termination of the lease and our future obligations under the lease (other than certain indemnification obligations) effective September 30, 2009, unless the termination date is extended as described below. This termination will release us from up to approximately $800,000 in estimated future payment obligations (based on a termination date of September 30, 2009). The lease will continue for four additional months, through January 31, 2010, if we raise a specified minimum amount in outside financing by September 15, 2009. In such event, the MPW Amendment allows us to elect an additional 11-month continuation of the lease, through December 31, 2010, if we are able to provide the landlord with reasonable assurances of an adequate cash horizon, the landlord accepts our election and we provide written notice of election by November 30, 2009. The monthly rent due under any extension of the lease would be at the rates specified in the eighth amendment to the lease. The MPW Amendment amends the Office Lease dated October 7, 2009, as amended, between us and the landlord (as successor in interest to Benaroya Capital Company, LLC), which Office Lease covers 4,990 square feet of space and, if not earlier terminated, would expire on March 31, 2014.

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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 cash resources and future financial condition, our ability to continue our operations, our cash horizon, efforts and ability to close on transactions to obtain additional funding and the sufficiency of such funding, our potential delisting from the Nasdaq Capital Market and the process for appealing the Nasdaq staff s determination to delist our securities, our product development and commercialization capabilities, goals and expectations, potential market opportunities, our plans for and anticipated results of our clinical development activities and the potential advantage of our technology and product candidates, the termination and potential extension of the termination date of our facility leases, and other statements that are not historical facts. Words such as may, can be, may depend, will, believes, estimates, expe anticipates, plans, projects, intends, or statements 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 factors, risks and other information we provide in the reports we file from time to time with the Securities and Exchange Commission, or SEC.

BUSINESS OVERVIEW

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 by facilitating the normal protein production or gene regulation capabilities of cells. Gene therapeutics may be used to treat a disease state by enabling cells to produce more of a certain protein or different proteins than they would normally produce. Vectors can also be used to deliver specific genetic sequences that, once delivered and expressed as an interfering RNA molecule, or RNAi, can shut down or interfere with the production of disease-specific genes by messenger RNA.

We are a leader in the development of gene therapeutics based on adeno-associated viral, or AAV, vectors, and in the development of AAV manufacturing technology. We have treated over 400 subjects in clinical trials using AAV-based gene therapeutic product candidates and, through our research and development activities, we have acquired expertise and intellectual property related to AAV-based gene therapeutic technologies. In addition, based on research developed by one of our collaborators to improve the delivery of AAV vectors, a new product opportunity emerged for a small molecule therapy to potentially treat neurological diseases associated with oxidative stress. We have applied our development expertise to this early-stage small molecule and in 2008 we initiated a preclinical program around that opportunity. As a result of our AAV- related efforts, we believe we have generated potential value through our development and manufacturing expertise, through the potential of our accumulated intellectual property portfolio and through our application of our expertise and intellectual property to promising product candidates.

In November 2008, we reprioritized our product development efforts and focused our internally funded efforts on ocular and neurological product candidates, including our first product development effort to evaluate the use of AAV to deliver expressed RNAi. This realignment focused our resources on creating near-term value balanced with the capabilities and resources currently available to us and our collaborators. We implemented this realignment to scale our operations down to match our projected financial resources and to focus our development efforts and intellectual property on the three programs that, in our view, offered the most near-term promise. The current status of each of these programs is as follows:

The first program is a clinical-stage AAV-based product candidate for the treatment of Leber s congenital amaurosis, or LCA, developed with Robin Ali, Ph.D., our collaborator at the University College London/Moorfields Eye Hospital, or UCL/M. LCA is an ocular disease, one cause of which is a mutation in the RPE65 gene that leads to

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blindness. This product candidate is currently enrolling subjects in a Phase I/II dose escalation clinical trial funded through a grant awarded to Dr. Ali.

The second program is a preclinical AAV-based Huntington s disease, or HD, product candidate under development with our collaborator, Beverly Davidson, Ph.D., at the University of Iowa, or UI. HD is an incurable neurodegenerative disorder that results from mutations to the gene that codes for the huntingtin protein. Preclinical studies focused on identifying a clinical candidate continue at UI. Based on our current cash constraints and an ongoing review of the program development timeline and funding requirements for future development, combined with an assessment of partnering interest from other parties to support future development efforts, we are in the process of evaluating whether we will continue with this program and maintain our license with UI around these technologies going forward.

The third program is a preclinical small-molecule-based product candidate to treat amyotrophic lateral sclerosis, or ALS, under development with our collaborator, John Engelhardt, Ph.D., at UI. ALS is a progressive neurodegenerative disease affecting the brain and spinal cord. Our efforts in this program have been partially funded by a grant to us from the U.S. Department of Defense, or DOD. In June 2009, our option to a license to certain UI technology for this program expired. In light of our current cash constraints, the expiration of the technology option, the amount of preclinical progress made so far in the program, and the estimated timeline and funding requirements for future development, we are in the process of evaluating our continued involvement in the ALS program going forward.

We are leaders in the development and application of processes to manufacture potential products at a scale amenable to late-stage clinical development and expandable to large-scale commercial production, and we have established broad capabilities in applying our AAV-based gene therapeutic technologies to multiple product candidates and therapeutic indications. We believe that our technology assets, know-how, intellectual property and product candidates are valuable assets and we are actively pursuing opportunities to monetize these assets as part of our efforts to raise capital.

In late 2008 and early 2009, we analyzed the financial impact of continuing to support our internal manufacturing infrastructure compared to purchasing manufacturing services from contract manufacturing organizations, or CMOs. We determined that, based on our progress in developing a robust set of reproducible manufacturing processes, we could feasibly outsource our manufacturing needs rather than maintain the infrastructure costs of supporting our in-house manufacturing capability. In connection with the decision to outsource manufacturing to CMOs, in February 2009 we replaced our collaboration and manufacturing agreements with Celladon with a license agreement and a new manufacturing agreement. Under the new Celladon agreements, we and Celladon Corporation agreed to conduct our previously agreed manufacturing campaign for Celladon s MYDICAR® congestive heart failure product candidate at our company facilities and, in parallel, transfer the manufacturing know-how and processes required to replicate our manufacturing and testing of MYDICAR® to third-party CMOs. In June 2009 we completed the manufacture of MYDICAR® and in July 2009 we completed our portion of the transfer of the manufacturing know-how and processes to a CMO. Under our Celladon license agreement, Celladon is obligated to pay us milestone payments upon successful completion of product development milestones, if any, and if a product is ultimately approved Celladon is obligated to pay us royalty payments on any sales of such product. Provided we raise adequate capital to continue our business, we plan to continue to maintain an internal knowledge base within the company to facilitate high-quality training and oversight of manufacturing information transfer to CMOs and provide for a high-level capability for continued development of new or improved manufacturing processes.

Additionally, in early 2009, in connection with our realignment efforts, we began to terminate our subcontract with Children s Hospital of Philadelphia, or CHOP, and Nationwide Children s Hospital, or NCH, for an HIV/AIDS vaccine project funded by the National Institute of Allergy and Infectious Diseases, or NIAID, as the program is entering into clinical trials. We also continued to realign our intellectual property portfolio to focus on our current priorities, which realignment included returning rights under licenses and/or ceasing to prosecute patents that were not specific to our current development program efforts. Based on the revenue we received from the new Celladon agreements, in combination with decreased operating costs resulting from our reduced infrastructure, external program support, reduced intellectual property costs and other spending reductions, we believe we have extended our cash horizon through mid-to-late August 2009.

Most of our expenses are related to our research and development programs and general and administrative support for these activities. We have financed our operations 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. These financing sources have historically allowed us to maintain adequate levels of cash and cash equivalents but, particularly given the current market environment and the limited cash horizon we have, they may not continue to do so.

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As of June 30, 2009, our accumulated deficit totaled $315.3 million and our cash balance was $2.5 million. We believe that our current financial resources, together with the cash we expect to receive from our collaborative partners, grants and other business activities, will only be sufficient to fund our operations through mid-to-late August 2009. Unless we raise sufficient additional capital by then, we expect to begin the process of ceasing operations or otherwise winding up our business.

As a result of the goodwill impairment charge we recognized in the fourth quarter of 2008, combined with accrued restructure charges totaling $7.6 million at March 31, 2009, we had a net worth deficit of $5.4 million at March 31, 2009 and shareholders equity of $2.0 million at June 30, 2009. Because our shareholders equity is below the $2.5 million required for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b) (formerly Marketplace Rule 4310(c)(3)) and we do not meet the alternative continued listing requirements of $35 million in market value of listed securities or $500,000 in net income from continuing operations, Nasdaq notified us of its determination to delist our securities effective at the opening of business on August 3, 2009. We appealed the Nasdaq staff s determination and were granted a hearing before a Nasdaq hearing panel, and the delisting of our securities has been stayed until the hearing is completed and the panel has issued a written decision. A written decision is expected within 35 days from the hearing date. We are also in non-compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market under Listing Rule 5550(a)(2) (formerly Marketplace Rule 4310(c)(4)) and, on August 10, 2009, Nasdaq notified us that the bid price deficiency serves as an additional basis for delisting our securities. We plan to address this issue of non-compliance with the bid price requirement in connection with the hearing before the Nasdaq panel. We can provide no assurance that the panel will grant our request for continued listing on the Nasdaq Capital Market or that we will be able to regain or maintain compliance with the listing requirements.

CRITICAL ACCOUNTING POLICIES, ESTIMATES AND ASSUMPTIONS

There have been no material changes from the critical accounting policies, estimates and assumptions disclosed the section entitled *Management s Discussion and Analysis of Financial Condition and Results of Operations* in Item 7 of our annual report on Form 10-K for the year ended December 31, 2008.

RESULTS OF OPERATIONS

Revenue

Revenue increased to $3.4 million for the three months ended June 30, 2009 from $2.2 million for the same period in 2008 as a result of revenue earned upon completion of our manufacture of MYDICAR® for the Celladon heart failure collaboration, offset in part by reduced revenue generated by the NIAID-funded HIV/AIDS vaccine project. Revenue increased to $5.4 million for the six months ended June 30, 2009 from $4.7 million for the same period in 2008 as a result of increased revenue generated by both pre-manufacturing and manufacturing efforts in our Celladon collaboration, offset by decreases in revenue reflecting that revenue for the HIV/AIDS vaccine project in 2008 included revenue generated from a vaccine product candidate manufacturing campaign, higher pass-through costs and higher labor costs.

Operating Expenses

Research and Development Expenses. Research and development expenses decreased to $1.9 million for the three months ended June 30, 2009 from $4.2 million for the same period in 2008. Research and development expenses decreased to $4.0 million for the six months ended June 30, 2009 from $8.1 million for the same period in 2008. The decreases in both periods reflect lower pass-through costs for outside services under our NIAID-funded HIV/AIDS vaccine subcontract, lower staffing costs, and lower clinical trial costs reflecting the substantial completion of our Phase I/II inflammatory arthritis program clinical trial in 2008.

The following table sets forth the allocation of total research and development costs between our programs that are or were in clinical development and those that are in research or preclinical stages of development:

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	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Programs in clinical development:				
Heart failure	$ 641,000	$ 962,000	$ 1,476,000	$ 1,465,000
Inflammatory arthritis	21,000	381,000	68,000	888,000
Indirect costs and other	747,000	1,398,000	1,406,000	2,319,000
Total clinical development program expense	1,409,000	2,741,000	2,950,000	4,672,000
Research and preclinical development program expense	482,000	1,415,000	1,061,000	3,430,000
Total research and development expense	$ 1,891,000	$ 4,156,000	$ 4,011,000	$ 8,102,000

Research and development costs attributable to programs in clinical development include the costs of salaries and benefits, 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, as a result, we do not incur or 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 program under a subcontract with CHOP and NCH and costs incurred for our ALS program funded by the DOD. 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 typically 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 each program.

General and Administrative Expenses. General and administrative expenses decreased to $1.0 million for the three months ended June 30, 2009 from $1.8 million for the same period in 2008. General and administrative expenses decreased to $2.4 million for the six months ended June 30, 2009 from $3.6 million for the same period in 2008. The decreases in both periods reflect lower intellectual property costs resulting from our return of licensed patent rights and cessation of prosecution of patents that are not specific to our current development program efforts, lower employee costs resulting from our reductions in force, lower stock-based compensation charges and lower shareholder annual meeting-related costs.

Restructure Charges. For the three months ended June 30, 2009, we recorded a net restructuring credit of $6.9 million compared with restructuring charges of $199,000 for the three months ended June 30, 2008. For the six months ended June 30, 2009, we recorded a net restructuring credit of $6.5 million compared with restructuring charges of $401,000 for the six months ended June 30, 2008.

The net restructuring credit for the three and six months ended June 30, 2009 reflects the reversal of previously accrued restructure charges as a result of a lease termination agreement we entered into on June 29, 2009 to terminate the lease for our Bothell facility, partially offset by restructuring charges related to workforce reductions and accretion expense. Under the terms of the lease termination agreement, we will be released from up to approximately $12 million in estimated payment obligations and other obligations under the lease provided that we pay a termination fee of $500,000, to be paid in installments beginning at the execution of the agreement and continuing through July 2010. Under the terms of the Agreement, $100,000 of the termination fee balance will be accelerated in the event that we receive a specified product development milestone payment from a collaborator and any remaining unpaid balance of the termination fee will be accelerated in the event that we receive a specified minimum amount in net proceeds from equity and/or debt financing.

Other Income and Expense

Investment Income. Investment income reflects interest income earned on our short-term investments. Investment income decreased to $2,000 for the three months ended June 30, 2009 from $73,000 for the same period in 2008. Investment income decreased to $12,000 for the six months ended June 30, 2009 from $198,000 for the same period in 2008. This decrease is due to lower average cash balances and lower interest rates compared to 2008.

Liquidity and Capital Resources

We had cash and cash equivalents of $2.5 million at June 30, 2009, compared to $5.2 million at December 31, 2008. The decrease primarily reflects cash used in operations of $2.7 million.

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Our primary sources of capital are proceeds from public and private sales of our equity securities and cash payments received from our collaborative partners. To a lesser degree, we have also financed our operations through interest earned on our cash and, in the last two years, through license revenue. These financing sources have historically allowed us to maintain adequate levels of cash and cash equivalents but, particularly in the current market environment and given our recent inability to secure additional financial resources notwithstanding our considerable efforts to date, we believe that there is a substantial risk that we will be unable to raise the cash resources necessary to support our ongoing operations. We are actively engaged in discussions that could result in an extension of our cash horizon, although we can provide no assurance that any transactions will be completed or that the capital we would obtain from any transaction would be sufficient.

For 2008 and the first half of 2009, our primary expenses were related to conducting the Celladon MYDICAR® manufacturing campaign and technology transfer, the development of our research and development programs, prosecution of our intellectual property interests, and general and administrative support for these activities.

Most of our revenue has been derived under collaborative research and development agreements relating to the development of our potential product candidates. We do not expect the revenue generated from our current or future collaborative research and development and manufacturing arrangements to be sufficient to fully fund the development and commercialization of our product candidates. As a result, even if we are able to secure additional financial resources in time to continue our operations, we do not expect to generate ongoing positive cash flow from our operations for the foreseeable future and our ability to generate any sustained positive cash flow is dependent upon our success at developing and commercializing our product candidates.

We will require substantial additional funding to continue our operations and to fund development and commercialization of our product development programs. While the ocular program to treat LCA, currently in clinical trials sponsored and funded by our collaborative partner UCL/M, will not require substantial funding or staff support from us in 2009, our neurological disease programs to treat HD and ALS require or will require funding in the future to support license payments, funding for intellectual property prosecution and/or funding for certain product development efforts. In light of our current cash constraints, the amount of preclinical progress made so far in the programs, and the estimated timeline and funding requirements for future development, we are in the process of evaluating our continued involvement in the HD and ALS programs going forward.

We currently require additional financial resources to continue our operations after August 2009. In June and July 2009, we continued to reduce our staff because of our inability to obtain additional funding in the second quarter of 2009. As of August 1, 2009, we employ approximately 15 full-time equivalent employees. Unless we raise additional capital by the end of August 2009, we expect to begin the process of ceasing operations. Moreover, we may decide to cease operations or otherwise wind up our business even if we receive additional funding, if we believe the amount of additional funding would be insufficient to allow us to make meaningful progress in developing our current product candidates.

Our current operating strategy is to carefully steward our available funds to advance one or more of our partnered product development programs while pursuing capital-raising opportunities. Our near-term financing strategy includes leveraging our capabilities and intellectual property assets in manufacturing and development into capital-raising opportunities to extend our cash horizon. For example, we are actively engaged in discussions that could involve selling or licensing technology, know-how, product candidates and other intellectual property assets, and we continue to pursue or evaluate additional product development or manufacturing collaborations, mergers or acquisitions or other strategic transactions, and issuing equity or debt in the public markets. In the business environment today, however, there is extreme competition for capital to fund biotechnology businesses that do not have product sales and do not have later stage products showing high levels of efficacy in Phase II clinical trials, and we can provide no assurance that our discussions will result in a transaction or generate sufficient capital.

The public and private capital markets have been experiencing extreme volatility and disruption for over a year, and the volatility and disruption have reached unprecedented levels in recent months. The scope and extent of the recent disruptions in the capital markets could continue to make it difficult or impossible for us to raise additional capital in public or private capital markets until conditions stabilize, and conditions may not sufficiently stabilize in the very short amount of time we have left before we reach the end of our financial resources and are forced to go out of business. Funding may not be available to us on reasonable terms, if at all.

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

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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 recorded, processed, summarized and reported within the time periods specified in 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.

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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, and the patient subsequently died. In their review of the SAE, both the National Institutes of Health Recombinant DNA Advisory Committee and the trial s independent data safety monitoring board concluded that the patient s death was caused by complications from an opportunistic infection, not by our tgAAC94 product candidate, as described in our Current Report on 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 FDA removed the hold it originally put on the clinical trial, permitting the clinical trial to resume. On March 3, 2009, we were served with a lawsuit filed by the patient s spouse, Robbie Mohr. The lawsuit was filed on August 18, 2008 in the 4th Judicial Circuit of Christian County, Illinois, against us, Abbot [sic] Laboratories Inc., and Western Institutional Review Board Inc. The complaint for the lawsuit alleges that the named parties negligence was the proximate cause of the patient s death and seeks unspecified compensatory damages in excess of $50,000.

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

In addition to the other information contained in this annual report, 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 sufficient additional capital or secure sufficient additional sources of funding in the very near term, we will be unable to continue our operations.

We have very limited capital resources and continue to incur significant operating losses, which threaten, and raise substantial doubt about, our ability to continue as a going concern. We currently expect that our existing financial resources will be sufficient to fund our operations only until mid-to-late August 2009, and actual results could differ from this estimate. This estimate is based on the receipt of anticipated funding from our collaborative partners and grant and our ability to successfully perform planned business activities, and actual results could differ from our estimates. If we are unable to secure additional capital by the end of August 2009, we expect to begin the process of ceasing operations or otherwise winding up our business. Given the short amount of time and the fact that we have so far been unable to secure additional funding sources, notwithstanding our considerable efforts to date, we believe there is a substantial risk that we will be unable to secure additional financial resources in time or that any such additional resources would be sufficient to support our ongoing operations. Even if we are able to extend our cash horizon, if we do not receive sufficient additional funding before we reach the end of our financial resources, we will nevertheless be forced to cease operations, seek bankruptcy protection or otherwise wind up our business. Moreover, in light of the early stage of our programs and the long timelines and substantial funding required for future development of our product candidates, we may decide to cease operations or otherwise wind up our business even if we are successful in raising additional capital, if we believe that the additional capital would be insufficient to allow us to make meaningful progress in developing our current product candidates.

The report of our independent registered public accounting firm on our audited financial statements included in our annual report on Form 10-K for the fiscal year ended December 31, 2008 contains a statement noting that we have incurred recurring losses and negative cash flows from operations that, due to our limited working capital, raise substantial doubt about our ability to continue as a going concern. Our plans to address these issues, which are discussed elsewhere in this report, are subject to numerous risks and contingencies, many of which are beyond our control, and we can give no assurance as to whether or how long we may be able to maintain our viability as a going concern.

Because our internally generated cash flow will not fund development and commercialization of our product candidates, even if we are able to secure additional financial resources in time to continue our operations, we will require substantial additional financial resources to continue to conduct business. Our short-term and long-term future capital requirements will depend on many factors. In the short term, our capital requirements depend on factors such as:

whether we decide to continue to pursue all or a portion of our current research and development programs, including continuing to secure and protect intellectual property related to these programs;

the number of employees required to maintain our product development and manufacturing operations and also provide

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appropriate levels of general and administrative support; and

the availability and success of collaborative, licensing, manufacturing or other agreements with or grants by third parties, and receiving payments under such agreements or grants when and as we anticipate.

In the longer term, our future capital requirements will depend on a number of factors, including:

whether we decide to pursue all or a portion of our current or future research and development programs;

the availability and success of collaborative, licensing, manufacturing or other agreements with third parties, and receiving payments under such agreements or grants when and as we anticipate;

our success in fulfilling our obligations under each of our facility lease settlements;

the rate and extent of scientific progress in our research and development programs;

whether MYDICAR®, Celladon Corporation s heart failure product candidate, advances into further stages of clinical development and commercialization and generates product development milestones and royalties for us;

competing technological and market developments;

which intellectual property we secure and protect related to our and our collaborators 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 existence and outcome of any litigation or administrative proceedings, including the current lawsuit relating to a serious adverse event, or SAE, that occurred in one of our clinical trials and any 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.

Additional sources of financing could involve one or more of the following:

selling or licensing our technology, intellectual property, product candidates or other assets;

strategic transactions, such as mergers and acquisitions;

extending or expanding our current product development collaborations, or entering into additional collaborations;

issuing equity or debt in the public or private markets; and/or

borrowing under loan or equipment financing arrangements.

Additional funding may not be available to us on reasonable terms, if at all. The public and private capital markets have been experiencing extreme volatility and disruption for over a year, and the volatility and disruption have reached unprecedented levels in recent months. 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 in the very short amount of time left before we reach the end of our financial resources and we are forced to cease operations, seek bankruptcy protection or otherwise wind up our business.

If we raise additional funds through the issuance of equity or debt securities, the securities may have rights, preferences or privileges senior to those of the rights of our common stock, and our common stockholders will experience additional dilution. 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

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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. 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. Even if our stock price increases sufficiently, we nonetheless may be delisted because of non-compliance with the Nasdaq Capital Market s $2.5 million shareholders equity requirement and/or $1.00 minimum bid price requirement, as described elsewhere in this quarterly report. If we are unsuccessful in our appeal of Nasdaq s delisting determination and we are delisted from the Nasdaq Capital Market, then our ability to raise additional capital through the equity markets will be substantially harmed. 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 we receive from our collaborations depends on continued scientific progress under the collaborations and our collaborators ability and willingness to continue or extend or fund 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 remaining development programs, suspend prosecution of our intellectual property portfolio, or reduce other operating activities or workforce, which could result in a loss or reduction of funding under any affected collaboration. 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.

Our recent reductions in force may harm our business.

In order to decrease our ongoing cost structure, we have decreased our headcount through voluntary and involuntary employee terminations in all areas of our business. Our employee headcount has decreased from 68 full-time equivalent employees at September 30, 2008 to approximately 15 full-time equivalent employees at August 1, 2009. These staff reductions will negatively impact our ability to execute on our business strategy and may result in failure to accomplish our business objectives. For example, recent headcount reductions in our product development staff would likely impair our ability to enter into new product research and development agreements and delay or hinder our performance under such agreements, we may be unable to successfully develop our current product candidates. In addition, our reductions in force may yield unanticipated consequences, such as attrition beyond our planned reductions, and we may encounter further difficulty in managing our business as a result.

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 the International AIDS Vaccine Initiative, or IAVI, and our subcontract with Nationwide Children s Hospital, or NCH, and Children s Hospital of Philadelphia, or CHOP, funded by the NIAID. We have incurred, and will continue to incur for the foreseeable future with respect to research and development programs that we fund, significant expense to develop potential product candidates, conduct preclinical studies and clinical trials, seek regulatory approval for 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 June 30, 2009, we had an accumulated deficit of $315.3 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.

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

As of June 30, 2009, the heart failure product candidate developed under our collaboration with Celladon is in a Phase I/II clinical trial, the product candidate for Leber s congenital amaurosis, or LCA, developed under our collaboration with the University College London/Moorfields Eye Hospital is in a Phase I/II clinical trial, we have completed a Phase I/II trial of our inflammatory arthritis candidate, and we have no product candidates in Phase III trials. Our partnered product candidates for ALS and Huntington s disease, or HD, are currently in preclinical development, and based on our current financial resources and anticipated product development timelines and funding required for future development, we are evaluating our continued involvement in these programs. Of the product candidates that we and/or our partners continue to develop, we will not generate any product revenue, commercial manufacturing revenue, revenue sharing or royalties for at least several years, and then only if

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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.

If we do not retain our existing personnel and attract and retain qualified personnel in the future, we may be unable to manage our business and develop and commercialize some of our potential products.

Our future success depends in large part on the efforts and abilities of, and our ability to attract and retain, key technical and management personnel. All of our remaining employees, including our executive officers, can terminate their employment with us at any time. Although we have programs in place designed to retain personnel, these programs may be insufficient particularly in light of our recent significant reductions. In addition, other companies, research and academic institutions and other organizations in our field compete intensely for employees. We instituted several reductions in force in 2008 and 2009, our chief executive officer and chief scientific officer resigned in November 2008 and we are, and for about a year have been, operating with a very short cash horizon. This creates uncertainty, which makes it more difficult to retain our current personnel and attract and retain qualified personnel in the future. In addition, our ability to attract and retain qualified employees may be adversely affected if the price of our common stock fails to increase sufficiently or declines in the future or if, we are unsuccessful in our appeal of the Nasdaq delisting determination and our stock is delisted from the Nasdaq Capital Market. If we experience significant turnover or difficulty in recruiting new personnel, our ability to manage our business could be materially impaired, our research and development of product candidates could be delayed and we could experience difficulty in generating sufficient funding to maintain our business.

If we do not receive new funding under collaborative agreements or grants, we may be unable to develop our potential products.

Historically a substantial portion of our operating expenses are funded through our collaborative agreements with third parties. Our development of a product candidate to treat ALS has been funded by a grant from the U.S. Department of Defense, or DOD. Our HIV/AIDS vaccine collaboration with CHOP and NCH has been funded through a subcontract with NIAID, which is a U.S. government agency. Until July 31, 2009, we had a heart failure development program funded by Celladon. Each of the DOD and NIAID grants provides for funding, collaborative development, intellectual property rights and/or expertise to develop certain of our product candidates. We expect to terminate our work for the DOD-funded preclinical efforts for ALS by the end of the fourth quarter of 2009. We also expect to complete our remaining development and manufacturing work related to the NIAID-funded HIV/AIDS vaccine candidate by the fourth quarter of 2009 and terminate our involvement in this program, as the vaccine candidate enters into clinical testing. To the extent that we do not have collaborative partners or grant funding for a program or a portion of a program that we do not fund internally, or to the extent that we do not receive the funding that we expect from our collaborative agreements or grants, unless we are able to obtain alternative sources of funding, we would be delayed in or unable to continue developing potential products under the affected program. With limited exceptions, each collaborator or grantor has the right to terminate its obligation to provide research funding at any time for scientific or business reasons. For example, in 2008 Sirna Therapeutics, a wholly-owned subsidiary of Merck & Co., Inc., 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.

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, contract research organizations, or CROs, manufacturers and other third parties and strategic partners to support and fund our discovery and development 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

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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 additional 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. However, we cannot 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.

If our clinical trials are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which could increase our development costs, delay the potential commercialization of our products, and make it difficult to raise additional capital.

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 an 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 or terminated, 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

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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 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.

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 ALS 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. Even though the NIH s Office of Biotechnology Recombinant DNA Advisory Committee, or RAC, and the trial s independent data safety monitoring board determined that the SAE was not caused by our drug, the spouse of that patient has 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, 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.

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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 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. For example, after an SAE occurred in our 2007 Phase I/II clinical trial of tgAAC94, our inflammatory arthritis product candidate, the FDA placed a hold on the trial for several months in order to conduct in-depth review of data. Although the SAE was determined to be unrelated 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 provide no assurance 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 that 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.

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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 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 may include, for example, clinical evaluation of our product candidates, product development activities performed under our research collaborations, research under sponsored research agreements and certain contract manufacturing-related 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

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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.

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 effort and 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.

In 2008 and continuing into 2009, we reviewed our very broad-based AAV patent portfolio. We determined that, based on the status of our and others current product development efforts and our current financial resources, certain intellectual property assets are not essential to our current business strategy and we have therefore either returned those rights to our licensors or ceased prosecution of those patents. Although we do not believe those proprietary rights are essential to our current business

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strategy, the loss of those rights could limit our business opportunities, including our ability to enter into strategic transactions such as mergers and acquisitions, license our technology, sell our product development programs or products, if successfully developed, or raise capital through issuing equity or debt.

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. For example in February 2009 we and Celladon agreed to transfer the manufacture of Celladon s MYDICAR® product to an external contract manufacturing organization. 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 or achieve profitability. 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 adeno-associated virus, or 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,

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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 an SAE that ultimately was attributed to an opportunistic 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

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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.

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Risks Related to Our Common Stock

We have been unable to comply with the minimum requirements for quotation on the Nasdaq Capital Market and, if we are unsuccessful in our appeal of the delisting determination from the Nasdaq staff, we will be delisted from the Nasdaq Capital Market. If we are delisted, the liquidity and market price of our common stock will 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, a market value of $1.0 million for our publicly held shares (public float), and $2.5 million in shareholders equity. At March 31, 2009, we had a net worth deficit of $5.4 million and, at June 20, 2009, we had shareholders equity of $2.0 million. Because our shareholders equity is below the $2.5 million required for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b) (formerly Marketplace Rule 4310(c)(3)) and we do not meet the alternative continued listing requirements of $35 million in market value of listed securities or $500,000 in net income from continuing operations, Nasdaq notified us of its determination to delist our securities effective at the opening of business on August 3, 2009. We appealed the Nasdaq staff s determination and were granted a hearing before a Nasdaq hearing panel. The delisting of our securities has been stayed until the hearing is completed and the panel has issued a written decision, which decision is expected within 35 days from the hearing date. We are also in non-compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market under Listing Rule 5550(a)(2) (formerly Marketplace Rule 4310(c)(4)) and, on August 10, 2009, Nasdaq notified us that the bid price deficiency serves as an additional basis for delisting our securities. We plan to address this issue of non-compliance with the bid price requirement at the hearing before the Nasdaq panel. We can provide no assurance that the panel will grant our request for continued listing on the Nasdaq Capital Market or that we will be able to regain or maintain compliance with the listing requirements.

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 continues to decline or does not increase sufficiently, we may be unable to raise additional capital by selling our stock. As our existing financial resources are only expected to be sufficient to fund our operations until the end of August 2009, an inability to raise capital could force us to go out of business. Declines in the price of our common stock or a failure of our stock price 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. Even if our stock price increases sufficiently, Nasdaq may nonetheless delist our common stock because of our non-compliance with the Nasdaq Capital Market s $2.5 million shareholders equity requirement and/or $1.00 minimum bid price requirement, as described above. If we are unsuccessful in our appeal of Nasdaq s delisting determination and are delisted from the Nasdaq Capital Market, our ability to raise additional capital through the equity markets will be substantially harmed.

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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 June 30, 2009, Special Situations held approximately 2.5 million shares of our common stock, Biogen Idec held approximately 2.2 million shares, Elan International Services, Ltd., or Elan, held approximately 1.2 million shares, and Renaissance Technologies held approximately 1.1 million shares. Together these holdings represent approximately 34% of our common shares outstanding as of June 30, 2009. 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 Targeted Genetics;
- 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, Elan and Renaissance Technologies have all sold shares of our common stock in the past 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.

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, Elan, Renaissance Technologies or other holders of significant amounts of shares of our stock could adversely impact the price of our common stock.

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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***

We held our annual meeting of shareholders in Seattle, Washington on May 14, 2009. Of the 20,447,198 shares issued and outstanding as of the record date for the annual meeting, 14,706,872, or 71.93%, of the total shares eligible to vote were represented at the meeting, in person or by proxy. At the annual meeting, our shareholders approved the following matters as indicated below.

1. Election of Directors.

At the annual meeting, our shareholders elected one Class 1 and two Class 3 directors to our Board of Directors, with the Class 1 director to serve for a one-year term expiring at the 2010 annual meeting of shareholders or until her successor is duly elected and qualified, and with each of the Class 3 directors to serve a three-year term expiring at the 2012 annual meeting of shareholders or until his successor is duly elected and qualified. Each nominee was elected by the votes set forth below.

Class 1 Director

Nominee	Votes For	Votes Withheld
B.G. Susan Robinson	13,235,724	1,471,148

Class 3 Directors

Nominee	Votes For	Votes Withheld
Nelson L. Levy	13,030,696	1,676,176
Michael S. Perry	11,159,803	3,547,069

The Board members whose terms in office continued after the annual meeting were Jeremy L. Curnock Cook (chairman), Joseph M. Davie and Roger L. Hawley.

2. Amendment to the Restated Articles of Incorporation to increase the number of authorized shares of common stock.

Our shareholders approved an amendment to our Amended and Restated Articles of Incorporation to increase the number of shares of authorized common stock from 45,000,000 shares to 445,000,000 shares. The amendment was approved by the vote set forth below.

	Voted
Votes For	11,888,959
Votes Against	2,709,966
Abstain	107,946

3. Amendment of the Targeted Genetics Stock Incentive Plan.

Our shareholders approved an amendment to the Targeted Genetics Stock Incentive Plan (the Plan) to increase the number of shares of common stock authorized for issuance under the Plan by 2,000,000 shares, from 2,200,000 shares to 4,200,000 shares. The amendment was approved by the votes set forth below.

	Voted
Votes For	6,451,921
Votes Against	646,565
Abstain	49,369

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4. Ratification of Independent Auditor.

Our shareholders ratified the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2009. The ratification was approved by the votes set forth below:

	Voted
Votes For	14,545,119
Votes Against	109,072
Abstain	52,681

Item 5. ***Other Information***

None.

Item 6. ***Exhibits***

See the Index to Exhibits included in this quarterly report.

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SIGNATURES

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

TARGETED GENETICS CORPORATION

Date: August 12, 2009

By: /s/ B.G. SUSAN ROBINSON
B.G. Susan Robinson,
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2009

By: /s/ DAVID J. POSTON
David J. Poston,
Vice President, Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

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INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Form	Date of First Filing	Exhibit Number	Filed Herewith
3.1	Amended and Restated Articles of Incorporation				X
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	
10.1	Amendment No. 4 to Exclusive License Agreement between Targeted Genetics and Alkermes, Inc. dated May 8, 2009*				X
10.2	Eighth Lease Amendment, dated as of November 11, 2008 between Met Park West IV, LLC (successor in interest to Benaroya Capital Company, LLC) and Targeted Genetics Corporation				X
10.3	Seventh Amendment to Olive Way Building Lease, dated as of December 30, 2008 between Targeted Genetics Corporation and Ironwood Apartments, Inc.				X
10.4	Lease Termination Agreement, dated as of June 29, 2009, between Targeted Genetics Corporation and Arden Realty Limited Partnership*				X
10.5	Targeted Genetics Corporation Stock Incentive Plan, effective as of March 3, 2009				X
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended				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, as amended				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

* Portions of these exhibits have been omitted based on a grant of or application for confidential treatment from the SEC. The omitted portions of these exhibits have been filed separately with the SEC.