TARGETED GENETICS CORP /WA/
Form 10-Q
November 16, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2009

OR

¨ 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, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 November 13, 2009: 20,652,697

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TARGETED GENETICS CORPORATION

Quarterly Report on Form 10-Q

For the quarter ended September 30, 2009

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PART I FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements

TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,974,000	$ 5,216,000
Accounts receivable	7,000	317,000
Prepaid expenses and other	253,000	132,000
Total current assets	4,234,000	5,665,000
Property and equipment, net	296,000	1,285,000
Other assets		200,000
Total assets	$ 4,530,000	$ 7,150,000
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 896,000	$ 1,735,000
Accrued employee expenses	32,000	368,000
Current portion of accrued restructure charges	387,000	656,000
Deferred revenue	482,000	1,227,000
Total current liabilities	1,797,000	3,986,000
Accrued restructure charges		6,934,000
Deferred rent		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, 20,652,530 shares issued and outstanding at September 30, 2009 and 20,238,865 shares issued and outstanding at December 31, 2009	207,000	202,000
Additional paid-in capital	317,203,000	316,900,000
Accumulated deficit	(314,677,000)	(320,874,000)
Total shareholders equity	2,733,000	(3,772,000)
Total liabilities and shareholders equity	$ 4,530,000	$ 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 September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Revenue under collaborative agreements	$ 3,711,000	$ 1,742,000	$ 9,094,000	$ 6,478,000
Operating expenses:				
Research and development	1,515,000	3,192,000	5,526,000	11,294,000
General and administrative	1,352,000	1,224,000	3,749,000	4,865,000
Restructure charge (credit)	115,000	196,000	(6,424,000)	597,000
Total operating expenses	2,982,000	4,612,000	2,851,000	16,756,000
Income (loss) from operations	729,000	(2,870,000)	6,243,000	(10,278,000)
Investment income		53,000	12,000	251,000
Other income		79,000		79,000
Loss on disposal of property and equipment	(58,000)		(58,000)	
Gain on debt restructure		77,000		77,000
Net income (loss)	$ 671,000	$ (2,661,000)	$ 6,197,000	$ (9,871,000)
Net income (loss) per common share (basic and diluted)	$ 0.03	$ (0.13)	$ 0.30	$ (0.50)
Shares used in computation of basic and diluted net income (loss) per common share	20,652,000	20,002,000	20,535,000	19,906,000

See accompanying notes to condensed consolidated financial statements

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TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,	
	2009	**2008**
Operating activities:		
Net income (loss)	$ 6,197,000	$ (9,871,000)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	684,000	399,000
Stock-based compensation	314,000	582,000
Loss (gain) on disposal of property and equipment	58,000	(76,000)
Gain on debt restructure		(77,000)
Other	(6,000)	(10,000)
Changes in assets and liabilities:		
Accounts receivable	310,000	2,243,000
Prepaid expenses and other	(121,000)	28,000
Current liabilities	(1,175,000)	(1,012,000)
Deferred revenue	(745,000)	1,786,000
Deferred rent	(2,000)	(5,000)
Accrued restructure charges	(7,203,000)	(424,000)
Other non-current assets	200,000	
Net cash used in operating activities	(1,489,000)	(6,437,000)
Investing activities:		
Purchases of property and equipment	(11,000)	(639,000)
Proceeds from the sale of equipment	258,000	76,000
Net cash received (used) in investing activities	247,000	(563,000)
Financing activities:		
Payments under debt and equipment financing arrangements		(259,000)
Net cash used in financing activities		(259,000)
Net decrease in cash and cash equivalents	(1,242,000)	(7,259,000)
Cash and cash equivalents, beginning of period	5,216,000	16,442,000
Cash and cash equivalents, end of period	$ 3,974,000	$ 9,183,000

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 nine months ended September 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 $4.0 million at September 30, 2009. On September 8, 2009, we entered into an agreement with Genzyme Corporation, or the Genzyme Agreement, under which we sold and licensed certain of our assets, including manufacturing technologies and other adeno-associated viral, or AAV, vector technology for up to $7 million in cash. Upon the closing of this transaction we received a payment of $3.5 million, and may receive up to an additional $3.5 million in installments payable upon mutual agreement of our achievement of specified transfer plan deliverables. We believe that our current financial resources, including the remaining cash installments under the Genzyme Agreement, will be sufficient to fund our operations through 2010. 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.

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 calculate potentially dilutive incremental shares issuable using the treasury stock method. The treasury stock method assumes that the proceeds received from the exercise of stock options and warrants, as well as stock option and restricted stock expense yet to be recorded for unvested shares would be used to repurchase common shares in the market at the average stock price during the 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 antidilutive securities not included in net income (loss) per share for the three- and nine-month periods ended September 30, 2009 and 2008:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Options to purchase common stock	381,000	725,000	1,064,000	742,000
Restricted stock units		801,000		674,000
Warrants to purchase common stock	7,814,000	7,914,000	7,814,000	7,914,000
Total securities excluded in net income (loss) per share	8,195,000	9,440,000	8,878,000	9,330,000

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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. This guidance is now a part of Accounting Standards and Codification, or ASC, 808-10, *Collaborative Arrangements.* This new guidance 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. ASC 808-10 is effective for fiscal years beginning after December 15, 2008. ASC 808-10 is effective for all of our existing collaborations in place after January 1, 2009. The adoption of ASC 808-10 did not have an effect on our financial position or results of operations for the three or nine months ended September 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. This guidance is now a part of ASC 855-10, *Subsequent Events.* ASC 855-10 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 ASC 855-10 did not have any impact on our results of operations, cash flows or financial position for the three or nine months ended September 30, 2009. We have evaluated subsequent events through November 16, 2009, the date that we filed our financial statements for the period ended September 30, 2009. Details of subsequent events can be found in Note 8 of these unaudited consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162.* This guidance is now a part of ASC 105-10, *Generally Accepted Accounting Standards.* This new guidance 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 have applied 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.

In October 2009, the FASB issued Update 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force,* or Accounting Standard Update, or ASU, 2009-13. ASU 2009-13 provides amendments for separating consideration in multiple-element arrangements, allowing multiple deliverable arrangements to be separated in more circumstances than under existing GAAP. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or ending after June 15, 2010. We are in the process of evaluating the effect of the adoption of ASU 2009-13.

2. Property and Equipment

The following table presents the property and equipment for the periods ended September 30, 2009 and 2008:

	September 30,	
	2009	**2008**
Furniture and equipment	$ 5,255,000	$ 8,030,000
Leasehold improvements		9,310,000

	5,255,000	17,340,000
Less accumulated depreciation and amortization	(4,959,000)	(16,055,000)
	$ 296,000	$ 1,285,000

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

During the quarter ending September 30, 2009, we sold equipment under both the Genzyme Agreement and the February 2009 license and manufacturing agreements with Celladon Corporation. Proceeds from these sales were recognized as revenue in accordance with EITF 00-21, *Revenue Arrangements with Multiple Element Arrangements,* which is now part of ASC 605-25, *Multiple Element Arrangements.*

Also during the period ending September 30, 2009, we sold or disposed of certain property and equipment that we no longer use as a result of the reprioritization of our development efforts. We recognized a gain of $139,000 on the disposal of property and equipment in our condensed consolidated statement of operations.

Additionally, we renegotiated the terms of both of lease for our office and laboratory space and our lease for our administrative office space, resulting in amendments to both of the leases and, with new month-to-month lease terms for our office and laboratory space and a new shorter term for our administrative office lease. As a result, we disposed of all remaining leasehold improvements associated with these spaces. We recognized a loss of $197,000 related to the disposal of these long-lived assets, which is reflected as a loss on the disposal of property and equipment in our condensed consolidated statement of operations.

3. 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 SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities,* 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. Under the Codification this guidance is now a part of ASC 420-10, *Exit or Disposal Cost Obligations.*

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 Bothell lease termination agreement, or Bothell Agreement, we were released from all obligations under the lease other than certain indemnification obligations. As consideration for the Bothell 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 Bothell Agreement and continuing through July 2010. As a result of the termination of our Bothell facility lease, in the second quarter of 2009 we recorded a $7.2 million reversal to the accrued restructure liability, which increased basic and diluted earnings per share by $0.30 for the second quarter and for the nine months ended September 30, 2009.

Following the rules of ASC 420-10, 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 nine-month period ended September 30, 2009:

	Restructure Costs
December 31, 2008 accrued liability	$ 7,590,000
Charges related to employee termination benefits	457,000
Accretion charge	319,000
Reversal of accrued restructure liability	(7,201,000)
Cash payments	(778,000)

September 30, 2009 accrued liability	$ 387,000

Adjustments to the accrued restructure liability for the nine months ended September 30, 2009 include $457,000 of employee termination benefits, accretion expenses of $319,000 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 September 30, 2009, we have recorded a cumulative amount of $623,000 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.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

4. Commitments

On September 25, 2009, we and Ironwood Apartments, Inc., the owner of the facility we used for office space and research and development activities, including our laboratory space, entered into a ninth amendment to our lease, or the Ironwood Amendment. The Ironwood Amendment provided for the lease to continue on a month-to-month basis until either party exercised its right to terminate the lease. Under the terms of the Ironwood Amendment, we paid our portion of the common area maintenance fees and utility payments for the month of September 2009 and, beginning in October 2009 through the remainder of the term of the lease, we were not required to pay base rent and were only responsible for utility payments. As Noted in Footnote 8 to the consolidated financial statements, this lease terminated on October 31, 2009.

On August 10, 2009, we and Metropolitan Park West IV, LLC (as successor in interest to Benaroya Capital Company, 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. The MPW Amendment amends the Office Lease dated October 7, 1996, as amended, between us and the landlord, and covers 4,990 square feet of space. Under the terms of the MPW Amendment, the lease will terminate on January 31, 2010, but may be extended through December 31, 2010 if we provide notice of our election to continue the lease to the landlord by November 30, 2009, provide the landlord with reasonable assurances of an adequate cash horizon, and the landlord accepts our election. The monthly rent due under any extension of the lease would be at the rates specified in the eighth amendment to the lease dated November 11, 2008.

We previously leased a facility in Bothell, Washington under a non-cancelable operating lease that originally expired in September 2015, which was intended to accommodate future manufacturing of our product candidates. On June 29, 2009, we entered into an agreement to terminate the Bothell facility lease. Upon execution of the Bothell lease termination agreement we were released from all obligations under the lease other than certain indemnification obligations. As consideration for the Bothell Agreement and for the discharge of our obligations under the lease, we agreed to pay a termination fee of $500,000, which we will be pay in installments through July 2010. Under the terms of the Bothell 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 of September 30, 2009 the balance remaining under the Bothell lease termination agreement is $387,000.

5. 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. Under the Codification this guidance is now a part of ASC 718-10, *Compensation Stock Compensation.*

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 ASC 718-10, 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 September 30, 2009 or the three- or nine-month periods ended September 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.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

The following table summarizes stock-based compensation expense and credits to expense related to employee stock options and restricted stock units under ASC 718-10 for the three and nine months ended September 30, 2009 and 2008:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Stock options:				
Research and development	$ 4,000	$ 6,000	$ 5,000	$ 99,000
General and administrative	17,000	6,000	12,000	41,000
Restricted stock units:				
Research and development	43,000	71,000	140,000	231,000
General and administrative	20,000	54,000	99,000	211,000
Restructure			58,000	
Total stock-based compensation expense	$ 84,000	$ 137,000	$ 314,000	$ 582,000

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 no stock options during the three months ended March 31, 2009 and 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 the three months ended September 30, 2009. We have granted no restricted stock units in 2009, released no restricted stock units during the three months ended September 30, 2009 and released 443,000 shares of restricted stock units during the nine months ended September 30, 2009. 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 nine months ended September 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.

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.

6. 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 were reimbursed for research and development and manufacturing activities we performed. 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, if any, after commercialization.

ASC 808-10 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 ASC 808-10, 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 ASC 808-10 did not affect our financial position or results of operations for the period ended September 30, 2009.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Genzyme	$ 3,031,000	$	$ 3,031,000	$
Celladon	521,000	1,237,000	5,067,000	3,438,000
NIAID	157,000	479,000	841,000	3,014,000
Department of Defense	2,000	26,000	155,000	26,000
Total Collaborative Revenue	$ 3,711,000	$ 1,742,000	$ 9,094,000	$ 6,478,000

Genzyme

In September 2009, we entered into the Genzyme Agreement, under which we sold and licensed certain of our assets, including manufacturing technologies and other AAV vector technology for up to $7 million in cash. Upon the closing of this transaction, we received a payment of $3.5 million, and may receive up to an additional $3.5 million in installments payable upon completion of specified transfer plan deliverables. Additionally, we may receive revenue from Genzyme in the event that Genzyme sublicenses the acquired intellectual property within specified time periods, and we may receive royalties in the event of commercial sales of products containing AAV vectors covered by the acquired intellectual property. We recognized revenue of $3.0 million in the third quarter under the Genzyme Agreement. Research and development costs allocated to the Genzyme Agreement that resulted in revenue totaled approximately $320,000 for the nine month period ended September 30, 2009.

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 new agreements, we granted Celladon exclusive use of certain proprietary AAV vector technology in a specified field relating to heart failure, we agreed to manufacture Celladon s MYDICAR® product candidate for phase III clinical studies, at Celladon s expense, and we 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. Research and development costs allocated to the Celladon program that resulted in revenue totaled approximately $3.7 million for the nine month period ended September 30, 2009.

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 United States. The direct costs of any clinical trials will be borne by the NIAID and are not part of the contract. In early 2009 we began to terminate our HIV/AIDS subcontract with CHOP and NCH and the final performance period under our work with the contract was completed on August 30, 2009. 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. Since the beginning of the contract we recognized cumulative total revenues of $11.5 million under this program.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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 $262,000 of revenue in this program, which includes $155,000 recognized in the nine months ended September 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 have terminated our participation in this program.

7. Income Taxes

Through September 30, 2009 we have recognized $6.2 million of net income, including $6.4 million of credits (income) related to the non-taxable reversal of previously recognized restructure charges. Accordingly we have no taxable income for the three or nine months ended September 30, 2009. We have sufficient unrecognized deferred tax assets attributable to net operating loss carryovers to offset projected taxable income related to the current year. Accordingly, based on our anticipated results for the fiscal year ended December 31, 2009, we project we will recognize these deferred tax assets to the extent of our current year net income, resulting in no income tax expense for the three and nine months ended September 30, 2009.

8. Subsequent Events

On October 31, 2009, we and Ironwood Apartments, Inc. terminated the Olive Way Building Lease dated November 20, 1992, as amended, or the Olive Way Lease. The Olive Way Lease covered 38,000 square feet in the facility we used for offices and research and development activities, including our laboratory space. We continue to maintain offices in our other leased facility under the lease with Metropolitan Park West IV, LLC, or Met Park, which is adjacent to the Olive Way building and has been leased by us since 1996. The terms of the Met Park lease are contained in the Lease Agreement dated October 7, 1996, as amended. Our headquarters address remains 1100 Olive Way, Suite 100, Seattle, WA 98101.

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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, 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, expects, anticipates, plans, projects, intends, or statements concerning potential or 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

Our business has been focused on 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.

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Gene therapeutics have not yet reached commercialization in the United States or other major markets of the world. As with most new therapeutic modalities, the path to commercialization meets significant hurdles along the way and takes longer than predicted. The ongoing constriction of the capital market s interest in funding biotechnology companies in our field and at our stage of development, combined with difficulties that we and other companies in the field have experienced in developing and commercializing products, have resulted in a significant lack of opportunities for us to obtain financing. We have responded to this less-than-favorable financing environment and the longer-than-expected product development timelines by reducing our employee count from approximately 68 full-time equivalent employees at September 30, 2008 down to 13 full-time equivalent employees at November 1, 2009, by significantly reducing our other expense categories and by critically evaluating all of our research and development efforts to focus on the most promising near term opportunities while also halting earlier stage, although promising, research efforts.

We previously reported that we had sufficient cash to continue our operations through August 2009. With the cash generated from the Genzyme Agreement, we are now able to fund our operations with up to $7 million of new capital, $3.5 million of which we received at the close of the transaction and up to $3.5 million we may receive in the fourth quarter of 2009 and first quarter of 2010 upon mutual agreement of our achievement of specified transfer plan deliverables. Our current strategy is to:

(1) Continue development of our lead product candidate for a form of blindness until we reach a milestone when data are available from clinical studies expected to occur in the next year;

(2) Support our current partner relationships with Celladon, Genzyme and Amsterdam Molecular Therapeutics, which could generate significant future milestone and royalty income for us without the need for us to participate in their development efforts; and

(3) Continue to evaluate alternatives for maximizing value for our shareholders, including continuing our product development efforts and pursuing potential mergers and acquisitions.

We have conducted a further strategic analysis of the programs that we narrowed our focus to in 2008, including examining the scientific data and development progress of each program, the funding required to move each program toward clinical trials, and commercialization and partnering opportunities for each program. As a result, the status of each program is as follows:

Our lead 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 that leads to blindness and one cause of LCA is a mutation in the RPE65 gene. Our product candidate uses AAV vectors to deliver a wild-type RPE65 gene. This product candidate is currently under evaluation in subjects in a Phase I/II dose escalation clinical trial funded through a grant awarded to Dr. Ali. It is anticipated that data will be available from this trial at different points of time throughout 2010.

Preclinical studies focused on identifying a candidate to develop a therapeutic for the treatment of Huntington s Disease, or HD, continue in the laboratory of 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. Based on preclinical data collected over the last year, scientists at UI are performing additional research efforts with the goal of identifying a product candidate to put on a development path. We continue to have a licensing relationship with UI around certain intellectual property resulting from Dr. Davidson s research efforts, which we evaluate from time to time.

We have discontinued our development efforts of a preclinical stage small-molecule-based product candidate to treat amyotrophic lateral sclerosis, or ALS, under development with our collaborator, John Engelhardt, Ph.D., at UI. 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 cash constraints at that time, as well as 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 no longer continuing development efforts related to the product candidate and have ended our efforts under the

DOD grant.

We have completed a Phase II clinical trial of our product candidate for inflammatory arthritis, tgAAC94, which included 127 patients in a randomized placebo controlled trial. The trial data demonstrated that tgAAC94 was well tolerated and showed preliminary signs of efficacy, most notably a 30% decrease in patient-reported pain and functional scores. We will not initiate additional clinical studies of tgAAC94 without additional external funding from a development and commercialization partner.

Historically we have devoted significant resources to 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. In late 2008 and early 2009, we analyzed the financial impact of continuing to support our internal manufacturing infrastructure

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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.

We also determined that our manufacturing assets could be monetized and, if sold, could provide significant funding to us while still allowing us to retain use of the technologies in our product development efforts through a license-back agreement. In September 2009, we entered into the Genzyme Agreement for the sale and license of certain manufacturing technologies and other AAV vector technology assets to Genzyme. Included in the sale was our license with Alkermes, Inc., which provided us with exclusive rights to certain AAV manufacturing patents.

As part of the transaction, Genzyme licensed back to us the AAV manufacturing and vector technology that was sold under the Genzyme Agreement for our use in specified product programs, including LCA, inflammatory arthritis and HD. Under the Genzyme Agreement, we received $3.5 million at closing and could receive up to $3.5 million total in milestone payments, all of which are dependent upon mutual agreement of our achievement of specified deliverables. Additionally, we could receive royalties upon commercial sales, if any, of products containing AAV vectors covered by the acquired intellectual property. For a specified time period, we also could receive revenue in the event that Genzyme sublicenses the intellectual property it acquired from us. We expect to complete the specified deliverables by the end of 2009 or early 2010.

We continue to hold several AAV-based assets. For certain therapeutic program efforts, we retained the use of the assets sold and licensed to Genzyme. In addition, we retained important intellectual property rights around AAV serotypes, certain therapeutic uses of AAV and other intellectual property and know-how relevant to AAV manufacturing. Moreover, we have three partner relationships which could generate future revenue upon successful attainment of development and commercialization milestones and/or from product sales royalties.

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. Our efforts under this contract are now complete. We continue 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 are not specific to our current development program efforts. Based on the revenue we received from Genzyme Agreement, and the revenue we received from the 2009 Celladon agreements, in combination with decreased operating costs resulting from our reduced infrastructure, including renegotiated facility leases resulting in significant rent reductions, reduced intellectual property costs and other spending reductions, we believe that our current financial resources, including cash to be received upon our completion of the specified transfer plan deliverables under the Genzyme Agreement, will be sufficient to fund our operations through 2010.

Most of our expenses have been 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 stage of our product candidates under development and current capital market environment, they may not continue to do so.

Our shareholders equity balance at March 31, 2009 amounted to a net worth deficit of $5.4 million. Because our shareholders equity at March 31, 2009 was 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 because we did 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, on July 23, 2009 the Nasdaq staff 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 the Nasdaq Hearings Panel. On August 10, 2009, we received an additional staff determination letter from the Nasdaq staff informing us that we had failed to regain compliance with the minimum $1.00 bid price per share requirement for continued listing on the Nasdaq Capital Market under Listing Rule 5550(a)(2) (formerly Marketplace Rule 4310(c)(4)), which served as an additional basis for delisting our securities. Our hearing before the Nasdaq Hearings Panel was on September 3, 2009. On September 28, 2009, we were notified by the Nasdaq Stock Market that the Nasdaq Hearings Panel had granted our request for continued listing on the Nasdaq Capital Market. Our continued listing is subject to conditions specified by Nasdaq, including:

- On or before January 19, 2010, we must evidence shareholders equity of at least $2.5 million, or demonstrate compliance with one of the alternative listing criteria set forth in Listing Rule 5550(b);

On or before February 8, 2010, we must have evidenced a closing bid price of $1.00 or more for a minimum of 10 consecutive trading days; and

We must demonstrate compliance with all other requirements for continued listing on the Nasdaq Capital Market.

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In addition, we must promptly notify the Hearings Panel of significant events that occur during the exception period, including any event that may call into question our historical financial information or that may impact our ability to maintain compliance with any Nasdaq listing requirements or the exception deadlines, and the Hearings Panel may reconsider the terms of the exception based on any such event.

If we do not satisfy the conditions specified above, the Hearings Panel will issue a final determination to delist our common stock and will suspend trading of our shares effective on the second business day after the Hearings Panel s final determination. At September 30, 2009, we reported shareholders equity of $2.7 million, which amount exceeds the $2.5 million required for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b). We can provide no assurance that we will be able to regain or maintain compliance with the Nasdaq listing requirements.

CRITICAL ACCOUNTING POLICIES, ESTIMATES AND ASSUMPTIONS

There have been no material changes from the critical accounting policies, estimates and assumptions disclosed in 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 $3.7 million for the three months ended September 30, 2009, from $1.7 million for the same period in 2008, as a result of revenue earned for the transfer of manufacturing technologies and other AAV vector technology under the Genzyme Agreement. This increase in revenue was offset in part by reduced revenues for the Celladon heart failure collaboration as we completed the manufacture of MYDICAR® in the second quarter of 2009 and in part by lower 2009 revenue generated by the NIAID-funded HIV/AIDS vaccine project. Revenue increased to $9.1 million for the nine months ended September 30, 2009 from $6.5 million for the same period in 2008, primarily as the result of revenue earned for the transfer of manufacturing technologies and other AAV vector technology under the Genzyme Agreement, as well as increased revenue generated by both pre-manufacturing and manufacturing efforts in our Celladon collaboration. This increase in revenue was partially offset by decreases in revenue for the HIV/AIDS vaccine project, and reflects revenue earned in 2008 that was 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 $1.5 million for the three months ended September 30, 2009 from $3.2 million for the same period in 2008. Research and development expenses decreased to $5.5 million for the nine months ended September 30, 2009 from $11.3 million for the same period in 2008. The decreases in both periods reflect lower costs for support of the heart failure program and lower outside services and lab supplies under our NIAID-funded HIV/AIDS vaccine subcontract. Lower research and development expenses for the year also reflect 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:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Programs in clinical development:				
Heart failure	$ 207,000	$ 833,000	$ 1,683,000	$ 2,298,000
Inflammatory arthritis	7,000	269,000	75,000	1,157,000
Indirect costs and other	786,000	1,212,000	2,192,000	3,531,000
Total clinical development program expense	1,000,000	2,314,000	3,950,000	6,986,000
Research and preclinical development program expense	515,000	878,000	1,576,000	4,308,000

Total research and development expense	$ 1,515,000	$ 3,192,000	$ 5,526,000	$ 11,294,000

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.

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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 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 increased to $1.4 million for the three months ended September 30, 2009 from $1.2 million for the same period in 2008. The increase reflects management incentive bonuses earned upon the successful execution of the Genzyme Agreement. General and administrative expenses decreased to $3.7 million for the nine months ended September 30, 2009 from $4.9 million for the same period in 2008. The decrease for the nine-month period reflects 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 partially offset by the management incentive bonuses earned in the third quarter of 2009.

Restructure Charges. For the three months ended September 30, 2009, we recorded restructuring charges of $115,000 compared with restructuring charges of $196,000 for the three months ended September 30, 2008. Restructuring charges for the third quarter of 2009 reflect severance costs for terminated employees. For the nine months ended September 30, 2009, we recorded a net restructuring credit of $6.4 million compared with restructuring charges of $597,000 for the nine months ended September 30, 2008.

The net restructuring credit for the nine months ended September 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 Bothell 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.

Loss on Sale of Property and Equipment. For the three months ended September 30, 2009, we recorded a loss on the sale of property and equipment of $58,000. This loss resulted primarily from the renegotiation of the terms of our office and laboratory space lease which resulted in a month-to-month lease. Accordingly we wrote off the remaining office and laboratory leasehold improvements connected to that lease.

Other Income and Expense

Investment Income. Investment income reflects interest income earned on our short-term investments. Investment income decreased to zero for the three months ended September 30, 2009 from $53,000 for the same period in 2008. Investment income decreased to $12,000 for the nine months ended September 30, 2009 from $251,000 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 $4.0 million at September 30, 2009, compared to $5.2 million at December 31, 2008. The decrease primarily reflects cash used in operations, partially offset by a $3.5 million upfront payment received for the sale of certain manufacturing technologies and other AAV vector technology to Genzyme Corporation.

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Our primary sources of capital have been proceeds from public and private sales of our equity securities and cash payments received from collaborative partners. These financing sources have historically allowed us to maintain adequate levels of cash and cash equivalents but, particularly in the current market environment, we believe that there is a substantial risk that we will be unable to raise the cash resources necessary to support our standalone ongoing operations past 2010. In September 2009, we sold and licensed certain manufacturing technologies and other AAV vector technology to Genzyme Corporation for up to $7 million in cash. We believe that the $3.5 million we received upon execution of the Genzyme Agreement, combined with up to $3.5 million of milestone payments we may receive from Genzyme upon mutual agreement of our achievement of a series of specific program deliverables, extends our cash horizon to and through 2010.

For 2008 and through the third quarter 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 fund the development and commercialization of our product candidates. As a result, although we were able to secure additional financial resources by selling our manufacturing intellectual property and other assets, we do not expect that we will be able 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 successfully developing and commercializing our product candidates.

We will require substantial additional funding to continue our operations and to fund development and commercialization of our LCA product development program. While our program to treat LCA is currently in clinical trials that are sponsored and funded by our collaborative partner UCL/M and will not require substantial funding or staff support from us in 2009, this program may require future funding from us in order to accelerate product development or to manufacture additional product supply for clinical testing or may require funding in the future to support license payments, funding for intellectual property prosecution and/or funding for certain additional product development efforts. In light of our current cash constraints, the amount of preclinical progress made so far in the HD and ALS programs, and the estimated timeline and funding requirements for future development, we have decided to discontinue our involvement in the ALS program and are evaluating our future involvement with the HD program.

As of November 1, 2009, we employ approximately 13 full-time equivalent employees. For the three months ended September 30, 2009 we increased our cash balance by consummating the Genzyme Agreement and we finished the quarter with approximately $4.0 million in cash. Despite this additional cash and our forecasts that we may earn up to an additional $3.5 million in cash through successful completion of a series of specific program deliverables connected to the Genzyme Agreement, we may decide to enter into a merger or acquisition transaction or cease operations or otherwise wind up our business if we believe the amount of available additional funding would be sufficient to allow us to make meaningful progress in developing our current product candidates.

In the business environment today, there is extreme competition for capital to fund biotechnology businesses that do not have product sales and do not have later-stage products in proven segments of the industry. Accordingly, we may not succeed in generating sufficient capital to continue our operations. The scope and extent of the recent disruptions and volatility in the public and private capital markets, combined with the focus of our efforts in the not-as-yet proven field of gene therapeutics, could continue to make it difficult or impossible for us to raise additional capital. Accordingly, additional funding to continue our operations 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 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, we will be unable to continue our operations.

Based on our current business plan we expect that our existing financial resources together with those generated in the fourth quarter of 2009 and first quarter of 2010 will be sufficient to fund our operations through 2010. Our estimate of a cash horizon through 2010 is based on the funds we received upon execution of the Genzyme Agreement, combined with up to $3.5 million in payments we may receive from Genzyme upon mutual agreement of our achievement of specified program deliverables. If we are unable to secure additional capital by the end of 2010, we may have to further change our business model, reduce headcount and/or reduce our expenses or begin a process of ceasing operations or otherwise winding up our business. Given the amount of time necessary to raise capital in the capital markets and our recent difficulty in securing 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 insufficient to support our ongoing operations beyond the end of 2010. Moreover, in light of the early stage status 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 in the near term. Even if we continue operations and are successful in raising additional capital, we may nonetheless decide to cease operations or otherwise wind up our business 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. While the completion of the transaction with Genzyme Corporation extended our cash funding horizon through 2010, additional funding will be necessary in order for us to reach our key product development milestones, and we may be unable 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 in 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 pursue and protect our intellectual property rights related to these programs;

the number of employees required to maintain our product development and manufacturing experience base and also provide appropriate levels of general and administrative support; and

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the availability and success of collaborative, licensing, manufacturing or other agreements with or grants by third parties, and whether we receive 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 outstanding facility lease settlements;

the rate and extent of scientific progress in our collaborative 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:

strategic transactions, such as mergers and acquisitions;

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

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

Additional funding may not be available to us on reasonable terms, if at all. The public and private capital markets have recently experienced extreme volatility and disruption for over a year. The scope and extent of the recent disruptions in the capital markets combined with the focus of our efforts in the not as yet proven field of gene therapeutics could continue to make it difficult or impossible for us to raise additional capital

in public or private capital markets. If we successfully 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 shareholders may experience additional dilution as a result. The perceived risk associated with the possible sale of a large number of shares of our common stock could cause some of our shareholders to sell their stock, thus causing the price of our stock to decline. In addition, actual or anticipated downward pressure on our stock price due to actual or anticipated sales of our 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, our ability to raise additional capital will be adversely affected. Additional declines in the price of our common stock, or a failure of the price of our common stock to increase sufficiently, could also further impair our ability to attract and retain qualified employees, further reduce the liquidity of our common stock and may 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. 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.

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If we are unable to successfully access sufficient additional capital, we may need to scale back, delay or terminate our remaining development programs, suspend prosecution of portions or all of our intellectual property portfolio, or reduce other operating activities or workforce, which could result in delays to our product development programs and, even if we are successful in our drug development efforts, delays in securing funding may compromise our ability to market any drug if we are not the first to market the drug. 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 13 full-time equivalent employees at November 1, 2009. These staff reductions will negatively impact our ability to execute on our business strategy and may result in our 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 existing agreements. In addition, our reductions in force may result in unplanned attrition that may adversely affect our ability to manage our business.

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 September 30, 2009, we had an accumulated deficit of $314.7 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 September 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 candidate Huntington s disease, or HD, is currently in preclinical development. Based on our current financial resources and anticipated product development timelines and funding required for future development, we recently terminated our participation in a Department of Defense-funded ALS program and we are evaluating our continued involvement in the HD program. 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 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.

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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. These circumstances create 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 meeting the conditions specified by the Nasdaq Hearings Panel 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 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. Until August 30, 2009 our HIV/AIDS vaccine collaboration with CHOP and NCH was 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. We have terminated our ALS grant from the U.S. Department of Defense. We self-fund the development efforts necessary to support our role in the development of the Leber s Congenital Amaurosis product under development at University College London/Moorfield s Eye Institute. Each of our past collaborations and grants provided for funding, collaborative development, intellectual property rights and/or expertise to develop certain of our product candidates. 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.

We may be unable 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 currently depend upon and expect to continue 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 product candidates and products and to market, sell, and distribute any products we successfully develop. We may be unable 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 or relationships, then we may be unable 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. 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 these parties may not 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 or ongoing 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;

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- 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
- 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.

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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 heart failure or LCA 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.

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,

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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 gene therapy-based product candidates for sale in the United States. 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.

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. In addition we recently sold and licensed certain of our assets, including manufacturing technologies and other AAV vector technology to Genzyme, and while we continue to hold a variety of AAV-based assets, if we choose to develop other AAV therapeutics then we will have to seek licenses from Genzyme and/or other parties for these expanded uses or develop or license replacement technology. Moreover 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.

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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 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.

If third parties do not perform as contractually required or otherwise expected in connection with the conduct our preclinical research and clinical trials, we may be unable 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 be unable to obtain regulatory approval for our product candidates.

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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 were not essential to our current business strategy or could not be monetized for example as we did in the Genzyme transaction and we have therefore either returned those rights to our licensors or ceased prosecution of those patents. Although we do not believe the proprietary rights we sold or returned are essential to our current business strategy, the loss of those rights could limit our future new business opportunities, including our ability to enter into new product development collaborations, strategic transactions such as mergers and acquisitions, licenses of our technology, or our ability to sell our product development programs or products, if successfully developed.

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 currently do not have the physical capacity to manufacture our potential products and must rely on third parties or contract providers for manufacturing capacity. This could limit our ability to conduct large clinical trials of a product candidate and to commercially launch a successful product candidate. If we are unable to obtain and maintain the necessary contract manufacturing capabilities, we will be unable to manufacture our potential products and may be unable 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.

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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. 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 any manufacturing facility. In addition, we may be unable to attain or maintain compliance with current or future regulations relating to manufacture, safety, handling, storage, record keeping or marketing of potential products. If we fail to comply with applicable regulatory requirements or discover previously unknown manufacturing, contamination, product side effects or other problems after we receive regulatory approval for a potential product, we may suffer restrictions on our ability to market the product or be required to withdraw the product from the market.

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

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

- regulatory requirements or action by the FDA or others;

adverse financial developments at or affecting the supplier;

unexpected demand for or shortage of raw materials;

labor disputes or shortages; and

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

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

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

We face increasingly intense competition from a number of commercial entities and institutions that are developing gene therapy technologies or products that would compete with our potential products. 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;

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manufacturing; and

marketing and distribution.

In addition, the competitive positions of other companies, institutions and organizations, including smaller competitors, may be strengthened through collaborative relationships. Consequently, our competitors may be able to develop, obtain patent protection for, obtain regulatory approval for, or commercialize new products more rapidly than we do, or manufacture and market competitive products more successfully than we do. This could limit the prices we could charge for the products that we are able to market or result in our products failing to achieve market acceptance.

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

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

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

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

Risks Related to Our Common Stock

We may be unable to comply with the minimum requirements for quotation on the Nasdaq Capital Market and, if we are unsuccessful in our efforts to comply with the conditions imposed by the Nasdaq Hearings Panel, we will be delisted from the Nasdaq Capital Market. If we are delisted, the liquidity and market price of our common stock is likely to 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 30, 2009, we had shareholders equity of $2.0 million. Because our shareholders equity balance at June 30, 2009 was 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 because we did 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, on July 23, 2009 the Nasdaq staff 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 the Nasdaq Hearings Panel. On August 10, 2009, we received an additional staff determination letter from the Nasdaq staff informing us that we had failed to regain compliance with the $1.00 minimum bid price per share requirement for continued listing on the Nasdaq Capital Market under Listing Rule 5550(a)(2) (formerly Marketplace Rule 4310(c)(4)), which served as an additional basis for delisting our securities. Our hearing before the Nasdaq Hearings Panel was on September 3, 2009. On September 28, 2009, we were notified by the Nasdaq Stock Market that the Nasdaq Hearings Panel had granted our request for continued listing on the Nasdaq Capital Market. Our continued listing is subject to conditions specified by Nasdaq, including the requirement that we evidence shareholders equity of at least $2.5 million (or demonstrate compliance with one of the alternative listing criteria set forth in Listing Rule 5550(b)) on or before January 19, 2010, that we evidence a closing bid price of $1.00 or more for a minimum of 10 consecutive trading days on or before February 8, 2010, and that we demonstrate compliance with all other requirements for continued listing on the Nasdaq Capital Market. In addition, we must promptly notify the Hearings Panel of significant events that occur during the exception period, including any event that may call into question our historical financial information or that may impact our

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ability to maintain compliance with any Nasdaq listing requirements or the exception deadlines, and the Hearings Panel may reconsider the terms of the exception based on any such event. If we do not satisfy these conditions, the Hearings Panel will issue a final determination to delist our common stock and will suspend trading of our shares effective on the second business day after the Hearings Panel s final determination. We may be unable to regain or maintain compliance with the Nasdaq 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 distribution of market price information for our shares and limited analyst coverage and could further limit investors interest in our securities. Also, 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 further 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 through 2010, any 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 if we do not maintain compliance with the continued listing requirements with respect to minimum shareholders equity. If we are unsuccessful in our efforts to comply with the conditions imposed by the Nasdaq Hearings Panel, as described above, and we are delisted from the Nasdaq Capital Market, our ability to raise additional capital through the equity markets will be substantially harmed.

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 October 31, 2009, 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 21% of our common shares outstanding as of October 31, 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.

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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.

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 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
None.

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: November 16, 2009 By: /s/ B.G. SUSAN ROBINSON
B.G. Susan Robinson,

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 16, 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	10-Q	8/12/09	3.1	
3.2	Amended and Restated Bylaws	8-K	12/28/07	3.1	
4.1	Registration Rights Agreement among Targeted Genetics Corporation and certain investors dated as of January 8, 2007	8-K	1/8/07	10.2	
4.2	Registration Rights Agreement among Targeted Genetics Corporation and certain purchasers dated as of June 22, 2007	8-K	6/25/07	10.2	
10.1	Eighth Amendment to Lease Agreement and Conditional Termination of Lease, dated as of July 20, 2009, between Targeted Genetics Corporation and Ironwood Apartments, Inc.				X
10.2	Ninth Amendment to and Continuation of Lease Agreement, dated as of September 1, 2009 between Targeted Genetics Corporation and Ironwood Apartments, Inc.				X
10.3	Ninth Amendment to Lease Agreement and Conditional Termination of Lease, dated as of August 10, 2009, between Metropolitan Park West IV, LLC and Targeted Genetics Corporation				X
10.4	Asset Purchase Agreement, dated as of September 8, 2009, between Genzyme Corporation and Targeted Genetics Corporation*				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.