

Bunge LTD  
Form 424B3  
March 19, 2007

**SUBJECT TO COMPLETION, DATED MARCH 19, 2007**

**PRELIMINARY PROSPECTUS SUPPLEMENT TO PROSPECTUS DATED MARCH 19, 2007**

Filed Pursuant to Rule 424(b)(3)  
Registration No. 333-138662

\$

## **BUNGE N.A. FINANCE L.P.**

**% Senior Notes due 2017**

**Fully and Unconditionally Guaranteed by**

**BUNGE LIMITED**

The notes will mature on , 2017. Interest will accrue from , 2007. Interest on the notes will be payable on and of each year, commencing on , 2007. The notes will be unsecured and rank equally in right of payment with any unsecured and unsubordinated indebtedness that Bunge N.A. Finance L.P. may incur in the future. The notes will be fully, unconditionally and irrevocably guaranteed on a senior unsecured basis by Bunge Limited. Bunge Limited's guarantee will rank equally in right of payment with its other unsecured and unsubordinated indebtedness and guarantees.

Bunge N.A. Finance L.P. may redeem the notes at its option, in whole or in part at any time at a redemption price described in this prospectus supplement. Upon the occurrence of a change of control of Bunge Limited that results in the notes no longer having an investment grade rating, holders of the notes may require Bunge N.A. Finance L.P. to repurchase some or all of the notes at a price equal to 101% of the principal amount of the notes to be repurchased plus any accrued and unpaid interest.

**See Risk Factors beginning on page S-4** of this prospectus supplement and on page 2 of the accompanying prospectus for a discussion of certain risks you should consider in connection with an investment in the notes.

	<b>Per Note</b>	<b>Total</b>
Public offering price	%	\$
Underwriting discounts and commissions	%	\$
Proceeds to Bunge N.A. Finance L.P.	%	\$

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the prospectus to which it relates is truthful or complete. Any representation to the contrary is a criminal offense.

We expect that delivery of the notes will be made to investors in book-entry form through The Depository Trust Company on or about , 2007.

**JPMorgan**

**Morgan Stanley**

The date of this prospectus supplement is \_\_\_\_\_, 2007.

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**You should rely only on the information contained in this document or to which we have referred you. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.**

The distribution of this prospectus supplement and the accompanying prospectus may be restricted by law in certain jurisdictions. You should inform yourself about and observe any of these restrictions. This prospectus supplement and the accompanying prospectus does not constitute, and may not be used in connection with, an offer or solicitation by anyone in any jurisdiction in which the offer or solicitation is not authorized, or in which the person making the offer or solicitation is not qualified to do so, or to any person to whom it is unlawful to make the offer or solicitation.

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Unless the context otherwise requires, references to we, us or our refer collectively to Bunge Limited and its subsidiaries.

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## FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus include forward-looking statements that reflect our current expectations and projections about our future results, performance, prospects and opportunities. We have tried to identify these forward-looking statements by using words including may, will, expect, anticipate, believe, intend, estimate, continue and similar expressions. These forward-looking statements are subject to a number of uncertainties and other factors that could cause our actual results, performance, prospects or opportunities, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or implied by, these forward-looking statements. These factors include the risks, uncertainties, trends and other factors discussed under the headings Risk Factors in this prospectus supplement, the accompanying prospectus and our Annual Report on Form 10-K for the year ended December 31, 2006, under the headings Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Item 1. Business Business Overview, Item 1A. Risk Factors and elsewhere. Examples of forward-looking statements include all statements that are not historical in nature, including statements regarding:

- our operations, competitive position, strategy and prospects;
- industry conditions, including the prices of agricultural commodities, energy and freight, cyclicity of the agribusiness industry, unpredictability of the weather and the impact of crop and animal disease on our business;
- estimated demand for the commodities and other products that we sell;
- the effects of economic, political or social conditions and changes in foreign exchange policy or rates;
- our ability to complete, integrate and benefit from acquisitions, joint ventures and strategic alliances;
- governmental policies affecting our business, including agricultural and trade policies;
- our funding needs and financing sources; and
- the outcome of pending regulatory and legal proceedings.

In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained in this prospectus supplement, the accompanying prospectus or in any document incorporated by reference herein or therein. Additional risks that we may currently deem immaterial or that are not presently known to us could also cause the forward-looking events discussed in this prospectus supplement, the accompanying prospectus or incorporated by reference herein or therein not to occur. Except as otherwise required by applicable securities laws, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or any other reason after the date of this prospectus supplement.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements to encourage companies to provide prospective information about their companies without fear of litigation. We would like to take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act in connection with the forward-looking statements included in this prospectus supplement, the accompanying prospectus or any document incorporated by reference herein or therein.

## SUMMARY

*This is only a summary and therefore does not contain all the information that may be important to you. You should read the entire prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus carefully, including the Risk Factors section elsewhere in this prospectus supplement and the accompanying prospectus, our consolidated financial statements and the related notes and the other information incorporated by reference into this prospectus supplement and the accompanying prospectus, before deciding whether or not to purchase the notes.*

### BUNGE N.A. FINANCE L.P.

Bunge N.A. Finance L.P., a newly-formed Delaware limited partnership, is an indirect, 100%-owned subsidiary of Bunge Limited. Bunge N.A. Finance L.P. has no independent operations other than acting as a finance company for Bunge. Bunge N.A. Finance L.P. does not, and will not, file separate reports with the SEC.

### BUNGE LIMITED

Bunge Limited will fully, unconditionally and irrevocably guarantee the payment of the principal of and interest on the notes offered hereby when due and payable. Bunge Limited is a limited liability company incorporated under the laws of Bermuda.

### Our Business

We are a leading global agribusiness and food company operating in the farm-to-consumer food chain. In 2006, we had total net sales of \$26,274 million. We believe we are:

- the world's leading oilseed processing company, based on processing capacity;
- the largest producer and supplier of fertilizer to farmers in South America, based on volume; and
- a leading seller of bottled vegetable oils worldwide, based on sales.

We conduct our operations in three divisions: agribusiness, fertilizer and food products. These divisions include four reporting segments: agribusiness, fertilizer, edible oil products and milling products.

*Agribusiness.* Our agribusiness division is an integrated business involved in the purchase, storage, transport, processing and sale of grains and oilseeds. Our agribusiness operations and assets are primarily located in North and South America and Europe, and we also have operations in India and China and marketing and distribution offices throughout the world.

*Fertilizer.* Our fertilizer division is involved in every stage of the fertilizer business, from mining of raw materials to the sale of fertilizer products. The activities of our fertilizer division are primarily located in Brazil.

*Food Products.* Our food products division consists of two business segments: edible oil products and milling products. These segments include businesses that produce and sell food products such as edible oils, shortenings, margarine, mayonnaise and milled products such as wheat flours and corn products. The activities of our food products division are primarily located in North America, Europe, Brazil and India.

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Bunge N.A. Finance L.P. and Bunge Limited have their principal executive offices and corporate headquarters at 50 Main Street, White Plains, New York 10606, and their telephone number is (914) 684-2800. Bunge Limited's registered office is located at 2 Church Street, Hamilton, HM 11, Bermuda.



## THE OFFERING

Issuer	Bunge N.A. Finance L.P.
Guarantor	Bunge Limited
Notes offered	\$ _____ aggregate principal amount of _____ % Senior Notes due 2017
Maturity date	_____, 2017.
Interest	_____ % per annum, payable semi-annually in arrears on _____ and _____ of each year, commencing on _____, 2007.
Ranking	The notes will be unsecured obligations of Bunge N.A. Finance L.P. and will rank equally in right of payment with future unsecured and unsubordinated indebtedness of Bunge N.A. Finance L.P.
Guarantee	All payments on the notes, including principal and interest will be fully, unconditionally and irrevocably guaranteed by Bunge Limited. Bunge Limited's guarantee will rank equally in right of payment with its other unsecured unsubordinated indebtedness and guarantees.
Further issuances	Under certain circumstances, Bunge N.A. Finance L.P. may, without the consent of the holders of the notes, from time to time issue other notes, including notes of the same series that have the same ranking as the notes.
Optional redemption	Bunge N.A. Finance L.P. may redeem the notes at any time, in whole or in part, in cash at the redemption price described in this prospectus supplement, plus accrued and unpaid interest to the date of redemption. See Description of Notes Optional Redemption by Bunge N.A. Finance L.P.
Change of control offer	Upon the occurrence of a change of control of Bunge Limited that results in the notes no longer having an investment grade rating, you will have the right, as holders of the notes, subject to certain exceptions, to require Bunge N.A. Finance L.P. to repurchase some or all of your notes at 101% of their principal amount, plus accrued and unpaid interest, if any. See Description of Notes Repurchase at the Option of Holders.
Covenants	The indenture will contain covenants that, among other things, limit Bunge Limited's ability, and the ability of certain of its subsidiaries, to: <ul style="list-style-type: none"> <li>• _____ incur certain liens;</li> <li>• _____ engage in sale-leaseback transactions; or</li> <li>• _____ merge, amalgamate or consolidate or sell all or substantially all of its assets.</li> </ul>

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	<p>These limitations will be subject to a number of important qualifications and exceptions. See Description of Notes Covenants.</p>
No prior market	<p>The notes will be new securities for which there is no market. Although the underwriters have informed Bunge N.A. Finance L.P. that they currently intend to make a market in the notes, they are not obligated to do so and may discontinue market-making at any time without notice. Accordingly, Bunge N.A. Finance L.P. cannot assure you that a liquid market will develop or be maintained.</p>
Use of proceeds	<p>Bunge N.A. Finance L.P. estimates that it will receive net proceeds of approximately \$ million from this offering, after deducting the underwriters commissions and the estimated offering expenses. Bunge N.A. Finance L.P. intends to use the net proceeds to purchase preferred stock of an indirect, 100%-owned, U.S. subsidiary of Bunge Limited, and the proceeds of such sale are expected to be used to repay existing indebtedness of Bunge. See Use of Proceeds.</p>

For a more complete description of the terms of the notes, see Description of Notes.

### **Risk Factors**

An investment in notes involves certain risks that a potential investor should carefully evaluate prior to making an investment in the notes. See Risk Factors beginning on page S-4 of this prospectus supplement and on page 2 on the accompanying prospectus.

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## **RISK FACTORS**

*You should read and carefully consider each of the risks and uncertainties described below and the other information in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and accompanying prospectus before making an investment in the notes.*

### **Risks Related to Our Business and Industries**

For a discussion of the risks related to our business and industries, see **Risk Factors** in the accompanying prospectus.

### **Risks Relating to this Offering**

*The notes are effectively subordinated to our secured debt.*

The notes are not secured by any of our assets. Therefore, in the event of our bankruptcy, winding up, liquidation or reorganization, holders of our secured debt will have claims with respect to the assets securing their debt that have priority over your claims as note holders. As of December 31, 2006, we had \$57 million of long-term debt that is secured by certain land, property, equipment, investments in our consolidated subsidiaries and export commodity contracts having a net carrying value of \$573 million. To the extent that the value of the secured assets is insufficient to repay our secured debt, holders of secured debt would be entitled to share in any of our remaining assets equally with you and any other unsecured lenders.

*We are a holding company and will depend upon funds from our subsidiaries to meet our obligations under the guarantee of the notes.*

We are a holding company and our only significant assets are our investments in our subsidiaries. As a holding company, we are dependent upon dividends, loans or advances, or other intercompany transfers of funds from our subsidiaries to meet our obligations, including our obligations under the guarantee. The ability of certain of our subsidiaries to pay dividends and make other payments to us may be restricted by, among other things, applicable laws as well as agreements to which those subsidiaries may be party. Therefore, our ability to make payments with respect to the guarantee may be limited.

*An active trading market for the notes may not develop.*

The notes constitute a new issue of securities, for which there is no existing market. We cannot provide you with any assurance regarding whether a trading market for the notes will develop or as to the liquidity or sustainability of any such market, the ability of holders of the notes to sell their notes or the price at which holders may be able to sell their notes. If a market were to develop, the notes could trade at prices that may be higher or lower than the initial offering price depending on many factors, including prevailing interest rates, our financial performance, developments in the industries in which we conduct business and changes in the overall market for investment grade securities. The underwriters have advised us that they currently intend to make a market in the notes. However, the underwriters are not obligated to do so, and any market-making with respect to the notes may be discontinued at any time without notice. If no active trading market develops, you may not be able to resell your notes at their fair market value or at all.

***We may not be able to repurchase the notes upon a change of control.***

Upon the occurrence of specific kinds of change of control events which result in the notes having a rating below investment grade by both Moody's Investors Service, Inc. and Standard & Poor's, we will be required to offer to repurchase all outstanding notes at 101% of their principal amount plus accrued and unpaid interest. The source of funds for any such purchase of the notes will be our available cash or cash generated from our operations or other sources, including borrowings, sales of assets or sales of equity. We may not be able to repurchase the notes upon such an event because we may not have sufficient financial resources to purchase all of the notes that are tendered upon a change of control. In addition, the terms of our other indebtedness, including the indebtedness of our subsidiaries, may restrict us from repurchasing the notes upon a change of control. Accordingly, we may not be able to satisfy our obligation to purchase the notes unless we are able to refinance certain indebtedness or obtain waivers from certain lenders. Our failure to repurchase the notes upon a change of control would cause a default under the indenture governing the notes and a cross default under the terms of our other indebtedness. Certain of our other indebtedness also provide that specific kinds of change of control events would be a default that would permit lenders to accelerate the maturity of borrowings thereunder.

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## USE OF PROCEEDS

We estimate that Bunge N.A. Finance L.P. will receive net proceeds of approximately \$      million from this offering, after deducting the underwriters' commissions and the estimated offering expenses payable by it.

Bunge N.A. Finance L.P. intends to use the net proceeds from this offering to acquire preferred stock of an indirect, 100%-owned, U.S. subsidiary of Bunge Limited. This indirect, 100%-owned, U.S. subsidiary will use the proceeds received from the sale of its preferred stock to Bunge N.A. Finance L.P. to reduce approximately \$      million of indebtedness under Bunge's revolving credit facilities and approximately \$      million under Bunge's commercial paper program. Borrowings under Bunge's revolving credit facilities, as of February 28, 2007, had a weighted average interest rate of 6.30%, with an average maturity of approximately 31 days. Indebtedness under Bunge's commercial paper program, as of February 28, 2007, had a weighted average interest rate of 5.66%, with an average maturity of 26 days.

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**CAPITALIZATION**

The following table sets forth our capitalization as of December 31, 2006 on an actual basis and on an as adjusted basis to give effect to this offering and the application of the net proceeds from the sale of the notes, as described under Use of Proceeds.

This table should be read in conjunction with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and our audited consolidated financial statements for the year ended December 31, 2006 included in our 2006 Annual Report. See Incorporation of Certain Documents by Reference.

	As of December 31, 2006							
	Actual				As Adjusted			
	(dollars in millions, except share data)							
Short-term debt, including current portion of long-term debt	\$	610			\$			
Long-term debt:								
Secured		57						
Unsecured		513						
6.78% Senior Guaranteed Notes, Series B, due 2009		53						
7.44% Senior Guaranteed Notes, Series C, due 2012		351						
7.80% Senior Notes due 2012		200						
5.875% Senior Notes due 2013		300						
4.375% Senior Notes due 2008		500						
5.35% Senior Notes due 2014		500						
5.10% Senior Notes due 2015		400						
% Senior Notes due 2017								
Total long-term debt								

Assuming successful commercialization of products under the Biogen collaboration, we could receive an aggregate of up to \$125 million in license fees, development funding, milestone payments, loans and equity investments connected to the Biogen agreements. We granted Biogen an exclusive worldwide license to sell any products developed in the collaboration. We will either receive royalties on sales of any products developed under the collaboration, or alternatively, we will sell products developed under the collaboration to Biogen at transfer prices that include sales-based and cost-based components, under a pricing formula specified in the developing and marketing agreement. The product manufacturing and supply provisions of the agreements are effective for the term of the patents covering our technology used to develop the product. Although Biogen may terminate the development and marketing agreement at any time after September 2001, its obligation under the related funding agreement to pay \$1 million in annual research funding payments continues through September 2003.

***Wyeth/Genetics Institute***

In November 2000, we entered into a collaboration with Wyeth/Genetics Institute, a unit of Wyeth Pharmaceuticals, to develop AAV vector-based gene therapy products for treating hemophilia A and, potentially, hemophilia B.

Under the terms of the collaboration agreements, Wyeth/Genetics Institute agreed to pay us \$5.6 million in up-front payments and up to \$15 million over the initial three-year development period for developing a hemophilia A product candidate. We also granted Wyeth/Genetics Institute an option to collaborate on the development of a hemophilia B product candidate, which if exercised, could provide us with additional development and milestone payments. Assuming successful commercialization of both products under this collaboration, we could receive an aggregate of up to approximately \$80 million in license fees, development funding and milestone payments. Wyeth/Genetics Institute will manage and fund the costs of clinical trials and related regulatory filings required for product approval and marketing and will have global marketing rights for any products resulting from the collaboration.

Wyeth/Genetics Institute also has agreed to loan us up to \$10 million to finance manufacturing facility expansions if specified conditions are met. In addition, Wyeth/Genetics Institute has agreed to pay us to manufacture product for clinical trials and, upon approval, for commercial use, according to a sales-based formula.

The research and development funding agreement is effective until October 2003, with an option to extend the term if both parties agree. The supply agreement is effective for the term of the initial product development period and can be extended should regulatory agencies approve a product for commercial use. Wyeth/Genetics Institute has the right to terminate both agreements at will, with 180 days' notice. If Wyeth/Genetics Institute exercises this right to terminate, all rights related to the hemophilia technology that we have granted or otherwise extended to Wyeth/Genetics Institute will return to us. If Wyeth/Genetics Institute exercises their right to terminate both agreements at will or if we exercise our right to terminate for cause, we would have an option to acquire a right and license to certain hemophilia patent rights controlled by

Wyeth/Genetics Institute.

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### ***Genzyme Corporation***

In 1999, Genovo entered into a research and development collaboration with Genzyme Corporation to develop potential products for treating lysosomal storage disorders. Under the terms of the development agreement, Genovo was committed to perform, for up to three years and at its own cost, up to \$2.9 million per year of research and development activities. A related option agreement gave Genzyme the option to purchase up to \$11.4 million of Genovo equity during the three-year research and development period, of which \$3.4 million had been purchased before our acquisition of Genovo in 2000. We assumed the Genzyme agreements when we acquired Genovo.

In 2000, we amended the 1999 development agreement to expand its technological scope and financial terms and establish a development plan for the second year of the three-year collaboration. Under the amended agreement, Genzyme will be required to pay milestone payments upon our achievement of specified regulatory milestones and to pay royalties on sales of any products developed under the collaboration. The development program under our agreement with Genzyme is effective through August 2002 and includes an option to extend the term if both parties agree. Genzyme has the right to terminate the development program at will, with 90 days' notice. If Genzyme exercises this right to terminate the development program, or upon its expiration, all rights that we have granted or otherwise extended to Genzyme will return to us, except that Genzyme will retain an exclusive license to certain Genovo-related manufacturing technology for use in the field of lysosomal storage disorders.

After executing the amended agreement, Genzyme exercised its option to purchase 311,295 shares of our common stock (as successor company to Genovo) at a purchase price of \$12.8495 per share, resulting in proceeds to us of \$4 million. Genzyme has not exercised a second option to acquire up to an additional 311,295 shares of our common stock also at a price of \$12.8495 per share. We are in negotiations with Genzyme to define the scope of ongoing development activities and the parameters around which Genzyme would make a further investment in us. If Genzyme elects not to make an additional investment or to provide less than the \$4 million we would receive if Genzyme exercised the second stock purchase option, the former Genovo shareholders and option holders will receive up to 155,648 additional shares of our common stock.

### ***International AIDS Vaccine Initiative***

In February 2000, we entered into a three-year collaboration with the International AIDS Vaccine Initiative and Children's Research Institute to develop a vaccine to prevent AIDS. The vaccine, which will utilize our AAV vectors to deliver selected HIV genes as a vaccine, is designed to elicit a protective immune response against HIV. Under this collaboration, vaccine candidates will be constructed based on subtypes of the virus most prevalent in Southern and Eastern Africa, and are expected to be evaluated in those regions. Under the terms of this public-private collaboration, IAVI will fund development, preclinical studies and Phase I clinical trials performed by us and by CRI. IAVI has also agreed to invest up to \$6 million in research funding during the initial three years of the collaboration.

Assuming successful development, we expect to manufacture the vaccine and will retain exclusive worldwide commercialization rights to any product that may stem from the collaboration. Under the terms of the collaboration, IAVI has retained rights to ensure that any successful vaccine will be distributed in developing countries at a reasonable price to be determined by IAVI. If we decline to produce the vaccine for developing countries in reasonable quantities and at a reasonable price, IAVI will have rights to obtain licenses from us that will allow IAVI to contract with other manufacturers to make the vaccine available at a reasonable price in those countries. In any event, however, we will retain exclusive rights to commercialize in industrialized countries any vaccine resulting from the collaboration.

The initial development periods of our collaborations with Genzyme and Elan will conclude in 2002 and the initial development periods of our other collaborations will conclude in 2003, unless we and our collaborators agree to extend the agreements. Substantially all of our revenue, and substantially all of our expected revenue for the next several years, is derived from our product development collaborations. If we were to lose the product development and other funding that our collaborative partners provide and are unable to obtain alternative funding, we may be unable to commercialize the product candidate covered by the affected collaborations. For a more detailed description of the risk, see the section entitled "Factors Affecting Our Operating Results, Our Business and Our Stock Price." If we lose significant collaborative funding or we are unable to raise additional capital when needed, we may be unable to develop our potential products and conduct our operations in Part II, Item 7 of this annual report.

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### ***Alkermes, Inc.***

In June 1999, we entered into a license agreement with Alkermes, Inc. in which we received exclusive rights to an issued patent and other pending patent applications related to AAV vector manufacturing. The issued patent broadly covers a manufacturing method that we believe is key to making AAV-based products in a commercially viable, cost-effective manner. The license to this technology, first developed by Children's Hospital in Columbus, Ohio, covers the use of cell lines for manufacturing AAV vectors and expands a limited field license to these rights that we previously acquired. Under the terms of the license agreement, we issued to Alkermes 500,000 shares of common stock and two warrants, each to purchase 1,000,000 additional shares of common stock. The warrants expire in June 2007 and June 2009 and have an exercise price of \$2.50 and \$4.16 per share, respectively. Alkermes will also receive milestone payments and royalties on the sale of any products manufactured using the licensed technology and is entitled to a portion of any sub-licensing payments that we may receive.

### **Relationship With Immunex Corporation**

Targeted Genetics was formed in 1989 as a subsidiary of Immunex, a biopharmaceutical company developing recombinant proteins as therapeutics. In connection with our formation, we issued Immunex shares of our preferred stock that were subsequently converted into 1,920,000 shares of common stock, in exchange for Immunex granting us an exclusive worldwide license to certain Immunex proprietary technology specifically applicable to gene therapy applications. The licensed technology relates to gene identification and cloning, panels of retroviral vectors, packaging cell technology, recombinant cytokines, DNA constructs, cell lines, promoter/ enhancer elements and immunological assays.

### **Patents and Proprietary Rights**

Patents and licenses are important to our business. Our strategy is to file or license patent applications to protect technology, inventions and improvements to inventions that we consider important to developing our business. To date, we have filed or exclusively licensed over 400 patent or patent applications with the United States Patent and Trademark Office, or USPTO, as well as foreign counterparts of some of these applications in Europe, Japan and other countries. Of these patent applications, over 100 patents have been issued or allowed by the USPTO and foreign counterparts. We also rely on unpatented proprietary technology such as trade secrets, know-how and continuing technological innovations to develop and maintain our competitive position.

The patent positions of pharmaceutical and biotechnology firms, including our patent positions, are uncertain and involve complex legal and factual questions for which important legal principles are largely unresolved, particularly with regard to human therapeutic uses. Patent applications may not result in the issuance of patents, and the coverage claimed in a patent application may be significantly reduced before a patent is issued. If any patents are issued, the patents may be subjected to further proceedings limiting their scope, may not provide significant proprietary protection and may be circumvented or invalidated. Patent applications in the United States and other countries generally are not published until more than 18 months after they are filed, and since publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be sure that we were, or our licensor was, the first creator of inventions covered by pending patent applications or the first to file patent applications for these inventions.

We have licensed technology underlying several issued and pending patents. Among these are two key patents that relate to the use of AAV vectors for gene delivery, which we licensed from the National Institutes of Health, or NIH, and the University of Florida Research Foundation. In addition, we have acquired nonexclusive rights to the CFTR gene being delivered in our tgAAVCF product candidate for cystic fibrosis, which uses our proprietary AAV delivery technology to deliver a copy of the CFTR gene. Licensing of intellectual property critical to our business involves complex legal, business and scientific issues. 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 or commercialize the affected product candidates. For example, in July 1997 the licensor of our licensed CFTR gene was notified that the USPTO had declared an interference proceeding to determine whether

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our licensor or an opposing party has the right to the patent application on the CFTR gene and related vector. Although we are not a party to the interference proceeding, its outcome could affect our license to the CFTR gene and related 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 right to the CFTR gene and the vector, and we cannot obtain 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 candidate. For a more detailed description of this risk, see the section entitled Factors Affecting Our Operating Results, Our Business and Our Stock Price Intellectual property disputes regarding third-party technology that we license may prevent or impair our ability to develop and commercialize our product candidates in Part II, Item 7 of this annual report.

In addition to patent protection, we rely on trade secret protection for our confidential and proprietary information and technology. To protect our trade secrets, we generally require our employees, consultants, scientific advisors and parties to collaborative agreements to execute confidentiality agreements. In the case of employees and consultants, the agreements also provide that all inventions resulting from work performed by them while employed by us will be our exclusive property. Despite these agreements, and other precautions we take to protect our trade secrets and other proprietary unpatented intellectual property, however, we may be unable to meaningfully protect our trade secrets and other intellectual property from unauthorized use or misappropriation by a third party. These agreements may not provide adequate remedies in the event of unauthorized use or disclosure of our confidential information. In addition, our competitors could obtain rights to our nonexclusively licensed proprietary technology or may independently develop substantially equivalent proprietary information and technology. If our competitors develop and market competing products using our unpatented or nonexclusively licensed intellectual property or substantially similar technology or processes, our products could suffer a reduction in sales or be forced out of the market.

A number of pharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Some of these technologies, applications or patents may conflict with our technologies or patent applications. This conflict could limit the scope of any patents that we may obtain for our technologies or result in denial of our patent applications. In addition, if patents or patent applications that cover our activities are or have been issued to other companies, we may be required to either obtain a license from the owner or develop or obtain alternative technology. A license may not be available on acceptable terms, if at all, and we may be unable to develop or obtain alternative technology.

As the biotechnology industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe on the patents of others. These other parties could bring legal actions against us claiming damages and seeking to stop clinical testing, manufacturing and marketing of the affected product or use of the affected process. If we are found by a court to have infringed on the proprietary rights of others, we could also face potential liability for significant damages and be required to obtain a license to the proprietary technology at issue if we continue to commercialize. A required license may not be available on acceptable terms, if at all, which could impair our ability to commercialize our product candidates. Similarly, administrative proceedings, litigation or both may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others. This type of litigation, regardless of its merit, could result in substantial expense to us and significantly divert the efforts of our technical and management personnel. An adverse outcome could adversely affect our business.



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### **Competition**

A number of companies and institutions are developing or considering the development of potential gene therapy and cell therapy treatments, including other gene delivery companies, biotechnology companies, pharmaceutical companies, universities, research institutions, governmental agencies and other healthcare providers. In addition to competition from these sources, our potential products will compete with more traditional therapies for the diseases on which we focus, including pharmaceutical products, medical devices and surgery. We also compete with others to acquire products or technology from research institutions or universities.

Many of our competitors have substantially more financial and other resources, larger research and development staffs and more experience and capabilities in researching, developing and testing product in clinical trials, obtaining FDA and other regulatory approvals and manufacturing, marketing and distributing products. In addition, the competitive positions of other companies may be strengthened through collaborative relationships, such as those with large pharmaceutical companies or academic institutions. As a result, our competitors may develop, obtain patent protection for, receive FDA and other regulatory approvals for or commercialize products more rapidly than we do or may manufacture and market their products more successfully than we do. Our competitors' technologies and products may be more effective or economically feasible than our potential products. If we are successful in commercializing our products, we will be required to compete with respect to manufacturing efficiency and marketing capabilities, areas in which we have no experience. These developments could limit the prices we are able to charge for any products we are able to commercialize or render our products less competitive or obsolete.

### **Governmental Regulation**

All of our potential products must receive regulatory approval before they can be marketed. Human therapeutic products are subject to rigorous preclinical and clinical testing and other premarket approval procedures administered by the Food and Drug Administration, or FDA, and similar authorities in foreign countries. In accordance with the federal Food, Drug and Cosmetics Act, the FDA exercises regulatory authority over the development, testing, formulation, manufacture, labeling, storage, record keeping, reporting, quality control, advertising, promotion, export and sale of our potential products. Similar requirements are imposed by foreign regulatory agencies. In some cases, state regulation may also apply.

Gene therapy and cell therapy are both relatively new technologies that have not been extensively tested in humans. The FDA reviews all product candidates for safety and efficacy at each stage of clinical testing. Both safety and efficacy standards must be met before the FDA permits clinical testing to proceed to the next stage or grants product approval. Obtaining approval from the FDA and other regulatory authorities for a new therapeutic product candidate, if approval is ever obtained, is likely to take several years. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or prevent the marketing of our product candidates. In addition, the regulatory requirements governing gene and cell therapy product candidates and commercialized products frequently change. The approval process, and ongoing compliance with applicable regulations after approval, involves substantial expenditures of financial and other resources.

Preclinical studies generally require studies in the laboratory or in animals to assess the potential product's safety and effectiveness. Preclinical studies include laboratory evaluation of toxicity, pharmacokinetics, or how the body processes and reacts to the drug, and pharmacodynamics, or whether the drug is actually having the expected effect on the body. Preclinical studies must be conducted in accordance with the FDA's Good Laboratory Practice regulations and, before any proposed clinical testing in humans can begin, the FDA must review the results of these preclinical studies as part of an Investigational New Drug application.

If preclinical studies of a product candidate, including animal studies, demonstrate safety, and laboratory test results are acceptable, then the potential product will undergo clinical trials to test the therapeutic agent in humans. Human clinical trials are subject to numerous governmental regulations that provide detailed procedural and administrative requirements designed to protect the trial participants. Each institution that conducts human clinical trials has an Institution Review Board charged with evaluating each trial and any trial amendments to ensure that the trial is ethical, patients are protected and the trial meets the institutional requirements. These evaluations include reviews of how the institution will communicate the risks inherent in the clinical trial to potential participants, so that the patients may give their informed consent. Clinical trials must be conducted in accordance with the FDA's

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Good Clinical Practices regulations and the protocols the company establishes to govern the trial objectives, the parameters to be used for monitoring safety, the criteria for evaluating the efficacy of the potential product and the rights of each trial participant with respect to safety. FDA regulations require us to submit these protocols as part of the application. A FDA review or approval of the protocols, however, does not necessarily mean that the trial will successfully demonstrate safety and/or efficacy of the potential product.

Institutions that receive NIH funding for gene therapy clinical trials must also comply with the NIH Guidelines, and the clinical trials are subject to a review by the NIH's Office of Biotechnology Activities Recombinant DNA Advisory Committee, or RAC. The outcome of this review can be either an approval to initiate the trial without a public review or a requirement that the proposed trial be reviewed at a quarterly committee meeting. A clinical trial will be publicly reviewed when at least three of the committee members or the Director of the Office of Biotechnology Activities recommends a public review. Should the RAC require a public hearing, the start of the trial must be delayed until after the hearing date. Although the 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. Additionally, before any NIH-funded clinical trial can begin, the Institutional Biosafety Committee must perform a review of the proposed clinical trial and ensure there are no safety issues associated with the trial.

Clinical trials are typically conducted in three phases. In Phase I, clinical trials generally involve a small number of patients, who may or may not be afflicted with the target disease, to determine the preliminary safety profile. In Phase II, clinical trials are conducted with larger groups of patients afflicted with the target disease in order to establish preliminary effectiveness and optimal dosages and to obtain additional evidence of safety. In Phase III, large-scale, multi-center, comparative clinical trials are conducted with patients afflicted with the target disease in order to provide enough data for the statistical proof of efficacy and safety required by the FDA and other regulatory agencies for market approval. We report our progress in each phase of clinical testing to the FDA, which may require modification, suspension or termination of the clinical trial if it deems patient risk too high. The length of the clinical trial period, the number of trials conducted and the number of enrolled patients per trial vary, depending on our results and FDA requirements for the particular clinical trial. Although we and other companies in our industry have made progress in the field of gene therapy, we cannot predict what the FDA or the RAC will require in any of these areas to establish to its satisfaction the safety and effectiveness of the product candidate.

If we successfully complete clinical trials for a product candidate, we must obtain FDA approval, as well as the approval of several other governmental and nongovernmental agencies, before we can market the product in the United States. Current FDA regulations relating to biologic therapeutics require us to submit an acceptable Biologics License Application, or BLA, to the FDA and receive approval before the FDA will permit commercial marketing. The BLA includes a description of our product development activities, the results of preclinical studies and clinical trials and detailed manufacturing information. Unless the FDA gives expedited review status, this stage of the review process generally takes at least one year. Should the FDA have concerns with respect to the potential product's safety and efficacy, it may request additional data, which could delay product review or approval. The FDA may ultimately decide that the BLA does not satisfy its criteria for approval and might require us to do any or all of the following:

- modify the scope of our desired product claims;
- add warnings or other safety-related information; and/or
- perform additional testing.

Because the FDA has not yet approved any gene therapy products, it is not clear what, if any, unforeseen issues may arise during the approval process. While we expect this regulatory structure to continue, we also expect the FDA's regulatory approach to product approval, and its requirements with respect to product testing, to become more predictable as its scientific knowledge and experience in the field of gene therapy increase. Adverse events in the field of gene therapy or other biotechnology-related fields, however, could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of gene therapy products.

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Once approved by the FDA, marketed products are subject to continual FDA review. Later discovery of previously unknown problems or failure to comply with applicable regulatory requirements may result in restrictions on marketing a product or in its withdrawal from the market, as well as potential criminal penalties or sanctions. In addition, the FDA requires that manufacturers of a product comply with current Good Manufacturing Practices requirements, both as a condition to product approval and on a continuing basis. In complying with these requirements, we expend significant amounts of time, money and effort in production, record keeping and quality control. Our manufacturing facilities are subject to periodic inspections by the FDA. If major problems are identified during these inspections that could impact patient safety, the FDA could subject us to possible action, such as the suspension of product manufacturing, product seizure, withdrawal of approval or other regulatory sanctions. The FDA could also require us to recall a product.

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. For example, our controlled use of hazardous materials in our research and development activities must comply with standards prescribed by state and federal law.

### **Employees**

At December 31, 2001, we had 173 full-time-equivalent employees, of which 151 are directly involved in research and development, or support our research and development efforts. 31 of these employees have Ph.D. or M.D. degrees and a significant number of our management and professional employees have prior experience with other biotechnology or pharmaceutical companies.

Competition among biotechnology and pharmaceutical companies for highly skilled scientific and management personnel is intense. We believe that we have compensation and benefit programs in place that will allow us to be competitive in this environment. If we are ineffective, however, in retaining our existing workforce and scientific advisors or in attracting additional qualified employees and advisors, our business will not succeed. None of our employees are covered by a collective bargaining agreement.

### **Item 2. *Properties***

We currently occupy an aggregate of approximately 90,000 square feet of laboratory and office space in Seattle, Washington and Sharon Hill, Pennsylvania. The leases on our Seattle laboratory and office facilities expire in March 2004 and contain options for us to extend the terms for two additional five-year periods. The average annual rent payment during the current terms of the Seattle leases total approximately \$1.4 million, including amounts related to landlord financing of leasehold improvement costs. The lease on our laboratory and office facilities in Sharon Hill expires in November 2005 and contains options for us to extend its term for two additional five-year periods. The annual rent payment during the current term of the Sharon Hill lease is approximately \$353,000. In July 2000, we leased approximately 76,000 square feet of space in Bothell, Washington for future large-scale manufacturing of our products. The lease on this facility expires in September 2015 and contains an option for us to extend its term for one additional five-year period. The average annual rent payment during the current term of the Bothell lease is approximately \$1.3 million. We believe that our current facilities in Seattle and Sharon Hill, together with additional expansion space available in our Bothell facility and the office complex adjoining our main Seattle building, will be adequate to meet our projected needs for the next several years. Within that time frame, however, we could be required to locate alternative facilities, depending on the extent of our growth and development.

### **Item 3. *Legal Proceedings***

We are not a party to any material legal proceedings, although from time to time we may become involved in disputes in connection with the operation of our business.

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

No matters were submitted to a vote of our security holders during the fourth quarter of 2001.

**Table of Contents****PART II****Item 5. *Market for the Registrant's Equity and Related Shareholder Matters***

Our common stock trades on the Nasdaq National Market under the symbol TGEN. As of March 5, 2002, we had approximately 263 shareholders of record and approximately 19,700 beneficial holders of our common stock.

We have never paid cash dividends and do not anticipate paying them in the foreseeable future. In addition, our loan agreements with Biogen, Inc. and Celltech Group plc restricts the amount of cash dividends we can pay.

The following table lists, for each calendar quarter indicated, the high and low bid quotations for our common stock, as quoted on the Nasdaq National Market. These quotes reflect inter-dealer prices, without retail mark-up or commission, and may not necessarily represent actual transactions.

	<b>High</b>	<b>Low</b>
<b>2001:</b>		
4th Quarter	\$ 3.50	\$ 1.71
3rd Quarter	5.87	1.45
2nd Quarter	6.60	3.00
1st Quarter	9.25	2.38
<b>2000:</b>		
4th Quarter	12.81	6.38
3rd Quarter	17.00	9.00
2nd Quarter	15.00	5.31
1st Quarter	28.00	3.63

In connection with a private placement of common stock in 1998, we issued warrants to purchase a total of 4,333,333 shares of common stock at an exercise price of \$2.00 per share. On January 18, 2001, The Equitable Life Assurance Company exercised warrants to purchase 1,000,000 shares of common stock. The transaction was exempt from registration under Section 4(2) of the Securities Act, on the basis that the transaction did not involve a public offering.

**Table of Contents****Item 6. Selected Financial Data**

	Year Ended December 31,				
	2001	2000	1999	1998	1997
<b>Statement of Operations Data</b>					
Revenue	\$ 18,880,000	\$ 11,403,000	\$ 6,848,000	\$ 7,510,000	\$ 1,328,000
Operating expenses	47,484,000	57,208,000	33,694,000	16,373,000	15,828,000
<b>Loss from operations</b>	<b>(28,604,000)</b>	<b>(45,805,000)</b>	<b>(26,846,000)</b>	<b>(8,863,000)</b>	<b>(14,501,000)</b>
Loss before cumulative effect of change in accounting principle	(27,170,000)	(43,973,000)	(26,655,000)	(8,687,000)	(14,188,000)
Cumulative effect of change in accounting principle (1)		(3,682,000)			
<b>Net loss</b>	<b>\$ (27,170,000)</b>	<b>\$ (47,655,000)</b>	<b>\$ (26,655,000)</b>	<b>\$ (8,687,000)</b>	<b>\$ (14,188,000)</b>
Basic and diluted net loss per share:					
Loss before cumulative effect of change in accounting principle (2)	\$ (0.62)	\$ (1.16)	\$ (0.83)	\$ (0.33)	\$ (0.70)
Cumulative effect of change in accounting principle (1)		(0.10)			
<b>Net loss per basic and diluted common share (2)</b>	<b>\$ (0.62)</b>	<b>\$ (1.26)</b>	<b>\$ (0.83)</b>	<b>\$ (0.33)</b>	<b>\$ (0.70)</b>
Shares used in computing basic and diluted net loss per common share	43,927,822	37,752,164	32,173,756	26,637,823	20,196,325
Proforma amounts assuming the accounting change is applied retroactively:					
Net loss			\$ (24,555,000)	\$ (14,468,000)	
Net loss per common share			\$ (0.77)	\$ (0.54)	

	December 31,				
	2001	2000	1999	1998	1997
<b>Balance Sheet Data</b>					
Cash and cash equivalents	\$ 25,186,000	\$ 38,630,000	\$ 7,153,000	\$ 11,957,000	\$ 5,038,000
Total assets	71,038,000	87,974,000	13,692,000	16,204,000	9,767,000
Long-term obligations	16,403,000	2,447,000	2,088,000	900,000	1,517,000
Redeemable preferred stock	12,015,000	12,015,000	12,015,000		
Total shareholders' equity (3)	25,386,000	51,417,000	(5,049,000)	11,982,000	5,592,000

- (1) Effective January 1, 2000, we changed our method of accounting for nonrefundable up-front license fees. See Note 1 to the consolidated financial statements.
- (2) The net loss per common share for 2001, 2000 and 1999 has been restated to eliminate the 7% dividend previously accrued on the Series B Preferred Stock. See Note 1 to the consolidated financial statements.
- (3) Shareholders' equity for 2001, 2000 and 1999 has been restated to classify the Series B Preferred Stock outside of permanent equity. See Note 1 to the consolidated financial statements.

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### **Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations Overview***

We develop gene therapy products and technologies to treat acquired and inherited diseases on our own and through various research and development collaborations with others. We have historically funded our product development efforts primarily through the sale of equity securities and through funding received from our product development partners. We have six major collaborations that provide ongoing funding for our research and development programs:

- a cystic fibrosis product development collaboration with Medeva Pharmaceuticals, Inc., now a wholly owned subsidiary of Celltech Group plc;

- an AAV-based AIDS vaccine development collaboration with the International Aids Vaccine Initiative;

- a multiple-product gene therapy product development collaboration with Biogen, Inc.;

- a lysosomal storage disorder product development collaboration with Genzyme Corporation;

- an AAV-based hemophilia product development collaboration with Wyeth/Genetics Institute, a unit of Wyeth Pharmaceuticals; and

Emerald Gene Systems, Ltd., our joint venture with Elan International Services, Ltd., a wholly owned subsidiary of Elan Corporation plc, for the development of enhanced gene delivery technology.

Our development collaborations with other entities typically provide us with funding, including one or more purchases of our equity securities, loans, payments for reimbursement of research and development costs and milestone fees and payments. We and our partner will typically agree on a development plan for the product candidate, which often extends for multiple years. The product candidate's progress is periodically reviewed with the partner. Our development partners often coordinate clinical evaluation of product candidates and marketing rights for product candidates that are successfully developed. We generally maintain manufacturing and royalty-based interests in successfully developed product candidates.

We have two lead product candidates in clinical trials, tgAAVCF for treating cystic fibrosis and tgDCC-E1A for treating cancer. tgAAVCF is currently in a Phase II clinical trial. tgDCC-E1A is currently in a Phase I clinical trial for treating ovarian cancer and a Phase II clinical trial for treating head and neck cancer. We are pursuing tgDCC-E1A initially as a company-funded program but anticipate entering into a strategic collaboration later in the development process. Our product candidates for treating hemophilia and lysosomal storage disorders, our potential vaccine to prevent HIV infection and the products we are developing with Elan and Biogen are all in preclinical development. 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 the section of this Item 7 entitled "Factors Affecting Our Operating Results, Our Business and Our Stock Price-Risks Related to Product Development and Regulatory Approval" and elsewhere in this annual report. As a result, we are unable to predict whether we will be able to successfully develop any of our product candidates or the time or cost successful development will require.

Although we believe that our technology appears promising, we do not know whether any commercially viable products will result from our research and development efforts or those of our collaborators. We anticipate that we will not generate revenue from the sale of commercial products for at least the next several years. Unless and until we successfully commercialize one or more product candidates, we expect to generate revenue primarily through research funding, milestone payments and licensing fees from current and potential future corporate collaborators. The timing and amount of our future revenue, will be subject to significant fluctuations, based in part on the success of our research activities, the receipt of necessary regulatory approvals, the timing of achievement of milestones and the extent to which associated costs are reimbursed under our collaborative arrangements. Each of our product

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candidates combines different licensed technology from several licensors. We will have an obligation to our licensors to pay royalties on products that utilize their technologies. Because each product may require a different set of technologies, third-party royalties will be determined and paid on a product-by-product basis. Royalty payment rates may also vary between products depending on the extent of licensed technology or because some technology licenses provide for lower royalties when the licensed technologies are combined with other royalty-bearing technologies. The royalty payment rates that we owe to our licensors will significantly influence the price and viability of our potential products.

Our research and development expenses may fluctuate due to the timing of expenditures for the varying stages of our research, product development and clinical development programs and the availability of capital resources. Because a significant portion of our revenue is directly tied to our research and development activities, our revenue will fluctuate with the level of future research and development activities. We expect that our revenue will continue to fluctuate as we proceed with our current development collaborations, enter into potential new development collaborations and licensing agreements and earn milestone payments.

As of December 31, 2001, our accumulated deficit totaled \$178.0 million. We expect to generate substantial additional losses for the foreseeable future, primarily due to the costs associated with our preclinical and clinical development programs, developing our manufacturing capabilities and preparing our products under development for commercialization. Our expenses are driven by our staffing levels, outside costs for supplies and materials and clinical trial activities. We increased our staffing, outside costs and clinical trial activities in 2001 and 2000 as a result of the greater number, complexity and advancing development stages of our collaborations. We anticipate 2002 staffing and outside costs for supplies, materials and clinical trial activities will continue at levels similar to those in 2001. As described in the section of this Item 7 entitled "Liquidity and Capital Resources," the initial development periods of three of our collaborations conclude in 2002 and 2003. If we and the collaborators do not agree to extend these collaborations, they will terminate. Absent new collaborative partnerships or extensions to our existing collaborative partnerships, we anticipate that both our research and development costs and our revenue will decrease in 2003. We will need to scale our research and development activities to match the levels of funding provided by our collaborators and other sources of capital available to us, which may be subject to fluctuation in the future.

We may be unable to achieve profitability on a sustained basis, if at all. Further, successful development of our product candidates will require that we access significantly higher amounts of capital than we currently have. We may be unable to obtain required funding when needed and on acceptable terms, obtain and maintain corporate partnerships or complete acquisition transactions necessary or desirable to complete the development of our product candidates.

In September 2000, we acquired Genovo, Inc., a privately held biotechnology company focused on developing therapeutic products based on AAV vectors. The purchase price totaled \$66.4 million, which consisted of 5,250,805 shares of our common stock, valued at \$58.4 million, assumed Genovo options valued at \$7.7 million and transaction costs of \$600,000 less \$300,000 allocated to the intrinsic value of unvested stock options that we assumed. In connection with the acquisition of Genovo, we recorded acquired in-process research and development, or IPR&D, expenses of \$28.0 million and acquisition-related intangibles of \$39.5 million, consisting of AAV vector know-how of \$12.7 million, workforce in place of \$1.6 million and goodwill of \$25.2 million.

### **Significant Accounting Policies**

There are several accounting policies that we believe are critical to the presentation of our consolidated financial statements. Note 1 to our consolidated financial statements *Description of Business and Summary of Significant Accounting Policies* summarizes each of our significant accounting policies. The most critical accounting policies include those related to revenue recognition, specifically as these policies relate to our collaborative development relationships with other companies, the accounting and presentation for our unconsolidated joint venture interest in Emerald, the application of assumptions and estimates in accounting for acquired IPR&D costs and the valuation of our intangible assets.

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We generate revenue from technology licenses, collaborative research arrangements and cost reimbursement agreements. Revenue under technology licenses and collaborative agreements typically consist of nonrefundable, up-front license fees, collaborative research funding, technology access fees and various other payments. Revenue from nonrefundable, up-front license fees and technology access payments is recognized ratably over the development period in the collaborative agreement. Revenue associated with performance milestones is recognized as earned, based upon the achievement of the milestones defined in the applicable agreements. Revenue under research and development cost-reimbursement contracts is recognized as the related costs are incurred. Advance payments received in excess of amounts earned are classified as deferred revenue.

We own 80.1% of Emerald's common stock and 80.1% of Emerald's preferred stock and Elan owns the remaining 19.9% of Emerald's common and preferred stock. The common stock of Emerald held by Elan is similar in all respects to the common stock held by us, except that those shares held by Elan do not have voting rights. The common shares held by Elan may be converted into voting common shares at Elan's election. Although we currently own 100% of the voting stock, Elan and its subsidiaries have retained significant minority investor rights that are considered participating rights under the FASB's Emerging Issues Task Force Bulletin 96-16, *Investors' Accounting for an Investee When the Investor Has a Majority of the Voting Interest but the Minority Shareholder Has Certain Approval or Veto Rights*. Because Elan's participating rights prevent us from exercising control over Emerald, we do not consolidate the financial statements of Emerald but instead account for our investment in Emerald under the equity method of accounting.

Our Series B 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 the preferred shares we hold in Emerald, which represents 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 the 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 million. The exchange right currently expires in April 2003, but is subject to extension by our mutual agreement with Elan.

Our estimates are based on assumptions we believe to be reasonable at the time we perform these estimates. Changes in the underlying assumptions may result in substantially different accounting estimates. For example, when we acquired Genovo in September 2000, we assigned value to the acquired assets on the basis of several estimates and assumptions. Changes in these underlying estimates may result in substantially different allocation of the overall purchase price and the amount of expenses recorded on our balance sheet as acquired IPR&D and intangible assets. In addition, we will make assumptions and estimates on a periodic basis when we evaluate the carrying value of goodwill for evidence of impairment.

The summary of significant accounting policies should be read in conjunction with our consolidated financial statements and related notes and this discussion of our results of operations and liquidity and capital resources.

## **Results of Operations**

### ***Revenue***

Revenue in 2001 totaled \$18.9 million, compared to \$11.4 million in 2000. This increase primarily resulted from our hemophilia product development collaboration with Wyeth/Genetics Institute and our multiple-product development collaboration with Biogen, both of which were established in late 2000. The increase also reflects growth in revenue earned from the Emerald joint venture and revenue earned under our AIDS vaccine collaboration with IAVI. The increase in revenue for 2001 was partially offset by a decrease in revenue earned under our development program with Celltech for a cystic fibrosis product candidate, under which we earned a \$2 million milestone payment in 2000. Revenue increased to \$11.4 million in 2000 from \$6.8 million in 1999, reflecting amounts generated under our collaboration agreement with Celltech, a full year of providing research and development services to Emerald and, to a lesser degree, revenue generated from a partial year of product development efforts in our collaborations with Wyeth/Genetics Institute, Biogen and IAVI.



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We generated \$2.8 million in revenue in 2001, \$1.9 million in revenue in 2000 and \$446,000 in revenue in 1999 from research and development activities performed for Emerald.

**Operating Expenses**

**Research and Development.** We incurred research and development expenses of \$31.5 million in 2001, compared to \$19.3 million in 2000. This increase resulted from increased research and development efforts in our hemophilia and AIDS vaccine product development collaborations, design costs associated with our large-scale manufacturing facility expansion and the addition of Genovo's research and development operations. The increase also reflects increased research and development activities to support our collaborations with Elan, as well as additional clinical and regulatory activities associated with the development for our cancer programs. Research and development expenses increased to \$19.3 million in 2000 from \$14.3 million in 1999, reflecting increased expenses related to our acquisition of Genovo's research and development operations, additional activities related to our collaborations with Wyeth/Genetics Institute and IAVI and, to a lesser extent, costs incurred to support the Emerald joint venture. The increase in total expenses in 2001 was partially offset by decreases in our tgDCC-E1A development expenses as tgDCC-E1A moved into clinical development.

Our research and development expenses for the years ended December 31, 2001, 2000 and 1999 were as follows:

	Year Ended December 31,		
	2001	2000	1999
Research and preclinical programs:	\$ 18,693,000	\$ 6,321,000	\$ 1,440,000
Clinical programs:			
Cystic fibrosis	2,521,000	3,959,000	5,440,000
Cancer products	2,630,000	2,251,000	770,000
Indirect costs	7,702,000	6,781,000	6,641,000
<b>Total Clinical Programs</b>	<b>12,853,000</b>	<b>12,991,000</b>	<b>12,851,000</b>
<b>Total research and development expense</b>	<b>\$ 31,546,000</b>	<b>\$ 19,312,000</b>	<b>\$ 14,291,000</b>

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.

Costs associated with our preclinical program activities increased each year, reflecting the addition of the AIDS vaccine collaboration with IAVI in early 2000, the hemophilia collaboration with Wyeth/Genetics Institute and the lysosomal storage disorder collaboration with Genzyme in late 2000 and increased activity in our self-funded RA and gene delivery technology development programs. Costs associated with our clinical program activities were relatively stable as increases in costs attributable to our cancer research and development programs were offset by decreases in costs attributable to our cystic fibrosis research and development costs.

**Equity in Loss of Unconsolidated, Majority-Owned Research and Development Joint Venture.** Our equity in the net loss of the Emerald joint venture increased to \$3.7 million in 2001 from \$2.5 million in 2000. Losses in both years reflect our 80.1% equity share in the loss generated by Emerald's research and development and licensing activities performed by Elan and us. In 1999, our equity in the net loss of Emerald was \$12.6 million, which included our 80.1% share of a \$15.0 million charge for an exclusive license to Elan's drug delivery technology and our 80.1% share of Emerald's 1999 collaboration costs.

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*In-Process Research and Development.* In 2000, we recorded \$28.0 million in IPR&D expenses, which reflects the portion of the purchase price paid to acquire Genovo that was allocated to acquired IPR&D. In 1999, we incurred an expense of \$3.2 million to acquire from Alkermes, Inc. an exclusive sublicense to a patent and patent applications related to the manufacture of AAV vectors. We acquired this license in exchange for shares of our common stock and warrants to purchase shares of our common stock.

We acquired ongoing IPR&D projects from Genovo in the fields of AAV manufacturing platforms, lysosomal storage disorders, glioma, hemophilia and hyperlipidemia. The amount recorded as IPR&D expense for the Genovo acquisition represents the present value of the estimated after-tax cash flows that we believe may be generated by the purchased technology that, as of the acquisition date, had not yet reached technological feasibility. We based the cash flow projections for revenue on estimates of growth rates and the aggregate size of the markets for each product, the probability of technical success given the stage of development at the time of acquisition, royalty rates based on prior licensing agreements, product sales cycles and the estimated life of the product's underlying technology. We deducted our estimated operating expenses and income taxes from our estimated revenue projections to arrive at our estimated after-tax cash flows. The rate that we used to discount projected cash flows for in-process technologies ranged from 30% to 45%, depending on the relative risk of each in-process technology, and were based primarily on internal rates of return, cost of capital, rates of return for research and development and our weighted average cost of capital at the time of acquisition. The acquired IPR&D projects consisted of the following:

AAV manufacturing platform projects related to hyperlipidemia, hemophilia, lysosomal storage disorders, and glioma, which pursue manufacture of AAV as a stable gene therapy vector capable of delivering genes to a variety of dividing and nondividing cells. Genovo estimated that the additional research and development costs to complete the AAV manufacturing platform projects in 2007 would be approximately \$23.8 million. Since the acquisition of Genovo, we have continued to perform preclinical development of the AAV manufacturing platform program we acquired from Genovo.

Technology in the area of lysosomal storage disorders, which is a family of approximately 40 genetic diseases, are normally single-gene defects that prevent the production of one or more lysosomal enzymes, which leads to abnormal deposits of substrates within lysosomal vacuoles. Genovo estimated the additional costs to complete these technologies at approximately \$9.0 million, with a targeted completion date in 2007. Since the acquisition of Genovo, we have been developing with Genzyme Corporation a product candidate for treating Fabry disease, which is currently in preclinical development.

Glioma technology, intended to treat brain tumors in adults. These tumors, which are highly malignant, are nearly always fatal and currently have no known curative treatment. Genovo had been developing a gene therapy product to treat glioma with Biogen. Genovo estimated that the additional costs to complete its glioma technology at approximately \$750,000, with a targeted completion date in 2006. Since our acquisition of Genovo, Biogen has begun a Phase I clinical trial of its gene therapy product candidate to treat glioma.

Technologies for treating hemophilia, which is a genetic disorder that results in prolonged external and/or internal bleeding. Genovo estimated the additional costs to complete its hemophilia technologies at approximately \$12.0 million, with a targeted completion date in 2009. We are working with Wyeth/ Genetics Institute to develop a gene therapy product candidate to treat hemophilia A, which is currently in preclinical development.

Technologies for treating hyperlipidemia, which is an elevation of lipids in the bloodstream that are transported as part of large molecules called lipoproteins. Genovo estimated that its hyperlipidemia technology would be completed in 2007, at an additional cost of approximately \$16.0 million. We currently have limited preclinical development activities focused on hyperlipidemia.

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Genovo based all of these estimates and projections on assumptions believed to be reasonable at the time of the acquisition, but that are inherently uncertain and unpredictable. If we do not successfully develop these projects, our business, operating results and financial condition may be adversely affected. As of the date of the acquisition, we concluded that Genovo's technologies under development, once completed, can be economically used only for their specifically intended purposes and that these in-process technologies have no alternative future use after taking into consideration the overall objectives of the project, progress toward the objectives and uniqueness of developments to these objectives. Given the uncertainties involved in developing these product candidates, we are unable to predict whether we will be able to successfully develop any of these product candidates or the time or costs involved in doing so. The risk of untimely completion includes the risk that competitors will develop alternative products.

*General and Administrative.* We incurred general and administrative expenses of \$6.2 million in 2001 as compared to \$5.7 million in 2000. This increase is attributable to higher business development and legal costs, including expenses related to the spin-out of our majority-owned cell therapy subsidiary, CellExSys, Inc., and increased administrative support for our growing number of collaborative partnerships. General and administrative expenses increased to \$5.7 million in 2000 from \$3.6 million in 1999. This increase reflected the addition of Genovo administrative costs, costs associated with integrating Genovo's operations into our own and greater business-development and legal costs related to establishing new development collaborations.

*Amortization of Acquisition-Related Intangibles.* We recorded amortization expenses of \$6.1 million in 2001, compared to \$1.7 million in 2000, for goodwill, noncompetition agreements and assembled workforce that we acquired when we purchased Genovo. We recorded no expenses related to amortization of acquired intangibles in 1999. In July 2001, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*, which requires use of a nonamortization approach to account for purchased goodwill and certain intangibles, effective January 1, 2002. Under this nonamortization approach, goodwill and certain intangibles will not be amortized into operating results, but instead will be reviewed for impairment and written down and charged to operating results only in the periods in which the carrying value of goodwill and certain intangibles is more than its fair value. Assembled workforce will be reclassified into goodwill in accordance with SFAS No. 142 and will be evaluated accordingly. We will continue to amortize noncompetition agreements over each agreement's estimated remaining useful life. We expect adoption of SFAS No. 142 to substantially reduce our amortization of goodwill and intangibles commencing January 1, 2002.

### ***Other Income and Expense***

*Investment Income.* Our investment income from marketable securities, all of which are cash equivalents, was \$1.9 million in 2001, compared to \$2.1 million in 2000 and \$426,000 in 1999. These fluctuations result from fluctuations in the level of our cash and investments during the periods and, to a lesser degree, from fluctuations in interest rates. Most of our cash is invested in a short-term bond mutual fund.

*Interest Expense.* Interest expense relates to interest on outstanding loans from our collaborative partners, notes and obligations under equipment financing arrangements and installment loans we use to finance purchases of laboratory and computer equipment, furniture and leasehold improvements. Interest expense increased to \$452,000 in 2001 from \$265,000 in 2000 and \$235,000 in 1999. The increase in 2001 is primarily due to higher average outstanding principal balances during the second half of the year, when we drew \$13.0 million on available loans and notes. We expect our interest expense to increase in 2002, to reflect our increased level of borrowings during 2001.

### ***Accounting Change***

In the fourth quarter of 2000, we adopted the provisions of the SEC's Staff Accounting Bulletin No. 101, or SAB 101, *Revenue Recognition in Financial Statements*. SAB 101 generally provides that nonrefundable up-front fees for licenses and rights to product candidates must be deferred and recognized as revenue over the product development period in which we are providing continuing services related to product development. Previously, we recognized revenue from nonrefundable up-front license fees when the technology was transferred and we had fulfilled all of our significant contractual obligations relating to the fees. The cumulative effect on prior years of implementing SAB 101 resulted in a noncash charge of \$3.7 million and a corresponding increase in deferred revenue. This cumulative effect adjustment was calculated as of January 1, 2000 and included in our financial results for 2000. We recognized \$1.6 million of revenue in 2001 and \$2.1 million in 2000 related to this change in accounting.

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### ***Restatement of Financial Information***

The consolidated balance sheets as of December 31, 2001 and 2000 and the consolidated statements of redeemable preferred stock and shareholders' equity for each of the three years in the period ended December 31, 2001, have 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 Emerald Gene Systems, our 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 for the periods described and to reflect the Series B preferred stock outside of permanent equity.

Net loss per common share for the years ended December 31, 2001, 2000 and 1999 has been restated to eliminate the 7% dividends previously accrued on the Series B preferred stock and included in 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 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 that should be added to the net loss when determining net loss applicable to common shareholders. This restatement does not affect net loss for any periods previously reported.

### ***Liquidity and Capital Resources***

In the last three years, we have financed our operations primarily through proceeds from public and private sales of our equity securities, which have totaled approximately \$47.5 million and through cash payments received from our development partners to fund the development of our product candidates, which totaled approximately \$60.2 million. To a lesser degree, we have also financed our operations through grant funding, interest earned on cash, cash equivalents and short-term investments and funding under equipment leasing agreements. These financing sources have historically allowed us to maintain adequate levels of cash and investments.

Our combined cash and cash equivalents totaled \$25.2 million at December 31, 2001 compared with \$38.6 million at December 31, 2000. During 2001, we used \$23.5 million to fund our operations, \$4.4 million to purchase capital equipment, \$2.8 million to fund our share of the operations of the Emerald joint venture and \$1.1 million to repay scheduled debt payments. The primary financing sources of our cash and cash equivalents in 2001 were \$13.0 million borrowed under debt financing commitments from our corporate partners, \$3.1 million in proceeds from the sale of common stock and \$2.4 million received under equipment financing agreements.

Our future cash requirements will depend on many factors, including the rate and extent of scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of our success in filing, prosecuting and enforcing patents, competing technological and market developments and the cost and success of product commercialization. We do not expect to generate positive cash flow from our operations for at least the next several years, because all of our product candidates are in pre-clinical and clinical development and we expect to continue incurring significant expense in advancing our research and development programs and commercializing our product candidates. Assuming our research efforts for existing collaborations are continued for the full research term, as of December 31, 2001 we have total committed funding of approximately \$65 million. This amount consists of i) \$25 million of cash on hand, ii) \$17 million expected to be received in 2002 under loan and equity commitments from our strategic partners, of which approximately \$4 million must be spent on the project sponsored by the partner providing the commitment, and iii) \$23 million in collaborative funding that we expect to receive from our development partners primarily in 2002 and 2003 to help fund costs associated with the development programs that they sponsor. In general, the obligation of our corporate collaborators to provide research funding can be terminated by our partners with notice.

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In the case of such an event, the collaboration agreements specify the rights, if any, that each party will retain. We also have warrants outstanding to purchase 3.3 million shares of our common stock at \$2.00 per share, which expire in April 2003. These warrants, if exercised would provide us with proceeds of up to \$6.7 million. The holder of these warrants, however, may not elect to exercise the warrant to purchase shares of our common stock.

Because internally generated cash flow will not be sufficient to fund development and commercialization of our product candidates, grow our business and expand research and development of our product candidates for treating additional diseases, we will require substantial additional financial resources. We may be unable to obtain funding when needed on acceptable terms, if at all. A significant portion of our operating expenses are funded through our collaborative development agreements with third parties. The initial development periods of our collaborations with Genzyme and Elan will conclude in 2002 and the initial development periods of our other collaborations will conclude in 2003. These development collaborations typically provide for extension options to continue development of product candidates. Absent new collaborative partnerships or extensions to our existing collaborative partnerships, our research and development revenue and funding will decrease in 2003. We may also need to scale a large portion of our future research and development activities to match the levels of funding provided by our collaborators or from other funding that may be available to us. Assuming that we conduct our currently planned operating activities and receive the funding anticipated from our collaborative partners, and that we are able to scale our operations to reflect any lesser amount of funding, we expect that our available cash, anticipated interest income and collaborative funding will be sufficient to finance our operations to 2004. We may require additional capital before that time, however, as a result of unanticipated loss of funding from collaborative partners, the implementation of additional research and development programs or other factors discussed in the section of this Item 7 entitled **Factors Affecting Our Operating Results, Our Business and Our Stock Price**. We may be unable to obtain financing when needed on acceptable terms, if at all.

In July 1999, we issued shares of our Series B convertible exchangeable preferred stock, valued at \$12 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 total 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.

We intend to take advantage of additional funding opportunities as they arise. If we fail to receive substantial amounts of our currently anticipated collaborative funding or fail to secure additional collaborative agreements, or if we fail to obtain alternative financing when needed, we will need to substantially reduce the scope and size of our operations. We may also need to reduce or terminate business development or other operating activities, or delay, curtail or terminate research and development of one or more of our product candidates.

The following are our contractual commitments associated with our debt and lease obligations:

	Payments Due by Period				
	Total	2002	2003-2005	2006-2007	After 2007
<b>Contractual Obligations</b>					
Lease commitments	\$ 23,853,000	\$ 2,903,000	\$ 6,300,000	\$ 2,725,000	\$ 11,925,000
Long term obligations	17,711,000	1,308,000	5,876,000	10,527,000	
<b>Total</b>	<b>\$ 41,564,000</b>	<b>\$ 4,211,000</b>	<b>\$ 12,176,000</b>	<b>\$ 13,252,000</b>	<b>\$ 11,925,000</b>

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### **Impact of New Accounting Pronouncements**

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangibles*. SFAS No. 141 requires that business combinations be accounted for using the purchase method of accounting, effective July 1, 2001. SFAS No. 142 requires the use of a nonamortization approach to account for goodwill and certain intangibles, effective January 1, 2002. Under this nonamortization approach, goodwill and certain intangibles will not be amortized into results of operations, but instead will be reviewed for impairment and written down through a charge to operations only in the periods in which the carrying value of goodwill and certain intangibles is more than its fair value. As of January 1, 2002, of the \$31.8 million of net goodwill and other purchased intangibles, \$31.4 million will be classified as goodwill and will no longer be amortized. The remaining \$0.4 million will be classified apart from goodwill and will continue to be amortized over its estimated remaining useful life. We expect adoption of this accounting standard to substantially reduce our amortization of purchased goodwill and intangibles commencing January 1, 2002. The amount of goodwill amortization that would have been recorded in 2002 is approximately \$5.6 million. Since future impairment reviews will be based on events and estimations in the future, we are currently unable to estimate the effect that such review may have on our consolidated financial statements.

The FASB also recently issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which is applicable to financial statements issued for fiscal years beginning after December 15, 2001. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and portions of Accounting Principles Bulletin Opinion No. 30, *Reporting the Results of Operations*. SFAS No. 144 provides a single accounting model for disposal of long-lived assets and significantly changes the criteria for classification of an asset as held-for-sale. If assets are classified as held-for-sale, they are not depreciated and are stated at the lower of fair value and carrying amount. SFAS No. 144 also requires us to display expected future operating losses from discontinued operations in the period or periods in which the losses are incurred, rather than as of the measurement date, as presently required. We do not expect the provisions of SFAS No. 144 to have a significant effect on our financial position or operating results as we currently do not hold any of our assets as held-for sale and we have no indication that an impairment of any of our long-lived assets exists.

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

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 Product Development and Regulatory Approval**

*If we are unable to successfully complete preclinical and clinical development of our product candidates, we will be unable to generate sufficient capital to maintain our business.*

All of our potential products are either in research and development or in early-stage clinical trials. Our ability to apply for and obtain regulatory approval of our potential products depends upon successful completion of additional research and development and testing, in both preclinical and clinical trials. A product candidate that appears promising at an early stage of research or development may not result in a commercially successful product. Our trials may fail to demonstrate the safety and efficacy of a prospective product, 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 potential product, and corporate partners that support development of that product candidate may terminate their support. If we are unable to successfully complete preclinical and clinical development of some or all of our product candidates, we may be unable to generate sufficient product revenue to maintain our business.

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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 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 under the subheading below entitled "Risks Related to Our Industry and Clinical Trials" and elsewhere in this "Factors Affecting Our Operating Results, Our Business and Our Stock Price" section.

*Failure to timely obtain regulatory approval for our product candidates could prevent or impair our ability to commercialize our products.*

Even if our clinical trials are successful, commercializing any product in the United States or abroad requires regulatory approval from the Food and Drug Administration, or FDA, and applicable state and foreign regulators. Moreover, the FDA and other applicable regulatory bodies 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 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 an NIH-funded clinical trial can begin, the NIH's Institution Biosafety Committee must review the proposed clinical trial to ensure that there are no safety issues associated with the trial. The regulatory process in the gene therapy industry is costly, time consuming and subject to unpredictable delays, and regulatory requirements governing gene and cell therapy products frequently change. In addition, 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. 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. To our knowledge, no gene therapy products have received regulatory approval in the United States or 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. We do not expect any of our product candidates to be approved for commercial sale for at least several years. Some or all of our product candidates may never receive regulatory approval or may not receive approval for all of the clinical applications for which we seek approval. 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 product sales or royalty revenue.

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

Our manufacturing operations are subject to the current Good Manufacturing Practices requirements 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. While we currently anticipate that we will be able to manufacture products that meet applicable regulatory requirements, we may be unable to attain or maintain compliance with current or future regulations. If we discover previously unknown manufacturing, contamination, product side effect or other problems after we receive regulatory approval for a potential product or fail to comply with applicable requirements, we may suffer restrictions on our ability to market the product or be required to withdraw the product from the market. Either of these, or an unexpected increase in the cost of compliance, could make it more difficult to maintain or improve our financial condition.

### **Risks Related to Our Business Operations**

*If we lose significant collaborative funding or we are unable to raise additional capital when needed, we may be unable to develop our potential products and conduct our operations.*

Because internally generated cash flow will not fund development and commercialization of our products, we will require substantial additional financial resources to develop and commercialize our potential products. A significant portion of our operating expenses are funded through our collaborative development agreements with third parties. If a current or future collaborator were to terminate its financial or scientific support of a potential product, we may be unable to complete development and commercialization of that product candidate. We currently

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have collaborations with five pharmaceutical and biotechnology companies and a public health organization that provide expertise and funding to develop our product candidates. The initial development periods of three of these collaborations – Emerald Gene Systems for enhanced gene delivery systems, Genzyme Corporation for lysosomal storage disorders and IAVI for AIDS vaccines – will conclude in 2002 or early 2003. Each of these agreements will terminate unless we and the collaborator agree to extend the agreement. Substantially all of our revenue and substantially all of our expected revenue for the next several years, are derived from our collaborations to develop product candidates. If we were to lose this revenue, or other sources of funding that our corporate partners provide, we may be unable to continue our research and development program for the potential product covered by the collaboration and our business would suffer. Assuming that we conduct our currently planned operating activities and receive the funding anticipated from existing corporate partners, and that we are able to scale our operations to reflect any lesser amount of funding, we expect that our available cash, anticipated interest income and collaborative funding will be sufficient to finance our operations to 2004. We may require additional capital before that time, however, as a result of unanticipated loss of funding from collaborative partners, the implementation of additional research and development programs or other factors discussed in this Factors Affecting Our Operating Results, Our Business and Our Stock Price section or elsewhere in this annual report. We may be unable to obtain financing when needed on acceptable terms, if at all.

We intend to take advantage of additional funding opportunities as they arise. Sources of additional funding could include one or more of the following:

- product development and funding collaborations;

- technology sales;

- technology licenses;

- issuing debt; or

- issuing equity.

If we lose significant amounts of collaborative funding or we are unable to obtain additional financing when needed, we will be forced to make substantial reductions in the scope and size of our operations. We may be forced to delay or terminate one or more research and development programs, curtail capital expenditures or reduce or terminate business development and other operating activities.

*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 small amounts of revenue and incurred significant net losses since inception. As of December 31, 2001, we had an accumulated deficit of \$178.0 million. We expect to continue to incur substantial additional losses in the future, primarily due to the following factors:

- we will not generate any product revenue for at least several years because all of our product candidates are in preclinical and clinical development and have not received regulatory approval for commercial sale; and

- we will continue to incur significant expense for the foreseeable future to develop our research and development programs, conduct preclinical and clinical trials, seek regulatory approval for our product candidates and provide general and administrative support for these activities.

We may never generate profits and, if we do become profitable, we may be unable to sustain or increase profitability.



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*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 successfully develop and commercialize our potential products.*

We have entered into various 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 and those of our partners. If we are unable to maintain our current licenses or obtain additional licenses on acceptable terms for technology used in our potential products, we and our corporate partners 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 some or all of our potential products. In addition, the license agreements for technology for which we hold exclusive licenses 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 licensors may convert the license to a nonexclusive license or terminate the license.

*We may be unable to develop and commercialize some of our potential products if our relationships with scientific consultants and corporate collaborators are not successful.*

Our success depends on the continued availability of outside scientific consultants and corporate collaborators to perform research and to provide or develop technology and processes to advance and augment our internal efforts. Competition for scientific consultants and corporate collaborators in gene therapy is intense. If we are unsuccessful in establishing additional and maintaining existing relationships with individual and corporate collaborators, we could experience delays in our research and development or loss of access to important enabling technology. We may be unable to enter into additional collaborations on acceptable terms, if at all. Even if we maintain our current scientific collaborations or establish new relationships, they may never result in the successful development of product candidates.

The development and commercialization of many of our potential products, and therefore, the success of our business, substantially depends on the performance of these scientific consultants and corporate collaborators. Because they are not our employees, we have limited control over their activities and the amount of time they devote to our business. If our scientific consultants do not dedicate sufficient time, or if our corporate partners do not commit sufficient financial and technical resources, to our research and development programs or the commercialization of our potential products, the preclinical or clinical development related to the collaboration could be delayed or terminated. Even if substantial time and resources are dedicated to developing our product candidates, we may be unable to successfully complete development and commercialization of our product candidates. Our current or future collaborators may provide scientific expertise, technology or funding for, or develop or market, competing products or alternative technologies.

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 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 corporate collaborations. We may be unable to secure our rights with respect to these technology or product candidates.

### **Risks Related to Our Industry and Clinical Trials**

*Adverse events in the field of gene therapy could damage public perception of our prospective 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 with a rare metabolic disorder died in a gene therapy trial using an adenoviral vector to deliver a therapeutic gene. Genovo, 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

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efficacy of gene therapy products derived from pathogenic viruses like adenoviruses. While our product candidates 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.

*The success of our early clinical trials are based on small numbers of patients over the short term and 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 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 will have a lasting effect. If a larger group of patients does not experience positive results, or any favorable results do not demonstrate a lasting effect, the product candidate may not receive approval from the FDA for further studies or commercialization. In addition, 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.

*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 products. We have experienced delays in our previous and current clinical trials, and we may experience similar delays in the future. If negative publicity as a result of adverse events in the biotechnology industry affects the willingness of patients to participate in our gene therapy trials, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products will be delayed. Delays in recruiting or enrolling patients to test our products result in increased costs, delays in advancing our product development and delays in proving the effectiveness of our technology, and could result in termination of the clinical trials altogether. Any of these events could delay or prevent the development of our product candidates.

*The success of our technology in animal models does not guarantee that the same results will be replicated in humans.*

Because animals are different from humans, the successful results of our technology in animal models may not be predictive of the results that we will see in our clinical trials with humans. If successful results for a potential product in animal models are not replicated in human 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.

## **Risks Related to Our Intellectual Property**

*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.

*Intellectual property disputes regarding third-party technology that we license may prevent or impair our ability to develop and commercialize our product candidates.*

We have licensed technology underlying several issued and pending patents, and have acquired rights to the gene delivered in our product candidate for cystic fibrosis. 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 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;
- 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 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.

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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.

*Intellectual property claims and litigation could strain our resources and subject us to significant liability for damages and 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.

### **Risks Related to the Capital Markets and Dilution**

*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. Our common stock has experienced, and is likely to continue to experience, price fluctuations that cause the market price of our common stock to decline. 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. Market fluctuations in the price of our common stock could adversely affect our collaborative opportunities and our future ability to sell equity securities at a price we deem appropriate, 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 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.

### **Additional Risks Related to Our Industry**

*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. Although we believe that our safety procedures for handling, storing and disposing of these materials comply with applicable laws and regulations, 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. This liability could exceed our financial resources. These hazardous materials are subject to federal, state and local regulations. We may be required to incur significant costs to comply with future environmental or other laws. Accidents unrelated to our operations could cause federal, state

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or local regulatory agencies to restrict our access to hazardous materials needed in our research and development efforts. If our access to these materials is limited, we could experience 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 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 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.

*Healthcare reform measures could impair our ability to successfully commercialize our potential products and become profitable.*

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 these proposals could affect our ability to successfully commercialize our product candidates. Even if the government does not adopt any such proposals or reforms, their announcement could impair our ability to raise capital.

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*Our ability to successfully commercialize our product candidates will substantially depend on the willingness of third-party payors to provide adequate reimbursement for the cost of our products.*

Sales of medical products and treatments substantially depend, both domestically and abroad, on the availability of reimbursement to the consumer from third-party payors. Considerable pressure to reduce healthcare costs may cause reimbursement to become more restricted in the future. 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.

### **Additional Risks Related to Our Business Operations**

*Our business will not succeed if our product candidates fail to achieve market acceptance.*

Even if our potential products succeed in clinical trials and are approved for marketing, these products may never achieve market acceptance. If marketing our products is unsuccessful 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 in this section or elsewhere in this annual report, we will be unable to generate sufficient product revenues to maintain our business.

*Our limited manufacturing capability may limit our ability to successfully introduce our potential products.*

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. Our current manufacturing facility, which is designed for manufacturing our AAV vectors for clinical and development purposes, is subject to initial and ongoing regulation by the FDA and other government agencies, and 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. 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 product to sustain our business. In addition, we are unlikely to become profitable if we or our contract providers are unable to manufacture our products in a cost-effective manner.

*If we do not attract and retain qualified personnel, we will be unable to successfully develop our potential products.*

Our future success depends in large part on our ability to attract and retain key technical and management employees and scientific advisors. We have programs in place to retain personnel, including competitive compensation packages and programs to create a positive work environment. Because other companies, research and academic institutions and other organizations in our field compete intensely for employees, however, we may be unable to retain our existing personnel or attract additional qualified employees and advisors. If we experience excessive turnover or difficulties in recruiting new personnel, our research and development could be delayed and we could experience difficulties in generating sufficient revenue to maintain our business.

*If we do not develop adequate 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 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. However, we may be unable to enter into marketing and distribution agreements on favorable terms, if at all. While we believe that our corporate partners will be motivated to market and distribute our potential products, our current and potential future partners may not commit sufficient resources to commercializing our products and technology on a timely basis. If our corporate partners do not adequately market and distribute our products 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.

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*Product liability and other claims and product recalls could exceed our insurance coverage and damage our reputation, which could significantly harm our financial condition.*

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. 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. We may also face product recalls and adverse publicity resulting from a product recall or a liability claim against us or a collaborative partner. 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, 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.

**Item 7A. *Quantitative and Qualitative Disclosures 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 December 31, 2001, we held \$25.2 million in cash and cash equivalents, which are primarily invested in a short-term bond fund invested in securities that, on the average, mature in less than 12 months. An analysis of the impact on these instruments of a hypothetical 10% change in short-term interest rates compared to interest rates at December 31, 2001, indicates that such change would not have a significant impact on expected fiscal year 2002 earnings.

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**Item 8. *Financial Statements and Supplementary Data***

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**REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS**

The Board of Directors and Shareholders  
Targeted Genetics Corporation

We have audited the accompanying consolidated balance sheets of Targeted Genetics Corporation as of December 31, 2001 and 2000, and the related consolidated statements of operations, redeemable preferred stock and shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Targeted Genetics Corporation at December 31, 2001 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

As described in Note 1 to the consolidated financial statements, in 2000 the Company changed its method of accounting for revenue recognition.

As described in Note 1 to the consolidated financial statements, the Company has restated its consolidated balance sheets as of December 31, 2001 and 2000 and its consolidated statements of operations and redeemable preferred stock and shareholders' equity for each of the three years in the period ended December 31, 2001.

ERNST & YOUNG LLP

Seattle, Washington  
February 14, 2002, except for the  
last two paragraphs of Note 1,  
as to which the date is  
July 29, 2002

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**TARGETED GENETICS CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2001	2000
	(restated)	(restated)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 25,186,000	\$ 38,630,000
Accounts receivable	2,475,000	3,087,000
Receivable from unconsolidated, majority-owned research and development joint venture	893,000	177,000
Prepaid expenses and other	935,000	292,000
	<u>29,489,000</u>	<u>42,186,000</u>
Total current assets	29,489,000	42,186,000
Property and equipment, net	8,308,000	6,206,000
Goodwill and other purchased intangibles, net	31,752,000	37,821,000
Other assets	1,489,000	1,761,000
	<u>\$ 71,038,000</u>	<u>\$ 87,974,000</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,452,000	\$ 3,579,000
Payable to unconsolidated, majority-owned research and development joint venture	1,123,000	262,000
Accrued employee expenses	1,114,000	696,000
Deferred revenue	4,631,000	6,906,000
Current portion of long-term obligations	1,308,000	838,000
	<u>11,628,000</u>	<u>12,281,000</u>
Total current liabilities	11,628,000	12,281,000
Deferred rent	640,000	404,000
Long-term obligations	16,403,000	2,447,000
Deferred revenue	4,966,000	9,410,000
Commitments		
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, 44,125,677 shares issued and outstanding at December 31, 2001 and 42,608,943 shares at December 31, 2000	441,000	426,000
Additional paid-in capital	202,927,000	201,803,000
Accumulated deficit	(177,982,000)	(150,812,000)
	<u>25,386,000</u>	<u>51,417,000</u>
Total shareholders' equity	25,386,000	51,417,000
	<u>\$ 71,038,000</u>	<u>\$ 87,974,000</u>

See accompanying notes to the consolidated financial statements.



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**TARGETED GENETICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2001	2000	1999
Revenue:			
Collaborative agreements	\$ 16,117,000	\$ 9,553,000	\$ 6,402,000
Collaborative agreement with unconsolidated, majority-owned research and development joint venture	2,763,000	1,850,000	446,000
<b>Total revenue</b>	<b>18,880,000</b>	<b>11,403,000</b>	<b>6,848,000</b>
Operating expenses:			
Research and development	31,546,000	19,312,000	14,291,000
Equity in net loss of unconsolidated, majority-owned research and development joint venture	3,666,000	2,474,000	12,610,000
Acquired in-process research and development		28,029,000	3,200,000
Amortization of acquisition-related intangibles	6,069,000	1,686,000	
General and administrative	6,203,000	5,707,000	3,593,000
<b>Total operating expenses</b>	<b>47,484,000</b>	<b>57,208,000</b>	<b>33,694,000</b>
Loss from operations	(28,604,000)	(45,805,000)	(26,846,000)
Investment income	1,886,000	2,097,000	426,000
Interest expense	(452,000)	(265,000)	(235,000)
Loss before cumulative effect of change in accounting principle	(27,170,000)	(43,973,000)	(26,655,000)
Cumulative effect of change in accounting principle		(3,682,000)	
<b>Net loss</b>	<b>\$ (27,170,000)</b>	<b>\$ (47,655,000)</b>	<b>\$ (26,655,000)</b>
Computation of basic and diluted net loss per common share:			
Loss before cumulative effect of change in accounting principle (restated)	\$ (0.62)	\$ (1.16)	\$ (0.83)
Cumulative effect of change in accounting principle		(0.10)	
<b>Net loss per common share (restated)</b>	<b>\$ (0.62)</b>	<b>\$ (1.26)</b>	<b>\$ (0.83)</b>
Shares used in computation of basic and diluted net loss per common share	43,927,822	37,752,164	32,173,756

See accompanying notes to the consolidated financial statements.

**Table of Contents****TARGETED GENETICS CORPORATION****CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED STOCK  
AND SHAREHOLDERS' EQUITY  
(Restated)**

	Series B Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders Equity
	Shares	Amount	Shares	Amount				
Balance at January 1, 1999		\$	30,652,375	\$ 307,000	\$ 88,149,000	\$ (76,502,000)	\$28,000	\$11,982,000
Net loss 1999						(26,655,000)		(26,655,000)
Unrealized gains on securities available for sale							(44,000)	(44,000)
Comprehensive loss								(26,699,000)
Issuance of Series B convertible exchangeable preferred stock for interest in unconsolidated, majority-owned research and development joint venture	12,015	12,015,000						
Sale of common stock to Celltech for cash, net of issuance costs of \$14,000			677,392	7,000	1,480,000			1,487,000
Sale of common stock to Elan, net of issuance costs of \$57,000			2,148,899	21,000	4,921,000			4,942,000
Issuance of common stock and warrants to Alkermes for technology rights, net of issuance costs of \$18,000			500,000	5,000	3,177,000			3,182,000
Exercise of stock options			40,509		56,000			56,000
Balance at December 31, 1999	12,015	12,015,000	34,019,175	340,000	97,783,000	(103,157,000)	(16,000)	(5,050,000)
Net loss 2000						(47,655,000)		(47,655,000)
Unrealized losses on securities available for sale							16,000	16,000
Comprehensive loss								(47,639,000)
Sale of common stock for cash, net of issuance costs of \$2,181,000			2,164,285	22,000	28,097,000			28,119,000
			382,739	4,000	4,992,000			4,996,000

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Issuance of common stock to Elan for cash, net of issuance costs of \$4,000								
Issuance of common stock in								
Genovo acquisition			5,250,805	53,000	66,077,000			66,130,000
Exercise of stock options			730,765	7,000	4,600,000			4,607,000
Exercise of warrants			61,174		254,000			254,000
Balance at December 31, 2000	12,015	12,015,000	42,608,943	426,000	201,803,000	(150,812,000)		51,417,000
Net loss and comprehensive loss 2001						(27,170,000)		(27,170,000)
Cancellation of shares held in escrow related to Genovo								
acquisition			(155,649)	(2,000)	(1,998,000)			(2,000,000)
Exercise of stock options			672,383	7,000	1,052,000			1,059,000
Exercise of warrants			1,000,000	10,000	1,990,000			2,000,000
Stock based compensation					80,000			80,000
Balance at December 31, 2001	12,015	\$12,015,000	44,125,677	\$ 441,000	\$ 202,927,000	\$ (177,982,000)	\$	\$25,386,000

See accompanying notes to the consolidated financial statements.

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**TARGETED GENETICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2001	2000	1999
Operating activities:			
Net loss	\$ (27,170,000)	\$ (47,655,000)	\$ (26,655,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle adjustment		3,682,000	
Equity in net loss of unconsolidated, majority-owned research and development joint venture	3,666,000	2,474,000	12,610,000
Acquired in-process research and development		28,029,000	3,200,000
Depreciation and amortization	2,623,000	1,473,000	1,614,000
Amortization of acquisition-related intangibles	6,069,000	1,686,000	
Stock-based compensation expense	80,000	301,000	
Changes in assets and liabilities:			
Increase (decrease) in deferred revenue	(6,719,000)	12,635,000	
Increase in accounts receivable	(1,388,000)	(1,695,000)	(1,289,000)
Decrease (increase) in accounts receivable from unconsolidated, majority-owned research and development joint venture	(716,000)	269,000	(446,000)
Decrease (increase) in prepaid expenses and other	(643,000)	(396,000)	62,000
Increase (decrease) in current liabilities	241,000	(972,000)	626,000
Increase in deferred rent	236,000	364,000	40,000
Increase (decrease) in other assets	178,000	(800,000)	
Net cash used in operating activities	(23,543,000)	(605,000)	(10,238,000)
Investing activities:			
Purchases of property and equipment	(4,411,000)	(2,797,000)	(1,856,000)
Investment in unconsolidated, majority-owned research and development joint venture	(2,805,000)	(2,807,000)	
Maturities and sales of securities available for sale		3,024,000	7,393,000
Purchases of securities available for sale			(483,000)
Net cash acquired in acquisition		359,000	
Net cash provided by (used in) investing activities	(7,216,000)	(2,221,000)	5,054,000
Financing activities:			
Loan proceeds from collaborative partners	13,000,000		1,000,000
Net proceeds from sales of capital stock	3,059,000	37,976,000	6,468,000
Proceeds from leasehold improvements and equipment financing arrangements	2,401,000	671,000	1,294,000
Payments under leasehold improvements and equipment financing arrangements	(1,145,000)	(1,292,000)	(1,348,000)
Net cash provided by financing activities	17,315,000	37,355,000	7,414,000
Net increase (decrease) in cash and cash equivalents	(13,444,000)	34,529,000	2,230,000
Cash and cash equivalents, beginning of year	38,630,000	4,101,000	1,871,000
Cash and cash equivalents, end of year	\$ 25,186,000	\$ 38,630,000	\$ 4,101,000
Supplemental information:			
Cash paid for interest	\$ 269,000	\$ 245,000	\$ 203,000
Acquisition-related common stock issued (recovered)	(2,000,000)	66,130,000	
Preferred stock dividend	945,000	885,000	376,000
Preferred stock issuance in exchange for interest in unconsolidated, majority-owned research and development joint venture			12,015,000

See accompanying notes to the consolidated financial statements





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### **TARGETED GENETICS CORPORATION**

#### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

##### **1. Description of Business and Summary of Significant Accounting Policies**

###### *Description of Business*

Targeted Genetics was incorporated in the state of Washington in March 1989. We operate our business in one reportable segment, research and product development. On both our own behalf and in connection with various collaborative agreements with others, we conduct research and development of gene therapy products and technologies for treating acquired and inherited diseases.

###### *Basis of Presentation*

Our consolidated financial statements include the accounts of Targeted Genetics, our wholly owned subsidiaries Genovo, Inc. and TGCF Manufacturing Corporation, and our majority owned subsidiary, CellExSys, Inc. The consolidated financial statements do not include Emerald Gene Systems, Ltd. our unconsolidated, majority-owned research and development joint venture with Elan International Services Ltd., a wholly owned subsidiary of Elan Corporation plc, because we do not have operating control of the joint venture. All significant inter-company transactions have been eliminated in consolidation.

###### *Cash Equivalents*

We consider to be cash equivalents all short-term investments that have a maturity at the time of purchase of three months or less, are readily convertible into cash and have insignificant interest rate risk. Our cash equivalents, recorded at cost, which approximates fair market value, consist principally of money market accounts and shares of a short-term, limited-maturity mutual fund.

###### *Fair Value of Financial Instruments*

We believe that the carrying amounts of financial instruments such as cash and cash equivalents, accounts receivable and accounts payable approximate fair value, because of the short-term nature of these items. We believe that the carrying amounts of the notes payable and equipment financing obligations approximate fair value because the interest rates on these instruments change with, or approximate, market interest rates.

###### *Property and Equipment*

Our financial statements present property and equipment at cost less accumulated depreciation, which includes the amortization of assets recorded under equipment financing leases. We compute depreciation of property and equipment using the straight-line method over the asset's estimated useful life, which ranges from three to seven years. Leasehold improvements are amortized over the asset's estimated useful life or the lease term, whichever is shorter.

###### *Purchased Intangible Assets*

Purchased intangible assets consist of acquired technology that is core to our development programs and goodwill. We amortize our purchased intangibles on the straight-line method over periods ranging from two to seven years.

###### *Long-Lived Assets*

In accordance with Statement of Financial Accounting Standards (SFAS) No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, we review the carrying value of intangible assets and other long-lived assets on a regular basis for the existence of facts or circumstances, both internal and external, that may indicate impairment. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. To date, we have no indication that an impairment of our intangible and other long-lived assets exists.

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*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 total 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.

*Stock Compensation*

As permitted by the provisions of Financial Accounting Standards Board (FASB) Statement No. 123, *Accounting for Stock-Based Compensation*, we have elected to follow Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for employee stock option grants, and we apply the disclosure-only provisions to account for our stock option plans. We do not recognize any compensation expense for options granted to employees because we grant all options at fair market value on the date of grant. Options granted to consultants are recorded as an expense over their vesting term based on their fair value, which is determined using the Black-Scholes method.

*Revenue Recognition under Collaborative Agreements*

We generate revenue from technology licenses, collaborative research arrangements and cost reimbursement contracts. Revenue under technology licenses and collaborative agreements typically consists of nonrefundable, up-front license fees, collaborative research funding, technology access fees and various other payments.

Revenue from nonrefundable, up-front license fees and technology access payments is recognized ratably over the development period in the collaborative agreement. Revenue associated with performance milestones is recognized as earned, based upon the achievement of the milestones defined in the applicable agreements. Revenue under research and development cost-reimbursement contracts is recognized as the related costs are incurred. Payments received in excess of amounts earned are classified as deferred revenue.

We previously recognized nonrefundable, up-front license fees as revenue when the technology was transferred and when all of its significant contractual obligations relating to the fees had been fulfilled. Effective January 1, 2000, we changed our method of accounting for nonrefundable up-front license fees to recognize such fees over the term of the related research and development collaboration arrangement on a straight-line basis, as this method best matches the effort provided. We believe that this change in accounting principle is preferable, based on guidance provided in the SEC's Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*. The \$3.7 million cumulative effect of the change in accounting principle, calculated as of January 1, 2000, was reported as a charge for the year 2000. The cumulative effect was recorded as deferred revenue that was recognized as revenue over the remaining term of the research and development collaboration agreements. \$2.1 million (\$0.06 per share) of the \$3.7 million cumulative effect was amortized as deferred revenue in 2000 and \$1.6 million (\$0.04 per share) was amortized in 2001. Had the change in accounting been in effect retroactively to January 1, 1999, net loss for 1999 would have decreased by \$2.1 million (\$0.07 per share).

*Relationships with Strategic Partners*

In connection with our collaborations with Biogen, Inc., Celltech Group plc and Genzyme Corporation and our joint venture with Elan, each strategic partner purchased shares of our common stock. The number of shares of our common stock that we issued to each of our strategic partners represented less than 10% of our total shares then outstanding. We cannot control or monitor shares of our stock that these partners may buy or sell in open market transactions. Although each of our collaborative partners influence the activities specific to their collaborations with us, our partners do not influence our management or operating policies generally or otherwise significantly influence our operating activities.

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Significant Revenue Relationships and Concentration of Risk*

Four companies accounted for 100% of the revenue we recorded from collaborative agreements in 2001 and 2000. One company accounted for 100% of our revenue from collaborative agreements in 1999. Emerald Gene Systems, our 80.1% unconsolidated, majority-owned research and development joint venture with Elan, accounted for all of our revenue from collaborative agreements with unconsolidated joint ventures. A change in the level of work or funding received from any one of these collaborative partners could disrupt our business and adversely affect our cash flow and results of operations.

*Research and Development Costs*

Research and development costs are expensed as incurred. Costs and expenses related to programs conducted under collaborative agreements that result in collaborative revenue totaled \$11.4 million in 2001, \$6.6 million in 2000 and \$6.7 million in 1999. See Notes 6 and 7 for more detailed information.

*Net Loss Per Common Share*

Net loss per common share is based on net loss after giving effect to preferred stock dividends, divided by the weighted average number of common shares outstanding during the period. Our diluted net loss per share is the same as our basic net loss per share because all stock options, warrants and other potentially dilutive securities are antidilutive and therefore excluded from the calculation of diluted net loss per share. The total number of shares that we excluded from the calculations of net loss per share were 13,535,778 shares in 2001, 14,028,623 shares in 2000 and 12,632,797 shares in 1999.

*Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Our actual results may differ from those estimates.

*Recent Accounting Pronouncements*

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangibles*. SFAS No. 141 requires that business combinations be accounted for using the purchase method of accounting, effective July 1, 2001. SFAS No. 142 requires the use of a nonamortization approach to account for goodwill and certain intangibles, effective January 1, 2002. Under this nonamortization approach, goodwill and certain intangibles will not be amortized into results of operations, but instead will be reviewed for impairment and written down through a charge to operations only in the periods in which the carrying value of goodwill and certain intangibles is more than its fair value. As of January 1, 2002, of the \$31.8 million of net goodwill and other purchased intangibles, \$31.4 million will be classified as goodwill and will no longer be amortized. The remaining \$0.4 million will be classified apart from goodwill and will continue to be amortized over its estimated remaining useful life. We expect adoption of this accounting standard to substantially reduce our amortization of purchased goodwill and intangibles commencing January 1, 2002. The amount of goodwill amortization that would have been recorded in 2002 is approximately \$5.6 million. Since future impairment reviews will be based on events and estimations in the future, we are currently unable to estimate the effect that such review may have on our consolidated financial statements. The following table reconciles the results of operations we reported for the years ended December 31, 1999, 2000 and 2001 to the amounts adjusted for the elimination of goodwill amortization that we would have recorded had we adopted SFAS No. 142 as of the beginning of each of those periods:

	Year ended December 31,		
	2001	2000	1999
Net loss	\$ (27,170,000)	\$ (47,655,000)	\$ (26,655,000)
Elimination of goodwill amortization	5,564,000	1,547,000	
Adjusted net loss	\$ (21,606,000)	\$ (46,108,000)	\$ (26,655,000)

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Net loss per common share:

Reported net loss per common share, restated	\$	(0.62)	\$	(1.26)	\$	(.83)
Goodwill amortization		0.13		.04		
		<u>          </u>		<u>          </u>		<u>          </u>
Adjusted net loss per common share	\$	(0.49)	\$	(1.22)	\$	(.83)
		<u>          </u>		<u>          </u>		<u>          </u>

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The FASB also recently issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which is applicable to financial statements issued for fiscal years beginning after December 15, 2001. SFAS No. 144 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 a single accounting model for disposal of long-lived assets and significantly changes the criteria for classification of an asset as held-for-sale. If assets are classified as held-for-sale, they are not depreciated and are stated at the lower of fair value and carrying amount. SFAS No. 144 also requires us to display expected future operating losses from discontinued operations in the period or periods in which the losses are incurred, rather than as of the measurement date, as presently required. We do not expect the provisions of SFAS No. 144 to have a significant effect on our financial position or operating results as we currently do not hold any of our assets as held-for sale and we have no indication that an impairment of any of our long-lived assets exists.

*Reclassifications*

Certain reclassifications have been made to conform prior year results to the current year presentation.

*Restatement of Financial Information*

The consolidated balance sheets as of December 31, 2001 and 2000 and the consolidated statements of redeemable preferred stock and shareholders' equity for each of the three years in the period ended December 31, 2001, have 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 Emerging Issues Task Force Topic D-98, *Classification and Measurement of Redeemable Securities*. We issued the Series B preferred stock in connection with the formation of Emerald Gene Systems, our 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 for the periods described and to reflect the Series B preferred stock outside of permanent equity.

Net loss per common share for the years ended December 31, 2001, 2000 and 1999 has been restated to eliminate the 7% dividends previously accrued on the Series B preferred stock and included in the net loss applicable to common shareholders. Because dividends would only be payable in common shares only 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 that should be added to the net loss when determining net loss applicable to common shareholders. This restatement does not affect net loss for any periods previously reported. Net loss per common share is as follows:

	Year ended December 31,		
	2001	2000	1999
As previously reported:			
Net loss	\$ (27,170,000)	\$ (47,655,000)	\$ (26,655,000)
Preferred dividend	(945,000)	(885,000)	(376,000)
Net loss applicable to common shareholders	\$ (28,115,000)	\$ (48,540,000)	\$ (27,031,000)
Net loss per common share	\$ (0.64)	\$ (1.29)	\$ (0.84)
As restated for the elimination of preferred dividends:			
Net loss	\$ (27,170,000)	\$ (47,655,000)	\$ (26,655,000)
Net loss per common share	\$ (0.62)	\$ (1.26)	\$ (0.83)



**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. Long-Lived Assets**

Property and equipment consisted of the following:

	<b>December 31,</b>	
	<b>2001</b>	<b>2000</b>
Furniture and equipment	\$ 9,848,000	\$ 7,288,000
Leasehold improvements	9,433,000	7,389,000
	<b>19,281,000</b>	<b>14,677,000</b>
Less accumulated depreciation and amortization	(10,973,000)	(8,471,000)
	<b>\$ 8,308,000</b>	<b>\$ 6,206,000</b>

We finance some of our equipment through equipment financing arrangements and pledge the equipment as security for the financing. The cost of equipment that has been pledged under financing arrangements totaled \$3.7 million at December 31, 2001 and \$2.4 million at December 31, 2000, with related accumulated depreciation of \$1.3 million for each period.

Goodwill and other purchased intangibles consisted of the following:

	<b>December 31,</b>	
	<b>2001</b>	<b>2000</b>
Goodwill	\$ 37,892,000	\$ 37,892,000
Other purchased intangibles	1,615,000	1,615,000
	<b>39,507,000</b>	<b>39,507,000</b>
Less accumulated depreciation and amortization	(7,755,000)	(1,686,000)
	<b>\$ 31,752,000</b>	<b>\$ 37,821,000</b>

**3. Long-Term Obligations**

Long-term obligations consisted of the following:

	<b>December 31,</b>	
	<b>2001</b>	<b>2000</b>
Loan payable to Biogen	\$ 10,000,000	\$
Loan payable to Celltech	2,000,000	1,000,000
Convertible loan payable to Elan	2,000,000	
Equipment financing obligations	3,153,000	1,732,000
Other long-term obligations	558,000	553,000

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	17,711,000	3,285,000
Less current portion	(1,308,000)	(838,000)
	<u>          </u>	<u>          </u>
	\$ 16,403,000	\$ 2,447,000
	<u>          </u>	<u>          </u>

Future aggregate principal payments related to long-term obligations are \$1.3 million in 2002, \$3.0 million in 2003, \$0.7 million in 2004, \$2.2 million in 2005 and \$10.5 million in 2006.

During 2001, we drew \$10.0 million against a \$10.0 million unsecured loan agreement from Biogen. Outstanding borrowings under this loan bear interest at the one-year LIBOR rate plus 100 basis points reset annually. At December 31, 2001, the interest rate was 3.4%. The loan agreement contains financial covenants establishing limits on our ability to declare or pay cash dividends. The loan is due in August 2006 and we may repay it at anytime without penalty.

Under our agreements with Celltech, we have drawn \$2.0 million under a \$2.0 million unsecured loan facility to partially fund the cost of establishing our tgAAVCF manufacturing facilities for clinical trials. This loan is due in November 2003. Interest accrues at a rate that is 150 basis points over the one-month LIBOR rate, but neither less than 5% nor more than 7% per year. At December 31, 2001, the interest rate was 5.0%. This loan agreement limits our ability to declare or pay cash dividends. We can, at our option and with Celltech's consent, repay the loan with our common stock at any time during the loan term, at a conversion price equal to the average closing price of the common stock over a specified period preceding the repayment date.



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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In connection with the formation of Emerald (see Note 7), Elan has committed to loan us up to \$12.0 million, in one or more draws, to support our share of Emerald's operating costs. Interest on borrowings under this loan facility accrues at a rate of 12.0% per annum, compounded semi-annually. Principal and interest outstanding under this loan facility are due in July 2005, payable either in cash or shares of our common stock. Interest is payable semi-annually and, if we elect not to pay, the interest is capitalized to principal and treated as a new borrowing from Elan. As of December 31, 2001, we had borrowed \$2.0 million under this facility.

Elan has the option to convert principal and interest outstanding under the loan facility, on a per-draw basis, into shares of our common stock. If Elan elects to convert outstanding amounts into shares of our common stock, the conversion price will be 150% of the average closing price of our common stock for a specified period of time before the date of the applicable draw on the note. As of December 31, 2001, if Elan had elected to convert the outstanding principal under the loan facility, it would have received 335,570 shares of our common stock.

We have the option to prepay principal and interest outstanding under the loan facility, in whole or on a per-draw basis, in either cash or shares of our common stock. If we elect to prepay outstanding amounts with our common stock, the conversion price will equal 150% of the average closing price of our common stock for a specified period of time before the date of the applicable draw and the average closing price of our common stock for a specified period of time before the date of prepayment. If we elect to prepay the outstanding amounts in cash, we will pay an amount equal to the higher of the amount of principal and interest outstanding under the applicable draw and the fair market value of our common stock into which the outstanding amount is convertible, based on a price per share equal to the average closing price of our common stock for a specified period of time before the date of prepayment.

If the issuance of shares to Elan upon conversion of amounts outstanding under the loan facility would result in Elan owning more than 19.9% of our total shares outstanding and we are unable to obtain shareholder approval of such issuance, we may be unable to issue shares of our common stock to repay amounts outstanding under the loan facility.

Equipment financing obligations relate to secured financing for the purchase of capital equipment and leasehold improvements. These obligations bear interest at rates ranging from 7.75% to 14.97% and mature from January 2002 to October 2005.

Other long-term obligations include a promissory note payable to Biogen, which we assumed in September 2000 as part of our acquisition of Genovo. This promissory note has an outstanding principal amount of \$650,000 and bears no interest. At the time of the acquisition, we discounted the note to reflect market interest rates, using an imputed interest rate of 5.6%. The note is due in September 2005.

**4. Redeemable Preferred Stock and Shareholders' Equity**

**Redeemable Preferred Stock**

*Series B Convertible Exchangeable Preferred Stock*

In July 1999, we issued shares of our Series B convertible exchangeable preferred stock, valued at \$12 million, to Elan in exchange for our 80.1% interest in Emerald (see Note 7). 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. As of December 31, 2001, the Series B preferred stock and accrued dividends were convertible into 4,283,471 shares of our common stock. At the expiration of the convertibility period, the Series B preferred stock would be convertible into approximately 5.47 million shares, an effective conversion price of \$2.20 per share. In addition, the Series B preferred stock will automatically convert into common stock in the event of specified transactions involving a change of control of Targeted Genetics. In the event that the issuance of common stock to Elan upon the conversion of the Series B preferred stock would result in Elan owning more than 19.9% of our then outstanding shares and we were unable to obtain shareholder approval for such issuance, we have the right, at our option, to redeem that number of shares that would exceed 19.9% of our then outstanding shares.

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### **TARGETED GENETICS CORPORATION**

#### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 Emerald to 50%. This exchange option is exercisable anytime through the later of April 2003 or six months after the completion of Emerald's initial research and development program, which is currently July 21, 2002, but is subject to extension. If Elan exercises its exchange right, it must make a cash payment to us equal to 30.1% of the total funding that we and Elan provided to Emerald after its formation. The exchange right is solely at Elan's option, and will terminate if the Series B preferred stock is converted into common stock. If the conversion occurs as a result of a specified transaction involving a change of control at Targeted Genetics, the exchange right will survive, but in order to exercise this exchange right, Elan will be required to tender the consideration it received upon the automatic conversion of the preferred stock in the transaction.

Elan, as a holder of Series B preferred stock, is not entitled to vote together with holders of common stock, including with respect to election of directors, or as a separate class, except as otherwise provided by the Washington Business Corporation Act.

#### **Shareholders' Equity**

##### *Stock Purchase Warrants*

In 1999, in connection with a technology license agreement, we issued to Alkermes, Inc. warrants to purchase 1,000,000 shares of our common stock at an exercise price of \$2.50, expiring in June 2007, and 1,000,000 shares at an exercise price of \$4.16 per share, expiring in June 2009. All of these warrants remain outstanding at December 31, 2001.

In connection with a private placement of common stock in 1998, we issued warrants to purchase a total of 4,333,333 shares of common stock at an exercise price of \$2.00 per share. In 2001 a warrant holder exercised warrants to purchase 1,000,000 shares of our common stock, resulting in \$2.0 million of proceeds. The remaining warrants issued in connection with the 1998 private placement expire in April 2003.

We have outstanding warrants to purchase a total of 35,141 shares related to equipment financing and consulting agreements. These warrants have a weighted average price of \$4.80 per share and expire between May 2002 and March 2004.

##### *Shareholder Rights Plan*

In 1996, our board of directors adopted a shareholder rights plan. Under our rights plan, each outstanding share of our common stock also represents one preferred stock purchase right. We adopted the rights plan to guard against partial tender offers and other abusive tactics that might be used in an attempt to gain control of Targeted Genetics without paying all shareholders a fair price for their shares. The rights plan will not prevent a change of control, but it is designed to deter coercive takeover tactics and to encourage anyone attempting to acquire us to first negotiate with our board. Generally, if any person or group becomes the beneficial owner of more than 15% of our outstanding common stock (an acquiring person), then each right not owned by the acquiring person or its affiliates would entitle its holder to purchase shares of our common stock at a 50% discount, which would result in a significant dilution of the acquiring person's interest in Targeted Genetics. If we or 50% or more of our assets or earnings are thereafter acquired, each right will entitle its holder to purchase shares of common stock of the acquiring entity for a 50% discount.

The rights plan expires in October 2006. Our board of directors will generally be entitled to redeem the rights for \$0.01 per right at any time before a person or group acquires more than 15% of our common stock. In addition, at any time after an acquiring person crosses the 15% threshold but before it acquires us or 50% of our assets or earnings, the board may exchange all or part of the rights (other than those held by the acquiring person) for one share of common stock per right.

##### *Stock Options*

We have granted non-qualified and incentive stock options to purchase up to 6,979,444 shares of common stock under our stock option plans. Beginning in 1999, we began granting all options under our 1999 Stock Option Plan (the 1999 Plan), and discontinued granting options under our two other plans. In connection with our acquisition of Genovo, we established the 2000 Genovo, Inc. Roll-over Stock Option Plan (the Genovo Plan). In 2001, our shareholders approved both the Genovo Plan and an increase in the number of shares available for grant under the 1999 Plan from 1.5 million shares to 3.5 million shares.

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The 1999 Plan, as amended, provides for option grants to our employees, directors and officers and to consultants, agents, advisors and independent contractors who provide services to us, or our subsidiaries. The exercise price of incentive stock options shall not be less than the fair market value of the shares on the date of grant. Options granted under the 1999 Plan expire no later than ten years from the date of grant and generally vest and become exercisable over a three or four-year period following the date of grant. As of December 31, 2001, 1,288,697 shares of our common stock were available for future grant under the 1999 Plan.

The Genovo Plan was established to convert Genovo employees' options to purchase shares of Genovo common stock into options to purchase our common stock. In 2000, we granted options to purchase 679,444 shares of our common stock at a weighted average exercise price of \$1.30 per share under the Genovo Plan to the former employees of Genovo. The size of the grant to each former Genovo employee was based on the number of shares subject to that employee's Genovo options at the effective time of the acquisition. Options granted under the Genovo Plan are fully vested and expire ten years from the date that the underlying Genovo stock options were granted. No additional options will be granted under the Genovo Plan.

The following table summarizes activity related to our stock option plans:

	Shares	Weighted Average Exercise Price	Options Exercisable
Balance, January 1, 1999	1,860,586	\$ 2.42	
Granted	835,265	1.94	
Exercised	(40,509)	1.39	
Canceled	(214,000)	2.51	
Balance, December 31, 1999	2,441,342	2.26	1,094,420
Granted	1,373,716	5.65	
Exercised	(419,470)	1.45	
Canceled	(74,810)	6.13	
Balance, December 31, 2000	3,320,778	3.66	1,782,082
Granted	1,510,075	5.27	
Exercised	(672,383)	1.57	
Canceled	(274,637)	5.05	
Balance, December 31, 2001	3,883,833	4.55	1,861,093

The following table summarizes information regarding our outstanding and exercisable options at December 31, 2001:

Range of Exercise Prices	Outstanding			Exercisable	
	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Number of Option Shares	Weighted Average Exercise Price
\$ 0.50 - \$ 1.22	421,179	\$ 1.07	6.05	405,554	\$ 1.07
1.38 - 1.99	699,339	1.72	6.93	439,354	1.71
2.02 - 3.00	646,064	2.27	8.09	302,412	2.32
3.09 - 6.50	905,172	5.08	7.27	374,255	4.80
6.66 - 8.56	883,367	7.21	8.77	232,272	7.59
8.88 - 21.38	328,712	10.86	8.53	107,246	11.01
	3,883,833	4.55	7.66	1,861,093	3.56



**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As allowed by SFAS 123, we do not recognize compensation expense on stock options granted to employees and directors. If we had elected to recognize compensation expense based on the fair market value at the grant dates for stock options granted, the pro forma net loss and net loss per common share would have been as follows:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Net loss:			
as reported	\$ (27,170,000)	\$ (47,655,000)	\$ (26,655,000)
pro forma	(32,278,000)	(53,693,000)	(27,610,000)
Basic net loss per share:			
as reported, restated	\$ (0.62)	\$ (1.26)	\$ (0.83)
pro forma	(0.73)	(1.42)	(0.86)

We estimated the fair value of each option on the date of grant using the Black-Scholes pricing model with the following weighted average assumptions:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Expected dividend rate	Nil	Nil	Nil
Expected stock price volatility	1.590	1.661	0.908
Risk-free interest rate	4.90%	6.47%	5.05%
Expected life of options	4 years	4 years	4 years
Weighted (per share) average fair value of options granted	\$ 5.27	\$ 9.90	\$ 1.94

Compensation expense included in the pro forma amounts above may not be representative of the effects on pro forma earnings for future years.

*Reserved Shares*

As of December 31, 2001, we had reserved shares of our common stock for future issuance as follows:

Stock options granted	3,883,833
Available for future grant	1,288,697
Stock purchase warrants	5,368,474
Conversion of Series B preferred stock and note	4,619,041
<b>Total</b>	<b>15,160,045</b>

**5. Acquisition of Genovo, Inc.**

In September 2000, we acquired Genovo, Inc., a privately held biotechnology company focused on developing therapeutic products based on AAV vectors. The purchase price for our acquisition of Genovo, Inc. was approximately \$66.4 million, which consisted of the following:

Issuance of 5,250,805 shares of common stock	\$ 58,461,000
Fair value of options to purchase 1,302,034 shares of common stock	7,668,000
Transaction costs	584,000
<b>Total consideration</b>	<b>66,713,000</b>
Less: intrinsic value of unvested stock options	(301,000)
<b>Purchase price</b>	<b>\$ 66,412,000</b>

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Of the \$66.4 million purchase price, \$28.0 million consisted of acquired in-process research and development (IPR&D) expenses, \$39.5 million consisted of intangibles, consisting of AAV vector know-how of \$12.7 million, assembled workforce of \$1.6 million, goodwill of \$25.2 million, \$1.9 million of tangible assets and \$3.0 of liabilities assumed.

We evaluated acquired IPR&D connected with our acquisition of Genovo by utilizing the present value of the estimated after-tax cash flows expected to be generated by the purchased technology, which had not reached technological feasibility at the effective time of the acquisition. We based the cash flow projections for revenue on estimates of growth rates and the aggregate size of the markets for each product or technology; the probability of technical success given the stage of development at the time of acquisition; royalty rates, based on prior licensing

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

agreements; product sales cycles; and the estimated life of the product's underlying technology. We deducted estimated operating expenses and income taxes from estimated revenue projections to arrive at estimated after-tax cash flows. We utilized discount rates of 30% to 45% to discount projected cash flows for in-process technologies, depending on the relative risk of each in-process technology. We computed these rates based primarily on our internal rates of return, cost of capital, rates of return for research and development and the weighted average cost of capital at the time of acquisition. Projected operating expenses include general and administrative expenses and research and development costs.

We based all of the foregoing estimates and projections regarding the Genovo acquisition on assumptions that we believed to be reasonable at the time of the acquisition but that are inherently uncertain and unpredictable. If we do not successfully develop the projects and technologies considered in these estimates, its business, operating results and financial condition may be adversely affected. As of the date of the acquisition, we concluded that the technologies under development, once completed, could be economically used only for their specifically intended purposes and that the in-process technology had no alternative future use after taking into consideration the overall objectives of the project, progress toward the objectives and uniqueness of developments to these objectives. If we fail in these development efforts, no alternative economic value will result from these technologies and the economic contribution that we projected from the IPR&D will not materialize. The risk of unsuccessful or untimely completion includes the risk that our competitors will develop alternative gene delivery technologies or will develop more effective or economically feasible technologies using more traditional approaches to treating human diseases.

In connection with our acquisition of Genovo, we established an escrow of 550,872 shares of our common stock held for the benefit of former Genovo stockholders, pending resolution of specified pre-acquisition contingencies related to Genovo. During 2001, a party associated with a pre-acquisition contractual matter notified us that it would dispute reimbursing us for a \$2.0 million settlement payment we made. Based on our review of the facts, we determined that the \$2.0 million receivable we had recorded in anticipation of reimbursement was not collectable. As a result, and in accordance with the terms of the Genovo merger agreement, we cancelled 155,649 shares held in escrow, valued at \$2.0 million. We reflected the \$2.0 million as a reduction of equity during 2001 and retired the shares.

Under the following circumstances, we may issue additional shares of our common stock as merger consideration, as follows:

Because specified Genovo licensing arrangements were unresolved at the time of the merger, we established an escrow of 700,000 shares of our common stock potentially issuable as additional merger consideration. Pending completion of negotiations, we may issue a portion of these shares in exchange for additional license rights. The escrow period ends in March 2002, but may be extended.

In connection with the Genovo merger and a collaborative research agreement previously entered into between Genzyme Corporation and Genovo, we assumed two outstanding options for Genzyme to purchase Genovo capital stock. After the merger, Genzyme exercised the first option to purchase 311,295 shares of our common stock (as successor company to Genovo) at a price of \$12.8495 per share. Genzyme has not exercised the second option to acquire up to an additional 311,295 shares of our common stock, also at a price of \$12.8495 per share. We are in negotiations with Genzyme to define the scope of ongoing development activities and the parameters around which Genzyme would make a further investment in us. Should Genzyme elect not to make an additional investment, or to provide us with less than \$4.0 million through exercise of the option agreement, the former Genovo shareholders and option holders could receive up to 155,648 additional shares of our common stock.

In each of these circumstances, the fair value of the shares issued to the former Genovo stockholders, if any, will be determined on the date the additional shares may be issued and will be reflected as additional purchase price. No amounts related to these contingencies have been included in the purchase price for the acquisition to date.

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table reflects unaudited consolidated pro forma results of operations for the years ended December 31, 2000 and 1999, giving effect to the Genovo acquisition as if it had occurred at the beginning of each respective period. These pro forma amounts are not necessarily indicative of what the actual consolidated results of operations would have been if the acquisition had been effective at the beginning of each of these periods. The pro forma information does not include the one-time charges for acquired IPR&D related to the acquisition of Genovo.

	Year end December 31,	
	2000	1999
Revenue	\$ 15,262,000	\$ 12,241,000
Net loss	(29,671,000 )	(38,820,000)
Basic and diluted net loss per share	\$ (.77)	\$ (1.04)
Shares used in computation of basic and diluted net loss per common share	38,372,000	37,425,00

**6. Collaborative and Other Agreements**

We have entered into six partnering relationships with pharmaceutical and biotechnology companies and a public health organization to develop several of our product candidates. Under these partnerships, we typically receive reimbursement for research and development activities performed by us under the collaboration. We may also receive milestone and upfront payments. The aggregate revenue we earned under all of our collaborative research and development collaborations were \$18.9 million in 2001, \$11.4 million in 2000 and \$6.8 million in 1999.

*Celltech Group Agreement*

In October 1998, we entered into a series of agreements with Medeva Pharmaceuticals, Inc. to collaborate on the development of our tgAAVCF gene therapy product for treating cystic fibrosis. In January 2000, Medeva merged with Celltech/Chiroscience to become part of Celltech Group plc and Celltech assumed Medeva's rights and responsibilities under these agreements. Under a research and development funding agreement, we granted Medeva an exclusive worldwide license to sell tgAAVCF, but retained rights for supplying bulk tgAAVCF product to support clinical trials and commercialization. In 1998, we received a license and technology access fee of \$5.0 million from Medeva at the time of signing and milestone payments of \$1.0 million at the initiation of Phase I clinical trials of the tgAAVCF product. In 2000, we received \$2.0 million at the initiation of Phase II clinical trials of the tgAAVCF product. We received no milestone payments from Celltech in 2001. In addition, Celltech agreed to pay up to \$5.0 million per year from October 1998 through October 2001 to support research and development activities for tgAAVCF and to reimburse us for certain clinical trial expenses. Celltech also agreed to fund the costs of the Phase II clinical trial, which was initiated in November 2000. Assuming successful development and regulatory approval, Celltech will have the exclusive right to market the product on a worldwide basis. Under a long-term supply agreement, we will manufacture and supply bulk product to Celltech under a specific pricing formula. Celltech has the option to terminate the agreements with 180 days' notice. Should Celltech exercise this right to terminate, all rights related to tgAAVCF technology we have granted or otherwise extended to Celltech would return to us.

We recognized revenue of \$5.0 million in 2001, \$8.6 million in 2000 and \$6.4 million in 1999 under the Celltech collaboration and we have recognized total revenue of \$23.4 million since the inception of the collaboration. Revenue recognized since inception include \$6.0 million of deferred revenue amortization resulting from our adoption of SAB 101, as follows: \$1.6 million in 2001, \$2.1 million in 2000 and 1999 and \$200,000 in 1998. Under related agreements, Celltech purchased 1,427,392 shares of our common stock for \$2.8 million and loaned us \$2.0 million.



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### **TARGETED GENETICS CORPORATION**

#### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

##### *Biogen Agreement*

In September 2000, we established a multiple-product development and commercialization collaboration with Biogen, Inc. Under the terms of the collaborative agreement, we granted Biogen an exclusive worldwide license to sell any products developed in the collaboration and assumed responsibility for manufacturing and supplying any developed products to Biogen to support product development, clinical trials and product commercialization. We will receive royalties on sales of any products that result from the collaborative product development efforts or, alternatively, we will sell product to Biogen at specified transfer prices. Upon initiation of the collaboration, Biogen paid us \$8.0 million, which included an up-front technology license of \$5.0 million and up-front prepaid research and development funding of \$3.0 million. Under a related three-year research and development funding agreement, Biogen agreed to provide a minimum of \$3.0 million of additional research and development funding, paid at a rate of a minimum of \$1.0 million per year. Although Biogen may terminate the development and marketing agreement at any time, its obligation under the related funding agreement to pay the minimum annual project funding would continue through September 2003.

We are amortizing the \$8.0 million up-front fee paid by Biogen over the initial three-year research and development period. We will recognize revenue on the \$1.0 million minimum annual project funding as we perform specified research and development efforts. We recognized revenue of \$2.6 million in 2001 and \$429,000 in 2000 related to the Biogen collaboration. These amounts include amortization of up-front payments and research funding earned during each period.

Under the related funding agreement, Biogen also agreed to provide us with loans of up to \$10.0 million, which amount we borrowed in 2001, and to purchase up to \$10.0 million of our common stock, none of which has been purchased, each at our discretion. Until August 2003, we can elect to have Biogen purchase the \$10.0 million of our common stock, subject to limitations on Biogen's percentage ownership of our stock, in one or more pieces, at a price per share equal to the average of the daily closing prices of a share of our common stock for a specified period of time before and after the applicable exercise date.

##### *Wyeth/Genetics Institute Agreement*

In November 2000, we entered into a collaboration to develop gene therapy products for treating hemophilia with Wyeth/Genetics Institute, a unit of Wyeth Pharmaceuticals. Under the terms of a research and development funding agreement, Wyeth/Genetics Institute paid us up-front payments of \$5.6 million and will pay us up to \$15.0 million to develop a product candidate for hemophilia A over a three-year research and development collaboration period ending in November 2003. We granted Wyeth/Genetics Institute an option to collaborate on the development of a hemophilia B product candidate under similar terms. Under a related supply agreement, Wyeth/Genetics Institute agreed to pay us to manufacture product for clinical trials and for commercial supply according to a sales-based formula assuming regulatory approval of products successfully developed. In addition, Wyeth/Genetics Institute agreed to manage and fund the costs of clinical trials and related regulatory filings required for product approval and marketing. Wyeth/Genetics Institute will retain global marketing rights for any products resulting from the collaboration.

Wyeth/Genetics Institute has also agreed, upon the occurrence of specified future events, to loan us up to \$10 million to finance manufacturing facility expansions if certain conditions are met. No amounts have been borrowed under this commitment.

Wyeth/Genetics Institute has the right to terminate both agreements at will, with 180 days' notice. Should Wyeth/Genetics Institute terminate the collaboration, all rights that were granted or otherwise extended to Wyeth/Genetics Institute related to the hemophilia technology that we have granted or otherwise extended to Wyeth/Genetics Institute would return to us. If Wyeth/Genetics Institute exercises their right to terminate both agreements at will or if we exercise our right to terminate for cause, we would have an option to acquire a right and license to certain hemophilia patent rights controlled by Wyeth/Genetics Institute.

We recognized revenue of \$6.5 million in 2001 and \$454,000 in 2000 under this collaboration. These revenue amounts include amortization in each period of the \$5.6 million of up-front payments and the collaborative research funding earned during the period.

##### *Genzyme Agreement*

In connection with the acquisition of Genovo in September 2000, we assumed a three-year development and license agreement with Genzyme Corporation that Genovo had entered into in August 1999. Under that agreement Genovo was committed to perform up to \$2.9 million per year of research and development activities related to



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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

product candidates for treating lysosomal storage disorders. In November 2000, we amended the development agreement to expand the collaboration's technological scope and modify financial terms. Under the terms of the amended agreement, should we achieve specified regulatory milestones, Genzyme would be required to make milestone payments and pay royalties to us on sales of any products developed under the agreement.

The development program under our agreement with Genzyme is effective through August 2002 and includes an option to extend the term if both parties agree. Genzyme has the right to terminate the development program at will, with 90 days' notice. Should Genzyme exercise this right to terminate the development program, or upon its expiration, all rights that we granted or otherwise extended to Genzyme would return to us, except that Genzyme will retain an exclusive license to certain Genovo-related manufacturing technology for use in the field of lysosomal storage disorders. We do not recognize revenue on the research that we perform in connection with this collaboration because to date we have funded this project through the proceeds received from the sale of equity securities to Genzyme.

In connection with our acquisition of Genovo, we also 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 Genovo acquisition date. After the execution of the amended agreement, Genzyme exercised its option to purchase 311,295 shares of our common stock for a total of \$4.0 million. Genzyme has not exercised the second option to acquire up to an additional 311,295 shares of our common stock also at a price of \$12.8495 per share. We are in negotiations with Genzyme to define the terms by which Genzyme would exercise its option or other means by which Genzyme would make an additional investment in us. Should Genzyme elect not to make an additional investment, or to provide less than the \$4.0 million through exercise of the option agreement, the former Genovo shareholders and option holders could receive up to 155,648 additional shares of our common stock.

*International AIDS Vaccine Initiative Agreement*

In February 2000, we entered into a three-year development collaboration with the International AIDS Vaccine Initiative (IAVI) and Children's Research Institute on the campus of Children's Hospital in Columbus, Ohio, to develop a vaccine to prevent AIDS. Under the terms of the collaboration, IAVI provides funding to support development, preclinical studies and manufacturing of product for clinical trial studies. The collaboration provides for up to \$6.0 million in cost reimbursable research funding from IAVI.

Under the terms of the IAVI agreement, we have rights to manufacture any vaccines developed under the collaboration and will retain worldwide exclusive commercialization rights, in developed countries, to any product that results from the collaboration. If we decline to produce the vaccine for developing countries in reasonable quantity and at a reasonable price, IAVI will have rights to obtain the necessary licenses from us that will allow IAVI to contract with other manufacturers to make the vaccine for use in those countries. We recognized \$1.9 million in revenue from IAVI in 2001 and \$23,000 of revenue in 2000, which is based on the research and development costs incurred during those periods.

*Alkermes License*

In June 1999, we entered into an agreement with Alkermes, Inc. to acquire the exclusive rights to a patent and other pending patent applications for manufacturing AAV vectors. The license to this technology, first developed by Children's Hospital in Columbus, Ohio, covers the use of cell lines for the manufacture of AAV vectors and expands a previously acquired limited field license to these rights. In exchange for this technology license, we issued 500,000 shares of our common stock, a warrant to purchase 1.0 million shares of our common stock at an exercise price of \$2.50 per share, which expires in June 2007, and a warrant to purchase another 1.0 million shares of our common stock at an exercise price of \$4.16 per share, which expires in June 2009. Both warrants were outstanding at December 31, 2001. During 1999, we recorded a \$3.2 million non-cash charge based on the fair value of the warrants and shares of common stock issued to Alkermes. The charge was recorded because the underlying technology is not complete and we will have to invest significant resources to develop and improve its commercial feasibility.

The Alkermes license agreement requires us to satisfy specified development requirements in order to maintain the exclusivity of the license. We are obligated to make clinical and regulatory development milestone payments for any product candidates using this technology, to pay royalties upon the sale of any products using the licensed technology and to make payments to Alkermes if we sublicense the technology covered by the license agreement.

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Emerald Gene Systems Joint Venture**

In July 1999, we formed Emerald Gene Systems, our joint venture with Elan. Emerald was formed to develop product candidates based on our expertise in gene delivery and Elan's expertise in drug delivery.

We own 80.1% of Emerald's common stock and 80.1% of Emerald's preferred stock and Elan owns the remaining 19.9% of Emerald's common and preferred stock. The common stock of Emerald held by Elan is similar in all respects to the common stock held by us, except that those shares held by Elan do not have voting rights. The common shares held by Elan may be converted into voting common shares at Elan's election. Although we currently own 100% of the voting stock, Elan and its subsidiaries have retained significant minority investor rights that are considered participating rights under the FASB's Emerging Issues Task Force Bulletin 96-16, *Investors' Accounting for an Investee When the Investor Has a Majority of the Voting Interest but the Minority Shareholder Has Certain Approval or Veto Rights*. Because Elan's participating rights prevent us from exercising control over Emerald, we do not consolidate the financial statements of Emerald, but instead account for our investment in Emerald under the equity method of accounting. We record our share of Emerald's net loss from operations as equity in net loss of unconsolidated, majority owned research and development joint venture in the accompanying statements of operations. The preferred shares of Emerald are entitled to a liquidation preference equal to the amount paid by Elan and us for the preferred stock. In addition, upon the exercise of the exchange option by Elan (see Note 4), all non-voting preferred shares that Elan holds in Emerald will automatically be converted into voting common shares on a one-for-one basis. Both the common stock and preferred stock of Emerald are subject to certain transfer restrictions, other than to an affiliate.

We acquired our 80.1% interest and Elan acquired its 19.9% interest in Emerald in exchange for capital contributions receivable of \$12.0 million and \$3.0 million, respectively. Both Elan and we licensed intellectual property to Emerald. Emerald valued the technology licensed by Elan to Emerald at \$15.0 million, which represented the consideration to be paid under the License Agreement. The \$15.0 million technology license fee represented rights to technology, which had not reached technological feasibility at the date of acquisition and did not have alternative future uses. This in-process research and development was immediately charged to expense by Emerald. Due to our 80.1% ownership interest, the value assigned by Emerald to the license of our technology was zero, representing our carrying value of the technology licensed. We are entitled to receive royalties if and when commercialization of product candidates occurs. The parties agreed to settle the capital contribution obligations to the joint venture and the technology license fee payable to Elan through a non-cash cross receipt agreement. This cross receipt agreement represented a written acknowledgement by all parties of the receipt of sums owed to and from Emerald, Elan and us. Simultaneous with the formation of the joint venture, we issued to Elan shares of our Series B convertible exchangeable preferred stock valued at \$12.0 million. These shares were issued in exchange for Elan's assumption of our capital contribution to Emerald. Because we did not receive any cash from the issuance of the Series B preferred stock, we have presented its issuance as a non-cash transaction in our financial statements.

We and Elan fund the expenses of Emerald in proportion to our respective ownership interests. A joint operating committee determines the nature and scope of activities to be performed by the joint venture on a periodic basis and at least annually. We provided \$2.8 million of cash funding to Emerald in 2001, \$2.8 million of cash funding in 2000 and no cash funding in 1999. We and Elan conduct Emerald's research and development and Emerald reimburses each company for the costs of research and development and related expenses plus a profit percentage. Our share of anticipated funding for 2002 is \$3.1 million. Reimbursement that we receive from Emerald is reflected as revenue from collaborative agreement with unconsolidated, majority-owned joint venture in the accompanying statements of operations and related expenses are included in research and development expense. Under a loan facility provided to us from Elan, we have the option to borrow up to \$12.0 million from Elan to fund our share of Emerald's expenses. In September 2001, we borrowed \$2.0 million against this loan facility.

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The condensed financial statements of Emerald are as follows:

	December 31,	
	2001	2000
Total assets, current	\$ 6,000	\$ 6,000
Current liabilities	1,393,000	331,000
Total shareholders' equity	(1,387,000)	(325,000)
Total liabilities and shareholders' equity	\$ 6,000	\$ 6,000

	Year Ended December 31,		July 21, 1999 (Inception) to Dec. 31, 1999
	2001	2000	
Revenue	\$	\$	\$
Expenses:			
Research and development	4,563,000	3,073,000	723,000
Technology access fee			15,000,000
General and administrative	14,000	14,000	19,000
Net loss	\$ (4,577,000)	\$ (3,087,000)	\$ (15,742,000)

**8. Commitments**

We lease our research and office facilities in Seattle, Washington under two non-cancelable operating leases that expire in March 2004. We lease a facility in Bothell, Washington under a non-cancelable operating lease that expires on October 2015, which facility is intended to accommodate future manufacturing of our product candidates. The research and office facility leases may be extended under two additional five-year renewal options. The manufacturing facility lease may be extended for an additional five-year period. We also lease research and office facilities in Sharon Hill, Pennsylvania, under a non-cancelable operating lease that expires in November 2005. This lease may be extended for two additional five-year periods.

Future minimum payments under non-cancelable operating leases at December 31, 2001 were as follows:

Year ending December 31,

2002	\$ 2,903,000
2003	2,920,000
2004	1,842,000
2005	1,538,000
2006	1,362,000
Thereafter	13,288,000
Total minimum lease payments	\$ 23,853,000

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Rent expense under operating leases was \$2.9 million for 2001, \$1.1 million for 2000 and \$587,000 for 1999.

### **9. Employee Retirement Plan**

We sponsor an employee retirement plan under Section 401(k) of the Internal Revenue Code. All of our employees and those of our subsidiaries who are 21 years old or older are eligible to participate in the plan. Our contributions to the 401(k) plan are made at the discretion of the board of directors and were \$192,000 in 2001, \$144,000 in 2000 and \$90,000 in 1999.

### **10. Income Taxes**

At December 31, 2001, we had net operating loss carryforwards of \$103.0 million and research and tax credit carryforwards of \$4.3 million. The carryforwards, which are available to offset future federal income taxes, begin to expire in 2008 if not utilized. We have provided a valuation allowance to offset the excess of deferred tax assets over the deferred tax liabilities, due to the uncertainty of realizing the benefits of the net deferred tax asset.

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Significant components of our deferred tax assets and liabilities were as follows:

	<b>December 31,</b>	
	<b>2001</b>	<b>2000</b>
Deferred tax assets		
Net operating loss carryforwards	\$ 39,150,000	\$ 33,210,000
Deferred revenue	400,000	640,000
Research and experimental credit carryforwards	4,300,000	3,430,000
Depreciation and amortization	1,340,000	1,060,000
Other	420,000	260,000
Gross deferred tax assets	45,610,000	38,600,000
Valuation allowance for deferred tax assets	(45,610,000)	(38,600,000)
Net deferred tax asset	\$	\$

Our utilization of federal income tax carryforwards is subject to limitation under Section 382 of the Internal Revenue Code. Our past sales and issuances of common stock have resulted in ownership changes, as defined under Section 382, and may result in limitations on our future use of some portion of the net operating loss carryforwards.

**11. Condensed Quarterly Financial Information (unaudited)**

The following tables present our unaudited quarterly results for 2001 and 2000. We believe that the following information reflects all normal recurring adjustments for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	<b>Quarter Ended</b>			
	<b>March 31, 2001</b>	<b>June 30, 2001</b>	<b>September 30, 2001</b>	<b>December 31, 2001</b>
Revenue	\$ 3,805,000	\$ 4,339,000	\$ 5,538,000	\$ 5,198,000
Net loss	(6,243,000)	(5,865,000)	(6,992,000)	(8,070,000)
Basic and diluted net loss per common share, restated	(0.14)	(0.13)	(0.16)	(0.18)

	<b>Quarter Ended</b>			
	<b>March 31, 2000</b>	<b>June 30, 2000</b>	<b>September 30, 2000</b>	<b>December 31, 2000</b>
Revenue	\$ 2,700,000	\$ 2,277,000	\$ 1,914,000	\$ 4,512,000
Loss before cumulative effect of change in accounting principle	(2,537,000)	(3,561,000)	(32,004,000)	(5,871,000)
Cumulative effect of change in accounting principle	(3,682,000)			
Net loss	(6,219,000)	(3,561,000)	(32,004,000)	(5,871,000)
Basic and diluted per common share amounts, restated:				
Loss before cumulative effect of change in accounting principle	\$ (0.07)	\$ (0.10)	\$ (0.86)	\$ (0.14)
Cumulative effect of change in accounting principle	(.11)			
Net loss	\$ (0.18)	\$ (0.10)	\$ (0.86)	\$ (0.14)

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

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**PART III**

**Item 10. Directors and Executive Officers of Registrant**

The information required by this Item with respect to our directors is incorporated by reference to the section captioned Election of Directors in the proxy statement for our annual meeting of shareholders to be held on May 9, 2002.

The information required by this Item with respect to our executive officers is incorporated by reference to the section captioned Executive Officers in the proxy statement for our annual meeting of shareholders to be held on May 9, 2002.

**Item 11. Executive Compensation**

The information required by this Item with respect to executive compensation is incorporated by reference to the section captioned Executive Compensation in the proxy statement for our annual meeting of shareholders to be held on May 9, 2002.

**Item 12. Security Ownership of Certain Beneficial Owners and Management**

The information required by this Item with respect to beneficial ownership is incorporated by reference from the section captioned Principal Shareholders in the proxy statement for our annual meeting of shareholders to be held on May 9, 2002.

**Item 13. Certain Relationships and Related Transactions**

The information required by this Item with respect to certain relationships and related-party transactions is incorporated by reference to the sections captioned Executive Compensation Change of Control Arrangements and Executive Compensation Arrangements with Management in the proxy statement for our annual meeting of shareholders to be held on May 9, 2002.

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**PART IV**

**Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

**(a) 1. Financial Statements**

The following consolidated financial statements are submitted in Item 8 of this report:

	<b>Page</b>
Report of Ernst & Young LLP, Independent Auditors	42
Consolidated Balance Sheets as of December 31, 2001 and 2000	43
Consolidated Statements of Operations for the years ended December 31, 2001, 2000 and 1999	44
Consolidated Statements of Redeemable Preferred Stock and Shareholders Equity for the years ended December 31, 2001, 2000 and 1999.	45
Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999	46
Notes to Consolidated Financial Statements	47

**Table of Contents****2. Financial Statement Schedules**

All financial statement schedules have been omitted because the required information is either included in the consolidated financial statements or the notes thereto or is not applicable.

**3. Exhibits**

3.1	Restated Articles of Incorporation (Exhibit 3.1)	(L)
3.2	Amended and Restated Bylaws (Exhibit 3.2)	(D)
4.1	Rights Agreement, dated as of October 17, 1996, between Targeted Genetics and ChaseMellon Shareholder Services (Exhibit 2.1)	(C)
4.2	First Amendment of Rights Agreement, dated July 21, 1999, between Targeted Genetics and ChaseMellon Shareholder Services (Exhibit 1.9)	(J)
10.1	Form of Indemnification Agreement between Targeted Genetics and its officers and directors (Exhibit 10.1)	(K)
10.2	Form of Senior Management Employment Agreement between the registrant and its executive officers (Exhibit 10.2)	(D)
10.3	Gene Transfer Technology License Agreement, dated as of February 18, 1992, between Immunex Corporation and Targeted Genetics* (Exhibit 10.3)	(K)
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10.6	PHS Patent License Agreement Exclusive, dated as of March 10, 1994, between National Institutes of Health Centers for Disease Control and Targeted Genetics* (Exhibit 10.10)	(E)
10.7	License Agreement, dated as of March 28, 1994, between Targeted Genetics and the University of Michigan* (Exhibit 10.13)	(E)
10.8	Patent and Technology License Agreement, effective as of March 1, 1994, between the Board of Regents of the University of Texas M.D. Anderson Cancer Center and RGene Therapeutics, Inc.* (Exhibit 10.29)	(A)
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10.10	Amendment to First Amended and Restated License Agreement, dated as of June 19, 1996, between The University of Tennessee Research Corporation and RGene Therapeutics, Inc.* (Exhibit 10.1)	(B)
10.11	Second Amendment to First Amended and Restated License Agreement, dated as of April 17, 1998, between The University of Tennessee Research Corporation and RGene Therapeutics, Inc.* (Exhibit 10.16)	(G)
10.12	License Agreement, dated as of March 15, 1997, between the Burnham Institute and Targeted Genetics* (Exhibit 10.23)	(E)
10.13	Exclusive Sublicense Agreement, dated June 9, 1999, between Targeted Genetics and Alkermes, Inc. (Exhibit 10.36)	(I)
10.14	Master Agreement, dated as of November 23, 1998, between Targeted Genetics and Medeva Pharmaceuticals, Inc.* (Exhibit 1.1)	(H)
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10.18	Funding Agreement, dated as of July 21, 1999, among Targeted Genetics, Elan International Services, Ltd., and Elan Corporation, plc (Exhibit 1.3)	(J)
10.19	Subscription, Joint Development and Operating Agreement, dated as of July 21, 1999, among Elan Corporation, plc, Elan International Services, Ltd., Targeted Genetics and Targeted Genetics Newco, Ltd. * (Exhibit 1.4)	(J)
10.20		(J)

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Convertible Promissory Note, dated July 21, 1999, issued by Targeted Genetics to Elan International Services, Ltd.  
(Exhibit 1.5)

10.21	License Agreement dated July 21, 1999, between Targeted Genetics Newco, Ltd. and Targeted Genetics * (Exhibit 1.6)	(J)
10.22	License Agreement, dated July 21, 1999, between Targeted Genetics Newco, Ltd. and Elan Pharmaceutical Technologies, a division of Elan Corporation, plc * (Exhibit 1.7)	(J)
10.23	Office Lease, dated as of October 7, 1996, between Benaroya Capital Company, LLC and Targeted Genetics (Exhibit 10.26)	(D)

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10.24	Canyon Park Building Lease, dated as of June 30, 2000, between Targeted Genetics and CarrAmerica Corporation (Exhibit 10.1)	(L)
10.25	Olive Way Building Lease, dated as of November 20, 1993, as amended, between Targeted Genetics and Ironwood Apartments, Inc. (successor in interest to Metropolitan Federal Savings and Loan Association) (Exhibit 10.29)	(K)
10.26	First Lease Amendment, dated May 12, 1997, between Targeted Genetics and Benaroya Capital Company, LLC (Exhibit 10.1)	(Q)
10.27	Second Lease Amendment, dated February 25, 2000, between Targeted Genetics and Benaroya Capital Company, LLC (Exhibit 10.2)	(Q)
10.28	Third Lease Amendment, dated April 19, 2000, between Targeted Genetics and Benaroya Capital Company, LLC (Exhibit 10.3)	(Q)
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10.31	Stock Option Plan for Nonemployee Directors (Exhibit 10.34)	(E)
10.32	1999 Restated Stock Option Plan, as amended January 23, 2001 (Exhibit 10.2)	(P)
10.33	2000 Genovo Inc. Roll-Over Stock Option Plan (Exhibit 99.1)	(N)
10.34	Agreement and Plan of Merger dated as of August 8, 2000, among Targeted Genetics, Inc., TGC Acquisition Corporation and Biogen, Inc.*	(M)
10.35	Development and Marketing Agreement, dated as of August 8, 2000, between Targeted Genetics and Biogen, Inc.* (Exhibit 10.1)	(M)
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10.37	Product Development Agreement, dated as of November 9, 2000, between Targeted Genetics and Genetics Institute, Inc. * (Exhibit 10.1)	(O)
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21.1	Subsidiaries of Targeted Genetics	
23.1	Consent of Ernst & Young LLP, Independent Auditors	

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

- |     |   |
|-----|---|
| (A) | Incorporated by reference to the designated exhibit included with Targeted Genetics Registration Statement on Form S-1 (No. 333-03592) filed on April 16, 1996, as amended.                   |
| (B) | Incorporated by reference to the designated exhibit included with Targeted Genetics Quarterly Report on Form 10-Q (No. 0-23930) for the period ended June 30, 1996, filed on August 12, 1996. |
| (C) | Incorporated by reference to Targeted Genetics Registration Statement on Form 8-A, filed on October 22, 1996.   |
| (D) | Incorporated by reference to the designated exhibit included with Targeted Genetics Annual Report on Form 10-K (No. 0-23930) for the year ended December 31, 1996, filed on March 12, 1997.   |
| (E) | Incorporated by reference to the designated exhibit included with Targeted Genetics Annual Report on Form 10-K (No. 0-23930) for the year ended December 31, 1997, filed on March 31, 1998.   |
| (F) | Incorporated by reference to the designated exhibit included with Targeted Genetics Registration Statement on Form S-8 (No. 333-58907), filed on July 10, 1998.                               |
| (G) | Incorporated by reference to the designated exhibit included with Targeted Genetics Annual Report on Form 10-K (No. 0-23930) for the year ended December 31, 1998, filed on March 10, 1999.   |
| (H) | Incorporated by reference to the designated exhibit included with Targeted Genetics Current Report on Form 8-K (No. 0-23930), filed on January 6, 1999.                                       |
| (I) | Incorporated by reference to the designated exhibit included with Targeted Genetics Quarterly Report on Form 10-Q (No. 0-23930) for the period ended June 30, 1999, filed on August 5, 1999.  |
| (J) | Incorporated by reference to the designated exhibit included with Targeted Genetics Current Report on Form 8-K (No. 0-23930), filed August 4, 1999.   |
| (K) | Incorporated by reference to the designated exhibit included with Targeted Genetics Annual Report on Form 10-K (No. 0-23930) for the year ended December 31, 1999, filed on March 23, 2000.   |

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- (L) Incorporated by reference to Targeted Genetics Quarterly Report on Form 10-Q (No. 0-23930) for the period ended June 30, 2000, filed on August 11, 2000.
- (M) Incorporated by reference to the designated exhibit included with Targeted Genetics Current Report on Form 8-K (No. 0-23930), filed on September 13, 2000.

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- (N) Incorporated by reference to the designated exhibit included with Targeted Genetics Registration Statement on Form S-8 (No. 333-48220), filed on October 19, 2000.
- (O) Incorporated by reference to the designated exhibit included with Targeted Genetics Current Report on Form 8-K (No. 0-23930), filed on February 21, 2001.
- (P) Incorporated by reference to Targeted Genetics Quarterly Report on Form 10-Q (No. 0-23930) for the period ended March 31, 2001, filed on May 11, 2001.
- (Q) Incorporated by reference to Targeted Genetics Quarterly Report on Form 10-Q (No. 0-23930) for the period ended June 30, 2001, filed on August 14, 2001.

*(c) Reports on Form 8-K*

On October 29, 2001, Targeted Genetics filed a Current Report on Form 8-K to announce the appointment of Todd E. Simpson to the position of Vice President, Finance and Administration, and Chief Financial Officer.



**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to be signed on its behalf by the undersigned, thereunto duly authorized in the city of Seattle, state of Washington, on August 13, 2002.

TARGETED GENETICS CORPORATION

By: /s/ H. STEWART  
PARKER

**President, Chief  
Executive Officer and  
Director**

Pursuant to the requirements of the Securities Exchange Act of 1934, this Amendment No. 1 has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ H. STEWART PARKER</u> <b>H. Stewart Parker</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	August 13, 2002
<u>/s/ TODD E. SIMPSON</u> <b>Todd E. Simpson</b>	Vice President, Finance and Administration and Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	August 13, 2002
<u>JEREMY L. CURNOCK COOK*</u> <b>Jeremy L. Curnock Cook</b>	Chairman of the Board	August 13, 2002
<u>JACK L. BOWMAN*</u> <b>Jack L. Bowman</b>	Director	August 13, 2002
<u>JOSEPH M. DAVIE, PH.D., M.D.*</u> <b>Joseph M. Davie, Ph.D., M.D.</b>	Director	August 13, 2002
<u>LOUIS P. LACASSE*</u> <b>Louis P. Lacasse</b>	Director	August 13, 2002
<u>NELSON L. LEVY, PH.D., M.D.*</u> <b>Nelson L. Levy, Ph.D., M.D.</b>	Director	August 13, 2002
<u>MARK RICHMOND, PH.D.*</u> <b>Mark Richmond, Ph.D.</b>	Director	August 13, 2002

\*By:

/s/ H. STEWART  
PARKER

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**H. Stewart Parker,**  
**as attorney in fact**

**Table of Contents****EXHIBIT INDEX**

3.1	Restated Articles of Incorporation (Exhibit 3.1)	(L)
3.2	Amended and Restated Bylaws (Exhibit 3.2)	(D)
4.1	Rights Agreement, dated as of October 17, 1996, between Targeted Genetics and ChaseMellon Shareholder Services (Exhibit 2.1)	(C)
4.2	First Amendment of Rights Agreement, dated July 21, 1999, between Targeted Genetics and ChaseMellon Shareholder Services (Exhibit 1.9)	(J)
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