TARGETED GENETICS CORP /WA/
Form 10-Q/A
August 14, 2002
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q/A
AMENDMENT NO. 1

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2002

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 No. 0-23930

TARGETED GENETICS CORPORATION
(Exact name of Registrant as specified in its charter)

Washington	**91-1549568**
(State of Incorporation)	**(IRS Employer Identification No.)**

1100 Olive Way, Suite 100
Seattle, WA 98101
(Address of principal executive offices, including zip code)

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

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 such filing requirements for the past 90 days. Yes x No ¨

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Common Stock, $.01 par value	44,158,730
(Class)	**(Outstanding at August 1, 2002)**

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Explanatory Note

Targeted Genetics files this amendment to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 to reflect a restatement of its financial statements related to the classification of its Series B convertible exchangeable preferred stock outside of permanent equity and the elimination of dividends on such preferred stock in the computation of net loss per common share. Targeted Genetics filed the original Form 10-Q for the quarter ended March 31, 2002 on May 15, 2002. Unless otherwise inidicated, all information is as of March 31, 2002.

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TARGETED GENETICS CORPORATION

Quarterly Report on Form 10-Q/A
For the quarter ended March 31, 2002

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PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements***

TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2002	December 31, 2001
	(unaudited, restated)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,023,000	$ 25,186,000
Accounts receivable	3,081,000	2,475,000
Receivable from unconsolidated, majority-owned research and development joint venture	287,000	893,000
Prepaid expenses and other	919,000	935,000
Total current assets	21,310,000	29,489,000
Property and equipment, net	7,698,000	8,308,000
Goodwill and other purchased intangibles, net	31,625,000	31,752,000
Other assets	1,463,000	1,489,000
	$ 62,096,000	$ 71,038,000
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,165,000	$ 3,452,000
Payable to unconsolidated, majority-owned research and development joint venture	270,000	1,123,000
Accrued employee expenses	699,000	1,114,000
Deferred revenue	4,473,000	4,631,000
Current portion of long-term obligations	1,197,000	1,308,000
Total current liabilities	9,804,000	11,628,000
Long-term obligations	16,891,000	17,043,000
Deferred revenue	4,370,000	4,966,000
Commitments (Notes 6 and 7)		
Series B convertible exchangeable preferred stock	12,015,000	12,015,000
Shareholders equity:		
Preferred stock, $0.01 par value, 6,000,000 shares authorized:		
Series A preferred stock, 800,000 shares designated, none issued and outstanding		
Series B preferred stock; 12,015 shares designated, issued and outstanding		
Common stock $0.01 par value, 80,000,000 shares authorized, 44,158,730 shares issued and outstanding at March 31, 2002 and 44,125,677 shares at December 31, 2001	442,000	441,000
Additional paid-in-capital	202,962,000	202,927,000
Accumulated deficit	(184,388,000)	(177,982,000)
Total shareholders equity	19,016,000	25,386,000
	$ 62,096,000	$ 71,038,000

The accompanying notes are an integral part of this statement.

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TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Quarter ended March 31,	
	2002	**2001**
Revenue:		
Collaborative agreements	$ 4,531,000	$ 3,128,000
Collaborative agreement with unconsolidated, majority-owned research and development joint venture	839,000	677,000
Total revenue	5,370,000	3,805,000
Operating expenses:		
Research and development	9,039,000	6,394,000
Equity in net loss of unconsolidated, majority-owned research and development joint venture	778,000	848,000
Amortization of purchased intangibles	126,000	1,517,000
General and administrative	1,653,000	2,027,000
Total operating expenses	11,596,000	10,786,000
Loss from operations	(6,226,000)	(6,981,000)
Investment income	87,000	802,000
Interest expense	(267,000)	(64,000)
Net loss	$ (6,406,000)	$ (6,243,000)
Net loss per common share (basic and diluted), restated	$ (0.15)	$ (0.14)
Shares used in computation of net loss per common share	44,137,000	43,517,000

The accompanying notes are an integral part of this statement.

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TARGETED GENETICS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Quarter ended March 31,	
	2002	**2001**
Operating activities:		
Net loss	$ (6,406,000)	$ (6,243,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity in net loss of unconsolidated, majority-owned research and development joint venture	778,000	848,000
Depreciation and amortization	801,000	694,000
Amortization of purchased intangibles	126,000	1,517,000
Stock-based compensation expense		80,000
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	(606,000)	298,000
Decrease in deferred revenue	(754,000)	(1,424,000)
Decrease (increase) in accounts receivable from unconsolidated, majority-owned research and development joint venture	606,000	(677,000)
Decrease in current and other assets	42,000	27,000
Decrease in current and other liabilities	(590,000)	(30,000)
Net cash used in operating activities	(6,003,000)	(4,910,000)
Investing activities:		
Investment in unconsolidated, majority-owned research and development joint venture	(1,631,000)	(11,000)
Purchases of property and equipment	(241,000)	(1,689,000)
Net cash used in investing activities	(1,872,000)	(1,700,000)
Financing activities:		
Payments under leasehold improvements and equipment financing arrangements	(324,000)	(204,000)
Net proceeds from sale of capital stock	36,000	2,218,000
Net cash provided by (used in) financing activities	(288,000)	2,014,000
Net decrease in cash and cash equivalents	(8,163,000)	(4,596,000)
Cash and cash equivalents, beginning of period	25,186,000	38,630,000
Cash and cash equivalents, end of period	$ 17,023,000	$ 34,034,000

The accompanying notes are an integral part of this statement.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. ***Basis of Presentation***

The condensed consolidated financial statements included in this quarterly report have been prepared by us without audit, according to the rules and regulations of the Securities and Exchange Commission, or SEC. Our condensed consolidated financial statements include the accounts of Targeted Genetics Corporation, our wholly owned subsidiaries Genovo, Inc. and TGCF Manufacturing Corporation, and our majority-owned subsidiary, CellExSys, Inc. The condensed consolidated financial statements do not include Emerald Gene Systems, Ltd., or Emerald, our unconsolidated, majority-owned research and development joint venture with Elan International Services Ltd., or Elan, a wholly owned subsidiary of Elan Corporation plc, because we do not have operating control of Emerald. All significant inter-company transactions have been eliminated in consolidation. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted in accordance with the SEC s rules and regulations. The 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.

Our results of operations for the quarter ended March 31, 2002, are not necessarily indicative of the results to be expected for the full year. The unaudited 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 amended annual report on Form 10-K/A for the year ended December 31, 2001.

2. ***Series B Convertible Exchangeable Preferred Stock***

Our Series B Convertible exchangeable preferred stock, which is currently valued at $12 million, is convertible into shares of our common stock or may be exchanged, at Elan s option, for a 30.1% ownership interest in Emerald. If Elan exercises its exchange right, it must make a cash payment to us equal to 30.1% of the joint venture losses that we and Elan funded after its formation. We periodically monitor the redemption value of the Series B preferred stock, as measured by 30.1% of the fair value of the joint venture that Elan would receive, less the cash payable to us upon exchange by Elan. If and when the redemption value of the Series B preferred stock exceeds its then current carrying value, we will increase the carrying value of the Series B preferred stock to the redemption value and recognize a corresponding dividend to the Series B preferred shareholder. We will recognize subsequent increases or decreases in redemption value of the Series B preferred stock; however, decreases will be limited to amounts previously recorded as increases, so as not to reduce the carrying amount of the Series B preferred stock below the original basis of $12.0 million. The exchange right currently expires in April 2003, but is subject to extension by our mutual agreement with Elan.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

3. ***Restatement of Financial Information***

The accompanying condensed consolidated balance sheet as of March 31, 2002 has been restated to present our Series B convertible exchangeable preferred stock, with a carrying amount of $12.0 million, outside of permanent shareholders equity, as a result of the adoption of the Emerging Issues Task Force, or EITF, Topic D-98, *Classification and Measurement of Redeemable Securities*. We issued the Series B preferred stock in connection with the formation of our Emerald Gene Systems joint venture with Elan. Shares of Series B preferred stock are exchangeable for a portion of our investment in Emerald. The effect of this restatement is to reduce total shareholders equity by $12 million and to reflect the Series B preferred stock outside of permanent equity.

Net loss per common share for the quarter ended March 31, 2001 has been restated to $0.14 per share from $0.15 per share as previously reported. This is the result of eliminating the 7% dividend previously accrued on the Series B preferred stock totaling $228,000 that had been added to the net loss when determining the net loss applicable to common shareholders. Because dividends only would be payable in common shares upon conversion of the Series B preferred stock into common stock, the amounts previously recorded as dividends actually represent adjustments to the conversion price that are accounted for under EITF Issue 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*. Because the commitment date fair value of the maximum number of common shares that could be issued pursuant to conversion of the Series B preferred stock is less than the proceeds of issuance of the Series B preferred stock, the Series B preferred stock does not contain a beneficial conversion feature subject to recognition pursuant to Issue 98-5. This restatement does not affect net loss for any periods previously reported.

4. ***Adoption of New Accounting Pronouncements***

On January 1, 2002, we adopted Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 discontinues the amortization of goodwill and certain intangibles. The provisions of this accounting standard require us to complete a transitional impairment test upon adoption and identify any impairment in the value of goodwill as a cumulative effect of a change in accounting principle. We performed a transitional impairment test as of January 1, 2002 and do not believe that an impairment in the value of our goodwill existed as of that date.

In accordance with SFAS No. 142, we will test goodwill for impairment in value at least annually and, if goodwill is impaired, we will write down the value of goodwill through a charge to expense. Because future impairment reviews will be based on future events and estimates, we are unable to estimate the effect that future reviews may have on our consolidated financial statements.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Our goodwill and other purchased intangibles balance of $31.6 million at March 31, 2002 and $31.8 million at December 31, 2001 represents the excess of Genovo acquisition costs over the fair value of Genovo s net assets. Of the $31.6 million of goodwill and other purchased intangibles at March 31, 2002, $31.4 million is classified as goodwill and will be subject to annual impairment tests. The remaining $238,000 of other purchased intangibles consists solely of noncompetition agreements with a gross carrying amount of $1.0 million less accumulated amortization of $772,000. Other purchased intangibles will continue to be amortized through September 2002, the estimated remaining useful life of these assets.

In accordance with SFAS No. 142, we discontinued the amortization of goodwill effective January 1, 2002. Adoption of SFAS No. 142 for the quarter ended March 31, 2002 eliminated $1.4 million of amortization expense, or $0.03 per common share, that would have been recorded had this standard not been adopted. The following table reconciles the results of operations we reported for the first quarter of 2001 to the amounts adjusted for the elimination of goodwill amortization that we would have recorded had we adopted SFAS No. 142 on January 1, 2001:

	Quarter ended March 31,	
	2002	**2001**
Net loss	$ (6,406,000)	$ (6,243,000)
Elimination of goodwill amortization		1,391,000
Adjusted net loss	$ (6,406,000)	$ (4,852,000)
Net loss per common share (basic and diluted)		
Reported net loss per common share, restated	$ (0.15)	$ (0.14)
Goodwill amortization		0.03
Adjusted net loss per common share, restated	$ (0.15)	$ (0.11)

On January 1, 2002, we also adopted SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and portions of APB Opinion No. 30, *Reporting the Results of Operations*. SFAS No. 144 provides guidance on accounting for the disposal, valuation and classification of long-lived assets and significantly changes the criteria for classification of an asset as held-for-sale. Adopting SFAS No. 144 did not have any effect our financial position or operating results because we currently do not hold any of our assets as held-for-sale and have no indication that any of our long-lived assets are impaired.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

5. ***Net Loss Per Common Share***

Net loss per common share is based on the weighted average number of common shares outstanding during the period. Our diluted net loss per common share is the same as our basic net loss per common share because all stock options, warrants and other potentially dilutive securities are antidilutive and therefore excluded from the calculation of diluted net loss per common share.

6. ***Genzyme Development Agreement***

In connection with our acquisition of Genovo in September 2000, we assumed a three-year development and license agreement, or Development Agreement, with Genzyme Corporation. Genzyme entered into the Development Agreement with Genovo in August 1999. Under the Development Agreement, Genovo was committed to perform up to $2.9 million per year of to-be-determined research and development activities related to product candidates for treating lysosomal storage disorders. Also in connection with our acquisition of Genovo, we assumed a separate agreement that granted Genzyme an option to purchase up to $11.4 million of Genovo equity, of which $3.4 million had been purchased as of the effective date of the Genovo acquisition. Upon our assumption of the agreement, each of the two remaining options under the assumed agreement became an option to purchase 311,295 shares of our common stock, at an exercise price of approximately $12.85 per share. Genzyme exercised its first option and purchased 311,295 shares of our common stock for a total of $4.0 million. Genzyme s second option was not exercised and has expired.

We have previously used a portion of the proceeds from Genzyme s investment in our common stock to fund development activities under the Development Agreement. As Genzyme did not elect to exercise its second option to purchase our common stock, we did not receive funds that would have been allocated toward further development activities under the Development Agreement. Minimal work was performed during the first quarter of 2002 and no formal plan has been put into effect as to specific development activities to be conducted during the remainder of the development program, which is scheduled to end in August 2002. As a result, we do not intend to continue with the lysosomal storage disorder program. At the end of the development program, the rights that we granted or otherwise extended to Genzyme will return to us, except that Genzyme will retain an exclusive, royalty-bearing license to certain Genovo-related technology for use in the field of lysosomal storage disorders. Further, our agreement not to develop competing technologies in the field of lysosomal storage disorders will continue.

The Genovo merger agreement provides that in the event Genzyme does not exercise the second option to purchase shares of our common stock, the former Genovo shareholders and optionholders are entitled to receive up to 155,648 shares of our common stock. These shares have a value of up to $260,000 and will be reflected as additional merger consideration upon issuance.

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TARGETED GENETICS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

7. ***Genovo Licensing Escrow***

The Genovo merger agreement established an escrow of 700,000 shares of our common stock potentially issuable as additional merger consideration for specified Genovo licensing arrangements that were unresolved at the time of the merger. We are currently in negotiations to resolve these licensing arrangements and once complete we will determine what portion of these shares will be issued as additional merger consideration. The fair value of the shares to be issued to the former Genovo stockholders and optionholders, if any, will be determined on the date the shares are issued and will be reflected as additional purchase price for the acquisition. In March 2002 we agreed to extend the escrow period for these shares to June 2002.

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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/A contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include statements about our product development and commercialization goals and expectations, potential market opportunities, our plans for and anticipated results of our clinical development activities and the potential advantage of our product candidates, and other statements that are not historical facts. Words such as believes, expects, anticipates, plans and intends, and other words of similar meaning, may identify forward-looking statements, but the absence of these words does not mean that the 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 entitled Factors Affecting Our Operating Results, Our Business and Our Stock Price in Item 2 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 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 SEC.

Business Overview

Targeted Genetics Corporation develops gene therapy products and technologies for treating both acquired and inherited diseases. Our gene therapy product candidates are designed to treat disease by regulating cellular function at a genetic level. This involves inserting genes into target cells and activating the inserted gene in a manner that provides the desired effect. We have assembled a broad base of proprietary intellectual property that we believe gives us the potential to address the significant diseases that are the primary focus of our business. Our proprietary intellectual property includes genes, methods of transferring genes into cells, processes to manufacture gene delivery product candidates and other proprietary technologies and processes. In addition, we have established expertise and development capabilities focused in the areas of preclinical research and biology, manufacturing and manufacturing process scale-up, quality control, quality assurance, regulatory affairs and clinical trial design and implementation. We believe that our focus and expertise will enable us to develop products based on our proprietary intellectual property.

Gene therapy products involve the use of delivery vehicles, called vectors, to insert genetic material into target cells. Our proprietary vector technologies include both viral vector technologies and synthetic vector technologies. Our viral vector development activities, which use modified viruses to deliver genes into cells, focus primarily on adeno-associated virus, or

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AAV, a common human virus that has not been associated with any human disease or illness. We believe that AAV provides a number of safety and gene delivery advantages over other viruses for several of our potential gene therapy products. Our synthetic vectors deliver genes using lipids, which are fatty, water-insoluble organic substances that can be absorbed through cell membranes. We believe that synthetic vectors may provide a number of gene delivery advantages for repeated, efficient delivery of therapeutic genes into rapidly dividing cells, such as certain types of tumor cells. We believe that using both viral and synthetic vector approaches provides advantages in our corporate partnering efforts and increases the probability of our potential products reaching the market.

We have two lead product candidates under development, one for treating cystic fibrosis that is in a Phase II clinical trial and another for treating cancer that is in Phase I and Phase II clinical trials. We also have a pipeline of product candidates in preclinical development focused on treating hemophilia, arthritis and cancer and a vaccine candidate for the prevention of AIDS. We have ongoing partnering relationships with four pharmaceutical and biotechnology companies and with one public health organization that provide funding and expertise to develop these product candidates. In each of our partnerships, we have retained a substantial financial interest in the sales of any products that result from our work. Through our partnership activities and other internally funded efforts, we have successfully advanced product candidates into clinical development, including Phase II clinical trials for our lead cystic fibrosis and cancer product candidates. In addition, we have developed processes to manufacture our potential products at a scale amenable to clinical development and expandable to large-scale production for commercialization, pending successful completion of clinical trials and regulatory approval. We believe that these successes in assembling a broad platform of proprietary intellectual property for developing and manufacturing potential products and in establishing collaborative relationships and advancing potential products to clinical evaluation serve to demonstrate the value of our intellectual property and our potential to develop gene therapy product candidates to treat a range of diseases.

Restatement of Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2002 has been restated to present our Series B convertible exchangeable preferred stock, with a carrying amount of $12.0 million, outside of permanent shareholders equity, as a result of the adoption of EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. We issued the Series B preferred stock in connection with the formation of our Emerald Gene Systems joint venture with Elan. Shares of Series B preferred stock are exchangeable our common stock or a portion of our investment in Emerald. The effect of this restatement is to reduce total shareholders equity by $12 million and to reflect the Series B preferred stock outside of permanent equity.

Net loss per common share for the quarter ended March 31, 2001 has been restated to $.14 per share from $.15 per share as previously reported. This is the result of eliminating the 7% dividend previously accrued on the Series B preferred stock totaling $228,000 that had been added to the net loss when determining the net loss applicable to common shareholders. Because dividends would only be payable in common shares upon conversion of the Series B preferred stock into common stock, the amounts previously recorded as dividends actually represent

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adjustments to the conversion price that are accounted for under EITF Issue 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*. Because the commitment date fair value of the maximum number of common shares that could be issued pursuant to conversion of the Series B preferred stock is less than the proceeds of issuance of the Series B preferred stock, the Series B preferred stock does not contain a beneficial conversion feature subject to recognition pursuant to Issue 98-5. This restatement does not affect net loss for any periods previously reported.

Developing pharmaceutical products involves extensive preclinical development, followed by human clinical trials that take several years or more to complete. The length of time required to completely develop any product candidate varies substantially according to the type, complexity and novelty of the product candidate, the degree of involvement by a development partner and the intended use of the product candidate. Our commencement and rate of completion of clinical trials may vary or be delayed for many reasons, including those discussed in this Section entitled Factors Affecting Our Operating Results, Our Business and Our Stock Price .

Results of Operations

Revenue. Revenue for the quarter ended March 31, 2002 increased to $5.4 million from $3.8 million for the first quarter of 2001. This increase reflects expanded activities under our hemophilia product development collaboration with Wyeth Pharmaceuticals, and our AIDS vaccine collaboration with the International AIDS Vaccine Initiative, or IAVI. The increase in revenue also reflects greater earnings from services we performed for Emerald Gene Systems, our joint venture with Elan Corporation plc. Increases in revenue from these collaborators during the quarter were partially offset by lower revenue earned under our development program for the treatment of cystic fibrosis, which continued in clinical development but involved lower levels of research and development.

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Research and Development Expense. Research and development expense for the quarter ended March 31, 2002 increased to $9.0 million from $6.4 million for the same period of 2001. This increase reflects expanded efforts in our preclinical product development programs for the treatment of arthritis and hemophilia and our AIDS vaccine program, in addition to related support and technology development activities. This increase also reflects higher expenses in our cancer program, partially offset by lower expenses associated with our cystic fibrosis program. Our research and development expenses for the quarters ended March 31, 2002 and 2001 were as follows:

	Quarter ended March 31,	
	2002	**2001**
Clinical programs:		
Cystic fibrosis	$ 165,000	$ 694,000
Cancer	375,000	626,000
Indirect costs	943,000	1,360,000
Total clinical programs	1,483,000	2,680,000
Research and preclinical programs	7,556,000	3,714,000
Total research and development Expense	$ 9,039,000	$ 6,394,000

Research and development costs attributable to clinical programs include costs of salaries, benefits, clinical trial site costs, outside services, materials and supplies incurred to support the clinical programs. Indirect costs allocated to clinical programs include facility and occupancy costs, intellectual property-related expenses, including patent prosecution and maintenance, and license and royalty payments. Costs attributed to research and preclinical programs largely represent our product pipeline generating activities. Because of the large number of research projects we have ongoing at any one time, and our ability to utilize resources across several projects, the majority of our research and preclinical development costs are not directly assigned to individual projects and are instead allocated among multiple projects. For purposes of reimbursement from our collaboration partners, we capture the level of effort expended on a project through our project management system which is based primarily on human resource time allocated to each project, supplemented by an allocation of indirect costs and other specifically identifiable costs, if any. As a result, the costs we allocate to a project are not intended to, and do not necessarily, reflect the actual costs of the project.

Equity in Loss of Joint Venture. We recognized a loss of $778,000 in the first quarter of 2002, as compared to $848,000 in the first quarter of 2001, for our 80.1% equity share in the losses of Emerald Gene Systems. This decrease is attributable to a decrease in Elan s joint venture activity during the period. Emerald was formed to develop enhanced gene delivery systems that combine our AAV and synthetic gene delivery technologies with Elan s drug delivery technologies.

Amortization of Intangibles. For the quarter ended March 31, 2002, amortization of intangibles, which includes amortization of noncompetition agreements acquired in connection with our acquisition of Genovo in 2000, decreased to $126,000 from $1.5 million for the first quarter of 2001. This decrease is attributable to our adoption of SFAS No. 142 as of January 1, 2002, under which goodwill and work force know-how are no longer amortized.

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General and Administrative Expenses. General and administrative expenses for the quarter ended March 31, 2002 decreased to $1.7 million from $2.0 million for the first quarter of 2001. The decrease is primarily attributable to nonrecurring expenses we incurred in early 2001 in connection with our acquisition of Genovo.

Investment Income. Investment income for the quarter ended March 31, 2002 decreased to $87,000 from $802,000 for the first quarter of 2001. The decrease resulted from lower average cash balances in 2002 and a decrease in both the yield and value per share of our short-term bond mutual fund.

Interest Expense. Interest expense for the quarter ended March 31, 2002 increased to $267,000 from $64,000 for the first quarter of 2001. This increase is attributable to higher average outstanding principal balances during the first quarter of 2002. We expect our interest expense to increase in 2002 as a result of our increased level of borrowings in 2001 and borrowings we plan to make in 2002.

Liquidity and Capital Resources

We have financed our operations primarily through proceeds from public and private sales of our equity securities and through cash payments received from our collaborative partners that we use to fund the development of specific product candidates as well as for general corporate uses. To a lesser degree, we have also financed our operations through interest earned on cash, cash equivalents and short-term investments, funding under equipment leasing agreements and research grants. These financing sources have historically allowed us to maintain adequate levels of cash and investments.

Our future cash requirements will depend on many factors, including:

- the rate and extent of scientific progress in our research and development programs;
- the timing, costs and scope of, and our success in, clinical trials, obtaining regulatory approvals and filing, prosecuting and enforcing patents;
- competing technological and market developments;
- the timing and costs of, and our success in, any product commercialization activities and facility expansions, if and as required; and
- the outcome of any litigation or administrative proceedings involving our intellectual property.

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All of our product candidates are in preclinical and clinical development and we expect to continue incurring significant expense in advancing our research and development programs. As a result, we do not expect to generate positive cash flow from our operations for at least the next several years, and only then if we can successfully develop and commercialize our product candidates. We will require substantial additional financial resources to fund the development and commercialization of our product candidates, grow our business and expand research and development of our product candidates for treating additional diseases.

Our combined cash and cash equivalents totaled $17.0 million at March 31, 2002, compared with $25.2 million at December 31, 2001. Our primary uses of cash for the first quarter of 2002 included $6.0 million to fund our operations, $241,000 to purchase capital equipment, $1.6 million to fund our share of the operations of the Emerald joint venture and $324,000 to repay scheduled debt payments.

In July 1999, we issued shares of our Series B convertible exchangeable preferred stock, valued at $12.0 million, to Elan in exchange for our 80.1% interest in Emerald. The Series B preferred stock, is convertible until July 2005, at Elan s option, into shares of our common stock, at an initial conversion price of $3.32 per share. Compounding dividends accrue semi-annually at 7% per year on the $1,000 per share face value of the stock, plus dividends. Dividends are not paid in cash but rather result in an increase in the number of shares of common stock issuable upon conversion. At the expiration of the convertibility period, the Series B preferred stock would be convertible into approximately 5.47 million shares, at an effective conversion price of $2.20 per share. Alternatively, Elan may exchange the Series B preferred stock for all shares of preferred stock that we hold in Emerald, which would increase Elan s ownership in the joint venture to 50%. If Elan exercises its exchange right, it must make a cash payment to us equal to 30.1% of the funding that we and Elan provided to Emerald after its formation. We periodically monitor the redemption value of the Series B preferred stock, as measured by 30.1% of the fair value of the joint venture that Elan would receive, less the cash payable to us upon exchange by Elan. If and when the redemption value of the Series B preferred stock exceeds its then current carrying value, we will increase the carrying value of the Series B preferred stock to the redemption value and recognize a corresponding dividend to the Series B preferred shareholder. We will recognize subsequent increases or decreases in redemption value of the Series B preferred stock; however, decreases will be limited to amounts previously recorded as increases, so as not to reduce the carrying amount of the Series B preferred stock below the original basis of $12.0 million. The exchange right currently expires in April 2003, but is subject to extension by our mutual agreement with Elan.

A significant portion of our operating expenses is funded through collaborations with third parties. We currently have strategic partnerships with four pharmaceutical and biotechnology companies and with one public health organization that provide collaborative funding and expertise to develop our product candidates:

a multiple-product collaboration with Biogen, Inc.;

a collaboration with Celltech Group plc to develop a treatment for cystic fibrosis;

the Emerald Gene Systems joint venture with Elan to develop enhanced gene delivery product candidates;

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a collaboration with Wyeth/Genetics Institute to develop treatments for hemophilia; and

a collaboration with the International AIDS Vaccine Institute, or IAVI, to develop an AIDS vaccine.

Under the collaborative agreements, we expect to receive approximately $35 million in collaborative funding over the next 18 months, consisting of:

a commitment by Biogen to purchase, at our discretion and before November 2003, up to $10 million of our common stock, or a lesser amount if the market price of our common stock at the time of sale would result in a purchase by Biogen that would increase its holdings to more than 19.9% of our outstanding common stock;

approximately $9 million available under a convertible note facility from Elan to fund our ongoing investment in Emerald, which facility we can access through September 2002; and

approximately $16 million in research and development payments we expect to receive from Biogen, Celltech, Genetics Institute and IAVI over the next 18 months, to reimburse expenses incurred in connection with the applicable collaboration.

With limited exceptions, each collaborator has the right to terminate its obligation to provide research funding at any time for scientific or business reasons. If we were to lose the collaborative funding expected from any strategic partner and were unable to obtain alternative sources of funding for the product candidate covered by the collaboration, we may be unable to continue our research and development program for that product candidate. In addition, to the extent that funding is provided by a collaborator for non-program-specific uses, the loss of significant amounts of collaborative funding could result in the delay, contraction or termination of research and development programs, a reduction in capital expenditures or business development and other operating activities, or any combination of these measures. For example, Genzyme Corporation has elected not to exercise an option to purchase up to $4 million of our common stock at an exercise price of approximately $12.85 per share, which option we granted to Genzyme in connection with our acquisition of Genovo. We would have used a portion of the proceeds from this option exercise to fund development activities in the lysosomal storage disorders, or LSD, program in which we collaborated with Genzyme and the remainder to help fund other development programs and for other general corporate purposes. As a result, we do not intend to continue with the LSD program. In addition, because we will not receive the Genzyme funds that we would have allocated to general corporate purposes, we will need to obtain additional capital to support our currently planned activities under our other research and development programs and to maintain our current facilities and staffing levels.

We are currently assessing our financing options and determining how to appropriately balance the advancement of our product candidates, continued investment in our core technologies and manufacturing capabilities and preparation for new development activities and potential products. We expect that our currently available resources, which include our cash, anticipated interest income and funding that we expect to receive from our collaborators, will be sufficient to fund our currently planned development and operating activities until mid-2003.

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We intend to pursue opportunities to obtain additional capital to fund our operations beyond that time. Additional sources of financing could involve one or more of the following:

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

selling or licensing our technology or product candidates;

issuing equity in the public or private markets; or

issuing debt.

We may be unable, however, to secure additional funding on acceptable terms, if at all.

If we cannot raise sufficient additional capital to fund our operations at our current levels, we intend to adjust our operating plans and development programs to enable us to fund our operations to 2004. These adjustments could include one or more of the following:

scaling back, delaying or terminating one or more of our research and development programs;

curtailing capital expenditures;

reducing business development and other operating activities; or

relinquishing some rights to our technology or product candidates or granting licenses, potentially on unfavorable terms.

We have warrants outstanding that entitle the holders to purchase 3.3 million shares of our common stock at $2.00 per share. These warrants, which expire in April 2003, would provide us with proceeds of up to $6.7 million if exercised. The holders, however, may elect not to exercise the warrants.

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Factors Affecting Our Operating Results, Our Business and Our Stock Price

In addition to the other information contained in this quarterly 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. The factors identified in this amended quarterly report represent factors identified as of March 31, 2002.

RISKS RELATED TO OUR BUSINESS

We have a history of losses and may never become profitable, which could result in a decline in the value of our common stock and a loss of your investment.

We have generated only small amounts of revenue since inception. We have incurred, and will continue to incur for the foreseeable future, significant expense to develop our research and development programs, conduct preclinical studies and clinical trials, seek regulatory approval for our product candidates and provide general and administrative support for these activities. As a result, we have incurred significant net losses since inception, and we expect to continue to incur substantial additional losses in the future. As of March 31, 2002, we had an accumulated deficit of approximately $184 million. We may never generate profits and, if we do become profitable, we may be unable to sustain or increase profitability.

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

Our product candidate for cystic fibrosis is in a Phase II clinical trial and our product candidate for cancer is in Phase I and Phase II clinical trials. Our product candidates for hemophilia, arthritis and cancer and our AIDS vaccine are all in preclinical research and development. Accordingly, we will not generate any product revenues for at least several years, and only then if we can successfully develop and commercialize our product candidates. Commercializing our potential products depends upon successful completion of additional research and development and testing, in both preclinical and clinical trials. Completion of clinical trials may take several years or more. The number and cost of clinical trials and the length of time necessary to complete clinical trials generally varies substantially according to the type, complexity, novelty and intended use of the product candidate. The commencement, cost and rate of completion of our clinical trials may vary or be delayed for many reasons, including the risks discussed elsewhere herein. If we are unable to timely and successfully complete preclinical and clinical development of some or all of our product candidates, we will 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 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 herein, we will be unable to generate sufficient product revenue to maintain our business.

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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.

To our knowledge, no gene therapy products have received regulatory approval from the U.S. Food and Drug Administration, or FDA, or similar regulatory agencies in other countries. Because our product candidates involve new and unproven technologies, we believe that regulatory approval may proceed more slowly than clinical trials involving traditional drugs. 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 and efficacy 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 from the National Institutes of Health, or NIH, are subject to review by the NIH s Office of Biotechnology Activities Recombinant DNA Advisory Committee, or RAC. Although NIH guidelines do not have regulatory status, the RAC review process can impede the initiation of the trial, even if the FDA has reviewed the trial and approved its initiation. Moreover, before a clinical trial can begin at an NIH-funded institution, that institution s Institutional Biosafety Committee must review the proposed clinical trial in an effort to ensure that there are no safety issues associated with the trial.

The regulatory process for our product candidates is costly, time-consuming and subject to unpredictable delays. The clinical trial requirements of the FDA, NIH and other agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary among trials and potential products. In addition, regulatory requirements governing gene and cell therapy products frequently change. Accordingly, we cannot predict how long it will take or how much it will cost to obtain regulatory approvals for clinical trials or for manufacturing or marketing our potential products. Some or all of our product candidates may never receive regulatory approval. A product candidate that appears promising at an early stage of research or development may not result in a commercially successful product. Our clinical trials may fail to demonstrate the safety and efficacy of a product candidate, for example, or we may encounter unacceptable side effects or other problems during or after clinical trials. Should this occur, we may have to delay or discontinue development of the product candidate, and corporate partners that support development of that product candidate may terminate their support. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

If we are unable to raise additional capital when needed, we will be unable to conduct our operations and develop our potential products.

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

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

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the timing, costs and scope of, and our success in, conducting clinical trials, obtaining regulatory approvals and pursuing patent prosecutions;

competing technological and market developments;

the timing and costs of, and our success in, any commercialization activities and facility expansions, if and as required; and

the outcome of any litigation or administrative proceedings involving our intellectual property.

As of March 31, 2002, we had approximately $17 million in cash and cash equivalents. In addition, we expect to receive approximately $35 million over the next 18 months under our agreements with strategic partners. We expect that these resources will be sufficient to finance our currently planned development and operating activities until mid-2003. We intend to pursue opportunities to obtain additional capital to fund our operations beyond that time. Additional sources of financing could involve one or more of the following:

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

selling or licensing our technology or product candidates;

issuing equity in the public or private markets; or

issuing debt.

Additional funding may not be available to us on reasonable terms, if at all. If we cannot raise sufficient additional capital to fund our operations at our current levels, we intend to adjust our operating plans and development programs to enable us to fund our operations to 2004. These adjustments may include scaling back, delaying or terminating one or more research and development programs, curtailing capital expenditures or reducing business development and other operating activities. We may also be required to relinquish some rights to our technology or product candidates or grant licenses on unfavorable terms, either of which would reduce the ultimate value to us of the technology or product candidates.

If we lose significant funding from our strategic partners or if our collaborative relationships are unsuccessful, we may be unable to develop our potential products.

A significant portion of our operating expenses is funded through our collaborative agreements with third parties. We currently have strategic partnerships with four pharmaceutical and biotechnology companies and with one public health organization that provide collaborative funding and expertise to develop our product candidates: a collaboration with Biogen, Inc. to

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develop multiple gene therapy product candidates, a collaboration with Celltech Group plc to develop treatments for cystic fibrosis, a joint venture with Elan Corporation plc, Emerald Gene Systems, to develop enhanced gene delivery systems, a collaboration with Wyeth/Genetics Institute to develop product candidates for treating hemophilia, and a collaboration with the International AIDS Vaccine Initiative, or IAVI, to develop an AIDS vaccine.

Under our strategic partnerships, we expect to receive approximately $35 million in collaborative funding over the next 18 months, consisting of:

- a commitment by Biogen to purchase, at our discretion and before November 2003, up to $10 million of our common stock, or a lesser amount if the market price of our common stock at the time of sale would result in a purchase by Biogen that would increase its holdings to more than 19.9% of our outstanding common stock;

- approximately $9 million available under a convertible note facility from Elan to fund our ongoing investment in Emerald, which facility we can access through September 2002; and

- approximately $16 million in research and development payments we expect to receive from Biogen, Celltech, Genetics Institute and IAVI over the next 18 months, to reimburse expenses incurred in connection with the applicable collaboration.

With limited exceptions, each collaborator has the right to terminate its obligation to provide research funding at any time for scientific or business reasons. If we were to lose the collaborative funding expected from any strategic partner and were unable to obtain alternative sources of funding for the product candidate covered by the collaboration, we may be unable to continue our research and development program for that product candidate. In addition, to the extent that funding is provided by a collaborator for non-program-specific uses, the loss of significant amounts of collaborative funding could result in the delay, contraction or termination of additional research and development programs, a reduction in capital expenditures or business development and other operating activities, or any combination of these measures. For example, Genzyme Corporation has elected not to exercise an option to purchase up to $4 million of our common stock at an exercise price of approximately $12.85 per share, which option we granted to Genzyme in connection with our acquisition of Genovo, Inc. We would have used a portion of the proceeds from this option exercise to fund development activities in our lysosomal storage disorders program in which we collaborated with Genzyme, and the remainder to help fund other development programs and for other general corporate purposes. As a result, we do not intend to continue with the lysosomal storage disorder program. In addition, because we will not receive the Genzyme funds that we would have allocated to general corporate purposes, we will need to obtain additional capital to support our currently planned activities under our other research and development programs and to maintain our current facilities and staffing levels.

Our collaborators, along with outside scientific consultants and contractors, also perform research, develop technology and processes to advance and augment our internal efforts and provide access to important intellectual property and know-how. Their activities include, for example, clinical evaluation of our product candidates, product development activities performed under our research and development collaborations, research under sponsored research

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agreements and contract manufacturing services. In addition, collaborations with established pharmaceutical and biotechnology companies and academic, research and public health organizations, particularly those that are leaders in the field, 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 many of our potential products, and therefore, the success of our business, depends on the performance of our scientific collaborators, consultants and contractors. If they do not dedicate sufficient time or 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. Competition for scientific consultants and collaborators 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.

Each of our strategic collaborations and scientific consulting relationships will conclude at the end of the term specified in the applicable agreement unless the parties agree to extend the relationship. The initial development period of the Emerald joint venture will conclude in 2002, the initial development period of our collaboration with IAVI will conclude in early 2003 and the initial development periods of our collaborations with Genetics Institute and Biogen will also conclude in 2003. The initial development period of our collaboration with Celltech ended in 2001, and this collaboration may be extended after the completion of the Phase II clinical trial for our cystic fibrosis product candidate, a portion of which continues to be funded by Celltech. We believe that the underlying programs have been successful and that our collaborations will be extended. However, a collaborator or consultant may decline to extend a collaboration, or may extend the collaboration with a significantly reduced scope, for a number of scientific or business reasons. In either case, the development of the affected product candidate could be delayed or terminated.

If we do not attract and retain qualified personnel, or if we are unable to secure our rights with respect to intellectual property invented or discovered by our consultants, we may be unable to develop and commercialize some of our potential products.

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

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Any rights in inventions or processes discovered by a scientific consultant may be contractually subject to the rights of his or her research institution in that work. Some consultants may have obligations to other entities under consulting agreements, invention assignment agreements or other agreements that may potentially conflict with their obligations to us. Disputes, and potentially litigation, may arise with respect to ownership of technology invented or discovered by a scientific consultant or with respect to a product candidate developed under collaborations. If we are unable to secure our rights, we may lose access to the intellectual property and the development of the affected product candidate could be delayed.

If we are unable to obtain and 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 license agreements, both exclusive and nonexclusive, 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. For example, we have licensed several issued and pending patents for the gene used in our cancer product development programs, the gene and vector delivered in our product candidate for cystic fibrosis and the processes that we use to manufacture our AAV-based product candidates. If we are unable to maintain our current licenses for third-party technology or, if necessary, obtain additional licenses on acceptable terms, we may be required to expend significant time and resources to develop or in-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, such as the license for the process that we use to manufacture our AAV-based product candidates, typically contain provisions requiring us to meet minimum development milestones in order to maintain the license on an exclusive basis. If we do not meet these requirements, our licensor may convert the license to a nonexclusive license or terminate the license.

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 critical to our business 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;

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the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our scientific collaborators; 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. For example, in 1997 the licensor of our licensed CFTR gene and related vector was notified that the United States Patent and Trademark Office, or USPTO, had declared an interference proceeding to determine whether our licensor or an opposing party has the right to the patent application on the CFTR gene and related vector. Our tgAAVCF product candidate for treating cystic fibrosis uses our proprietary AAV delivery technology to deliver a normal copy of the CFTR gene. Interference proceedings before the USPTO are confidential, involving the opposing parties only, and can take several years to complete. Although we are not a party to the interference proceeding, its outcome could affect our license to the CFTR gene and related vector. The USPTO could rule that our licensor has priority of invention on both the CFTR gene and vector that we license, that our licensor has priority of invention on neither the gene nor the vector, or that our licensor has priority of invention on only the gene or only the vector. If the USPTO or Court of Appeals ultimately determines that our licensor does not have rights to both the CFTR gene and the vector, we believe that we will be subject to one of several outcomes:

our licensor could agree to a settlement arrangement under which we continue to have rights to the gene and the vector at our current license royalties;

the prevailing party could require us to pay increased license royalties to maintain our access to the gene, the vector or both, as applicable, which licensing royalties could be substantial; or

we could lose our license to the gene, the vector, or both.

If our licensor does not retain its rights to the CFTR gene and the vector, and we cannot maintain access at a reasonable cost or develop or license a replacement gene and vector at a reasonable cost, we will be unable to commercialize our potential tgAAVCF product. Similar or other outcomes may result from disputes relating to our intellectual property.

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The success of our clinical trials and preclinical studies may not be indicative of results in a large number of patients or long-term efficacy.

Results in early-stage clinical testing are based on limited numbers of patients. Our reported progress and results from our early phases of clinical testing of our product candidates for cystic fibrosis and cancer 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 the favorable results we have achieved in clinical trials will have a lasting effect. If a larger group of patients does not experience positive results, or if any favorable results do not demonstrate a lasting effect, our product candidates for cystic fibrosis and cancer, or any other potential products that we advance to clinical trials, may not receive approval from the FDA for further clinical trials or commercialization. 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.

In addition, 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. If successful results for a potential product in animal models are not replicated in clinical trials, we may have to expend greater resources to pass the clinical trial stage and obtain regulatory approval of the product candidate or abandon its development.

Failure to recruit patients could delay or prevent clinical trials of our potential products, which could cause a delay or inability to develop those potential products.

Identifying and qualifying patients to participate in testing our potential products is critical to our near-term success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. We have experienced delays in our previous and current clinical trials, and we may experience similar delays in the future. If patients are unwilling to participate in our gene therapy trials because of negative publicity from adverse events in the biotechnology industry or for other reasons, the timeline for recruiting patients, 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 proving the effectiveness of our technology or termination of the clinical trials altogether.

We may be unable to adequately protect our proprietary rights, which may limit our ability to successfully market any products.

Our success substantially depends 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 for genes, processes, practices and techniques critical to our present and potential product candidates. If we fail to obtain and maintain patent or other intellectual-property protection for this technology, our competitors could market competing products using those genes, processes, practices and techniques. The patent process takes several years and involves considerable expense. In addition, patent applications and patent positions in the field of biotechnology are highly uncertain and involve complex legal, scientific and factual questions. Our patent applications may not result in issued patents and the scope of any patent may be reduced both before and after the patent is issued. Even if we secure a patent, the patent may not provide significant protection and may be circumvented or invalidated.

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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 substantially 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 could suffer a reduction in sales or be forced out of the market.

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 the biotechnology industry expands, the risk increases that other companies may claim that our processes and potential products infringe on their patents. 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 a litigation or 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, health care providers or other sellers or users of our products. 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 and 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.

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If we do not develop adequate 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.

We currently do not have the capacity to manufacture large-scale commercial quantities of our potential products. To do so, we will need to expand our current facilities and staff or supplement them through the use of contract providers. If we are unable to obtain and maintain the necessary manufacturing capabilities, either alone or through third parties, we will be unable to manufacture sufficient products to sustain our business. Moreover, we are unlikely to become profitable if we, or our contract providers, are unable to manufacture our products in a cost-effective manner.

In addition, we have no experience in sales, marketing and distribution. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. We intend to enter into collaborations with corporate partners 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 corporate 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.

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 FDA and other federal, state and local regulations. For example, our current manufacturing facility, which is designed for manufacturing our AAV vectors for clinical and development purposes, is subject to the Good Manufacturing Practices requirements and other regulations of the FDA, as well as to other federal, state and local regulations such as the Occupational Health and Safety Act and the Environmental Protection Act. Any future manufacturing facilities that we may construct for large-scale commercial production will also be subject to regulation. We may be unable to obtain regulatory approval for or maintain in operation this or any other manufacturing facility. In addition, we may be unable to attain or maintain compliance with current or future regulations relating to manufacture, safety, handling, storage, record-keeping or marketing of potential products. If we fail to comply with applicable regulatory requirements or discover previously unknown manufacturing, contamination, product side effect 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.

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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 therapy. For example, in November 1999, a patient being treated for a rare metabolic disorder died in a gene therapy trial using an adenoviral vector to deliver a therapeutic gene. Genovo, Inc., a company we later acquired, was providing partial funding for this investigator-sponsored trial conducted at the University of Pennsylvania. Other patient deaths, though unrelated to gene therapy, have occurred in other clinical trials. These deaths 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. For example, there has been concern in the past regarding the potential safety and efficacy of gene therapy products derived from pathogenic viruses like adenoviruses. While our product candidates based on viral gene delivery systems use AAV vectors, which are nonpathogenic, and nonviral vectors, the public and the medical community nonetheless may conclude that our technology is unsafe. Moreover, to the extent that unfavorable publicity or negative public perception arising from other biotechnology-related fields such as human cloning and stem-cell research are linked in the public mind to gene therapy, our industry will be harmed.

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

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

Our research and development activities involve the controlled use of hazardous materials, including chemicals, biological materials and radioactive compounds. Our safety procedures for handling, storing and disposing of these materials must comply with federal, state and local laws and regulations, including, among others, those relating to solid and hazardous waste management, biohazard material handling, radiation and air pollution control. We may be required to incur significant costs in the future to comply with environmental or other applicable laws and regulations. In addition, we cannot eliminate the risk of accidental contamination or injury from hazardous materials. If a hazardous material accident occurred, we could be held liable for any resulting damages, and this liability could exceed our 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.

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The intense competition and rapid technological change in our market may result in pricing pressures and 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 and cell therapy technologies. Our competitors include early-stage and more established gene delivery companies, other biotechnology companies, pharmaceutical companies, universities, research institutions and government agencies developing gene therapy products or other biotechnology-based therapies designed to treat the diseases on which we focus. We also face competition from companies using more traditional approaches to treating human diseases, such as surgery, drugs and other pharmaceutical products. In addition, we compete with other companies to acquire products or technology from research institutions or universities. Many of our competitors have substantially more financial and infrastructure resources and larger research and development staffs than we do. Many of our competitors also have greater experience and capabilities than we do in:

research and development;

clinical trials;

obtaining FDA and other regulatory approvals;

manufacturing; and

marketing and distribution.

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

Gene therapy is a new and rapidly evolving field and is expected to continue to undergo significant and rapid technological change and competition. Our competitors may develop new technologies and products that are available for sale before our potential products or that may be more effective than our potential products. 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.

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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 substantially depend, both domestically and abroad, 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 sufficient 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

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

In recent years, 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 like ours without earnings and product revenues, has been highly volatile and is likely to remain so in the future. In addition, 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 the past, securities class action litigation has been brought against companies that experience volatility in the market price of their securities. Market fluctuations in the price of our common stock could also adversely affect our collaborative opportunities and our future ability to sell equity securities at a price we deem appropriate. As a result, you could lose all or part of your investment.

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If we are unable to comply with the minimum requirements for quotation on the Nasdaq National Market and we lose our quotation on Nasdaq, the liquidity and market price of our common stock would decline.

To maintain the quotation of our common stock on the Nasdaq National Market, we must satisfy the financial and other requirements of the National Association of Securities Dealers, or NASD for inclusion on Nasdaq. These requirements currently include, but are not limited to, a minimum bid price of $1.00 for common stock and a minimum net worth of at least $4 million. The NASD has recently implemented a change in the listing requirements that requires issuers to maintain a minimum of $10 million in net equity. This new requirement, which replaces the minimum net worth requirement, becomes effective in November 2002. If we are unable to comply with the minimum bid price requirement, the new net equity standard or other current or future NASD listing requirements, our stock could cease to be quoted on the Nasdaq National Market. In that event, our common stock would be traded only in the over-the-counter market, which would impair the liquidity of our common stock and likely result in a decline in its market price, and you could lose all or part of your investment.

Our future capital-raising activities could involve the issuance of equity securities, which would dilute your investment and could result in a decline in the trading price of our common stock.

To meet all or a portion our long-term funding requirements, we may sell securities in the public or private equity markets if and when conditions are favorable, even if we do not have an immediate need for additional capital at that time. Furthermore, we may enter into financing transactions at prices that represent a substantial discount to market price. Raising funds through the issuance of equity securities will dilute the ownership of our existing shareholders. A negative reaction by investors and securities analysts to any discounted sale of our equity securities could result in a decline in the trading price of our common stock.

Item 3. ***Quantitative and Qualitative Disclosure About Market Risk***

Because of the short-term nature of our investments, we believe that our exposure to market rate fluctuations on those investments is minimal. Currently, we neither employ any derivative or other financial instruments or derivative commodity instruments to hedge any market risks nor plan to employ these instruments in the future. At March 31, 2002, we held $17.0 million in cash and cash equivalents, which are primarily invested in a short-term bond fund that invests in securities that, on the average, mature in less than 12 months. An analysis of the impact on these securities of a hypothetical 10% change in short-term interest rates from those in effect at March 31, 2002, indicates that such a change in interest rates would not have a significant impact on our expected earnings in 2002.

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PART II OTHER INFORMATION

Item 1. ***Legal Proceedings***

None.

Item 2. ***Changes in Securities and Use of Proceeds***

Some of our loan agreements contain financial covenants establishing limits on our ability to declare or pay cash dividends.

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 and Reports on Form 8-K***

(a) See the Index to Exhibits included in this quarterly report.

(b) On January 23, 2002, we filed an amendment to our current report on Form 8-K, initially filed October 2, 2000 and amended November 9, 2000. The amended current report, which relates to our acquisition of Genovo, Inc., provides a pro forma statement of operations for the year ended December 31, 2000.

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SIGNATURES

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

TARGETED GENETICS CORPORATION
(Registrant)

Date: August 13, 2002 By: /s/ H. STEWART PARKER

H. Stewart Parker,
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 13, 2002 By: /s/ TODD E. SIMPSON

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

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TARGETED GENETICS CORPORATION

INDEX TO EXHIBITS

Exhibit No.	Description	Note
3.1	Restated Articles of Incorporation (Exhibit 3.1)	(A)
3.2	Amended and Restated Bylaws (Exhibit 3.2)	(B)
4.1	Rights Agreement, dated as of October 17, 1996, between Targeted Genetics and ChaseMellon Shareholder Services, L.L.C. (Exhibit 2.1)	(C)
4.2	First Amendment to Rights Agreement, dated July 21, 1999, between Targeted Genetics and ChaseMellon Shareholder Services, L.L.C. (Exhibit 1.9)	(D)

(A) Incorporated by reference to the designated exhibit included with Targeted Genetics Corporation s Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, filed August 11, 2000.

(B) Incorporated by reference to the designated exhibit included with Targeted Genetics Corporation s Annual Report on Form 10-K for the year ended December 31, 1996, filed March 17, 1997.

(C) Incorporated by reference to the designated exhibit included with Targeted Genetics Corporation s Registration Statement on Form 8-A, filed October 22, 1996.

(D) Incorporated by reference to the designated exhibit included with Targeted Genetics Current Report on Form 8-K, filed August 4, 1999.