

TARGETED GENETICS CORP /WA/

Form 10-K

March 31, 2009

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

**▶ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the Fiscal Year Ended December 31, 2008**

**OR**

**.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number No. 0-23930**

**TARGETED GENETICS CORPORATION**

(Exact Name of Registrant as Specified in Its Charter)

**Washington**  
(State of Incorporation)

**91-1549568**  
(IRS Employer Identification No.)

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1100 Olive Way, Suite 100

Seattle, WA 98101

(Address of Principal Executive Offices, Including Zip Code)

(206) 623-7612

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$0.01 Par Value**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

The aggregate market value of common stock held by non-affiliates of the Registrant as of June 30, 2008 was approximately \$11.8 million based on the closing price of \$0.59 per share of the Registrant's common stock as listed on the NASDAQ Capital Market.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock as of March 27, 2009

| Title of Class                 | Number of Shares |
|--------------------------------|------------------|
| Common Stock, \$0.01 par value | 20,447,198       |

**DOCUMENTS INCORPORATED BY REFERENCE**

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(1) The information required by Part III of this report, to the extent not set forth in this report, is incorporated by reference from the proxy statement for the 2009 annual meeting of shareholders to be held on May 14, 2009. The definitive proxy statement for the 2009 annual meeting of shareholders will be filed with the Securities and Exchange Commission within 120 days after December 31, 2008, the end of the fiscal year to which this report relates.

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**TARGETED GENETICS CORPORATION**

**ANNUAL REPORT ON FORM 10-K**

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**PART I**

**Item 1. Business.**

**Forward-Looking Statements**

This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include statements about our cash resources and future financial condition, our ability to continue as a going concern, our ability to obtain additional funding or enter into strategic collaborations, our product development and commercialization goals and expectations, potential market opportunities, our plans for and anticipated results of our clinical development activities and the potential advantage of our product candidates and other statements that are not historical facts. Words such as *may*, *can be*, *may depend*, *will*, *believes*, *estimates*, *expects*, *anticipates*, *plans*, *projects*, *intends*, or statements concerning *potential* and other words of similar meaning or the negative thereof may identify forward-looking statements, but the absence of these words does not mean that the statement is not forward-looking. In making these statements, we rely on a number of assumptions and make predictions about the future. Our actual results could differ materially from those stated in or implied by forward-looking statements for a number of reasons, including the risks described in the section entitled *Risk Factors* in Part I, Item 1A of this annual report.

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

**Business Overview**

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

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

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

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preclinical program around that opportunity. As a result of these AAV- and small molecule-related efforts, we believe we have generated potential value through our development and manufacturing expertise, through the potential of our accumulated intellectual property portfolio and through our application of our expertise and intellectual property to promising product candidates.

We finished 2008 with \$5.2 million in cash and cash equivalents and have operated with a cash horizon of less than one year since early 2008. We believe that our current financial resources and the cash we expect to receive from our collaborative partners are sufficient only to fund our operations through the second quarter of 2009. Our short cash horizon, combined with the progressive deterioration of the general capital markets during 2008 and early 2009, has substantially harmed our ability to plan and execute our product development strategies. In November 2008, our chief executive officer and our chief scientific officer resigned from the company and the board of directors named a new chief executive officer. In response to our short cash horizon and the tight capital markets, our new management proactively realigned our product development priorities and narrowed our product development activities to three programs. We also executed cost reductions, including reductions to our staffing levels, salary reductions for our most senior executives, reductions of our intellectual property portfolio, curtailment of capital expenditures and other cost reductions.

*Product Development.* In our November 2008 product development reprioritization, we focused our internally funded efforts on ocular and neurological product candidates, including our first product development effort to evaluate the use of AAV to deliver expressed RNAi. This realignment focused our resources on creating near-term value balanced with the capabilities and resources currently available to us and our collaborators. We implemented this realignment to scale our operations down to match our projected financial resources and to focus our expertise and intellectual property on the programs we believe offer the most promise.

As a result, our development efforts currently are focused on:

a clinical-stage AAV-based product candidate for treatment of Leber's congenital amaurosis, or LCA, developed with Robin Ali, Ph.D., our collaborator at the University College London/Moorfields Eye Hospital, or UCL/M;

a preclinical AAV-based Huntington's disease, or HD, product candidate under development with our collaborator, Beverly Davidson, Ph.D., at the University of Iowa, or UI; and

a preclinical small molecule-based product candidate to treat amyotrophic lateral sclerosis, or ALS, under development with our collaborator, John Engelhardt, Ph.D., at UI and funded by a grant from the U.S. Department of Defense, or DOD.

We also:

maintained our development and manufacturing collaboration with Celladon Corporation, or Celladon, in support of the development and clinical testing of AAV-based gene therapies for the treatment of congestive heart failure. We recently replaced the original collaboration with a license and new manufacturing arrangement as described below;

maintained our collaboration with the National Institutes of Health and Children's Hospital of Philadelphia into early 2009 to support the initiation of clinical trials by these collaborators of an AAV-based HIV-vaccine product candidate;

realigned our intellectual property portfolio to focus on our current priorities, which included returning rights under licenses and/or cessation of prosecution of patents that are not specific to our current development program efforts; and

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suspended self-funded efforts to advance our inflammatory arthritis product candidate, tgAAC94, as we believe continued development of this product candidate will require a partner that has the resources to take the product into Phase II development and, if successful, onto commercialization.

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We believe these efforts, combined with continued cost reductions and suspension of most external costs related to our product development efforts, have extended our cash horizon through the second quarter of 2009.

Our active product pipeline is now as follows:

| <b>Description</b>          | <b>Indication</b>             | <b>Status</b>   |
|-----------------------------|-------------------------------|---|
| AAV delivery of RPE65 gene  | Leber's Congenital Amaurosis  | Phase I/II, clinical trial funded through a grant awarded to our collaborator Robin Ali, Ph.D. at the University College London/Moorfields Eye Hospital |
| AAV expression of RNAi      | Huntington's Disease          | Preclinical, development efforts underway with our collaborator Beverly Davidson, Ph.D., at the University of Iowa                                      |
| Inhibition of NADPH oxidase | Amyotrophic Lateral Sclerosis | Preclinical, development efforts underway with our collaborator John Engelhardt, Ph.D., with 2009 efforts funded by the Department of Defense           |

We continue to explore exciting new product development opportunities related to AAV delivery to allow us to leverage our substantial development and manufacturing expertise and intellectual property assets. For example, we believe that AAV may have an important role in providing a viable delivery vehicle for RNA therapeutics, including interfering RNA and microRNA. While we have not embarked on development efforts in this arena, other than through our HD program, we are evaluating potential product candidates and exploring potential funding mechanisms for such activities.

*Significant development and manufacturing expertise.* We are leaders in the development and application of processes to manufacture potential products at a scale amenable to late-stage clinical development and expandable to large-scale commercial production. In prior periods, we scaled up internal capabilities to manufacture at a 250 liter scale and in 2009 we are initiating activities that create flexibility for our manufacturing process, particularly in light of our limited financial resources. To accomplish this we have begun the process of enabling a third party contract manufacturing organization, or CMO, to potentially manufacture on our behalf using our processes. This will allow us to have the financial flexibility to either maintain our manufacturing resources in house or shift to the use of a CMO. We have established broad capabilities in applying our AAV-based gene therapeutic technologies to multiple product candidates and therapeutic indications. Through our efforts to develop a new class of therapeutics, we have built the development, manufacturing, quality, preclinical, clinical and regulatory expertise necessary to move candidates from research into clinical development. We believe our current capabilities and expertise provide a strong foundation to move gene therapeutics and, potentially, other product candidates from product discovery to commercialization.

In late 2008 and early 2009, we analyzed the financial impact of continuing to support our internal manufacturing infrastructure compared to purchasing manufacturing services from CMOs. We determined that, based on our progress in developing a robust set of manufacturing processes, we could feasibly outsource our manufacturing needs rather than maintain the infrastructure costs of supporting the Company's in-house manufacturing capability, including the costs of employing approximately 35 people, capital equipment and operating costs. In connection with this decision, in February 2009 we and Celladon agreed to complete our previously agreed manufacturing campaign for Celladon's MYDICAR® congestive heart failure product candidate at our company facilities and, in parallel, transfer the manufacturing know-how and processes required to replicate our manufacturing and testing of MYDICAR® to a third party CMO. We plan to continue to maintain an internal knowledge base within the company to facilitate



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high-quality training and oversight of manufacturing information transfer to CMOs and provide for continued development of new or improved manufacturing processes. However, we believe that we have built a very capable manufacturing unit, both in terms of facility and competency, and we may pursue retaining this infrastructure if we successfully raise the necessary funding to support such capability in mid-2009 or if the capability could be maintained by an acquirer of our manufacturing asset.

*Intellectual property assets.* We have developed and licensed significant proprietary intellectual property, including methods of transferring genetic material into cells, processes to manufacture and purify gene therapeutic candidates, uses of AAV to deliver RNA therapeutics, including RNAi, and other proprietary technologies and processes. Because patent and license rights are important assets of our business, our current strategy is to continue to file or license patent applications to protect technology, inventions and improvements to inventions that we consider important to developing our business. In 2008 and early 2009, we analyzed the financial impact of continuing to support our very broad-based strategy of intellectual property for our AAV patent portfolio. We determined that, based on our current financial resources and the status of our current product development efforts, certain intellectual property assets are not essential for currently identified product opportunities and, as a result, we have either returned those rights to our licensors and/or have ceased prosecution of those patents. However, we continue to maintain intellectual property that supports our core product development and manufacturing infrastructure capabilities. We also rely on unpatented proprietary technology such as trade secrets, know-how and continuing technological innovations.

## ***Business Strategy***

Our current strategic focus includes:

*Pursuing strategic transaction opportunities.* We are committed to gene therapeutics and have made substantial progress toward late-stage development of AAV-based gene therapeutics. However, gene therapeutic products have not yet reached commercialization in the U.S., Europe or Japan. We realize that our available resources, the current economic environment and a lack of available financing opportunities may make it impossible or undesirable to proceed as an independent entity. As a result, we believe it is prudent to pursue potential strategic combinations, product diversification and/or additional expense reduction strategies, with a particular focus on companies or product candidates to which we might be able to contribute our significant development and manufacturing expertise and intellectual property portfolio. We believe that a combination of novel product candidates developed from our expertise in gene therapeutics, along with complementary product candidates or technologies, may provide a beneficial balance of value and risk diversification for our shareholders. Because we believe a sale of the company, a merger with another company or other strategic transaction may provide value to shareholders, we are exploring potential strategic transaction opportunities in tandem with our other business strategies.

*Scaled development of our pipeline.* Our current priority is applying our substantial expertise and intellectual property to the development of promising product candidates, and we are currently focusing our efforts to advance three programs: the LCA program with our collaborator Dr. Robin Ali at UCL/M for the treatment of eye disease, the ALS program with our collaborator Dr. John Engelhardt at UI for the treatment of ALS and the HD program with our collaborator Dr. Beverly Davidson at UI as our first RNAi-based therapeutic candidate.

*Maximizing the value of our manufacturing and development expertise, our pipeline and our intellectual property.* Our strategy is to utilize our product development, regulatory and manufacturing capabilities in new product collaboration opportunities, which may be similar to the development and manufacturing collaboration we previously entered into with Celladon or limited to just product development. We also continue to pursue opportunities to license our

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technology and leverage our portfolio of AAV-related intellectual property assets to generate revenue. We may also pursue selling intellectual property that is not being used in current product development efforts or selling or licensing our rights to partnered or self-funded product candidates that we are or were developing.

### **2008 Achievements**

In 2008, we made progress in our development collaborations and our product development programs. Specifically:

In April 2008, we acquired full exclusive rights to our preclinical HD program from Sirna Therapeutics, a wholly owned subsidiary of Merck & Co., Inc., or Merck.

In April 2008, we and our collaborators published preclinical data characterizing the novel use of AAV to deliver small interfering RNA for the treatment of HD.

In April 2008, we and our collaborators announced encouraging interim results from a Phase I/II clinical trial demonstrating that the treatment of three young adults with LCA with an AAV vector containing the RPE65 coding sequence resulted in improved visual function in one patient.

In May and June 2008, we announced positive interim Phase I/II clinical trial findings for the clinical trial of tgAAC94 for the treatment of inflammatory arthritis.

In October 2008, the DOD's Amyotrophic Lateral Sclerosis Research Program awarded grant funding of up to \$2.4 million for us to apply towards preclinical development of a small molecule for an investigational new drug for the treatment of ALS.

In October 2008, we announced positive results for the completed clinical trial of tgAAC94 for the treatment of inflammatory arthritis. The data demonstrated that tgAAC94 is well tolerated and there is a trend in improvement based on patient reported outcome measures.

In November 2008, we realigned and narrowed our product development priorities to focus on our ocular and neurological product candidates, including our first product development effort to evaluate the use of AAV to deliver expressed RNAi. In conjunction with this pipeline prioritization, we reduced our payroll costs by 25% and reduced other costs by 15% as compared to 2008, including reductions resulting from the resignations of our chief executive officer and chief scientific officer.

### **Primary Product Development Programs**

#### ***Leber's Congenital Amaurosis***

Leber's congenital amaurosis is part of a family of eye retinitis pigmentosa diseases and generally causes blindness before adulthood. One cause of LCA is a mutation in the RPE65 gene. The RPE65 gene makes a protein in the retinal epithelium that is necessary for the normal visual pigment cycle to take place. Without this protein, the eye photoreceptor cells do not work properly, leading to blindness.

We initiated our LCA program in 2005 when we entered into a collaboration agreement for an AAV-RPE65 product candidate with the University College London and Moorfields Eye Hospital. In May 2007, UCL/M initiated a Phase I/II clinical trial for this program using vector we manufactured. In April 2008, our collaborator at UCL/M, Robin Ali, Ph.D., reported promising early results at a conference for the Association for Research in Vision and Ophthalmology, indicating improved visual mobility and night vision in

one patient. The findings were published in the May 2008 issue of the *New England Journal of Medicine*. We anticipate completion of the current trial, including dose escalation, in mid to late 2010. Based on the possible short time to market for a potential drug of this type, assuming the continued success of the current clinical trial and that we raise additional capital to fund continued work in this program, we intend to continue pursuing an LCA product candidate and, potentially, leverage our work on the AAV-RPE65 product candidate to pursue treatment of additional ocular

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diseases. We currently have the right under the collaboration agreement to use the data, know-how and other proprietary information from the clinical trial to commercialize product candidates outside the United Kingdom, and are in the process of negotiating worldwide commercialization rights in exchange for royalties and milestone payments.

### ***Huntington s Disease***

Huntington s disease is an incurable neurodegenerative disorder that results from a mutation in the gene that codes for the huntingtin protein. This mutant gene produces a defective huntingtin protein that leads to eventual development of the progressive disease. HD generally shows onset in mid-life and, according to the Huntington s Disease Society of America, one of out of every 10,000 Americans has HD and an additional 200,000 are at risk of onset. There are no effective drugs to treat or prevent this disease.

HD is a dominant genetic disease, which means that a single copy of the mutant gene can cause the disease. It also means that delivery of a correct copy of the gene will not be effective to treat or prevent the disease. Rather, the function of the mutant HD gene must be blocked. A potentially effective way to do this is to use recently discovered small interfering RNA, also referred to as RNAi. RNAi can bind to mRNA, a step between the gene and the protein, and cause the degradation of the mRNA before the mRNA is used for production of protein. In this way, RNAi can be used to reduce the amount of disease-causing proteins by preventing or reducing the mRNA that is available for the production of proteins.

In 2005, we formed a collaboration with Sirna Therapeutics, or Sirna, to develop AAV-based approaches for the treatment of HD. This collaboration also included an academic group at the University of Iowa. The HD program is focused on developing therapeutic RNAi to target the gene that encodes the HD protein. Because RNAi must be administered directly to the brain, which is the site of the disease, infrequent dosing is highly desirable. Consequently, this program uses the AAV delivery system to deliver an RNAi construct that targets the HD RNA and can be expressed for a prolonged period. The program is based upon initial proof of concept of correction of HD using this approach in a mouse model of HD that was reported by our collaborators at UI.

Sirna was purchased by Merck in December 2006. Following a subsequent review by the Merck Research Laboratories, or MRL, certain programs at Sirna were determined to be outside of the broader MRL objectives. In May 2008, we acquired Sirna s portions of the rights to the HD program and brought this program fully into our internal development pipeline. The transfer of rights to us from Merck included the assignment of a license agreement with Beverly Davidson, Ph.D. at UI and access to intellectual property owned by Sirna/Merck that relates to development of an expressed AAV therapeutic for the treatment of HD.

Our HD program takes advantage of our expertise and intellectual property in production and use of AAV delivery systems, applying them to the field of RNAi. We think that a promising application of AAV as a delivery system is in the field of delivering short hairpin structures and micro RNAs to be expressed by a cell. In the late 1990 s, when therapeutic RNA molecules such as RNAi were initially tested in animals, we believe we were the first to develop and file patent applications on the use of AAV vectors to express these potential therapeutics. We believe expressed therapeutic RNA, where the drug is delivered and synthesized inside the cell by the AAV vector, will have significant advantages over traditionally delivered synthetic oligonucleotides, which must be delivered externally to the cells and taken up by the cells. We believe these improvements offered by an AAV vector approach will provide for increased bioavailability, a longer drug half life and infrequent dosing, all of which are significant advantages for certain disease indications. The program currently is focused on optimization and testing of lead drug candidates in mouse models by Dr. Davidson at UI. Based on successful identification of a drug candidate and assuming we raise additional capital to fund continued work in the HD program, we intend to conduct a safety study in non-human primates and move forward to clinical trials.

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### ***Amyotrophic Lateral Sclerosis***

Amyotrophic lateral sclerosis, commonly known as Lou Gehrig's disease, is a progressive neurodegenerative disease affecting neurons in the brain and spinal cord. The degeneration of these motor neurons limits communication from the brain and spinal cord to muscle fibers throughout the body, leading to the inability of the brain to initiate and control muscle movement. Early symptoms of ALS often include muscle weakness, resulting in loss of control in arms and legs, speech, swallowing or breathing. Death follows within an average of 3-5 years of diagnosis. ALS currently affects approximately 30,000 patients in the United States and affects approximately 5,600 additional patients per year. There is no cure for ALS, and an effective treatment for ALS would fill a significant unmet clinical need. In the past ten years over 20 drugs have been evaluated, with only riluzole (Rilutek) emerging as an approved product for treatment of ALS.

Based on novel observations made, and experiments performed, in the laboratory of John Engelhardt, Ph.D. at the University of Iowa, a long-time collaborator of ours, a role for the mechanism of oxidative stress in the neurological condition of ALS has recently been described. We believe that these findings for the role of oxidative stress in ALS may potentially have implications for other neurodegenerative diseases, as the same mechanism may be common to other neurodegenerative disorders such as Parkinson's disease and Alzheimer's disease.

Dr. Engelhardt's preclinical studies addressing a certain mutation of ALS have indicated that a certain gene mutation present in inherited forms of ALS activates NADPH oxidase, leading to increased production of superoxide, causing neuronal death. Dr. Engelhardt's studies further identified a small molecule compound that may potentially regulate oxidase involved in the production of superoxide. Dr. Engelhardt has broadly filed patent applications covering the drug candidates we are testing as well as additional compounds that may be involved in the mechanism of oxidative stress and its role in neuronal death. We believe that this compound and the mechanism of action elucidated in the Engelhardt studies can be generalized to the larger ALS population, and we have an option to license Dr. Engelhardt's patent rights related to this compound and mechanism of action. Under our grant with the Department of Defense, we are manufacturing and testing this ALS small molecule drug candidate for use in preclinical pharmacokinetic and safety studies. If these studies have favorable results and we raise additional funding, our goal is to initiate a clinical program to test this drug candidate in all subsets of ALS patients. Once data have been generated in the ALS patient population, our aim is to expand evaluation of the small molecule drug candidate to other neurodegenerative diseases such as Parkinson's disease and Alzheimer's disease, where the same mechanism may contribute to the disease.

### **Other Product Development Programs**

#### ***Heart Failure***

According to the American Heart Association, over five million Americans currently suffer from heart failure, and approximately 550,000 new cases are diagnosed each year. Heart failure results from the inability of the heart to pump blood efficiently, which is frequently caused by the loss of contractility of the heart muscle. The contraction and expansion of the heart muscle is dependent upon movement of calcium within the heart muscle. One protein that is central to the process of calcium movement in the heart muscle is SERCA2a, the relative amount and activity of which is lower in failing hearts. It has not yet been possible to develop conventional pharmaceutical drugs to address this problem. As a result of data from pre-clinical studies, we believe that delivery of the gene that produces SERCA2a directly to the heart muscle should lead to production of more SERCA2a protein, which may improve the ability of the heart to contract and thus improve its ability to pump blood.

In 2004, we entered into a product development and manufacturing collaboration with Celladon, a company focused on the delivery of genes to the heart that may have a therapeutic benefit in the treatment of heart failure. Under the original collaboration agreement, Celladon also funded our

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product development efforts. We contributed our proprietary AAV technology to deliver the SERCA2a gene for use in the field of heart failure, and we manufactured the rAAV1-SERCA2a vector for use in the clinical trials sponsored by Celladon.

In May 2007, Celladon initiated a Phase I/II clinical trial of rAAV1-SERCA2a, also known as MYDICAR<sup>®</sup>. The trial is a two-stage, dose-escalation trial designed to evaluate the safety and feasibility of a single coronary artery infusion of four dose levels of an AAV1 vector expressing the transgene for SERCA2a to subjects with ischemic or non-ischemic cardiomyopathy and New York Heart Association Class III/IV symptoms of heart failure. In Stage 1 of the trial, 12 subjects were enrolled in four cohorts and each cohort was treated with one of four escalating doses of open-label MYDICAR<sup>®</sup>. In Stage 2 of the trial, up to 37 subjects will be randomized to receive either MYDICAR<sup>®</sup> in one of three doses or placebo. Celladon is currently enrolling patients for Stage 2.

In February 2009, we and Celladon agreed to replace our product development and manufacturing collaboration with a license agreement and new manufacturing agreement. Under the terms of the modified agreements, we granted Celladon exclusive use of certain proprietary AAV vector technology in an expanded field, including heart failure, where changes in calcium cycling have contributed to or caused disease conditions. The modified agreements enable Celladon to manufacture MYDICAR<sup>®</sup> through CMOs or a commercial product development partner and under the agreements Celladon increased its payments to us in the first six months of 2009 to support manufacture of MYDICAR<sup>®</sup> for phase III clinical studies at our facilities. In addition, we and Celladon agreed to a new milestone payment and royalty structure covering potential development and commercialization of products in the permitted field, and Celladon agreed to make payments to us in the event of specified strategic transactions involving Celladon. If Celladon is successful in commercializing a product covered by the license agreement, we could receive significant future revenue in milestone payments and royalties on product sales. Our current work plan for manufacturing efforts with Celladon extends through July 2009 and Celladon has the right to terminate the license agreement without cause with sixty days notice after June 30, 2009.

In late 2004, in connection with the formation of the original collaboration, we received \$6.0 million cash from the sale of shares of our common stock to investors of Celladon. Since 2004, we have recognized cumulative revenue of \$13.7 million in connection with the agreements with Celladon, including the recognition of the first development milestone payment. In the future, we also may earn additional development milestone payments, regulatory milestone payments, royalties on sales of potential future products, and payments relating to partnering, licensing and/or merger or asset sale transactions for products covered by the license agreement.

## ***HIV/AIDS Vaccine***

Since 2000, as part of a collaboration with the International AIDS Vaccine Initiative, or IAVI, and Nationwide Children's Hospital (formerly known as Columbus Children's Research Institute), or NCH, and with the addition of Children's Hospital of Philadelphia, or CHOP, in 2006, we have been developing an AAV prophylactic vaccine candidate, which we call tgAAC09, to protect against the progression of human immunodeficiency virus, or HIV, infection to AIDS for high-risk populations in developing nations. Beginning in 2003 and through 2007, we reported data that tgAAC09 is safe and well-tolerated at all dose levels in various Phase I and Phase II clinical trials and reported data from a Phase II study that indicate modest, dose-dependent immunogenicity. Based on these data, we and our collaborative partners agreed that, ultimately, a more immunogenic vaccine would probably involve several additional HIV-1 genes. This avenue is to be explored in subsequent trials that we currently expect the National Institute of Allergy and Infectious Disease, or NIAID, to initiate in 2009 or 2010 utilizing drug that we manufactured on their behalf.

Under the terms of our collaboration with IAVI, we received the rights to utilize the findings from the IAVI-funded program to develop and commercialize HIV/AIDS vaccines for both the developed world and for any additional vaccine candidates. While the terms of our IAVI collaboration extend until

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the expiration of the term of the last patent within the patent rights controlled by us and utilized in the IAVI vaccine, we completed work on this collaboration in 2007 as the product candidate completed Phase II clinical trials. As a result, we do not expect any additional funding from IAVI.

In 2005, we extended the scope of our HIV/AIDS vaccine program to include the developed world, through a contract awarded by the NIAID to NCH in collaboration with CHOP and us. The NIAID is part of the National Institutes of Health, or NIH. This NIAID vaccine program focuses efforts on developing an AAV-based, multi-component vaccine that will contain various antigens from different HIV strains and will be tested in a prime-boost approach using different AAV serotypes. Under this program, we have recognized \$10.6 million of revenue for our portion of the development, manufacture and preclinical testing of vaccine candidates, with the funding amount for each year depending on the scope of our development efforts for that year. We and the NIAID have completed preclinical testing and manufacturing and aim to advance into clinical trials in healthy volunteers in mid-to-late 2009 or 2010. In early 2009, in connection with our realignment efforts, we began to terminate our portion of the contract as our work on the program is nearing completion and the program is entering into clinical trials. The direct costs of any clinical trials will be borne directly by the NIAID. Upon termination, we will only be reimbursed for costs related to the program that occurred up to the termination date. We expect a decreased amount of funding from NIAID in 2009 as we wind down our portion of the development efforts and terminate our involvement in this program.

## ***Inflammatory Arthritis***

Since before 2000, we self-funded development of a product candidate, which we call tgAAC94, for the treatment of inflammatory arthritis, including rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. Researchers have found that the cytokine called tumor necrosis factor-alpha, or TNF-alpha, plays a pivotal role in this disease process and have shown TNF-alpha inhibitor therapies to be a valuable strategy to treat inflammatory arthritis. TNF-alpha inhibition is a validated therapeutic strategy for treating inflammatory arthritis, and three TNF-alpha inhibitors are now sold worldwide. However, some patients do not have a complete response to these systemically delivered TNF-alpha inhibitor agents and still have significant room for improvement in inflammation and tender and swollen joint counts. These patients may be ideal candidates for localized delivery of TNF-alpha inhibitor therapy administered directly to the joint. tgAAC94 is an AAV vector product candidate designed to deliver a DNA sequence encoding a potent TNF-alpha inhibitor directly to the affected joint. In 2004, we initiated a Phase I clinical trial to evaluate the safety of escalating doses of tgAAC94 in 15 subjects with rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis who were not being treated with systemic TNF-alpha inhibitors. Based on the favorable results of this Phase I safety study, we initiated a follow-on Phase I/II clinical trial of tgAAC94 administered directly to affected joints of subjects with inflammatory arthritis. This double-blinded, placebo-controlled study was designed to evaluate higher doses of tgAAC94 in patients with rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis who may or may not be receiving concomitant treatments of TNF-alpha inhibitor therapy. This Phase I/II clinical trial was completed in October 2008 and, based on the data, we found that our potential product candidate demonstrated safety and tolerability and we reported encouraging data on improvement based on patient-reported symptoms-early signs of efficacy that suggested further study is warranted. In the fourth quarter of 2008, as a part of a strategic alignment of our product priorities, we decided that we will only move this program forward into the next clinical studies with additional funding from a development and commercialization partner.

## **Research and Development Expenses**

Research and development expenses were \$15.2 million in 2008, \$17.7 million in 2007 and \$14.5 million in 2006.

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### **Significant Sources of Revenue**

Our primary source of revenue is from our collaborative agreements. In 2008, revenues from our collaboration with Celladon accounted for 56% our revenue, and revenues under our subcontract with the NIAID accounted for 42% of our revenue.

### **Patents, License Agreements and Proprietary Rights**

Our patent position, licensing arrangements and proprietary technology are subject to risks and uncertainties, including those described in the section entitled *Risk Factors* in Item 1.A of this annual report.

Patents and licenses are important to our business. In the past, our strategy has been to broadly file or license patent applications to protect technology, inventions and improvements to inventions that we considered important to developing our business. We broadly sought patent protection for and licensed technologies that related to our business strategy and the product development candidates in our pipeline and/or that may have been important to future product candidates. This strategy resulted in our owning or licensing numerous patents or patent applications that were filed with the United States Patent and Trademark Office and foreign jurisdictions.

In 2008 and early 2009, we reviewed our very broad-based AAV patent portfolio. We determined that, based on the status of our and others' current product development efforts and our current financial resources, certain intellectual property assets are not essential to our current business strategy and we have therefore either returned those rights to our licensors or ceased prosecution of those patents. However, we continue to maintain intellectual property that supports our core product development and manufacturing infrastructure capabilities. This proprietary intellectual property includes methods of transferring genetic material into cells, processes to manufacture and purify gene delivery product candidates and other proprietary technologies and processes. We also rely on unpatented proprietary technology such as trade secrets, know-how and continuing technological innovations.

We have licensed technology underlying a number of issued and pending patents, including two licenses to patents covering certain aspects of the manufacture of AAV and the use of AAV vectors for gene delivery. Our exclusive license with Alkermes, Inc. provides us with rights to patents broadly covering a manufacturing method that we believe is critical to making AAV-based products in a commercially viable, cost-effective manner. This technology, developed by NCH, covers the use of cell lines for manufacturing AAV vectors. Our license with the University of Pennsylvania, or Penn, provides us with exclusive and non-exclusive licenses to AAV vectors, including exclusive rights to components of a specific serotype of AAV called AAV1. AAV vectors may be particularly well-suited for the development of certain product candidates based on characteristics of the AAV1 serotype. As a result of our efforts to refocus our patent portfolio to align it with our current business strategy, we entered into an amended license agreement with Penn in January 2009 and we relinquished our rights and eliminated our financial and other obligations with respect to a number of patents and patent applications licensed from Penn.

Many of our exclusive licenses include the right to sublicense the rights thereunder to third parties. For example, we have the right under the Penn license to sublicense our patent rights, and when we enter into such a sublicense we must pay Penn certain financial payments including fees. In 2006, we entered into our first non-exclusive, perpetual sublicense under the Penn license with Amsterdam Molecular Therapeutics B.V., or AMT. We may receive milestone payments based on the progress of AMT's products subject to the license from clinical trial phases to regulatory approvals, as well as royalties based on a percentage of net sales of products subject to the license. We have an obligation to pay Penn a portion of the sublicense payments we receive from AMT or any other future sublicense. For example, in September 2007, we received one of the defined milestone payments from AMT and we paid Penn a portion of that milestone. We also have license agreements for some of our technologies that may require us to sublicense certain of our rights.



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Our licenses have many financial and other obligations. Our licenses contain provisions generally found in biotechnology licenses, including upfront licensing payments, annual maintenance fees, product development milestones and a royalty on sales of products subject to the license. Our licenses generally extend through the life of the patent rights granted under the license. In general, our licensors have the right to terminate the license if we breach the agreement or become insolvent. Our exclusive licenses typically include diligence requirements that must be met to retain exclusivity, which generally requires us to develop the licensed technology within a specified time frame, and may include technology advancement requirements, product development milestones and reporting of our investment in the technology. In general, if we do not meet these diligence hurdles of our license agreements, we lose exclusivity for certain or all indications included in the license field. In addition, in certain instances our licenses include provisions under which license exclusivity is granted for a specified period of time and then may shift to non-exclusive rights or some combination of exclusivity and non-exclusivity.

We will continue to periodically review our intellectual property portfolio, including in-licensed and owned patents, patent applications, trade secrets, know-how and continuing technological innovations to evaluate the scope of the intellectual property necessary to conduct our core business. These reviews allow us to identify patents and technology that may no longer be relevant, useful or necessary in conducting our business to consider amending our current in-licenses accordingly to either increase or decrease our rights and obligations. We may also identify new intellectual property we wish to access either from external sources through new in-licensing or identify areas in which we wish to focus on further developing and protecting our own proprietary information. Decisions implemented as a result of these periodic reviews may impact the overall scope, rights and obligations of our intellectual property portfolio.

The patent positions of pharmaceutical and biotechnology firms, including our patent position, are uncertain and involve complex legal and factual questions for which important legal issues are largely unresolved, particularly with regard to gene therapy 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. In addition, the costs of resolving any complex legal issues or proceedings regarding the coverage of any patent application may be prohibitive or may limit our ability to resolve such conflicts, resulting in significantly reduced coverage of the affected patent. Licensing of intellectual property critical to our business also 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.

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 and licensing 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 intellectual property, 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

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that may be related to our business. Some of these technologies, applications or patents may conflict with our technologies, patents 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, or exclusive licenses covering 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 exclusive licensee 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 commercial sales related to 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, significantly divert the efforts of our technical and management personnel and materially and adversely affect our business.

## **Competition**

Competition among biotechnology and pharmaceutical companies that research, develop, manufacture and commercialize therapeutic products is significant. In the field of gene therapy, numerous companies and institutions are developing or considering the development of gene 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 sources developing competitive gene therapy technologies, our potential products will compete with non-gene therapy products in development and on the market for the therapeutic indications we are targeting. These competitive products could include small molecules, proteins, monoclonal antibodies and other pharmaceutical products, medical devices and surgery. Products in development could make our products obsolete before they ever get to the market. Products on the market could negatively affect the commercial opportunity for our products. Intense competition could heighten disputes pursued in an effort to slow our development, including lawsuits, demands, threats or patent challenges. We also compete with others to acquire products or technology from research institutions, universities and other companies. In addition, we compete with others to maintain and attract the scientific and business personnel necessary to advance our programs.

Many of our competitors have substantially more financial and other resources, larger research and development staff and more experience and capabilities in researching, developing and testing products in clinical trials, obtaining U.S. Food and Drug Administration, or 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, receive FDA and other regulatory approvals 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

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compete with respect to achieving commercial manufacturing efficiency and marketing capabilities that are comparable to other types of drugs, areas in which we have no experience. These cost and marketing advantages of our competitors' technologies and products or potential technologies or products 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.

Each of our product candidates developed by us or our collaborators is aimed at competitive target markets. A number of products are currently under development by other companies to treat each of the disease targets that we and our collaborators seek to address. For example, there are a number of treatments successfully marketed to treat people with heart failure. Products in development or on the market for heart failure could negatively affect the development path and market opportunity for MYDICAR®. Delays in clinical development, whether connected or not connected to our drug candidates or to gene therapeutics, could delay our development timelines.

## **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 pre-market approval procedures administered by the 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 regulations may also apply.

Gene therapeutics are based on relatively new technologies that have not been extensively tested or shown to be effective in humans. The FDA reviews all product candidates for safety at each stage of clinical testing. Safety standards must be met before the FDA permits clinical testing to proceed to the next stage. Also, efficacy must be demonstrated before the FDA 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 therapy product candidates and commercialized products are subject to change. The approval process, and ongoing compliance with applicable regulations after approval, involves substantial expenditures of financial and other resources. To date we have not received approval of any of our product candidates.

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, how the body processes and reacts to the drug and pharmacodynamics, the effects the drug is actually having 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 Institutional Review Board or Ethics Committee charged with evaluating each trial and any trial amendments to ensure that the trial is ethical, subjects 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 subjects may give their informed consent. Clinical trials must be conducted in accordance with the FDA's 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

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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 research involving recombinant DNA must also comply with the NIH Recombinant DNA Guidelines, and the clinical trials conducted at those institutions are subject to a review by the NIH's Office of Biotechnology Activities, or OBA, Recombinant DNA Advisory Committee, or RAC. The purpose of the RAC is to provide advice and recommendations to the NIH Director on the conduct and oversight of research involving recombinant DNA, including the content and implementation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, or NIH Guidelines. All protocols involving gene transfer are submitted to the RAC. The outcome after submission can be either an assessment of protocol without a public review or a requirement that the protocol be publicly reviewed at a quarterly committee meeting. Although the RAC does not have regulatory status, the RAC review process can impede the initiation of the trial because no research participant can be enrolled until the RAC review process has been completed and Institutional Biosafety Committee, or IBC, approval (from the clinical trial site) has been obtained, even if the FDA has reviewed and approved the protocol and initiation of the clinical trial. The final IBC approval is granted only after the RAC review process has been completed and the IBC ensures compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines. No research participant can be enrolled at the clinical trial site until the NIH OBA receives the IBC approval (from the clinical trial site), the Institutional Review Board approval and Institutional Review Board-approved informed consent document.

Clinical trials are typically conducted in three phases, often involving multiple clinical trials in each phase. In Phase I, clinical trials generally involve a small number of subjects, 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 subjects 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 subjects 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, and the FDA 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 subjects 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 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 or similar approval required by foreign regulatory agencies, as well as the approval of several other governmental and nongovernmental agencies, before we can market the product in the United States or in foreign countries. 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

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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 increases. 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. For example, the FDA placed a clinical hold on our Phase I/II clinical trial of tgAAC94, our inflammatory arthritis product candidate, after a patient participating in the clinical trial experienced a serious adverse event. While this clinical hold did not affect our enrollment, as all subjects had been enrolled into the trial, it did delay the completion of the study.

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, recordkeeping and quality control. Our manufacturing facilities (or if a CMO does the manufacturing for the applicable product or product candidate, the CMO's 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**

As of December 31, 2008, we had 58 full-time-equivalent employees and, as of March 1, 2009, we had 47 full-time-equivalent employees. Six of our 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. We also rely on a number of temporary staff positions and third-party consultants. None of our employees are covered by a collective bargaining agreement.

## **Available Information**

We were incorporated in the state of Washington in 1989. Our executive offices are located at 1100 Olive Way, Suite 100, Seattle, Washington 98101, and our telephone number is (206) 623-7612. We file annual, quarterly and current reports, proxy statements and other information with the SEC. We make available in the investor relations portion of our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports after filing these reports with the SEC. Our website is located at [www.targetedgenetics.com](http://www.targetedgenetics.com). You may also obtain free copies of our periodic reports on the SEC web site at <http://www.sec.gov>.

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### Item 1A. Risk Factors.

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

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

***If we are unable to raise additional capital or secure additional sources of funding in the very near term, we will be unable to continue our operations.***

We have very limited capital resources and continue to incur significant operating losses, which threaten, and raise substantial doubt about, our ability to continue as a going concern. We currently expect that our existing financial resources will be sufficient to fund our current level of operations only through the second quarter of 2009, and actual results could differ from this estimate. This estimate is based on our ability to successfully perform planned activities and the receipt of expected funding under our collaborations and grants, and actual results could differ from our estimates. If we are unable to secure additional capital by early in the second quarter of 2009, we will be forced to implement additional cost reduction measures, such as staff reductions and suspending some or all of our self-funded product development efforts, to further extend our cash horizon. Even if we are able to extend our cash horizon, if we do not receive sufficient additional funding in time, we will be required to cease operations, declare bankruptcy or otherwise wind up our business, which may result in the loss of all or substantially all of the investment of our shareholders.

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

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

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

the number of employees required to maintain our product development and manufacturing operations and also provide required general and administrative support;

our success in performing under our agreements with Celladon Corporation and the grant from the Department of Defense, or DOD for our amyotrophic lateral sclerosis, or ALS, program; and

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

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

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



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the timing, costs and scope of, and our success in, conducting clinical trials, obtaining regulatory approvals and maintaining and expanding our patent portfolio;

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

our success in pursuing a settlement of our remaining obligations under our facility lease in Bothell, Washington after surrendering control of that facility in February 2009 and discontinuing rent payments, and whether the landlord terminates the lease as a result of this default and, among other potential remedies, accelerates our obligations due under the lease;

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

whether we are successful in transferring our manufacturing technology and know-how to a CMO;

competing technological and market developments;

which intellectual property we secure and protect related to our research and development programs;

the existence and outcome of any litigation or administrative proceedings involving intellectual property; and

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

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

strategic transactions, such as mergers and acquisitions;

selling or licensing our technology or product candidates;

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

issuing equity in the public or private markets;

borrowing under loan or equipment financing arrangements; and

issuing debt.



## Edgar Filing: TARGETED GENETICS CORP /WA/ - Form 10-K

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

If we raise additional funds through the issuance of equity or debt securities, the securities may have rights, preferences or privileges senior to those of the rights of our common stock, and our common stockholders will experience additional dilution. The perceived risk associated with the possible sale of a large number of shares of our common stock could cause some of our shareholders to sell their stock, thus causing the price of our stock to decline. In addition, actual or anticipated downward pressure on our stock price due to actual or anticipated sales of stock could cause some institutions or individuals to engage in short sales of our common stock, which may itself cause the price of our stock to decline.

If our stock price continues to decline, or does not increase sufficiently, we may be unable to raise additional capital. Additional declines in the price of our common stock, or a failure of the price of our

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common stock to increase sufficiently, could also impair our ability to attract and retain qualified employees, reduce the liquidity of our common stock and result in the delisting of our common stock from the NASDAQ Capital Market. Even if our stock price increases sufficiently, we nonetheless expect to be delisted because of non-compliance with the \$2.5 million shareholders equity requirement of Marketplace Rule 4310(c)(3) resulting from our goodwill impairment. If we are delisted from the NASDAQ Capital Market as we currently expect, then our ability to raise additional capital through the equity markets will be substantially harmed. Debt financing, if available, may require that we pledge our assets, including our intellectual property, or may require restrictive covenants that would restrict our business activities.

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

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

Substantially all of our revenue since 2005 has been derived from collaborative research and development agreements in connection with the development of our potential product candidates, including our collaborations with Celladon Corporation and the International AIDS Vaccine Initiative, or IAVI, and our subcontract with Nationwide Children's Hospital, or NCH, and Children's Hospital of Philadelphia, or CHOP, funded by the National Institute of Allergy and Infectious Disease, or NIAID. We have incurred, and will continue to incur for the foreseeable future, significant expense to develop our research and development programs, conduct preclinical studies and clinical trials, seek regulatory approval for our product candidates and provide general and administrative support for these activities. As a result, we have incurred significant net losses since inception, and we expect to continue to incur substantial additional losses in the future.

As of December 31, 2008, we had an accumulated deficit of \$320.9 million. We may never be able to commercialize our products or generate profits and, if we do become profitable, we may be unable to sustain or increase profitability.

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

As of December 31, 2008, the heart failure product candidate developed under our collaboration with Celladon is in a Phase I/II clinical trial, the HIV/AIDS product candidate developed under our collaboration with IAVI has completed both a Phase I and Phase II trial, the product candidate for Leber's congenital amaurosis, or LCA, developed under our collaboration with the University College London/Moorfields Eye Hospital is in a Phase I/II clinical trial, we have completed a Phase I/II trial of our inflammatory arthritis candidate, and we have no product candidates in Phase III trials. Our product candidates for ALS and Huntington's disease, or HD, are currently in preclinical development. Of the product candidates that we and/or our partners are currently developing, we will not generate any product revenue, commercial manufacturing revenue, revenue sharing or royalties for at least several years, and then only if we and/or our partners can successfully commercialize our product candidates. Commercializing our potential products depends on successful completion of additional research and development and testing, in both preclinical development and clinical trials. Clinical trials may take several years or more to complete. The commencement, cost and rate of completion of our clinical trials may vary or be delayed for many reasons. If we are unable to successfully complete preclinical

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and clinical development of some or all of our product candidates in a timely manner, we may be unable to generate sufficient product revenue to maintain our business.

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

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

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

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

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

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

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

delays in enrolling patients into clinical trials;

lower than anticipated retention rates of patients in clinical trials;

the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, poorly executed testing or unacceptable design;

an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;

the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval; or

an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation.

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

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

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

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inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that a trial presents unacceptable health risks; or

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, or CROs, and other third parties.

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

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

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

Clinical trials and the marketing of any potential products may expose us to liability claims resulting from the testing or use of our products. Gene therapy treatments are new and unproven, and potential known and unknown side effects of gene therapy may be serious and potentially life-threatening. Product liability claims may be made by clinical trial participants, consumers, healthcare providers or other sellers or users of our products. For example, a patient in one of our clinical trials experienced an SAE and subsequently died. Even though the NIH's Office of Biotechnology Recombinant DNA Advisory Committee, or RAC, and the trial's independent data safety monitoring board determined that the SAE was not caused by our drug, the spouse of that patient has filed a lawsuit alleging that various named parties' negligence, including ours, was the proximate cause of the patient's death. Although we currently maintain liability insurance, the costs of product liability and other claims against us may exceed our insurance coverage. In addition, we may require increased liability coverage as additional product candidates are used in clinical trials or commercialized. Liability insurance is expensive and may not continue to be available on acceptable terms. A product liability or other claim or product recall not covered by or exceeding our insurance coverage could significantly

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harm our financial condition. In addition, adverse publicity resulting from a product recall or a liability claim against us, one of our partners or another gene therapy company could significantly harm our reputation and make it more difficult to obtain the funding and collaborative partnerships necessary to maintain our business.

***If we lose our collaborative partners or we do not receive the funding we anticipate under our collaborative agreements or grants, we may be unable to develop our potential products.***

A substantial portion of our operating expenses are funded through our collaborative agreements with third parties. Our HIV/AIDS vaccine collaboration with CHOP and NCH is funded through a subcontract with NIAID, which is a U.S. government agency. We also have a heart failure program with a biotechnology company, Celladon, and a grant from the U.S. Department of Defense, or DOD, in support of developing a product candidate to treat ALS. Each of these collaborations or grants provides for funding, collaborative development, intellectual property rights and/or expertise to develop certain of our product candidates. The Celladon contract providing funding for our development and manufacturing efforts terminates at the end of that campaign, but no later than July 31, 2009. We also expect to complete the work plan for the DOD-funded preclinical efforts for ALS by the end of the fourth quarter of 2009. We expect to complete our development and manufacturing work related to the NIAID-funded HIV/AIDS vaccine candidate in the first half of 2009 and terminate our involvement in this program, as the vaccine candidate enters into clinical testing. To the extent that we lose collaborative partners or grant funding for a program or a portion of a program that we do not fund internally, or to the extent that we do not receive the funding that we expect from our collaborative agreements or grants, unless we are able to obtain alternative sources of funding, we would be delayed in or unable to continue developing potential products under the affected program (or, in the case of Celladon, complete the current manufacturing campaign). With limited exceptions, each collaborator or grantor has the right to terminate its obligation to provide research funding at any time for scientific or business reasons. For example, in 2008 Sirna Therapeutics, a wholly-owned subsidiary of Merck & Co., Inc., ceased collaborating with us on our HD program and instead transferred the rights necessary to conduct the program to us. In addition, to the extent that funding is provided by a collaborator for non-program-specific uses, the loss of significant amounts of collaborative funding could result in the delay, reduction or termination of additional research and development programs, a reduction in capital expenditures or business development and other operating activities, or any combination of these measures, which could seriously harm our business.

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

We expect to depend on collaborators, partners, licensees, CROs, manufacturers and other third parties and strategic partners to support and fund our discovery and development efforts, to formulate product candidates, to conduct clinical trials for some or all of our product candidates, to manufacture clinical and commercial scale quantities of our product candidates and products and to market, sell, and distribute any products we successfully develop. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with additional collaborators, partners, licensees, clinical investigators, manufacturers and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates, which will in turn adversely affect our business. For example, we do not intend to move the development of our treatment of inflammatory arthritis, tgAAC94, forward to additional clinical studies without additional external funding from a third party.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts of our expenditures will be paid to third parties in these relationships. However, we

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cannot control the amount or timing of resources our contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all.

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

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

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

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

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

Both before and after approval of our product candidates, we, our product candidates and our suppliers are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: warning letters; fines and other monetary penalties; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution. We or the FDA may suspend or terminate human clinical trials at any time on various grounds. For example, after an SAE occurred in our 2007 Phase I/II clinical trial of tgAAC94, our inflammatory arthritis product candidate, the FDA placed a hold on the trial for several months in order to conduct in-depth review of data. Although the SAE was determined to be unrelated to our product, completion of the trial was delayed by approximately six months because of the hold.

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

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

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

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

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

We have entered into exclusive and nonexclusive license agreements that give us and our partners rights to use technologies owned or licensed by commercial and academic organizations in the research, development and commercialization of our potential products. We believe that we will need to obtain additional licenses to use patents and unpatented technology owned or licensed by others for use, compositions, methods, processes to manufacture compositions, processes to manufacture and purify gene therapeutics candidates and other technologies and processes for our present and potential product candidates. If we are unable to maintain our current licenses for third-party technology or obtain additional licenses on acceptable terms, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates. In addition, the license agreements for technology for which we hold exclusive licenses typically contain provisions that require us to meet minimum development milestones in order to maintain the license on an exclusive basis for some or all fields of the license. We also have license agreements for some of our technologies that



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may require us to sublicense certain of our rights. If we do not meet these requirements, our licensor may convert all or a portion of the license to a nonexclusive license or, in some cases, terminate the license.

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

the scope of rights granted under the license agreement and other interpretation-related issues;

the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

the sublicensing of patent and other rights under our collaborative development relationships;

the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

the priority of invention of patented technology.

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

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

Our future success depends in large part on the efforts and abilities of, and our ability to attract and retain, key technical and management personnel. All of our employees, including our executive officers, can terminate their employment with us at any time. We have programs in place designed to retain personnel, including competitive compensation packages and programs to create a positive work environment. Other companies, research and academic institutions and other organizations in our field compete intensely for employees, however, and we may be unable to retain our existing personnel or attract additional qualified employees and consultants. We have recently instituted a reduction in force, our chief executive officer and chief scientific officer have recently resigned and we are, and have been, operating with a very short cash horizon. This may give rise to uncertainty, which may make it more difficult to attract and retain qualified personnel. In addition, our ability to attract and retain qualified employees may be adversely affected by significant declines in the price of our common stock or if, as we currently expect, our stock is delisted from the NASDAQ Capital Market. If we experience significant turnover or difficulty in recruiting new personnel, our research and development of product candidates could be delayed and we could experience difficulty in generating sufficient revenue to maintain our business.

***Our recent reductions in force may harm our business.***

In order to decrease our ongoing cost structure, we have decreased our headcount through voluntary and involuntary employee terminations in all areas of our business. Our employee headcount decreased from 68 full-time equivalent employees at September 30, 2008 to 47 full-time equivalent employees at March 1, 2009. These staff reductions may impact our ability to execute on our business strategy and may result in failure to accomplish our business objectives. For example, if the anticipated negative effects of headcount reductions on our product development programs are greater than or



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different than we anticipated, our ability to successfully develop our potential products could be harmed. In addition, our reductions in force may yield unanticipated consequences, such as attrition beyond our planned reductions, and we may encounter difficulty in managing our business as a result.

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

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

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

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

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

The successful results of our technology in preclinical studies using animal models may not be predictive of the results that we will see in our clinical trials with human subjects. In addition, results in early-stage clinical trials generally test for drug safety rather than efficacy and are based on limited numbers of subjects. Drug development involves a high degree of risk and our reported progress and results from our early phases of clinical testing of our product candidates may not be indicative of progress or results that will be achieved from larger populations, which could be less favorable. Moreover, we do not know if any favorable results we achieve in clinical trials will have a lasting or repeatable effect. If a larger group of subjects does not experience positive results or if any favorable results do not demonstrate a beneficial effect, our product candidates that we advance to clinical trials may not receive approval from the FDA for further clinical trials or commercialization. For example, in March 2005, we discontinued the development of tgAAVCF, our product candidate for the treatment of cystic fibrosis, following the analysis of Phase II clinical trial data in which tgAAVCF failed to achieve the efficacy endpoints of the trial.

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

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

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

In 2008 and early 2009, we reviewed our very broad-based AAV patent portfolio. We determined that, based on the status of our and others' current product development efforts and our current financial resources, certain intellectual property assets are not essential to our current business strategy and we have therefore either returned those rights to our licensors or ceased prosecution of those patents. Although we do not believe those proprietary rights are essential to our current business strategy, the loss of those rights could limit our business opportunities, including our ability to license our technology and sell our products, if successfully developed.

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

Our potential products require significant development of new processes and design for the advancement of the product candidate through manufacture, preclinical and clinical testing. We may be

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unable to continue development or meet critical milestones with our partners due to technical or scientific issues related to manufacturing or development. We currently do not have the physical capacity to manufacture large-scale quantities of our potential products. This could limit our ability to conduct large clinical trials of a product candidate and to commercially launch a successful product candidate. In order to manufacture product at such scale, we will need to expand or improve our current facilities and staff or supplement them through the use of contract providers. For example in February 2009 we and Celladon agreed to transfer the manufacture of Celladon's MYDICA<sup>®</sup> product to an external contract manufacturing organization. If we are unable to obtain and maintain the necessary manufacturing capabilities, either alone or through third parties, we will be unable to manufacture our potential products in quantities sufficient to sustain our business or achieve profitability. Moreover, we are unlikely to become profitable if we, or our contract providers, are unable to manufacture our potential products in a cost-effective manner.

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

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

Even if we obtain regulatory approvals for the commercial sale of our product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

the prevalence of adverse side effects;

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

the effectiveness of our marketing and distribution strategy;

publicity concerning our products or competing products and treatments; and

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

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

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

Commercialization of any products will require continued compliance with the FDA and other federal, state and local regulations. For example, our current manufacturing facility, which is designed for manufacturing our adeno-associated virus, or AAV, vectors for clinical and development purposes, is subject to the Good Manufacturing Practices requirements and other regulations of the FDA, as well as to other federal, state and local regulations such as the Occupational Health and Safety Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and the Environmental Protection Act. Any future manufacturing facility that we may construct for large-scale commercial



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

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

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

regulatory requirements or action by the FDA or others;

adverse financial developments at or affecting the supplier;

unexpected demand for or shortage of raw materials;

labor disputes or shortages; and

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

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

## **Risks Related to Our Industry**

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

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

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





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

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

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

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

research and development;

clinical trials;

obtaining FDA and other regulatory approvals;

manufacturing; and

marketing and distribution.

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

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



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

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

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

**Risks Related to Our Common Stock**

***We expect that we will be unable to comply with the minimum requirements for quotation on the NASDAQ Capital Market and will be delisted from the NASDAQ Capital Market. As a result, we expect the liquidity and market price of our common stock to decline.***

Our stock is listed on the NASDAQ Capital Market. In order to continue to be listed on the NASDAQ Capital Market, we must meet specific quantitative standards, including maintaining a minimum bid price of \$1.00 for our common stock, a market value of \$1 million for our publicly held shares (public float), and \$2.5 million in shareholders equity. On April 23, 2008, we received a notice from the NASDAQ Stock Market, or NASDAQ, informing us that for 30 consecutive business days the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under Marketplace Rule 4310(c)(4). The letter stated that, under Marketplace Rule 4310(c)(8)(d), we would be provided with 180 calendar days to regain compliance with the bid price requirement. NASDAQ has since suspended enforcement of the bid price and public float requirements until July 20, 2009, at which time we will have five business days to regain compliance with those requirements. If, on July 27, 2009, we meet all of the NASDAQ Capital Market's initial listing criteria set forth in Marketplace Rule 4310(c) (other than the bid price criterion), but have not regained bid price compliance, we will be afforded an additional 180 calendar days to regain bid price compliance. To regain compliance with a listing standard, we must meet that standard for a minimum of 10 consecutive business days.

As a result of the goodwill impairment charge recognized in the fourth quarter of 2008, our net worth has fallen to a deficit of \$3.8 million, which is below the \$2.5 million in shareholders equity required under Marketplace Rule 4310(c)(3). We expect that NASDAQ will notify us on or before July 27, 2009 of our non-compliance with the \$2.5 million shareholders equity requirement and our continued non-compliance with the \$1.00 bid price requirement and \$1 million public float requirement. Because of our non-compliance with the minimum shareholders equity requirement, we do not expect to be eligible for the additional time period to regain compliance with the bid price requirement. Thereafter, we expect that the NASDAQ staff will provide written notification that our securities will be delisted. Upon such notice, we may appeal the NASDAQ staff's determination to a listing qualifications panel, pursuant to the procedures set forth in the NASDAQ Marketplace Rule 4800 Series. There can be no assurance that, if we were to appeal such a determination, the appeal would be successful.

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If we were to be delisted from the NASDAQ Capital Market, trading, if any, in our shares may continue to be conducted on the Over-the-Counter Bulletin Board or in a non-NASDAQ over-the-counter market, such as the pink sheets. Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could restrict investors' interest in our securities. Also, a delisting could have a material adverse effect on the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than \$5.00 per share, our shares could be subject to Rule 15c-9 under the Securities Exchange Act of 1934, as amended, which, among other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a penny stock under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities and our ability to raise additional capital in an already challenging capital market.

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

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

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

If our stock price declines or does not increase sufficiently, we may be unable to raise additional capital. As our existing financial resources are only expected to be sufficient to fund our current level of operations through the second quarter of 2009, an inability to raise capital could force us to go out of business. Declines in the price of our common stock or a failure of our stock price to increase sufficiently could also impair our ability to attract and retain qualified employees, reduce the liquidity of our common stock and result in the delisting of our common stock from the NASDAQ Capital Market. Even if our stock price increases sufficiently, we nonetheless expect to be delisted because of non-compliance with the \$2.5 million shareholders equity requirement of Marketplace Rule 4310(c)(3) resulting from our goodwill impairment. If we are delisted from the NASDAQ Capital Market as we currently expect, our ability to raise additional capital through the equity markets will be substantially harmed.

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

A small number of investors own a significant number of shares of our common stock. As of March 13, 2009, Special Situations held approximately 2.5 million shares of our common stock, Biogen Idec held approximately 2.2 million shares, Elan International services, Ltd., or Elan, held approximately 1.2 million shares, and Renaissance Technologies held approximately 1.1 million

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shares. Together these holdings represent approximately 34% of our common shares outstanding as of March 13, 2009. This concentration of stock ownership may allow these shareholders to exercise significant control over our strategic decisions and block, delay or substantially influence all matters requiring shareholder approval, such as:

approval of significant corporate transactions, such as a change of control of Targeted Genetics;

election of directors; or

amendment of our charter documents.

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

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

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

The stock market in general and the market for biotechnology-related companies in particular have experienced extreme price and volume fluctuations, often unrelated to the operating performance of the affected companies. The market price of the securities of biotechnology companies, particularly companies such as ours without earnings and product revenue, has been highly volatile and is likely to remain so in the future. Any report of clinical trial results that are below the expectations of financial analysts or investors could result in a decline in our stock price. We believe that in the past, similar levels of volatility have contributed to the decline in the market price of our common stock, and may do so again in the future. Trading volumes of our common stock can increase dramatically, resulting in a volatile market price for our common stock. The trading price of our common stock could decline significantly as a result of sales of a substantial number of shares of our common stock, or the perception that significant sales could occur. In addition, the sale of significant quantities of stock by Special Situations, Biogen Idec, Elan, Renaissance Technologies or other holders of significant amounts of shares of our stock could adversely impact the price of our common stock.

## **Item 2. Properties.**

We lease approximately 42,000 square feet of laboratory, manufacturing and office space in two buildings in Seattle, Washington. The lease on our primary laboratory, manufacturing and office space (representing 37,000 square feet) expires in April 2014 and the lease on our administrative office space (representing 5,000 square feet) expires in March 2014 and has one option to renew for an additional five-year period. We believe that our Seattle facilities are sufficient to support our research, manufacturing and administrative needs under our current operating plan.

Since 2000, we have also leased approximately 76,000 square feet of space in Bothell, Washington, intended for future large-scale manufacturing of our products. The lease on this facility expires in September 2015 and we have never occupied this facility and do not currently plan to commence the construction of this facility or otherwise occupy this facility. As a result, for many years we have endeavored to sublease all or part of the facility and have pursued negotiations to revise or somehow reduce the expenditures connected with this facility. In February 2009, we surrendered

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control of the facility to the building owner and discontinued rent payments, such actions constituting a default under the lease, and we are pursuing a settlement of our remaining obligations under the building lease. There can be no assurances that we will be successful in negotiating a settlement with the landlord, and the landlord may terminate the lease as a result of our default and, among other potential remedies, accelerate our obligations due under the lease.

**Item 3. Legal Proceedings.**

In July 2007, we were notified that a patient experienced a serious adverse event, or SAE, while enrolled in the clinical trial of tgAAC94, our product candidate to treat arthritis, and the patient subsequently died. In their review of the SAE, both the National Institutes of Health Recombinant DNA Advisory Committee and the trial's independent data safety monitoring board concluded that the patient's death was caused by complications from an opportunistic infection, not by our tgAAC94 product candidate, as described in our Current Report on Form 8-K filed on December 6, 2007. In addition, after the U.S. Food and Drug Administration, or FDA, reviewed the safety data on all 127 patients in the trial and data from the SAE, the FDA removed the hold it originally put on the clinical trial, permitting the clinical trial to resume. On March 3, 2009, we were served with a lawsuit filed by the patient's spouse, Robbie Mohr. The lawsuit was filed on August 18, 2008 in the 4<sup>th</sup> Judicial Circuit of Christian County, Illinois, against us, Abbot [sic] Laboratories Inc., and Western Institutional Review Board Inc. The complaint for the lawsuit alleges that the named parties' negligence was the proximate cause of the patient's death and seeks unspecified compensatory damages in excess of \$50,000.

**Item 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 2008.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.**

*Market Information.* Our common stock trades on the NASDAQ Capital Market under the symbol TGEN. From May 20, 1994 until January 8, 2003, our common stock was traded on the NASDAQ National Market (now known as the NASDAQ Global Market) under the symbol TGEN.

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

|              | High    | Low     |
|--------------|---------|---------|
| <b>2008:</b> |         |         |
| 4th Quarter  | \$ 0.55 | \$ 0.13 |
| 3rd Quarter  | 0.90    | 0.36    |
| 2nd Quarter  | 1.08    | 0.56    |
| 1st Quarter  | 1.80    | 0.46    |
| <b>2007:</b> |         |         |
| 4th Quarter  | \$ 2.40 | \$ 1.45 |
| 3rd Quarter  | 3.23    | 1.45    |
| 2nd Quarter  | 5.55    | 2.70    |
| 1st Quarter  | 5.90    | 2.45    |

The last reported bid quotation for our common stock, as quoted on the NASDAQ Capital Market on March 13, 2009 was \$0.10 per share.

*Holders.* As of March 13, 2009, we had 272 shareholders of record and approximately 15,000 beneficial holders of our common stock.

*Dividends.* We have never paid cash dividends and do not anticipate paying them in the foreseeable future.

*Recent Sales of Unregistered Securities.* None.

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

The selected consolidated financial data set forth below at December 31, 2008 and 2007, and for the fiscal years ended December 31, 2008, 2007 and 2006, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and with Management's Discussion and Analysis of Financial Condition and Results of Operations. The selected consolidated financial data set forth below at December 31, 2006, 2005 and 2004, and for the years ended December 31, 2005 and 2004, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC. All share and per share information set forth below (including shares outstanding and earnings per share) reflect the retroactive adjustment for a one-for-ten reverse stock split we implemented in May 2006.

|  | Year Ended December 31, |                     |                           |                     |                        |
|--|-------------------------|---------------------|---------------------------|---------------------|------------------------|
|  | 2008 <sup>(3)</sup>     | 2007 <sup>(1)</sup> | 2006 <sup>(1)(3)(4)</sup> | 2005 <sup>(1)</sup> | 2004 <sup>(1)(2)</sup> |
| <b>Statement of Operations Data</b>                                  |                         |                     |                           |                     |                        |
| Revenue  | \$ 8,718,000            | \$ 10,332,000       | \$ 9,864,000              | \$ 6,874,000        | \$ 9,652,000           |
| Operating expenses   | 29,885,000              | 26,886,000          | 46,593,000                | 26,221,000          | 24,822,000             |
| Loss from operations   | (21,167,000)            | (16,554,000)        | (36,729,000)              | (19,347,000)        | (15,170,000)           |
| Net loss applicable to common stock                                  | \$ (20,720,000)         | \$ (16,127,000)     | \$ (33,990,000)           | \$ (19,198,000)     | \$ (14,257,000)        |
| Net loss per basic and diluted common share                          | \$ (1.04)               | \$ (0.98)           | \$ (3.47)                 | \$ (2.24)           | \$ (1.79)              |
| Shares used in computing basic and diluted net loss per common share | 19,954,000              | 16,504,000          | 9,788,000                 | 8,564,000           | 7,945,000              |

|                                      | 2008         | 2007          | December 31,<br>2006 | 2005          | 2004          |
|--------------------------------------|--------------|---------------|----------------------|---------------|---------------|
| <b>Balance Sheet Data</b>            |              |               |                      |               |               |
| Cash and cash equivalents            | \$ 5,216,000 | \$ 16,442,000 | \$ 6,206,000         | \$ 14,122,000 | \$ 34,096,000 |
| Total assets                         | 7,150,000    | 28,474,000    | 17,467,000           | 48,798,000    | 69,965,000    |
| Long-term obligations                |              |               | 570,000              | 8,177,000     | 10,182,000    |
| Total shareholders' equity (deficit) | (3,772,000)  | 16,240,000    | 5,367,000            | 30,571,000    | 49,762,000    |

(1) Operating expenses include restructure charges of \$954,000 in 2008, \$2.1 million in 2007, \$2.0 million in 2006, \$1.7 million in 2005 and \$884,000 in 2004. See Note 4 of the notes to our consolidated financial statements.

(2) Results reflect a \$1.0 million gain on the sale of a majority-owned subsidiary in July 2004.

(3) Operating expenses include a goodwill impairment charge of \$7.9 million in 2008 and \$23.7 million in 2006. See Note 8 of the notes to our consolidated financial statements.

(4) Reflects a \$2.6 million gain on the restructure of our Biogen Idec debt in November 2006. See Note 5 of the notes to our consolidated financial statements.





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

**Overview**

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

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

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

Our development efforts currently focus on:

a clinical stage AAV-based product candidate for treatment of Leber's congenital amaurosis, or LCA, developed in collaboration with Robin Ali, Ph.D. at the University College London/Moorfields Eye Hospital, or UCL/M;

a preclinical AAV-based Huntington's disease, or HD, product candidate under development with our collaborator Beverly Davidson, Ph.D., at the University of Iowa, or UI; and

a preclinical small molecule-based product candidate to treat amyotrophic lateral sclerosis, or ALS, under development with our collaborator John Engelhardt, Ph.D., at UI and funded by a grant from the U.S. Department of Defense, or DOD.

As of December 31, 2008, our accumulated deficit totaled \$320.9 million. We expect to generate substantial additional losses for the foreseeable future, primarily due to the costs associated with funding our development programs for LCA, HD, and ALS or other product candidates we pursue in the future, and developing and maintaining our intellectual property assets.

Most of our expenses are related to the support and advancement of our research and development programs, the conduct of preclinical studies and clinical trials and general and administrative support for these activities. We have financed our operations primarily through proceeds

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from public and private sales of our equity securities, through cash payments received from our collaborative partners for product development and manufacturing activities and through proceeds from the issuance of debt and loan funding under equipment financing arrangements. During 2007, we completed two private placements of our common stock generating approximately \$26.0 million to fund our programs and operations. We did not sell any stock in 2008. At December 31, 2008, we had a cash balance of \$5.2 million. We expect that this cash, combined with cash we expect to receive from Celladon Corporation, or Celladon, to fund certain manufacturing and product development efforts, will be sufficient to fund our operations through the second quarter of 2009. This estimate is based on our ability to successfully perform planned activities and the receipt of expected funding under our collaborations and grants, and actual results could differ from our estimates.

We will require access to significant amounts of additional capital in order to continue our operations and successfully develop our partnered product candidates and any internally funded product candidates. We may be unable to obtain this funding on acceptable terms, or at all. If we are not successful in raising additional funding to support our operations, we will have to curtail portions of our operations or cease operating as a company.

### **Critical Accounting Policies, Estimates and Assumptions**

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States. As we prepare our financial statements we are required to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an ongoing basis, we evaluate these estimates, including those related to revenue, accrued restructure charges, goodwill and stock-based compensation. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. Note 1 of the notes to our consolidated financial statements, *Description of Business and Summary of Significant Accounting Policies*, summarizes our significant accounting policies that we believe are critical to the presentation of our consolidated financial statements. Our most critical accounting policies, estimates and assumptions are:

#### ***Revenue Recognition Policy***

We generate revenue from technology licenses, collaborative research arrangements and agreements to provide research, development and manufacturing services. 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.

For collaboration agreements, we initially defer revenue from nonrefundable, up-front license fees and technology access payments and then recognize it systematically over the service period of the collaboration agreement, which is often the development period. We recognize revenue associated with performance milestones as earned, typically based upon the achievement of the specific milestones defined in the applicable agreements. We generally recognize revenue under research and development contracts as the related costs are incurred. When contracts include multiple elements we follow the Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, which requires us to satisfy the following before revenue can be recognized:

- 1) the delivered items have value to the customer on a stand-alone basis;
- 2) any undelivered items have objective and reliable evidence of fair value; and
- 3) delivery or performance is probable and within our control for any delivered items that have a right of return.

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We have determined that, for these contracts, the manufacturing activities and research and development activities can be accounted for as separate units of accounting and we allocate the revenue to each unit based on relative fair value. We recognize revenue for manufacturing activities when the manufacturing campaign is substantially complete and we recognize revenue for research and development activities on a percentage-of-completion basis. We classify advance payments received in excess of amounts earned as deferred revenue.

Based upon the terms specified in our collaboration agreements, we receive advance payments from some of our collaboration partners before the project work has been performed. These payments are deferred and recognized as revenue when the costs are incurred.

### ***Estimated Restructure Charges Associated with the Bothell Facility***

We follow the provisions of Statement of Financial Accounting Standards, or SFAS, No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or SFAS No. 146, as it relates to our facility in Bothell, Washington (which we have never occupied) and we have recorded restructure charges on the related operating lease. Accrued restructure charges, and in particular, those charges associated with exiting a facility, are subject to many assumptions and estimates. Under SFAS No. 146, an accrued liability for lease termination costs is initially measured at fair value, based on the remaining lease payments due under the lease and other costs, reduced by any sublease rental income that could be reasonably obtained from the property, and discounted using a credit-adjusted risk-free interest rate.

We have periodically evaluated our restructure estimates and assumptions and recorded additional restructure charges as necessary to reflect current market conditions and delays in subleasing the Bothell facility. Prior to 2007, we updated our restructure estimates and assumptions based on our evaluation of our ability to sublease the Bothell facility in light of tightening credit markets and deteriorating conditions in the Bothell real estate market. In the fourth quarter of 2007, based on a number of factors, including a continued increase in vacancy rates in the Bothell market and an increase in available office space in the competing downtown real estate markets, we concluded that we would not be able to successfully sublease the facility. Accordingly, we removed from our restructure estimates the assumed Bothell facility sublease income and the related tenant improvement and brokerage commission cost assumptions and recorded additional restructure charges of \$1.2 million. As of December 31, 2008, we continued to believe that we would not be able to successfully sublease the facility and there were no changes to our remaining assumptions. We have recorded \$8.5 million in restructure charges for this property since December 2002, when we first established a restructure reserve for exiting the Bothell facility. We also record accretion expense based upon the estimated remaining lease costs and the present value of these costs at an assumed discount rate of 10%. We recorded accretion expense as a restructure charge of \$788,000 in 2008, \$727,000 in 2007 and \$751,000 in 2006.

We will continue to evaluate any additional information that may become available with respect to the estimates and assumptions as they relate to the facility. For example, on February 3, 2009 we communicated to the owner of the Bothell facility that we were surrendering the building to them and discontinuing payments on the lease, such actions constituting a default under the lease, and are seeking to negotiate a settlement for our remaining obligations under the lease. This action had no financial impact on our 2008 financial statements. There can be no assurance that we will be successful in negotiating a settlement with the landlord, and the landlord may terminate the lease as a result of our default and, among other potential remedies, accelerate our obligations due under the lease. If circumstances with the lease for this facility change, including a successful negotiation of reduced charges for the lease, some portion of the remaining accrued restructure charges related to the facility may be reversed. A reversal, if any, would be reflected as a reduction of restructure expenses and a non-recurring gain in the period in which our obligations under this lease change. We are currently unable to determine the likelihood of any future adjustments to our accrued restructure charges.

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### ***Goodwill and Other Intangible Assets***

When we purchased Genovo, Inc. in 2000, we recorded intangible assets of \$39.5 million on our financial statements, which represented know-how, an assembled workforce and goodwill. Between 2000 and 2002, we recognized \$8.1 million of amortization of the goodwill and intangible assets. In 2002, we adopted SFAS No. 142, *Goodwill and Other Intangible Assets*, or SFAS No. 142. SFAS No. 142 discontinued amortization of goodwill and requires us to perform goodwill impairment tests annually or more frequently if events and changes in business conditions indicate that the carrying amount of our goodwill may not be recoverable. We assess any potential impairment using a two-step process. Since we have only one reporting unit for purposes of applying SFAS No. 142, the first step requires us to compare the fair value of our total company, measured by market capitalization, to our net book value of our assets. If our fair value is less than the net book value, goodwill is potentially impaired and we are required to proceed to step two of the impairment analysis. In step two, the implied fair value of goodwill is calculated as described below and compared to its carrying amount. If the goodwill carrying amount exceeds the implied fair value, we recognize an impairment loss equal to that excess.

For the step two portion of the valuation analysis we generally base our measurement of our fair value on a weighted analysis of the present value of future discounted cash flows and market valuation approach. The discounted cash flows model indicates the fair value of the company based on the present value of the cash flows that we expect to generate in the future. Our significant estimates in the discounted cash flows model include: our weighted average cost of capital; the probability associated with bringing our product candidates to market; and our long-term rate of growth and profitability of our business. The market valuation approach indicates the fair value of the company based on our fully diluted market capitalization, using either the stock price on the valuation date or the average stock price over a range of dates around the valuation date, plus the book value of our interest-bearing debt, and an estimated acquisition premium which is based on observable transactions of comparable companies.

We believe the weighted use of discounted cash flows and market approach for the second step of the analysis is the best method for determining the fair value of the company because these are the most common valuation methodologies used within our industry and the weighted use of both models compensates for the inherent risks associated with either model if used on a stand-alone basis.

The implied goodwill amount is determined by allocating our fair value, calculated as described above, to all of our assets and liabilities, including intangible assets such as in-process research and development, developed technology and trademarks and trade names, as if we had been acquired in a hypothetical business combination as of the date of the impairment test.

As a result of an interim goodwill impairment test performed in 2006, we recognized a non-cash loss on impairment of goodwill of \$23.7 million, based on an assessment that the implied value of goodwill was \$7.9 million. In the fourth quarter of 2008, due to the continued decline in the market price of our common stock and a restructuring implemented in November 2008 to realign and narrow our product development priorities, we concluded that sufficient indicators existed to require us to perform an interim assessment of goodwill to determine if our remaining \$7.9 million goodwill balance was impaired. We performed the two-step analysis described above, which indicated an implied goodwill balance of zero, resulting in a non-cash impairment loss of \$7.9 million for 2008. For additional information about our goodwill impairment recorded in 2008, see Note 8 in the notes to the consolidated financial statements.

The process of evaluating the potential impairment of goodwill is subjective and requires significant judgment. In estimating our fair value, we make estimates and judgments about our future revenues and cash flows, application of a discount rate, and the potential control premium relative to the market price of our stock at the valuation date. In estimating the fair value of our net assets, including intangible assets, we make estimates and judgments relating to the fair value of specific

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assets and liabilities. These estimates generally involve projections of the cash flows that may be provided by specific assets such as in-process research and development, completed technology and trademarks and trade names, including assumptions as to the probability of bringing drug candidates to market, the timing of product development, the market size addressed by our potential products, and the application of discount rates. Changes in these estimates could affect our conclusion as to whether an impairment has occurred and could significantly impact the amount of impairment recorded.

**Stock-Based Compensation**

We apply SFAS No. 123R, Share-Based Payment, or SFAS No. 123R, fair value recognition provisions using the modified prospective transition method. Under the modified prospective method, compensation expense includes: (a) compensation cost for all share-based stock awards granted prior to, but not yet vested as of, the January 1, 2006 required implementation date, based on the grant-date fair value used for prior pro forma disclosures, adjusted for forfeitures and (b) compensation cost for all stock awards granted after January 1, 2006, based on the grant-date fair value estimate in accordance with the provisions of SFAS No. 123R. According to the guidelines of SFAS No. 123R, we did not restate results for periods prior to the required January 1, 2006 implementation date. Following SFAS No. 123R, we recorded stock compensation expense of \$718,000 for 2008, \$966,000 for 2007 and \$861,000 for 2006. This expense is classified as follows in the consolidated statement of operations:

|                                       | Year Ended December 31, |                   |                   |
|---------------------------------------|-------------------------|-------------------|-------------------|
|                                       | 2008                    | 2007              | 2006              |
| Stock-based compensation:             |                         |                   |                   |
| Research and development              | \$ 393,000              | \$ 508,000        | \$ 465,000        |
| General and administrative            | 261,000                 | 458,000           | 396,000           |
| Restructure charges                   | 64,000                  |                   |                   |
| <b>Total stock-based compensation</b> | <b>\$ 718,000</b>       | <b>\$ 966,000</b> | <b>\$ 861,000</b> |

Determining the appropriate fair value model and calculating the fair value of stock awards requires the input of highly subjective assumptions, including the expected life of the share-based payment awards and stock price volatility. We base our volatility and expected life estimates on our historical data. The assumptions used in calculating the fair value of share-based payment awards represent our best estimates, and as estimates they involve inherent uncertainties and the application of judgment. As a result, if factors change and we use different assumptions, our future stock-based compensation expense could be materially different from the amounts currently recorded in our financial statements. For example, in the fourth quarter of 2007, we booked an additional \$229,000 of stock-based compensation due to refinements to our estimates of forfeitures. There were no significant adjustments related to changes in our assumptions in 2008. In addition, we are required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. See Note 1 of the notes to our consolidated financial statements for a further discussion of stock-based compensation.

**Application of New Accounting Standards**

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 provides guidance for using fair value to measure assets and liabilities and requires expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS No. 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. SFAS No. 157 does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS No. 157 did not have an effect on our financial position or results of operations.

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In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115*, or SFAS No. 159. SFAS No. 159 permits entities to choose to measure certain financial assets and liabilities at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS No. 159 did not have an effect on our financial position or results of operations.

In July 2007, the EITF reached a consensus on Issue No. 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for fiscal years beginning after December 15, 2007 and early adoption was not permitted. The adoption of EITF 07-3 changed our policy on nonrefundable prepayments for research and development services: such costs are now deferred and recognized as the services are rendered, whereas under the previous policy such payments were charged to research and development expense as paid. This change did not have a material effect on our financial position or results of operations for 2008.

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

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

**Results of Operations****Revenue**

|  | Year Ended December 31, |                      |                     |
|--|-------------------------|----------------------|---------------------|
|  | 2008                    | 2007                 | 2006                |
| Revenue from collaborative agreements: |                         |                      |                     |
| Heart failure Celladon                 | \$ 4,843,000            | \$ 3,982,000         | \$ 4,220,000        |
| HIV/AIDS vaccine NIAID                 | 3,668,000               | 5,389,000            | 1,548,000           |
| HIV/AIDS vaccine IAVI                  |                         | 309,000              | 2,262,000           |
| Huntington's disease Sirna             |                         | 52,000               | 47,000              |
| Other                                  | 107,000                 |                      | 37,000              |
| Other revenues:                        |                         |                      |                     |
| License agreements AMT                 | 100,000                 | 600,000              | 1,750,000           |
| <b>Total revenue</b>                   | <b>\$ 8,718,000</b>     | <b>\$ 10,332,000</b> | <b>\$ 9,864,000</b> |

Revenue in 2008 was \$8.7 million, compared to \$10.3 million in 2007, representing revenue from collaborative agreements and licenses. The decrease in revenue reflects a decrease in research and development and manufacturing activities under our HIV/AIDS vaccine project in collaboration with Children's Hospital of Philadelphia, or CHOP, and Nationwide Children's Hospital, or NCH, which is funded by the National Institute of Allergy and Infectious Disease, or NIAID, to \$3.7 million in 2008 from \$5.4 million in 2007. As expected, we did not receive any revenue from our International AIDS Vaccine

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Initiative, or IAVI, collaboration in 2008 due to less development activity. Licensing revenue decreased to \$100,000 in 2008 from \$600,000 in 2007 due to revenue received from a milestone earned in 2007 related to a non-exclusive license to certain of our AAV1 vector gene delivery system patent rights we granted to Amsterdam Molecular Therapeutics B.V., or AMT. Revenue under our heart failure collaboration with Celladon increased to \$4.8 million in 2008 compared to \$4.0 million in 2007, reflecting higher research and development and manufacturing activities as we planned and prepared for the next phase of development.

Revenue in 2007 was \$10.3 million, compared to \$9.9 million in 2006. Revenue earned under the NIAID-funded HIV/AIDS vaccine project in collaboration with CHOP and NCH increased to \$5.4 million in 2007 from \$1.5 million in 2006, reflecting increased research and development activities, support of preclinical studies and initiation of vector manufacturing for clinical trials. Revenue earned under our heart failure collaboration with Celladon decreased slightly to \$4.0 million in 2007 from \$4.2 million in 2006. Revenue from our IAVI collaboration decreased to \$309,000 in 2007 from \$2.3 million in 2006. We recognized \$600,000 in licensing revenue in 2007, compared to \$1.8 million in 2006, related to our non-exclusive license agreement with AMT.

We expect our 2009 revenue to consist primarily of revenue from the Celladon program; our ALS effort, funded by the DOD, which was initiated in the fourth quarter of 2008 and is expected to be completed during 2009; and the NIAID-funded HIV/AIDS vaccine subcontract with CHOP and NCH, which we also expect to complete in 2009. We expect that our revenue for 2009 will decrease as compared to 2008 because our revenue-generating collaborative programs will emphasize clinical development in 2009, which results in a shift of the work from us to the collaborative partner. We expect our 2009 revenue generated under our revised agreements with Celladon will be at approximately the same level as in 2008. For 2009, because our HIV/AIDS efforts are focused on advancing the NIAID-funded HIV/AIDS vaccine efforts, we expect no activity or related funding within the IAVI-funded portion of our HIV/AIDS development work, which is consistent with 2008. Our NIAID-funded HIV/AIDS vaccine collaboration will be focused primarily on clinical activities in 2009 and we will be terminating our involvement in this program, and as a result we expect revenue under this program to decrease compared to 2008 due to less development activity. Our revenue for the next several years will depend on the successful achievement of milestones in our current product development collaborations and whether we enter into any new product development collaborations, manufacturing arrangements or licenses.

## ***Operating Expenses***

*Research and Development.* Research and development costs include salaries, costs of outside collaborators and outside services, costs of materials and supplies, clinical trial expenses, royalty and license costs and allocated facility, occupancy and utility expenses. Research and development expenses totaled \$15.2 million in 2008, compared to \$17.7 million in 2007. This decrease reflects lower clinical trial costs for our inflammatory arthritis program, as we have completed our Phase I/II clinical trial. This decrease was partially offset by increased activity on the heart failure product candidate developed in collaboration with Celladon during 2008. Research and development expenses totaled \$17.7 million in 2007, compared to \$14.5 million in 2006. This increase is due to increased research and development costs for the NIAID-funded HIV/AIDS vaccine program in collaboration with CHOP and NCH and costs incurred to support the initiation of clinical trials in May 2007 for the heart failure product candidate developed in collaboration with Celladon. In addition, costs related to our inflammatory arthritis program increased due to a higher number of enrolled subjects in our Phase I/II clinical trial. These cost increases were partially offset by lower costs for our HIV/AIDS vaccine collaboration with IAVI resulting from less development activity.

We currently expect our research and development expenses in 2009 to decrease as compared to 2008, reflecting decreased efforts supporting our partnered programs and lower inflammatory arthritis clinical trial expenses as we completed the Phase I/II trial in 2008. Our research and development



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expenses 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. We expect that our expenses will continue to fluctuate as we proceed with our current development programs and collaborations and enter into potential new development collaborations, manufacturing arrangements and licensing agreements and scale our expenses to reflect our cash balances.

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

|   | Year Ended December 31, |                      |                      |
|---|-------------------------|----------------------|----------------------|
|   | 2008                    | 2007                 | 2006                 |
| <b>Programs in clinical development:</b>                    |                         |                      |                      |
| Heart failure (Celladon) <sup>(1)</sup>                     | \$ 3,394,000            | \$ 1,402,000         | \$                   |
| Inflammatory arthritis                                      | 1,333,000               | 3,671,000            | 2,888,000            |
| HIV/AIDS vaccine (IAVI)                                     |                         | 213,000              | 1,602,000            |
| Indirect costs and other                                    | 4,747,000               | 4,054,000            | 2,863,000            |
| <b>Total clinical development program expense</b>           | <b>9,475,000</b>        | <b>9,340,000</b>     | <b>7,353,000</b>     |
| <b>Research and preclinical development program expense</b> | <b>5,708,000</b>        | <b>8,369,000</b>     | <b>7,129,000</b>     |
| <b>Total research and development expense</b>               | <b>\$ 15,183,000</b>    | <b>\$ 17,709,000</b> | <b>\$ 14,482,000</b> |

(1) Includes costs incurred after the clinical trial was initiated in May 2007. Costs incurred before the initiation of the clinical trial are included as research and preclinical development program expense.

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

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

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

*General and Administrative.* General and administrative expense decreased to \$5.8 million in 2008 compared to \$7.0 million in 2007. The decrease reflects lower employee costs as a result of the November 2008 reduction in force and decreases in executive compensation implemented with the realignment of our product development priorities. Additionally, we incurred lower shareholder meeting-

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related costs, lower intellectual property costs and lower stock-based compensation charges in 2008. General and administrative expenses increased to \$7.0 million in 2007, compared to \$6.4 million in 2006, due to increased compensation costs, costs related to increased patent prosecution and issuance activities and higher stock-based compensation charges. We expect our general and administrative expenses in 2009 to decrease as compared to 2008 as a result of our cost-cutting efforts.

*Restructure Charges.* Accrued restructure charges represent our best estimate of the fair value of the liability to exit the Bothell facility as determined under SFAS No. 146 and are computed as the fair value of the difference between the remaining lease payments due on these leases and estimated sub-lease costs and rental income. During each year, we adjusted our liability to reflect our updated subleasing assumptions for the Bothell facility.

Restructure charges consist of the following:

|  | Year Ended December 31, |              |              |
|--|-------------------------|--------------|--------------|
|  | 2008                    | 2007         | 2006         |
| Charges related to changes in assumptions              | \$                      | \$ 1,421,000 | \$ 860,000   |
| Accretion expense                                      | 788,000                 | 727,000      | 751,000      |
| Employee termination and partial lease termination fee | 166,000                 |              | 395,000      |
| Total restructure charges                              | \$ 954,000              | \$ 2,148,000 | \$ 2,006,000 |

As of December 31, 2008, our accrued restructure balance was \$7.6 million.

Restructure charges decreased to \$954,000 for 2008, compared to \$2.1 million in 2007 and \$2.0 million in 2006. Restructure charges for 2008 include accretion expense of \$788,000 and \$166,000 for employee termination benefits related to the reduction in force implemented as a part of our efforts to realign and narrow our product development priorities. We had no restructure charges related to our Bothell facility for 2008 because we made no changes in 2008 related to our restructure estimates and assumptions. Restructure charges for 2007 include \$1.5 million primarily related to changed sublease assumptions resulting from our determination that, based on a decline in the Bothell real estate market, we would not be able to sublease the facility, and accretion expense of \$727,000. Restructure charges for 2006 include \$860,000 related to changes in our expectations regarding market conditions for subleasing our Bothell facility, including time to find a sublease tenant and adjusting our assumptions with respect to sublease income, \$221,000 for employee termination benefits related to our efforts to realign our cost structure, \$174,000 related to the early termination of a portion of our Seattle facility lease resulting from the headcount reductions, and accretion expense of \$751,000.

*Goodwill Impairment Charge.* We periodically and annually on each October 1<sup>st</sup> evaluate the carrying value of our goodwill in accordance with SFAS No. 142 and if there is evidence of an impairment in value, we reduce the carrying value of the asset. As discussed in Note 8 of the notes to our consolidated financial statements, in the fourth quarter of 2008, due to a continued decline in the market price of our common stock and the restructuring we implemented in November 2008 to realign and narrow our product development priorities, we concluded that sufficient indicators existed to perform an interim assessment of goodwill to determine if there was further impairment to our remaining \$7.9 million goodwill balance. This evaluation resulted a non-cash impairment charge of \$7.9 million. We previously recognized a non-cash goodwill impairment charge of \$23.7 million during 2006 as a result of a decline in our share price during June 2006 that reduced our market capitalization to an amount less than the fair value of our net assets.

*Gain on debt restructure.* In 2006, we signed an agreement to restructure \$8.15 million of debt payable to Biogen Idec. Under the agreement, we granted Biogen Idec one million shares of our common stock with a fair value of \$2.9 million in exchange for \$5.65 million of debt, made an immediate loan repayment of \$500,000 and agreed to a loan payable balance of \$2.2 million. We recorded a \$2.6 million gain on this debt restructure. Inherent in our determination of the gain on debt

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restructure is an estimate of the amounts and timing of future principal and interest payments. To the extent that changes in our estimates resulted in decreases in estimated future interest payments, such gain was deferred until realized. In August 2008, we made our final principal and interest payment to Biogen Idec. The difference between the final principal and interest payment and the estimated liability established in 2006 was recognized as a realized gain of \$77,000.

*Investment Income.* Investment income reflects interest income earned on our short-term investments and realized gains or losses on our investment in Chromos Molecular Systems Inc, or Chromos. Investment income decreased to \$279,000 for 2008, compared to \$428,000 for 2007. In 2007, we recognized realized losses related to other-than-temporary impairment charges on our investment in Chromos resulting from the declining market value of Chromos securities combined with a decline in Chromos then-current financial position. We evaluated the investment on December 31, 2007 and, based on facts surrounding the financial outlook for Chromos, concluded that the fair value of our investment had declined to zero. Accordingly, we recognized a realized loss of \$341,000 for 2007. Excluding the \$341,000 loss related to the write-down of our investment in Chromos, our investment income for 2007 was \$769,000. This overall decrease in 2008 compared to 2007 is due to lower average cash balances and lower interest rates compared to 2007. Our investment income was \$428,000 in 2007 compared to \$567,000 in 2006, due primarily to the recognition of realized losses related to other-than-temporary impairment charges on our investment in Chromos due to the declining market value of Chromos securities combined with a decline in Chromos then-current financial position.

*Interest Expense.* Our interest expense relates to interest on outstanding loans from Biogen Idec and obligations under equipment financing arrangements that we used to purchase laboratory and computer equipment, furniture and leasehold improvements. Our interest expense decreased to zero in 2008, compared to \$1,000 in 2007 and \$411,000 in 2006. As a result of the restructure of the Biogen Idec debt in 2006, the carrying value of the remaining debt included the related estimated future interest payments. All equipment financing arrangements were paid in full during the first quarter of 2008 and we fully repaid the remaining Biogen Idec loan balance in August 2008.

## **Liquidity and Capital Resources**

We had cash and cash equivalents of \$5.2 million at December 31, 2008, compared to \$16.4 million at December 31, 2007 and \$6.2 million at December 31, 2006. The decrease in our cash and cash equivalents in 2008 primarily reflected our net loss from operations and the resulting cash used in operations of \$10.3 million, capital purchases of \$738,000 and the final payment of our Biogen note payable of \$258,000. The increase in our cash and cash equivalents in 2007 primarily reflected net proceeds of \$26.0 million from our January 2007 and June 2007 sales of our common stock, partially offset by our net loss in 2007 and the resulting cash used in operations of \$13.9 million, loan repayments of \$1.4 million on our Biogen Idec debt and our equipment financing arrangements and cash used for capital purchases of \$554,000.

Our primary sources of capital are public and private sales of our equity securities and cash payments received from our collaborative partners and through proceeds from the issuance of debt. To a lesser degree, we have also financed our operations through interest earned on our cash and loan funding under equipment leasing agreements and, in the last two years, through license revenue. These financing sources have historically allowed us to maintain adequate levels of cash and cash equivalents but, particularly in the current market environment, they may not continue to do so. Our primary expenses are related to the development of our research and development programs, the conduct of preclinical studies and clinical trials and general and administrative support for these activities.

Most of our revenue has been derived under collaborative research and development agreements relating to the development of our potential product candidates. We do not expect the revenue

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generated from our current or future collaborative research and development and manufacturing arrangements to be sufficient to fully fund the development and commercialization of our product candidates. As a result, we do not expect to generate ongoing positive cash flow from our operations for the foreseeable future and our ability to generate any sustained positive cash flow is dependent upon our success at developing and commercializing our product candidates.

We will require substantial additional financial resources to continue our operations and to fund development and commercialization our three primary product development programs, which are LCA, HD and ALS. We will continue later-stage development of our inflammatory arthritis product development only if we receive funding from a partner.

In November 2008, we reported that we had changed our product development focus to include only LCA, HD and ALS. During 2008, we spent approximately \$488,000 on these programs to support research and development activities and to support LCA clinical trial costs. We currently are not reimbursed for any costs we incur to advance our HD or LCA product development efforts and we must partially self-fund our ALS product development efforts. Unless we receive additional funding to support our operations in 2009, we expect to spend less than \$500,000 on these programs, largely for patent prosecution support, licensing costs and expenses for research supplies. We fund these costs from our working capital and expect to do so for the foreseeable future, although our strategy is to ultimately seek a partner to fund later-stage development of at least one of these programs.

Our operating cash flows are primarily influenced by our losses from operations, net of the effect of non-cash items such as stock-based compensation, depreciation and amortization of our property and equipment, accounts receivable, deferred revenue and restructure activity. Depreciation and amortization charges for 2008 were \$516,000, compared to \$602,000 in 2007 and \$720,000 in 2006. The decrease in 2008 as compared to 2007 and 2006 primarily reflects lower depreciation on laboratory equipment. Stock-based compensation expense was \$718,000 in 2008, compared to \$966,000 in 2007 and \$861,000 in 2006. Accounts receivable at December 31, 2008 was \$317,000, which decreased from \$2.6 million at December 31, 2007 due to the timing of cash received. Cash provided by deferred revenue activity in 2008 compared to cash used in 2007 and in 2006 reflects higher levels of pre-funded work in 2008 under our collaborative agreements. Substantially all of our deferred revenue at December 31, 2008 and 2007 is related to the heart failure collaboration with Celladon. The net decrease in our restructure reserve of \$553,000 in 2008 was due to rent payments offset by accretion. In 2007 and 2006, increases in our restructure reserve, offset by payments of rent for our Bothell facility, resulted in net increases of \$766,000 in 2007 and \$228,000 in 2006.

Our \$259,000 in cash used for financing activities in 2008 represented \$259,000 of loan repayments, including the final payment of \$258,000 to Biogen Idec. In 2007 we made \$1.4 million of loan payments, including \$1.3 million to Biogen Idec and \$26,000 of equipment financing payments, and in 2006 we made \$1.2 million of loan payments, including \$1.0 million to Biogen Idec and \$155,000 of equipment financing payments.

Sales of the shares of our common stock contributed significantly to our cash flows from financing activities in both 2007 and in 2006. Our financial results in 2007 include approximately \$26.0 million of proceeds as a result of the sale of 8.9 million shares of our common stock and our 2006 financial results include approximately \$4.8 million of proceeds as a result of the sale of 1.3 million shares of our common stock. We sold no stock in 2008.

Our current operating strategy is to carefully steward our available funds to advance our three primary programs while leveraging our development and manufacturing capabilities and intellectual property assets into additional capital-raising opportunities. Key to this strategy is the completion of a manufacturing campaign of cGMP materials for a Phase III clinical trial of MYDICAR® under our agreement with Celladon, both for the cash that it provides to support 2009 operations and for the value generated for us through fulfilling this contractual commitment.

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We believe that our current financial resources and the cash we expect to receive from our collaborative partners and grants will only be sufficient to fund our operations through the second quarter of 2009. This estimate is based on our ability to successfully perform planned activities and the receipt of expected funding under our collaborations and grants, and actual results could differ from our estimates. Unless we raise additional capital by early in the second quarter of 2009, we will further reduce our staff and suspend some or all of our self-funded product development efforts, including our self-funded portion of the LCA and HD programs, to further extend our cash horizon and, if we do not receive additional funding, we will be required to cease our operations.

***Collaboration and Grant Funding***

Our development and manufacturing collaborations have historically provided us with funding in several forms, including purchases of our equity securities, loans, reimbursement of research and development costs and milestone fees and payments. We and our partners typically agree on a target disease and create a development plan for the product candidate, which generally extends for multiple one-year terms or through development milestones and is subject to termination or extension. For example, in 2004 when we and Celladon initiated our collaboration to develop a product candidate to treat congestive heart failure, Celladon's investors purchased \$6.0 million of our equity and we and Celladon established a product development plan under which Celladon agreed to reimburse our product development expenses. Under our agreements with Celladon, Celladon will also pay milestone fees and payments if Celladon reaches certain development and commercialization milestones, and will make payments to us in the event of specified strategic transactions involving Celladon.

The funding from each of our collaborative partners or grant funding sources generally fully offsets our incremental program costs from the relevant collaboration or grant and our overhead and fixed costs related to that effort. Our revenue from collaborative agreements, grants and licenses totaled \$8.7 million in 2008, \$10.3 million in 2007 and \$9.9 million in 2006. Assuming that we complete all of the planned development activities for each of our funded projects, we expect to earn revenue from our collaborative partners of approximately \$6.0 million to \$7.0 million in 2009, with the majority of that revenue to be earned during the first half of the year. Our revenue plan for 2009 includes our expectation that we accomplish the current work plan with Celladon and our work under the DOD-funded ALS program, as well as successfully wind-down our support of the NIAID-funded HIV/AIDS vaccine work plans as that program enters clinical trials and we terminate our involvement in the program.

Each of our collaborations has provisions that allow our partners the right to terminate the underlying collaboration and the obligation to provide research and development funding at any time with 60 to 90 days notice. If we were to lose the collaborative funding expected from the DOD-funded ALS grant or the funding expected from Celladon and we were unable to obtain alternative sources of funding, we would be unable to continue our research and development program for that product candidate (or, in the case of Celladon, complete the current manufacturing campaign) and/or we would not have sufficient resources available to fund our operations for as long as currently expected.

**Table of Contents****Contractual Commitments and Long-Term Debt Obligations**

We also have lease and purchase commitments that draw on our cash resources. The following table presents our contractual commitments:

| Contractual Obligations                      | Payments Due through Year Ending December 31: |                     |                     |                     |                     |                     | Total                |
|--|---|---------------------|---------------------|---------------------|---------------------|---------------------|----------------------|
|  | 2009  | 2010                | 2011                | 2012                | 2013                | Thereafter          |                      |
| Operating lease obligations <sup>(1)</sup> : |   |                     |                     |                     |                     |                     |                      |
| Seattle facilities occupied                  | \$ 741,000                                    | \$ 812,000          | \$ 817,000          | \$ 822,000          | \$ 827,000          | \$ 207,000          | \$ 4,226,000         |
| Bothell facility not occupied                | 1,362,000                                     | 1,431,000           | 1,636,000           | 1,636,000           | 1,636,000           | 2,862,000           | 10,563,000           |
| Purchase obligations <sup>(2)</sup>          | 1,692,000                                     |                     |                     |                     |                     |                     | 1,692,000            |
| <b>Total</b>                                 | <b>\$ 3,795,000</b>                           | <b>\$ 2,243,000</b> | <b>\$ 2,453,000</b> | <b>\$ 2,458,000</b> | <b>\$ 2,463,000</b> | <b>\$ 3,069,000</b> | <b>\$ 16,481,000</b> |

- (1) Operating lease obligations represent our commitments for our facilities in Seattle and Bothell, Washington. Lease payments for our laboratory, manufacturing and office space in Seattle will total \$4.2 million between January 1, 2009 and the end of the lease in 2014. Lease payments on the Bothell facility will total \$10.6 million between January 1, 2009 and the end of the term of the Bothell lease in 2015. We have been unsuccessful in our efforts to sublease or otherwise reduce the costs of our Bothell facility and, in February 2009, we surrendered the building to the landlord and discontinued rent payments, such actions constituting a default under the lease, and are pursuing a negotiated settlement to our obligations under the facility lease. There can be no assurance that we will be successful in negotiating a settlement with the landlord, and the landlord may terminate the lease as a result of our default and, among other potential remedies, accelerate all of our obligations due under the lease. We may also seek to sublease a portion of our laboratory space in our Seattle facility.
- (2) Outstanding purchase obligations primarily include commitments for research and development contracts, our annual financial statement audit and other miscellaneous general and administrative purchases.

As of December 31, 2008 we had no long-term debt obligations and no equipment financing obligations.

**Capital Requirements**

Our research and development expenses 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 portion of our revenue and expense is directly tied to our research and development activities, our revenue will fluctuate in part with the level of future research and development activities. We expect that our revenue and expense will continue to fluctuate as we proceed with our current development collaborations, enter into potential new development collaborations and licensing agreements and potentially earn milestone payments.

Over the past several years, we have scaled our development activities to the level of available cash resources and financial support from collaboration partners. Our research and development and general and administrative expenses decreased by approximately 15% in 2008 compared to 2007 and increased by approximately 19% in 2007 compared to 2006. We expect these expenses to decrease in 2009 as a result the completion of our inflammatory arthritis program during 2008 and lower costs necessary to support our NIAID-funded HIV/AIDS vaccine project and our collaboration with Celladon.

Assuming that our product development programs progress at the rates currently planned and assuming that we receive the approximately \$6.0 million to \$7.0 million of revenues we expect to earn

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from our collaborative partners and grants during 2009, we believe that our net cash requirements during 2009 will be approximately \$6.0 million to \$7.0 million. This amount also assumes that we achieve our current operating plan (which includes successfully accomplishing the current work plan with Celladon and our work under the DOD-funded ALS program, as well as successfully winding down our support of the work plans for our NIAID-funded HIV/AIDS vaccine program in collaboration with NCH and CHOP), that we reduce our manufacturing staff and operating costs if we do not successfully identify new sources to fund our manufacturing operation, and that we incur minimal costs to support our three primary product development programs pending funding for those activities.

We need to raise additional capital to continue our operations and support the advancement of our three primary product development programs for LCA, HD and ALS, and assuming satisfactory results, plan and initiate further pre-clinical and clinical testing of our potential product candidates. We expect that our cash and cash equivalents at December 31, 2008, plus the funding expected from our collaborative partners and grants to fund 2009 work activities, will only be sufficient to fund our current level of operations only through the second quarter of 2009. This estimate is based on our ability to perform, and success of, planned collaboration activities and the receipt of planned funding from our collaborators, and actual results could differ from our estimates. Unless we raise additional capital, we will be forced to further reduce our staff and suspend some or all of our self-funded product development efforts to further extend our cash horizon. Even if we are able to extend our cash horizon, if we do not receive sufficient additional funding in time, we will be required to cease our operations.

Our near-term financing strategy includes advancing our clinical development programs, leveraging our development and manufacturing capabilities and intellectual property assets into additional capital raising opportunities, and seeking capital through a wide variety of sources, including accessing the public and private capital markets and pursuing potential strategic transactions. We plan to carefully steward our available cash to provide the longest possible time to allow our financing strategies to come to fruition. In the capital markets today there is extreme competition for capital to fund biotechnology businesses that do not have product sales and do not have later stage products showing high levels of efficacy in Phase II clinical trials. Moreover, in the biotechnology industry there is a low level of success in clinical trials and our ability to raise capital depends in part on clinical trial success.

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

strategic transactions, including mergers and acquisitions;

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

entering into additional product development or manufacturing collaborations;

extending or expanding our current collaborations;

issuing equity or debt in the public or private markets;

borrowing under loan or equipment financing arrangements; and/or

issuing debt.

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

We expect the level of our future operating expenses to be driven by the needs of our product development programs and our lease obligations, offset by the availability of funds through equity or debt offerings, partner-funded collaborations or other financing or business development activities. The



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size, scope and pace of our product development activities depend on the availability of these resources. Our future cash requirements will depend on many factors, including those discussed in the risk factor entitled *If we are unable to raise additional capital or secure additional sources of funding in the very near future, we will be unable to continue our operations* in Part I, Item 1A of this annual report. If we do not successfully access additional funding by early in the second quarter of 2009, we will be forced to implement additional cost reduction measures, such as staff reductions, scaling back or suspending or delaying our work on our three primary product development programs, reducing our intellectual property prosecution, subleasing portions of our lab facilities, curtailing capital expenditures or reducing other operating activities. We may also be required to relinquish some rights to our technology or product candidates or grant licenses on unfavorable terms, either of which would reduce the ultimate value to us of the technology or product candidates, or to sell assets significantly below their potential worth. If we are unable to secure additional capital, we will be required to cease operations, declare bankruptcy or otherwise wind up our business.

## **Off-Balance Sheet Arrangements**

Although we do not have any joint ventures or other similar off-balance sheet items, in the ordinary course of business we enter into agreements that require us to indemnify counterparties against third-party claims. These may include:

agreements with vendors and suppliers, under which we may indemnify them against claims arising from our use of their products or services;

agreements with clinical investigators, under which we may indemnify them against claims arising from their use of our product candidates;

real estate and equipment leases, under which we may indemnify lessors against third-party claims relating to our use of their property;

agreements with licensees or licensors, under which we may indemnify the licensee or licensor against claims arising from their use of our intellectual property or our use of their intellectual property; and

agreements with initial purchasers and underwriters of our securities, under which we may indemnify them against claims relating to their participation in the transactions.

The nature and terms of these indemnifications vary from contract to contract and generally a maximum obligation is not stated. Because we are unable to estimate our potential obligation, and because management does not expect these indemnifications to have a material adverse effect on our consolidated financial position, results of operations or cash flows, no related liabilities are recorded at December 31, 2008 or 2007. We hold insurance policies that mitigate potential losses arising from certain indemnifications and, historically, we have not incurred significant costs related to performance under these obligations.

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

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of

Targeted Genetics Corporation

We have audited the accompanying consolidated balance sheets of Targeted Genetics Corporation (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2008. 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 the standards of the Public Company Accounting Oversight Board (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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations that, due to its limited working capital, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As discussed in Note 13 to the consolidated financial statements, in 2007 the Company changed its accounting for income taxes upon the adoption of Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109.

/s/ Ernst & Young LLP

Seattle, Washington

March 18, 2009

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

|   | December 31,  |               |
|---|---------------|---------------|
|   | 2008          | 2007          |
| <b>ASSETS</b>   |               |               |
| Current assets:   |               |               |
| Cash and cash equivalents   | \$ 5,216,000  | \$ 16,442,000 |
| Accounts receivable   | 317,000       | 2,611,000     |
| Prepaid expenses and other current assets   | 132,000       | 243,000       |
| <br>  |               |               |
| Total current assets  | 5,665,000     | 19,296,000    |
| Property and equipment, net   | 1,285,000     | 1,052,000     |
| Goodwill  |               | 7,926,000     |
| Other assets  | 200,000       | 200,000       |
| <br>  |               |               |
| Total assets  | \$ 7,150,000  | \$ 28,474,000 |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)</b>  |               |               |
| Current liabilities:  |               |               |
| Accounts payable and accrued expenses   | \$ 1,735,000  | \$ 2,161,000  |
| Accrued employee expenses   | 368,000       | 1,507,000     |
| Current portion of accrued restructure charges  | 656,000       | 574,000       |
| Deferred revenue  | 1,227,000     | 79,000        |
| Current portion of long-term obligations owed to a related party  |               | 336,000       |
| <br>  |               |               |
| Total current liabilities   | 3,986,000     | 4,657,000     |
| Accrued restructure charges   | 6,934,000     | 7,569,000     |
| Deferred rent   | 2,000         | 8,000         |
| Commitments and contingencies (Notes 2 and 6)   |               |               |
| Shareholders' equity (deficit):   |               |               |
| Preferred stock, \$0.01 par value, 600,000 shares authorized: Series A preferred stock, 180,000 shares designated, none issued and outstanding  |               |               |
| Common stock, \$0.01 par value, 45,000,000 shares authorized, 20,238,865 shares issued and outstanding at December 31, 2008 and 19,814,161 shares issued and outstanding at December 31, 2007 | 202,000       | 198,000       |
| Additional paid-in capital  | 316,900,000   | 316,196,000   |
| Accumulated deficit   | (320,874,000) | (300,154,000) |
| Total shareholders' equity (deficit)  | (3,772,000)   | 16,240,000    |
| <br>  |               |               |
| Total liabilities and shareholders' equity (deficit)  | \$ 7,150,000  | \$ 28,474,000 |

*See accompanying notes to consolidated financial statements*

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

|   | Year Ended December 31, |                        |                        |
|---|-------------------------|------------------------|------------------------|
|   | 2008                    | 2007                   | 2006                   |
| <b>Revenue:</b>   |                         |                        |                        |
| Collaborative revenue   | \$ 8,618,000            | \$ 9,732,000           | \$ 8,114,000           |
| Licensing revenue   | 100,000                 | 600,000                | 1,750,000              |
| <b>Total revenue</b>  | <b>8,718,000</b>        | <b>10,332,000</b>      | <b>9,864,000</b>       |
| <b>Operating expenses:</b>  |                         |                        |                        |
| Research and development  | 15,183,000              | 17,709,000             | 14,482,000             |
| General and administrative  | 5,822,000               | 7,029,000              | 6,382,000              |
| Restructure charges   | 954,000                 | 2,148,000              | 2,006,000              |
| Goodwill impairment charge  | 7,926,000               |                        | 23,723,000             |
| <b>Total operating expenses</b>   | <b>29,885,000</b>       | <b>26,886,000</b>      | <b>46,593,000</b>      |
| <b>Loss from operations</b>   | <b>(21,167,000)</b>     | <b>(16,554,000)</b>    | <b>(36,729,000)</b>    |
| Investment income, net  | 279,000                 | 428,000                | 567,000                |
| Other income  | 91,000                  |                        |                        |
| Interest expense  |                         | (1,000)                | (411,000)              |
| Gain on the restructure of debt owed to a related party                   | 77,000                  |                        | 2,583,000              |
| <b>Net loss</b>   | <b>\$ (20,720,000)</b>  | <b>\$ (16,127,000)</b> | <b>\$ (33,990,000)</b> |
| <b>Net loss per common share (basic and diluted)</b>                      | <b>\$ (1.04)</b>        | <b>\$ (0.98)</b>       | <b>\$ (3.47)</b>       |
| Shares used in computation of basic and diluted net loss per common share | 19,954,000              | 16,504,000             | 9,788,000              |

*See accompanying notes to consolidated financial statements*

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## TARGETED GENETICS CORPORATION

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT)

|   | Common Stock |            | Additional<br>Paid-In-<br>Capital | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Loss | Total<br>Shareholders<br>Equity<br>(Deficit) |
|---|--------------|------------|-----------------------------------|------------------------|---|--|
|   | Shares       | Amount     |                                   |                        |   |  |
| Balance at<br>December 31, 2005   | 8,569,424    | \$ 86,000  | \$ 280,543,000                    | \$ (250,037,000)       | \$ (21,000)                                   | \$ 30,571,000                                |
| Net loss 2006   |              |            |                                   | (33,990,000)           |   | (33,990,000)                                 |
| Unrealized loss on available-for-sale<br>securities                               |              |            |                                   |                        | (18,000)                                      | (18,000)                                     |
| Comprehensive net<br>loss 2006  |              |            |                                   |                        |   | (34,008,000)                                 |
| Stock-based compensation  |              |            | 861,000                           |                        |   | 861,000                                      |
| Issuance of shares for cash, net of<br>issue costs of \$162,000                   | 1,279,124    | 13,000     | 4,813,000                         |                        |   | 4,826,000                                    |
| Issuance of shares to vendors and<br>collaborative partners                       | 45,000       |            | 141,000                           |                        |   | 141,000                                      |
| Issuance of shares in<br>debt restructure   | 1,000,000    | 10,000     | 2,890,000                         |                        |   | 2,900,000                                    |
| Exercise of stock options   | 28,188       |            | 76,000                            |                        |   | 76,000                                       |
| Balance at<br>December 31, 2006   | 10,921,736   | \$ 109,000 | \$ 289,324,000                    | \$ (284,027,000)       | \$ (39,000)                                   | \$ 5,367,000                                 |
| Net loss 2007   |              |            |                                   | (16,127,000)           |   | (16,127,000)                                 |
| Unrealized loss on available-for-sale<br>securities                               |              |            |                                   |                        | 39,000  | 39,000                                       |
| Comprehensive net<br>loss 2007  |              |            |                                   |                        |   | (16,088,000)                                 |
| Stock-based compensation  |              |            | 966,000                           |                        |   | 966,000                                      |
| Exercise of stock options   | 12,632       |            | 39,000                            |                        |   | 39,000                                       |
| Issuance of shares and warrants for<br>cash, net of issue costs of<br>\$2,227,000 | 8,879,793    | 89,000     | 25,867,000                        |                        |   | 25,956,000                                   |
| Balance at<br>December 31, 2007   | 19,814,161   | \$ 198,000 | \$ 316,196,000                    | \$ (300,154,000)       | \$  | \$ 16,240,000                                |
| Net loss and comprehensive net<br>loss 2008                                       |              |            |                                   | (20,720,000)           |   | (20,720,000)                                 |
| Stock-based compensation  |              |            | 718,000                           |                        |   | 718,000                                      |
| Vested Restricted Stock Units, net of<br>14,151 shares withheld for taxes         | 424,704      | 4,000      | (14,000)                          |                        |   | (10,000)                                     |
| Balance at<br>December 31, 2008   | 20,238,865   | \$ 202,000 | \$ 316,900,000                    | \$ (320,874,000)       | \$  | \$ (3,772,000)                               |

See accompanying notes to consolidated financial statements



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

|  | Year Ended December 31, |                      |                     |
|--|-------------------------|----------------------|---------------------|
|  | 2008                    | 2007                 | 2006                |
| <b>Operating activities:</b>   |                         |                      |                     |
| Net loss   | \$ (20,720,000)         | \$ (16,127,000)      | \$ (33,990,000)     |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                         |                      |                     |
| Depreciation and amortization  | 516,000                 | 602,000              | 720,000             |
| Loss (gain) on sale/disposal of fixed assets                                       | (87,000)                | (24,000)             | 8,000               |
| Stock-based compensation   | 718,000                 | 966,000              | 861,000             |
| Stock issued to vendors and collaborative partners                                 |                         |                      | 141,000             |
| Goodwill impairment charge   | 7,926,000               |                      | 23,723,000          |
| Gain on the restructure of debt to a related party                                 | (77,000)                |                      | (2,583,000)         |
| Loss (gain) on investments   |                         | 340,000              | (8,000)             |
| Other  | (10,000)                |                      |                     |
| <b>Changes in assets and liabilities:</b>  |                         |                      |                     |
| Accounts receivable  | 2,294,000               | (1,113,000)          | (1,118,000)         |
| Prepaid expenses and other   | 111,000                 | (29,000)             | 93,000              |
| Other assets   |                         | 6,000                | 11,000              |
| Current liabilities  | (1,565,000)             | 906,000              | 405,000             |
| Deferred revenue   | 1,148,000               | (172,000)            | (27,000)            |
| Deferred rent  | (6,000)                 | (3,000)              | (100,000)           |
| Accrued restructure charges  | (553,000)               | 766,000              | 228,000             |
| <b>Net cash used in operating activities</b>                                       | <b>(10,305,000)</b>     | <b>(13,882,000)</b>  | <b>(11,636,000)</b> |
| <b>Investing activities:</b>   |                         |                      |                     |
| Purchases of property and equipment  | (738,000)               | (554,000)            | (81,000)            |
| Proceeds from sales of property and equipment                                      | 76,000                  | 24,000               |                     |
| Proceeds from sales of investments   |                         | 16,000               | 49,000              |
| <b>Net cash used in investing activities</b>                                       | <b>(662,000)</b>        | <b>(514,000)</b>     | <b>(32,000)</b>     |
| <b>Financing activities:</b>   |                         |                      |                     |
| Net proceeds from sales of capital stock and warrants                              |                         | 25,956,000           | 4,826,000           |
| Proceeds from the exercise of stock options  |                         | 39,000               | 76,000              |
| Repayment of debt owed to a related party  | (258,000)               | (1,337,000)          | (995,000)           |
| Payments under equipment financing arrangements                                    | (1,000)                 | (26,000)             | (155,000)           |
| <b>Net cash provided by (used in) financing activities</b>                         | <b>(259,000)</b>        | <b>24,632,000</b>    | <b>3,752,000</b>    |
| <b>Net increase (decrease) in cash and cash equivalents</b>                        | <b>(11,226,000)</b>     | <b>10,236,000</b>    | <b>(7,916,000)</b>  |
| Cash and cash equivalents, beginning of year                                       | 16,442,000              | 6,206,000            | 14,122,000          |
| <b>Cash and cash equivalents, end of year</b>                                      | <b>\$ 5,216,000</b>     | <b>\$ 16,442,000</b> | <b>\$ 6,206,000</b> |
| <b>Supplemental information:</b>   |                         |                      |                     |
| Cash paid for interest   | \$ 9,000                | \$ 62,000            | \$ 550,000          |
| Non-cash exchange of common stock issued in debt restructure                       | \$                      | \$                   | \$ 2,900,000        |

*See accompanying notes to 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 Corporation was incorporated in the state of Washington in March 1989. We conduct research and development of gene therapy products and technologies for treating both acquired and inherited diseases. We develop these programs on our own and under various collaborative agreements with others.

***Basis of Presentation***

Our consolidated financial statements include the accounts of Targeted Genetics, our wholly owned subsidiaries Genovo, Inc. (*inactive*) and TGCF Manufacturing Corporation (*inactive*). There have been no intercompany transactions for all years included in this report.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. 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.

***Cash Equivalents***

Cash equivalents include short-term investments that have a maturity at the time of purchase of three months or less, are readily convertible into cash and we believe have an insignificant level of valuation risk attributable to potential changes in interest rates. Our cash equivalents are recorded at cost, which approximates fair market value, and consist primarily of money market accounts.

***Fair Value of Financial Instruments***

We believe that the carrying amounts of financial instruments such as cash and cash equivalents, available-for-sale securities, 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 in 2007 and 2006 approximated fair value because the interest rates on these instruments changed with, or approximated, market interest rates.

***Property and Equipment***

Property and equipment is stated at cost less accumulated depreciation. We compute depreciation of property and equipment using the straight-line method over the asset's estimated useful life. The useful lives of our furniture and equipment ranges from three to seven years, and our leasehold improvements are amortized over the shorter of the asset's estimated useful life or the remainder of the lease term. Our leasehold improvements are currently being amortized over useful lives which range from three months to eight years. Depreciation and amortization expense was \$516,000 in 2008, \$602,000 in 2007 and \$720,000 in 2006. Depreciation expense includes depreciation of property and equipment acquired under capital leases.

***Prepaid Expenses and Other***

Prepaid and other current assets consists primarily of prepaid expenses, including prepaid insurance and contracted services agreements.

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Business and Summary of Significant Accounting Policies (continued)**

***Goodwill and Purchased Intangibles***

When we purchased Genovo in 2000, we recorded intangible assets of \$39.5 million on our financial statements, which represented know-how, an assembled workforce and goodwill. We follow Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*, or SFAS No. 142, which discontinued amortization of goodwill and requires us to perform goodwill impairment tests annually or more frequently if events and changes in business conditions indicate that the carrying amount of our goodwill may not be recoverable. We assess any potential impairment using a two-step process. Since we have only one reporting unit for purposes of applying SFAS No. 142, the first step requires us to compare the fair value of our total company, as measured by market capitalization, to our net book value. If our fair value is greater, then no impairment is indicated. If our fair value is less than the net carrying value of our assets, then we are required to perform the second step to determine the amount, if any, of goodwill impairment. In step two, the implied fair value of goodwill is measured using a weighted analysis of the present value of future discounted cash flows and market valuation approach and compared to its carrying amount. If the goodwill carrying amount exceeds the implied fair value, an impairment loss must be recognized equal to that excess. The implied goodwill amount is determined by allocating fair value to all of our assets and liabilities, including intangible assets such as in-process research and development, developed technology and trademarks and trade names, as if we had been acquired in a hypothetical business combination as of the date of the impairment test. In 2006, we engaged an independent valuation firm to assist with the evaluation, including the assessment of our estimated fair value and the hypothetical purchase price allocations, and to assist us in building financial models to continue to assess these factors going forward.

As a result of an interim goodwill impairment test performed in 2006, we recognized a \$23.7 million non-cash loss for the impairment of goodwill, based on an assessment that the implied value of goodwill was \$7.9 million. In the fourth quarter of 2008, due to continued decline in the market price of our common stock and a restructuring implemented in November 2008 to realign and narrow our product development priorities, we concluded that sufficient indicators existed to require us to perform an interim assessment of goodwill to determine if there was further impairment to our remaining \$7.9 million goodwill balance. This analysis resulted in an implied goodwill balance of zero and a non-cash impairment charge of \$7.9 million.

***Other Assets***

Other assets consists of a \$200,000 certificate of deposit that is pledged as collateral for the Bothell facility lease.

***Accrued Restructure Charges***

We follow the provisions of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, or SFAS No. 146, as it relates to our facilities in Bothell, Washington, employee termination benefits and lease termination fees for facilities related to our administrative office space in Seattle. Under SFAS No. 146, we have recorded restructure charges on the operating leases for the Bothell facility. Accrued restructure charges, and in particular those charges associated with exiting a facility, are subject to many assumptions and estimates. Under SFAS No. 146, an accrued liability for lease termination costs is initially measured at fair value, based on the remaining lease payments due under the lease and other costs and discounted using a credit-adjusted risk-free interest rate. We use a

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Business and Summary of Significant Accounting Policies (continued)**

risk-free annual interest rate of 10%. The assumptions as to whether a facility can be subleased, estimated sublease rental income, the period of time to execute a sublease and the costs and concessions necessary to enter into a sublease significantly impact the accrual and may differ from what actually occurs. We review these estimates periodically and adjust the accrual when necessary.

***Stock Compensation***

Effective January 1, 2006, we adopted SFAS No. 123R, *Share-Based Payment*, or SFAS No. 123R, and elected to adopt the modified prospective application method. Accordingly, stock-based compensation cost is measured at the grant date, based on the fair value of the award and is recognized as an expense over the requisite service period. For stock awards granted after January 1, 2006, stock-based compensation expenses are recognized over the award vesting period under the straight-line attribution method. Previously reported amounts have not been restated.

***Revenue Recognition under Collaborative Agreements***

We generate revenue from technology licenses, collaborative research arrangements and agreements to provide research, development and manufacturing services. 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.

For collaborative agreements, we initially defer revenue from nonrefundable, up-front license fees and technology access payments and then recognize it systematically over the service period of the collaborative agreement, which is often the development period. We recognize revenue associated with performance milestones as earned, typically based upon the achievement of the specific milestones defined in the applicable agreements.

We recognize revenue under research and development contracts as the related costs are incurred. When contracts include multiple elements we follow the Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, which requires us to satisfy the following before revenue can be recognized:

- 1) the delivered items have value to the customer on a stand-alone basis;
- 2) any undelivered items have objective and reliable evidence of fair value; and
- 3) delivery or performance is probable and within our control for any delivered items that have a right of return.

We have determined that, for these contracts, the manufacturing activities and the research and development activities can be accounted for as separate units of accounting, and we allocate the revenue to each unit based on relative fair value. We recognize revenue for manufacturing activities when the manufacturing campaign is substantially complete and we recognize revenue for research and development activities on a percentage-of-completion basis. We classify advance payments received in excess of amounts earned as deferred revenue.

Based upon the terms specified in our collaboration agreements, we receive advance payments from some of our collaboration partners before the project work has been performed. These payments are deferred and recognized as revenue when the costs are incurred.



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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Business and Summary of Significant Accounting Policies (continued)**

***Significant Revenue Relationships and Concentration of Risk***

Our primary source of revenue is from our collaborative agreements. In 2008, revenues from our collaboration with Celladon Corporation, or Celladon, accounted for 56% our revenue, and revenues under our subcontract with the National Institute of Allergy and Infectious Diseases, or NIAID, accounted for 42% of our revenue. Under our original 2004 collaboration and manufacturing agreements with Celladon, Celladon provided its intellectual property and funded development and manufacturing efforts and we provided our proprietary AAV technology. In February 2009, we and Celladon replaced the 2004 agreements with a license agreement and a new manufacturing agreement. Under the new agreements, we granted Celladon exclusive use of certain proprietary technology in a specified field related to heart failure, subject to the payment of milestone and royalty payments, and agreed to manufacture drug substance for a Phase III clinical trial (at Celladon's expense) and engage in technology transfer efforts through July 2009. For 2009, we expect to earn revenues from Celladon and from the U.S. Department of Defense, or the DOD, through a grant for our collaboration with John Engelhardt, Ph.D. at the University of Iowa, or UI, for the development of a treatment of amyotrophic lateral sclerosis, or ALS. A significant change in the level of work or timing of work activities and the funding received from either of these collaborations could disrupt our business and adversely affect our cash flow and results of operations.

***Research and Development Costs***

Research and development costs include salaries, costs of outside collaborators and outside services, clinical trial expenses, royalty and license costs and allocated facility, occupancy and utility expenses. We expense research and development costs as incurred. Research and development costs related to programs conducted under collaborative agreements that result in collaborative revenue totaled approximately \$11.4 million in 2008, \$10.3 million in 2007 and \$5.6 million in 2006.

***Operating Leases***

We have operating leases for our laboratory, manufacturing and office space facilities located in Seattle and Bothell, Washington. These lease agreements contain rent escalation clauses and rent holidays. For scheduled rent escalation clauses during the lease terms or for rental payments commencing at a date other than the date of initial occupancy, we record minimum rental expenses on a straight-line basis over the terms of the leases in our consolidated statement of operations. When we make leasehold improvements to our facilities, we amortize them over the shorter of the useful life of the asset or the remaining term of the lease. We currently have \$52,000 of leasehold improvements related to our Seattle facilities that we are amortizing over the shorter of the useful life of the asset or the remainder of the current lease terms, which expire at the end of the first quarter of 2014 for our main laboratory, manufacturing and office facility and for our administrative office space. Rent for our Bothell facility is recorded as restructure charges in our consolidated statement of operations and the lease expires in September 2015. See Note 4.

***Net Loss per Common Share***

Net loss per common share is based on net loss divided by the weighted average number of common shares outstanding during the period. For each fiscal year reported, our diluted net loss per share is the same as our basic net loss per share because all stock options, restricted stock units, warrants and other potentially dilutive securities are antidilutive with respect to computing our net loss.

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Description of Business and Summary of Significant Accounting Policies (continued)**

per share and therefore are excluded from our calculation of diluted net loss per share. The total number of shares that we excluded from the calculation of net loss per share were 9,304,987 shares in 2008, 9,229,250 shares in 2007 and 1,035,085 shares in 2006.

***Recently Issued Accounting Standards***

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 provides guidance for using fair value to measure assets and liabilities and requires expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS No. 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. SFAS No. 157 does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS No. 157 did not have an effect on our financial position or results of operations.

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

In July 2007, the EITF reached a consensus on Issue No. 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF 07-3 is effective for fiscal years beginning after December 15, 2007 and early adoption was not permitted. The adoption of EITF 07-3 changed our policy on nonrefundable prepayments for research and development services: such costs are now deferred and recognized as the services are rendered, whereas under the previous policy such payments were charged to research and development expense as paid. This change did not have a material effect on our financial position or results of operations for 2008.

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

**2. Liquidity and Management's Plans**

We have prepared the accompanying financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. However, we have incurred net losses since our inception, we have negative operating cash flows and

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****2. Liquidity and Management's Plans (continued)**

we have an accumulated deficit of \$320.9 million as of December 31, 2008. Our cash balance as of December 31, 2008 was \$5.2 million, our accounts receivable balance was \$317,000 and our current liabilities were \$4.0 million. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of this uncertainty.

Under our operating plan for 2009, we project 2009 net operating cash flow deficits of approximately \$6.0 million to \$7.0 million. This projection assumes that we complete all of the planned development activities for each of our funded projects, resulting in up to approximately \$6.0 million to \$7.0 million of 2009 funding from our collaborative partners and from grants. Our projected 2009 net operating cash flow deficit also assumes that we achieve our current operating plan, which includes successfully accomplishing the current work plan with Celladon and our work under the DOD-funded ALS program, as well as successfully winding down our support of the work plans for our HIV/AIDS vaccine program in collaboration with Nationwide Children's Hospital, or NCH, and Children's Hospital of Philadelphia, or CHOP, which is funded by the NIAID as that program enters clinical trials and we terminate our involvement in the program in connection with our realignment efforts. Our estimate of 2009 net operating cash flow deficit also assumes that we reduce our manufacturing staff and operating costs if we do not successfully identify new sources to fund our manufacturing operation, and also includes incurring minimal costs to support our three primary product development programs pending funding for those activities.

We believe that our current resources and the cash we expect to receive from our collaborative partners will only be sufficient to fund our operations through the second quarter of 2009. This estimate is based on our ability to perform, and success of, planned collaboration activities and the receipt of planned funding from our collaborators, and actual results could differ from our estimates. We are seeking additional financing in order to fund our operations through 2009; however, we cannot provide assurances that we will be successful in obtaining additional financing for 2009 or when and as needed in the future. If we do not raise additional funds by in the middle of the second quarter of 2009, we will implement additional cost reduction measures, such as a reduction in workforce, scaling back or suspending or delaying our work on our three primary product development programs, reducing our intellectual property prosecution, subleasing portions of our lab facilities, curtailing capital expenditures, reducing other operating activities, and/or the pursuit of alternative financing transactions that would likely be on terms disadvantageous to us and dilutive to our shareholders. We could also be required to relinquish rights to our technology or product candidates or grant licenses on unfavorable terms, either of which would reduce the ultimate value to us of the technology or product candidates, or to sell assets likely at values significantly below their potential worth. If we are unable to secure additional capital, we will be required to cease operations, declare bankruptcy or otherwise wind up our business.

**3. Property and Equipment**

Property and equipment consisted of the following:

|  | December 31, |              |
|--|--------------|--------------|
|  | 2008         | 2007         |
| Furniture and equipment                        | \$ 8,030,000 | \$ 7,313,000 |
| Leasehold improvements                         | 9,310,000    | 9,289,000    |
|  | 17,340,000   | 16,602,000   |
| Less accumulated depreciation and amortization | (16,055,000) | (15,550,000) |
|  | \$ 1,285,000 | \$ 1,052,000 |





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## TARGETED GENETICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**3. Property and Equipment (continued)**

In the past, we have generally financed a portion of our equipment through equipment financing arrangements, which include extensions and purchase options and require us to pledge the financed equipment as security. The cost of equipment pledged under financing arrangements totaled zero at December 31, 2008 and \$50,000 at December 31, 2007.

**4. Restructure Charges**

Restructure charges primarily include contract termination costs related to building lease activity and employee termination costs. In 2002, we began to pursue options to sublease, or terminate, our lease on the Bothell facility, which we have never occupied. We record accrued restructure charges as they relate to the lease on this facility. Accrued restructure charges represent our best estimate of the fair value of the liability remaining under the lease and are computed as the present value of the difference between the remaining lease payments due less the net of sublease income and expense. These assumptions are periodically reviewed and adjustments are made to the accrued restructure charge when necessary. We record accretion expense as the difference between estimated cost and the present value of these costs using an assumed discount rate of 10%. Accretion expense is recorded on an ongoing basis through the end of the lease term in September 2015 and is reflected as a restructure charge in the accompanying consolidated statements of operations.

We also record employee termination benefit costs associated with restructuring our business or reductions in force as restructure charges. Employee termination benefit costs include one-time termination benefits that are not a part of an existing benefit arrangement, including severance payments, stock-based compensation charges related to modified stock awards and payments for post-employment medical coverage.

The tables below present our total estimated restructure charges and a reconciliation of the associated liability:

|   | Employee<br>Termination<br>Benefits | Contract<br>Termination<br>Costs | Other<br>Associated<br>Costs | Total         |
|---|-------------------------------------|----------------------------------|------------------------------|---------------|
| Incurring in 2002                                     | \$ 725,000                          | \$ 1,602,000                     | \$                           | \$ 2,327,000  |
| Incurring in 2003                                     | 5,000                               | 5,153,000                        | 32,000                       | 5,190,000     |
| Incurring in 2004                                     |                                     | 884,000                          |                              | 884,000       |
| Incurring in 2005                                     |                                     | 1,709,000                        |                              | 1,709,000     |
| Incurring in 2006                                     | 221,000                             | 1,785,000                        |                              | 2,006,000     |
| Incurring in 2007                                     |                                     | 2,148,000                        |                              | 2,148,000     |
| Incurring in 2008                                     | 166,000                             | 788,000                          |                              | 954,000       |
| Cumulative incurred to date                           | 1,117,000                           | 14,069,000                       | 32,000                       | 15,218,000    |
| Estimated future charges<br>attributable to accretion |                                     | 2,994,000                        |                              | 2,994,000     |
| Total expected to be incurred                         | \$ 1,117,000                        | \$ 17,063,000                    | \$ 32,000                    | \$ 18,212,000 |

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## TARGETED GENETICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 4. Restructure Charges (continued)

|  | Restructure<br>Costs |
|--|----------------------|
| December 31, 2007 accrued liability              | \$ 8,143,000         |
| Charges related to employee termination benefits | 166,000              |
| Accretion expense                                | 788,000              |
| Amount paid in 2008                              | (1,507,000)          |
| <br>   |                      |
| December 31, 2008 accrued liability              | \$ 7,590,000         |

Restructuring charges for 2008 include \$166,000 of employee termination benefits recognized during the fourth quarter of 2008 related to the restructuring announced in November 2008 in order to reduce expenses and realign and narrow our product development priorities. This restructuring resulted in a workforce reduction of seven employees, primarily in early-stage research and development groups and in operational and general and administrative functions. Additionally, our chief executive officer and chief scientific officer resigned from the company. The majority of these benefits were paid during 2008; however, \$22,000 will be paid in 2009 and is included in the accrued restructure liability as of December 31, 2008. In addition to this adjustment to the accrued restructure liability, we incurred \$788,000 of accretion expense in 2008. The total of these charges and adjustments to the liability are reflected as restructure charges in the accompanying consolidated statement of operations.

On February 3, 2009, we communicated to the owner of the Bothell facility that we were surrendering the building to them and discontinued rent payments. We are seeking to negotiate a settlement with the facility landlord of our remaining obligations under our Bothell lease. This action had no impact on our 2008 financial statements. Through December 31, 2008, we have recorded contract termination costs totaling \$12.9 million for the Bothell facility. Under the terms of the current Bothell lease, we would incur an additional \$3.0 million in accretion expense and would pay \$10.6 million in rent through the expiration of the lease in September 2015, subject to reduction by the amount of lease payments received by the landlord if the facility is re-leased to another tenant. We periodically evaluate our restructure estimates and assumptions and record additional restructure charges as necessary. Because restructure charges are estimates based upon assumptions regarding the timing and amounts of future events, significant adjustments to the accrual may be necessary in the future based on the actual outcome of events and as we become aware of new facts and circumstances. If we were to successfully negotiate a settlement with the facility landlord that reduces our remaining obligations under our Bothell lease or if we were to decide to resume use of the Bothell facility, a portion or all of any remaining accrued restructure charges related to the facility would be reversed. This reversal would be reflected as a reduction of restructure expenses and reflected in the period in which use is resumed. We are unable to determine the likelihood of any future adjustments to our accrued restructure charges. At December 31, 2008, we had a \$200,000 certificate of deposit recorded within other assets that was pledged as collateral for the Bothell facility lease. In March 2009, we forfeited this collateral to the owner of the Bothell facility.

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**TARGETED GENETICS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**5. Long-Term Obligations**

Long-term obligations consisted of the following:

|                                | December 31, |            |
|--------------------------------|--------------|------------|
|                                | 2008         | 2007       |
| Loan payable to Biogen Idec    | \$           | \$ 335,000 |
| Equipment financing obligation |              | 1,000      |
|                                |              | 336,000    |
| Less current portion           |              | (336,000)  |
| Long term obligation           | \$           | \$         |

In 2000, we acquired Genovo, Inc. and assumed a \$650,000 note payable to Biogen Inc. (a predecessor to Biogen Idec) and in 2001 we borrowed an additional \$10.0 million from Biogen under a loan commitment executed in connection with our acquisition of Genovo of which we repaid \$2.5 million in 2005. In 2006, we signed an agreement to restructure the remaining \$8.15 million of debt payable to Biogen Idec, a beneficial owner of approximately 11% of our outstanding common shares as of December 31, 2008. Under the agreement, Biogen Idec agreed to exchange \$5.65 million of debt for one million shares of our common stock with a fair value of \$2.9 million and we agreed to immediately pay \$500,000 of the remaining debt. The terms of the restructure resulted in a loan payable balance of \$2.2 million, which consisted of \$2.0 million principal and \$167,000 of estimated future interest payments to be paid to Biogen Idec in two installments: \$1.0 million plus accrued interest, which we paid on August 1, 2007, with the remaining loan balance due and which we paid on August 1, 2008. Outstanding borrowings under this unsecured loan agreement bore interest at the one-year London Interbank Offered Rate, or LIBOR, plus 1%, which was reset quarterly. While in place, the loan contained financial covenants establishing limits on our ability to declare or pay cash dividends. We accounted for this transaction as a troubled debt restructure in accordance with SFAS No. 15, *Accounting by Debtors and Creditors of Troubled Debt Restructures*, which resulted in a gain on debt restructure of \$2.6 million and decreased basic and diluted loss per share by \$0.26. We calculated the gain as the difference between the original principal and interest payments due on the Biogen Idec debt as compared to the cash payments made, the fair value of the common stock issued in the debt restructure and the remaining principal and interest payments due. Until the loan balance was repaid, we applied one-third of certain up-front payments received from future corporate collaborations and one-third of certain milestone payments to the outstanding balance on this loan payable, first to repayment of any accrued and unpaid interest on the principal being repaid, and second to the repayment of outstanding principal.

Inherent in our original determination of the gain on debt restructure was an estimate of the amounts and timing of future principal and interest payments. To the extent that changes in our estimates resulted in decreases in estimated future interest payments such gain was deferred until realized. In August 2008, we made our final principal and interest payment to Biogen Idec. The difference between the final principal and interest payment and the estimated liability established in 2006 was recognized as a realized gain on debt restructure of \$77,000 and decreased basic and diluted loss per share by \$0.004.

**6. Commitments**

We lease our laboratory, manufacturing and office facilities in Seattle, Washington under two non-cancelable operating leases. The lease on our primary laboratory, manufacturing and office space expires in April 2014. The lease on our administrative office space expires in March 2014 and contains



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## TARGETED GENETICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 6. Commitments (continued)

an option to extend the lease for an additional five years. We lease a facility in Bothell, Washington under a non-cancelable operating lease that expires in September 2015, which was intended to accommodate future manufacturing of our product candidates. We have surrendered this facility to the landlord and ceased making rent payments, such actions constituting a default under the lease, and are seeking to negotiate a settlement of our remaining obligations under the lease. There can be no assurance that we will be successful in negotiating a settlement with the landlord, and the landlord may terminate the lease as a result of our default and, among other potential remedies, accelerate our obligations due under the lease. We follow SFAS No. 146 as it relates to our Bothell facility lease and have recorded an accrued restructure liability of \$7.6 million as of December 31, 2008. This accrual represents the estimated fair value of this liability based on the present value of future lease payments, with no offset for any assumed sublease payments. Any future lease payments on the facility in Bothell will reduce the amount of the accrued restructure liability. The table below includes our future minimum lease payments under each of our non-cancelable operating leases, which are as follows:

| Year Ended December 31,             | Bothell<br>Facility  | Research and<br>Office Facility | Total                |
|-------------------------------------|----------------------|---------------------------------|----------------------|
| 2009                                | \$ 1,362,000         | \$ 741,000                      | \$ 2,103,000         |
| 2010                                | 1,431,000            | 812,000                         | 2,243,000            |
| 2011                                | 1,636,000            | 817,000                         | 2,453,000            |
| 2012                                | 1,636,000            | 822,000                         | 2,458,000            |
| 2013                                | 1,636,000            | 827,000                         | 2,463,000            |
| Thereafter                          | 2,862,000            | 207,000                         | 3,069,000            |
| <b>Total minimum lease payments</b> | <b>\$ 10,563,000</b> | <b>\$ 4,226,000</b>             | <b>\$ 14,789,000</b> |

We recognized rent expense under operating leases of \$991,000 in 2008, \$977,000 in 2007 and \$869,000 in 2006.

## 7. Investments

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

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

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

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

As of December 31, 2008, we held shares of Chromos Molecular Systems Inc., or Chromos, a publicly traded company whose common stock was listed on the Toronto Stock Exchange. The Chromos securities were delisted from the Toronto Stock Exchange at the close of the market on May 8, 2008, and as a result there is not an active market for the stock. In October 2008, Chromos entered into a restructure agreement under which all assets, liabilities and equity are now controlled by a newly formed company, Calyx Bio-ventures. We believe the value of our existing shares, when



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## TARGETED GENETICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 7. Investments (continued)

converted into shares of the newly formed company, is de minimis and such value has not been recognized in our financial statements. Through December 31, 2007, we recorded our common stock investment in Chromos at fair market value and recorded changes in the fair market value of the Chromos stock in accumulated other comprehensive loss. The basis on which the cost of securities sold was determined by using the specific identification method. We also periodically evaluated our Chromos stock for signs of impairment that may be other-than-temporary, which would necessitate a reduction in the carrying value of the investment and charge to expense. During 2007, we determined that our investment was other-than-temporarily impaired and the fair value of our investment was zero, due to the declining market value of Chromos stock and a decline in Chromos financial position. Accordingly, we wrote the asset down to the fair market value of the Chromos stock and recognized realized losses of \$341,000. This investment is classified as a Level 3 on the fair value hierarchy and there were no changes to the balance during the period ending December 31, 2008.

There was no investment activity for the period ending December 31, 2008. Following is a summary of our Investment activity for the period ended December 31, 2007:

|                              | Fair Value | Unrealized Losses | Proceeds from the sale of securities | Net Realized Loss |
|------------------------------|------------|-------------------|--------------------------------------|-------------------|
| Marketable equity securities | \$         | \$                | \$ 16,000                            | \$ 340,000        |

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

## 8. Goodwill

We performed our annual impairment assessment of goodwill in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, on October 1, 2008 and determined we had no impairment as of that date. However, in the fourth quarter of 2008, the market price of our common stock continued to decline and we implemented a restructuring to realign and narrow our product development priorities. Based on these factors, we concluded that sufficient indicators existed to require us to perform an interim assessment of goodwill. Accordingly, we performed an interim first step of our impairment assessment and determined there was potential impairment of goodwill. In the first step, because we are comprised of only one reporting unit, we compared our fair value, as measured by market capitalization, to the net carrying value of our assets. Because our indicated fair value in this test was essentially equal to the net carrying value of our assets and materially below the net carrying value of our assets for the two weeks immediately proceeding the December 31, 2008 measurement date, we performed the second step of the evaluation to measure and evaluate the amount of the impairment loss. This analysis required us to measure the implied fair value of goodwill using a weighted average analysis of the present value of future discounted cash flows and market valuation approach. The implied goodwill amount is determined by allocating our estimated fair value to assets and liabilities, including intangible assets such as in-process research and development, completed technology, and trademarks and trade names using a hypothetical purchase price allocation as if we had been acquired in a business combination as of the date of the impairment test. This evaluation indicated an implied goodwill balance of zero and resulted in a non-cash impairment loss of \$7.9 million for 2008.



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**TARGETED GENETICS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. Other Comprehensive Loss**

Comprehensive loss is the total of net loss and all other non-owner changes in equity. Comprehensive loss includes unrealized gains and losses from investments and foreign currency translations on our common stock investment in Chromos, as presented in the following table:

|   | 2008                  | December 31,<br>2007  | 2006                  |
|---|-----------------------|-----------------------|-----------------------|
| Net loss as reported                                    | \$(20,720,000)        | \$(16,127,000)        | \$(33,990,000)        |
| Other comprehensive loss:                               |                       |                       |                       |
| Unrealized gain (loss) on available-for-sale securities |                       | 54,000                | (16,000)              |
| Foreign currency translation adjustment                 |                       | (15,000)              | (2,000)               |
| <b>Total other comprehensive loss</b>                   | <b>\$(20,720,000)</b> | <b>\$(16,088,000)</b> | <b>\$(34,008,000)</b> |

**10. Shareholders Equity****Stock Purchase Warrants**

We follow EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, or EITF 00-19, as it relates to our outstanding warrants. Using the guidance in EITF 00-19, we have determined that our outstanding warrants do not meet the requirements to be classified as a liability and have no impact on our consolidated financial statements.

As of December 31, 2008, we have the following warrants outstanding and exercisable to purchase shares of our common stock:

|  | Outstanding<br>and<br>Exercisable | Exercise<br>Price | Expiration       |
|--|-----------------------------------|-------------------|------------------|
| Alkermes                                       | 100,000                           | \$ 41.60          | June 9, 2009     |
| Shareholders in January 2007 private placement | 779,079                           | 5.41              | January 11, 2012 |
| Shareholders in June 2007 private placement    | 7,034,782                         | 3.25              | June 27, 2012    |
| <b>Total warrants</b>                          | <b>7,913,861</b>                  |                   |                  |

In 1999, in connection with a technology license agreement, we issued to Alkermes, Inc. a warrant to purchase 100,000 shares of our common stock at an exercise price of \$25.00 per share, which expired in June 2007, and a warrant to purchase 100,000 shares of our common stock at an exercise price of \$41.60 per share, which expires in June 2009.

On January 11, 2007, in connection with a private placement, we issued warrants to purchase up to 763,000 shares of our common stock. These warrants expire in January 2012 and are exercisable at a price of \$5.41 per share. We also issued a warrant to purchase 16,119 shares of our common stock, with the same terms as those issued pursuant to this private placement, as compensation to the placement agent in this transaction.

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On June 27, 2007, in connection with a private placement, we issued warrants to purchase up to 6.7 million shares of our common stock. These warrants expire in June 2012 and are exercisable at a price of \$3.25 per share. We also issued a warrant to purchase 334,989 shares of our common stock, with the same terms as those issued pursuant to this private placement, as compensation to the placement agent in this transaction.

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**10. Shareholders Equity (continued)**

***Stock-Based Compensation***

In May 2007, our shareholders approved our proposal to amend, restate and rename the Targeted Genetics Corporation 1999 Stock Option Plan into the Targeted Genetics Corporation Stock Incentive Plan, or Stock Incentive Plan. The Stock Incentive Plan provides for the issuance of long-term incentive awards, or Awards, in the form of nonqualified and incentive stock options, or Options, stock appreciation rights, stock grants and restricted stock units. The Awards and Options may be granted by our Board of Directors to our employees, directors and officers and to consultants, agents, advisors and independent contractors who provide services to us. The exercise price for Options must not be less than the fair market value of the shares on the date of grant. Options expire no later than ten years from the date of grant and generally vest and become exercisable over a four-year period following the date of grant. Restricted stock units generally vest over a three-year period following the date of grant. Every non-employee member of our Board of Directors receives an annual nonqualified stock option or restricted stock unit grant and these awards vest in their entirety on the one-year anniversary of the date of grant provided that the grantee is continuing to provide services to us as of that date. Upon the exercise of stock options and the vesting of restricted stock units, we issue the resulting shares from shares reserved for issuance under our Stock Incentive Plan.

Effective January 2006, we adopted SFAS No. 123R, *Share-Based Payment*, which requires us to expense the fair value of share-based payments granted over the vesting period. This compensation expense includes: (a) compensation cost for all share-based stock options granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value used for prior pro forma disclosures adjusted for forfeitures and (b) compensation cost for all share-based payments granted after January 1, 2006, based on the grant-date fair value estimate in accordance with the provisions of SFAS No. 123R. We value awards granted after January 1, 2006 at fair value in accordance with provisions of SFAS No. 123R and recognize stock-based compensation expense on a straight line basis over the service period of each award. Stock-based compensation expense is reduced by an estimated forfeiture rate derived from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, we may record adjustments to increase or decrease compensation expense in future periods. For example, in the fourth quarter of 2007, we recorded an additional \$229,000 of stock-based compensation expense due to refinements in our estimates of forfeitures. This adjustment increased our basic and diluted loss per share by \$0.01. There were no significant adjustments related to changes in our estimates for the year ending December 31, 2008.

As a part of our overall efforts to reduce expenses and realign and narrow our product development priorities, we implemented a workforce reduction in November 2008. As a part of the terms of the workforce reduction, we modified the outstanding restricted stock units for those affected. Under the revised restricted stock unit agreements there were two different types of modified awards: (a) the award did not cancel upon termination of service but maintained the original vesting terms without a service requirement and (b) the award did not cancel upon termination of service and was immediately vested in full. Under SFAS No. 123R, these modified awards were revalued on the effective date of the modification and the entire stock-based compensation charge was recognized in full during the fourth quarter of 2008 as there is no longer a service requirement. We recorded expense of \$64,000 relating to these awards in the quarter ending December 31, 2008. This expense is reflected as restructure charges in the accompanying consolidated statement of operations.

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## TARGETED GENETICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 10. Shareholders Equity (continued)

Following is a summary of the amount included as stock-based compensation expense in the accompanying consolidated statement of operations:

|  | Year Ended December 31, |            |            |
|--|-------------------------|------------|------------|
|  | 2008                    | 2007       | 2006       |
| Stock options:                         |                         |            |            |
| Research and development expense       | \$ 105,000              | \$ 355,000 | \$ 465,000 |
| General and administrative expense     | 45,000                  | 240,000    | 396,000    |
| Restricted stock units:                |                         |            |            |
| Research and development expense       | 288,000                 | 153,000    |            |
| General and administrative expense     | 216,000                 | 218,000    |            |
| Restructure expense                    | 64,000                  |            |            |
| Total stock-based compensation expense | \$ 718,000              | \$ 966,000 | \$ 861,000 |

**Stock Options**

The following table summarizes activity related to our Options:

|                                | Shares    | Weighted<br>Average<br>Exercise<br>Price | Remaining<br>Average<br>Contractual<br>Term | Intrinsic<br>Value |
|--------------------------------|-----------|--|---|--------------------|
| Balance, December 31, 2005     | 704,088   | 20.90                                    |   |                    |
| Granted                        | 349,800   | 3.28                                     |   |                    |
| Exercised                      | (28,188)  | 2.70                                     |   |                    |
| Expired                        | (7,963)   | 43.83                                    |   |                    |
| Forfeited                      | (182,652) | 13.94                                    |   |                    |
| Outstanding, December 31, 2006 | 835,085   | 15.39                                    |   |                    |
| Granted                        | 15,800    | 3.88                                     |   |                    |
| Exercised                      | (12,632)  | 3.10                                     |   |                    |
| Expired                        | (13,892)  | 40.66                                    |   |                    |
| Forfeited                      | (45,512)  | 8.96                                     |   |                    |
| Outstanding, December 31, 2007 | 778,849   | 15.28                                    |   |                    |
| Granted                        |           |  |   |                    |
| Exercised                      |           |  |   |                    |
| Expired                        | (29,324)  | 17.03                                    |   |                    |
| Forfeited                      | (43,546)  | 9.88                                     |   |                    |
| Outstanding, December 31, 2008 | 705,979   | 15.54                                    | 3.63  | \$                 |

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|                                  |         |          |      |    |
|----------------------------------|---------|----------|------|----|
| Exercisable at December 31, 2008 | 690,898 | \$ 15.77 | 3.54 | \$ |
|----------------------------------|---------|----------|------|----|

The aggregate intrinsic value is determined using the closing price of our common stock of \$0.22 on December 31, 2008. There were no stock options exercised in 2008. The intrinsic value of stock options exercised was \$22,000 in 2007 and \$94,000 in 2006.

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## TARGETED GENETICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 10. Shareholders Equity (continued)

As of December 31, 2008, total unrecognized compensation cost related to unvested options was approximately \$34,000, net of estimated forfeitures, which we expect to recognize over a weighted average period of approximately one year.

The following table summarizes information regarding our outstanding and exercisable Options at December 31, 2008:

| Range of Exercise Prices   | Number of Option Shares | Outstanding                     | Weighted Average                   | Exercisable             | Weighted Average                |
|----------------------------|-------------------------|---------------------------------|------------------------------------|-------------------------|---------------------------------|
|                            |                         | Weighted Average Exercise Price | Remaining Contractual Life (Years) | Number of Option Shares | Weighted Average Exercise Price |
| \$1.80 \$3.24              | 82,365                  | \$ 2.52                         | 5.94                               | 77,508                  | \$ 2.54                         |
| 3.80 3.80                  | 187,000                 | 3.80                            | 4.68                               | 187,000                 | 3.80                            |
| 3.87 9.10                  | 144,520                 | 7.27                            | 4.01                               | 134,296                 | 7.32                            |
| 10.80 14.90                | 142,450                 | 13.14                           | 3.18                               | 142,450                 | 13.14                           |
| 15.30 148.80               | 149,644                 | 47.64                           | 1.09                               | 149,644                 | 47.64                           |
| Balance, December 31, 2008 | 705,979                 | 15.54                           | 3.63                               | 690,898                 | 15.77                           |

The fair value of each Option is estimated on the date of the grant using the Black-Scholes-Merton option pricing model. There were no options granted in the year ended December 31, 2008. The weighted average fair value of options granted was \$3.09 per share in 2007 and \$1.84 per share in 2006. The following are the assumptions for the periods noted:

|                                       | 2007 |         | 2006 |         |
|---------------------------------------|------|---------|------|---------|
| Expected dividend rate                | Nil  |         | Nil  |         |
| Expected stock price volatility range | 1.05 | 1.11    | 1.05 | 1.11    |
| Risk-free interest rate range         | 4.54 | 4.58%   | 4.25 | 4.85%   |
| Expected life of options range        | 4    | 5 years | 4    | 5 years |

*Expected Dividend:* We do not anticipate any dividends.

*Expected Life:* Our expected life represents the period that we expect our stock-based awards to be outstanding. We determine expected life based on historical experience and vesting schedules of similar awards.

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

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

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



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## TARGETED GENETICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 10. Shareholders Equity (continued)

*Restricted Stock Units*

|                              | Shares    | Weighted<br>Average<br>Grant Date<br>Fair Value |
|------------------------------|-----------|---|
| Nonvested, December 31, 2006 |           | \$  |
| Granted                      | 542,000   | 3.07  |
| Vested                       |           |   |
| Forfeited                    | (5,500)   | 3.14  |
| Nonvested, December 31, 2007 | 536,500   | 3.07  |
| Granted                      | 672,000   | 0.64  |
| Vested                       | (438,855) | 1.84  |
| Forfeited                    | (84,498)  | 2.09  |
| Nonvested, December 31, 2008 | 685,147   | 1.59  |

The fair value of each Award is estimated on the date of the grant using the closing market price of our common stock. The total fair value of shares vested was \$206,000 for the year ended December 31, 2008. As of December 31, 2008, total unrecognized compensation cost related to unvested restricted stock units was approximately \$514,000, net of estimated forfeitures, which we expect to recognize over a weighted average period of approximately two years.

*Reserved Shares*

As of December 31, 2008, we had reserved shares of our common stock for future issuance as follows:

|  | Shares<br>Reserved |
|--|--------------------|
| Stock options and restricted stock units outstanding       | 1,391,126          |
| Available for future grants under the Stock Incentive Plan | 328,180            |
| Warrants   | 7,913,861          |
| Total shares reserved                                      | 9,633,167          |

As of December 31, 2008, we had 15,127,968 shares authorized for issuance but not yet reserved.

## 11. Collaborative and Other Agreements

We have entered into various product development relationships and license arrangements with pharmaceutical and biotechnology companies and non-profit organizations. Under these partnerships, we typically are reimbursed for research and development and



manufacturing activities we perform and, in certain cases, we have received milestone and upfront payments and may receive additional milestone payments, payments upon the occurrence of certain transactions involving covered products and royalties from product sales after commercialization.

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****11. Collaborative and Other Agreements (continued)**

Revenues earned under our research and development collaborations and license agreements are as follows:

|             | Year Ended December 31, |               |              |
|-------------|-------------------------|---------------|--------------|
|             | 2008                    | 2007          | 2006         |
| Celladon    | \$ 4,843,000            | \$ 3,982,000  | \$ 4,220,000 |
| NIAID       | 3,668,000               | 5,389,000     | 1,548,000    |
| IAVI        |                         | 309,000       | 2,262,000    |
| AMT license | 100,000                 | 600,000       | 1,750,000    |
| Other       | 107,000                 | 52,000        | 84,000       |
|             | \$ 8,718,000            | \$ 10,332,000 | \$ 9,864,000 |

***Celladon***

In 2004, we entered into a collaboration agreement and manufacturing agreement with Celladon focused on the development of AAV-based drugs for the treatment of heart failure. In connection with the formation of this collaboration, certain of Celladon's investors purchased 395,413 shares of our common stock at \$15.20 per share resulting in net proceeds to us of \$6.0 million. We recorded the proceeds as equity at the fair value of the common stock, which approximated market value. Under the collaboration agreement, we agreed to contribute up to \$2.0 million to support these development activities and then to be reimbursed for efforts over that amount. We met this \$2.0 million threshold during 2005. During 2008, we earned \$4.8 million from our development activities under the Celladon collaboration, which consisted primarily of internal development and manufacturing efforts. We were also entitled to receive milestone payments during the development of product candidates under the collaboration as well as royalties and manufacturing profits from the commercialization of product candidates developed under the collaboration. In February 2009, we and Celladon agreed to replace the prior collaboration and manufacturing agreements with a license agreement and new manufacturing agreement. Under the terms of the modified agreements, we granted Celladon exclusive use of certain proprietary AAV vector technology in a specified field relating to heart failure, agreed to manufacture Celladon's MYDICAR<sup>®</sup> product candidate for phase III clinical studies, at Celladon's expense, and agreed to transfer technology to enable Celladon to manufacture MYDICAR<sup>®</sup> in the future through contract manufacturing organizations or a commercial partner. In addition, we and Celladon agreed to a new milestone payment and royalty structure covering development and commercialization of products in the permitted field, and Celladon agreed to make payments to us in the event of specified strategic transactions involving Celladon. Our current work plan with Celladon extends through July 2009.

***National Institute of Allergy and Infectious Diseases***

In 2005, we extended the scope of our HIV/AIDS vaccine program to include the developed world via a contract awarded by the NIAID to NCH in collaboration with CHOP and us. Under the original award the NIAID established a \$22 million budget for the overall collaboration, of which they identified a subcontract budget of up to \$18.2 million of funding over five years for our efforts for the development, manufacture and preclinical testing of vaccine candidates. Since 2005 investigators at CHOP and NCH completed the design of the vaccine candidates and we have manufactured the vectors for the clinical trials that are planned to be conducted in the U.S. The direct costs of any clinical trials will be borne by the NIAID and are not part of the contract. This NIAID-funded vaccine program

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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**11. Collaborative and Other Agreements (continued)**

complements work we performed under the IAVI vaccine program. The NIAID awards funding under this program in annual installments. Total cumulative funding awarded to us under our subcontract is \$15.8 million for the performance period through August 30, 2009, and we have recognized cumulative revenues of \$10.6 million through December 31, 2008. In 2009 we expect to receive less NIAID funding and recognize less HIV/AIDS vaccine program revenue, as compared to 2008, as we wind down our portion of the development efforts and terminate our involvement in the program.

***International AIDS Vaccine Initiative***

In 2000, we entered into a three-year development collaboration with IAVI and NCH (formerly known as Columbus Children's Research Institute) to develop a vaccine to protect against the progression of HIV infection to AIDS. The collaboration originally had a three-year term and was extended several times until 2006, when the program was further extended until the expiration of the term of the last patent within the patent rights controlled by us and utilized in the IAVI vaccine. Under the terms of the collaboration, IAVI provided funding to us to support development, preclinical studies and manufacturing of product for clinical trials on a cost reimbursement basis. We completed work on this collaboration in 2007 as the product candidate completed Phase II clinical trials.

In 2006, in connection with the extension of the collaboration, we also received the rights to utilize the findings from the IAVI-funded program to develop and commercialize HIV/AIDS vaccines for both the developed world and for any additional vaccine candidates. We granted IAVI the rights to technology and intellectual property utilized in the programs for use in their efforts to develop an HIV/AIDS vaccine for the developing world. Since inception, we have received \$28.5 million in funding from IAVI for the development of HIV/AIDS vaccines for the developing world. As we have completed our work under the collaboration, we do not expect to receive additional funding from IAVI.

***Amsterdam Molecular Therapeutics B.V.***

In 2006, we granted a non-exclusive perpetual license to Amsterdam Molecular Therapeutics, or AMT, for the patent rights related to an AAV1 vector gene delivery system. Under the agreement, we sublicensed certain patent rights under our license with the University of Pennsylvania, or Penn, and AMT paid us an upfront payment of \$1.75 million. We may receive milestone payments based on the progress of the licensed products from clinical trial phases to regulatory approvals and royalties based on a percentage of net sales of the licensed products. In September 2007, we received a milestone payment upon initiation of a clinical trial for the first such product candidate, AMT-011, an AAV1-based therapy for a metabolic disease called lipoprotein lipase deficiency.

***Sirna Therapeutics***

In 2005, we established a collaboration with Sirna, now a wholly-owned subsidiary of Merck & Co., Inc., or Merck, to develop AAV-based approaches to treating Huntington's disease, or HD. Under the terms of the collaboration, we and Sirna agreed to co-develop HD product candidates, with both parties sharing in the costs of development and any potential future revenues that result from the collaboration. Sirna was purchased by Merck in December 2006. Following a subsequent review by the Merck Research Laboratories, or MRL, certain programs at Sirna were determined to be outside of the broader MRL objectives. In April 2008, we acquired Sirna's rights to the HD program and brought this program fully into our internal development pipeline. The transfer of rights to us from Merck included

**Table of Contents****TARGETED GENETICS CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****11. Collaborative and Other Agreements (continued)**

the assignment of a license agreement with Beverly Davidson, Ph.D. at the University of Iowa and access to intellectual property owned by Sirna/Merck that relates to development of an expressed AAV therapeutic for the treatment of HD.

**12. Employee Retirement Plan**

We sponsor an employee retirement plan under Section 401(k) of the Internal Revenue Code of 1986, as amended, or the Code. All of our employees who meet minimum eligibility requirements are eligible to participate in the plan. Matching contributions to the 401(k) plan are made at the discretion of our Board of Directors and were \$76,000 in 2008, \$90,000 in 2007 and \$17,000 in 2006. We suspended matching contributions effective February 1, 2006 and reinstated matching contributions effective January 1, 2007. Our Board of Directors suspended matching contributions effective January 1, 2009.

**13. Income Taxes**

At December 31, 2008, we had net operating loss carry-forwards, or NOLs, of approximately \$200.0 million and research tax credit carry-forwards of approximately \$6.0 million. The carry-forwards begin to expire in 2008 if not utilized, and may be further subject to the application of Section 382 of the Code, as discussed further below. We have provided a valuation allowance to offset the deferred tax assets, due to the uncertainty of realizing the benefits of the net deferred tax asset.

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

|  | December 31,  |               |
|--|---------------|---------------|
|  | 2008          | 2007          |
| Deferred tax assets                            |               |               |
| Net operating loss carry-forwards              | \$ 67,940,000 | \$ 65,160,000 |
| Capital loss carry-forwards                    | 2,100,000     | 2,110,000     |
| Research and orphan drug credit carry-forwards | 5,980,000     | 5,740,000     |
| Depreciation and amortization                  | 2,330,000     | 2,340,000     |
| Restructure and other                          | 3,460,000     | 3,720,000     |
| Gross deferred tax assets                      | 81,810,000    | 79,070,000    |
| Valuation allowance for deferred tax assets    | (81,810,000)  | (79,070,000)  |
| Net deferred tax asset                         | \$            | \$            |

The increase in the valuation allowance was \$2.7 million for 2008 and \$2.4 million for 2007. The capital losses generated by the sale of CellExSys and Chromos shares may only be carried forward to offset future capital gains and will begin to expire after 2009 if not utilized. Our valuation allowances as of December 31, 2008 and December 31, 2007 include an allowance for the capital loss carry-forward.

Our past sales and issuances of stock have likely resulted in ownership changes as defined by Section 382 of the Code. A study has not been done at this time because the full valuation allowance eliminating potential profit and loss adjustments due to changes in the gross amount of the NOLs and credits would be offset by a change in the valuation allowance. It is possible that a future analysis may result in the conclusion that a substantial portion, or perhaps substantially all, of the NOLs and credits will expire due to the limitations of Sections 382 and 383 of the Code. As a result, the utilization of our net operating losses and tax credits may be limited and a portion of the carry-forwards may expire unused.



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**TARGETED GENETICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**13. Income Taxes (continued)**

We adopted the provisions of FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, on January 1, 2007. Previously, we had accounted for tax contingencies in accordance with SFAS 5, *Accounting for Contingencies*. As required by FIN 48, which clarifies SFAS No. 109, *Accounting for Income Taxes*, we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, we applied FIN 48 to all tax positions for which the statute of limitations remained open. We do not have any material unrecognized tax benefits as of January 1, 2007 or December 31, 2008.

We are subject to income taxes only in the U.S. federal jurisdiction. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. With few exceptions, we are no longer subject to U.S. federal tax examinations by tax authorities for the years before 2005. However, tax years from 1994 to 2004 may be subject to examination in the event that we utilize the NOLs from those years in our current or future year tax returns.

We have a policy of recognizing interest and penalties accrued related to unrecognized tax benefits as additional tax expense for all periods presented. During the years ended December 31, 2008, 2007, and 2006, we did not recognize any interest and penalties. We have not accrued any interest and penalties at December 31, 2008 and December 31, 2007.

As part of the implementation of FIN 48, we analyzed the ability to sustain our research credit carryforwards based solely on the technical merits of the credit calculations. Based on this analysis, we have reduced our research credit carryforwards by approximately \$2.7 million, before valuation allowance, as of December 31, 2007 to reflect the amount of credit that we believe is more likely than not to be sustained upon examination.

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

None.

**Item 9A. Controls and Procedures.**

*Evaluation of disclosure controls and procedures.* The term disclosure controls and procedures is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, or the Exchange Act. These rules refer to the controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within required time periods. Our management has evaluated, with the participation of our chief executive officer and our chief financial officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report on Form 10-K. Based on this evaluation, our chief executive officer and our chief financial officer have concluded that, as of December 31, 2008, our disclosure controls and procedures are effective.

*Management's report on internal control over financial reporting.* Our management is responsible for establishing and maintaining an adequate internal control structure and procedures over our financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. These rules refer to the controls and procedures of a company that are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of the assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and Board of Directors; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

There are inherent limitations to the effectiveness of any system of internal control over financial reporting, such as resource constraints, judgments used in decision-making, assumptions about the likelihood of future events, the possibility of human error and the risk of fraud. Accordingly, even an effective system of internal control over financial reporting can provide only reasonable assurance with respect to the preparation and presentation of financial statements in accordance with accounting principles generally accepted in the United States, and may not prevent or detect misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting are or will be capable of preventing or detecting all errors or all fraud.

Our management evaluated, with the participation of the chief executive officer and our chief financial officer, the effectiveness of our internal control over financial reporting as of the end of the period covered by this report. This evaluation was based on criteria set forth in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on this evaluation, our management concluded that, as of December 31, 2008, our internal control over financial reporting was effective.

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This annual report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this annual report on Form 10-K.

*Changes in internal control over financial reporting.* There was no change in our internal control over financial reporting that occurred during the period covered by this annual report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Item 9B. Other Information.**

On March 27, 2009, we and B.G. Susan Robinson, our president and chief executive officer, entered into a Senior Management Employment Agreement, or the Robinson Agreement. The Robinson Agreement supersedes in its entirety the Change in Control Agreement entered into with Ms. Robinson on March 13, 2008, which was entered into when she was serving as vice president, business development.

The material terms of the Robinson Agreement are as follows:

while employed by us or our subsidiary following a change in control (as defined in the Robinson Agreement), Ms. Robinson would receive an annual base salary no less than that in effect prior to the change in control and an annual bonus equal to at least the average of the three annual bonuses paid to Ms. Robinson in the three years prior to the change in control;

if Ms. Robinson's employment were to be involuntarily terminated for any reason other than death, disability or cause (as defined in the Robinson Agreement), or if she were to resign for good reason (as defined in the Robinson Agreement), during the two-year period following a change in control, then Ms. Robinson would be entitled to receive the following severance benefits:

*Cash Payment.* Ms. Robinson would be entitled to receive a cash lump-sum payment equal to 1.25 times the sum of her annual salary before the change in control (or on the date of termination, if higher) plus a percentage of that annual salary equal to her percentage bonus for the year prior to the change in control. If no percentage bonus has been determined or if no bonus was paid to Ms. Robinson in the prior year, then the percentage bonus would be 10%.

*COBRA Benefits.* Ms. Robinson (and her dependents) would be eligible to receive payments for up to a year to cover that portion of the COBRA premiums, if any, equal to the company-paid portion of comparable coverage as in effect on the date of termination. Our obligation to pay COBRA would cease, however, if Ms. Robinson were to be provided substantially comparable benefits by another employer during this one-year period.

*Gross-Up Payment.* In the event that the payments and benefits Ms. Robinson receives were to be subject to an excise tax on account of these payments being deemed (in whole or in part) parachute payments for purposes of the Internal Revenue Code, then Ms. Robinson would receive a cash payment equal to an amount sufficient to compensate her for the excise taxes (including any applicable interest and penalties) on the payments and benefits received (including the cash payment and any related taxes on such payment).

a change in control includes approval by our shareholders of a reorganization or merger or a plan for the liquidation or dissolution of Targeted Genetics or a sale of substantially all of our assets, the acquisition by any person of 15% or more of our voting securities if such acquisition is not approved in advance by a majority of the incumbent directors, the acquisition by any person of 33% or more of our voting securities if such acquisition is approved in advance by a majority of incumbent directors, or certain changes in the composition of our Board.



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cause includes certain acts of willful misconduct, fraud, ethical misconduct or conduct that could result in a crime against us or Ms. Robinson's conviction of a felony, or unreasonable refusal by Ms. Robinson to perform her duties and responsibilities to us. Good reason includes the assignment to Ms. Robinson of duties materially inconsistent with her responsibilities prior to the change in control, material failure by us or the successor company (as the case may be) to pay compensation owed to Ms. Robinson, certain requirements that Ms. Robinson relocate her location of employment by more than thirty miles, or the material breach of the provisions of the employment agreement by us or the successor company (as the case may be).

the Robinson Agreement has a two-year term, subject to automatic renewal, and continues in effect until the second anniversary following a change in control.

The Robinson Agreement amends Ms. Robinson's Change in Control Agreement in the following material respects:

under the Robinson agreement, the definitions of change of control cause and good reason are as set forth above;

under the Robinson Agreement, while employed by us or our subsidiary following a change in control, Ms. Robinson would receive an annual base salary no less than that in effect prior to the change in control and an annual bonus equal to at least the average of the three annual bonuses paid to Ms. Robinson in the three years prior to the change in control;

under the Robinson Agreement, upon her death or disability, Ms. Robinson's insurance benefits would be limited to payment of COBRA premiums, if applicable;

under the Robinson Agreement, following the termination of Ms. Robinson's employment for good reason, and other than for death, disability or cause, following a change in control, payments by us to cover insurance would be limited to payment for up to a year of that portion of the COBRA premiums, if any, equal to portion we paid for comparable coverage as in effect on the date of termination;

under the Robinson Agreement, Ms. Robinson would receive a tax gross-up payment in the event payments to her are subject to excise taxes under the Internal Revenue Code;

the Robinson Agreement has a two-year term subject to automatic renewal and continues in effect until the second anniversary following a change in control;

the Robinson Agreement increases the required notice period for termination of the agreement by us from thirty days to nine months.

The foregoing description of the Robinson Agreement is qualified in its entirety by reference to the Senior Management Employment Agreement with Ms. Robinson attached to this annual report as Exhibit 10.2 and incorporated into this Item 9B by reference.

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**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this Item is incorporated by reference to the sections captioned *Proposal One Election of Directors, Management, Section 16(a) Beneficial Ownership Reporting Compliance* and *Corporate Governance* in the proxy statement for our annual meeting of shareholders to be held on May 14, 2009.

***Code of Ethics***

We have a Code of Conduct, which applies to all employees, officers and directors of Targeted Genetics, including our chief executive officer and chief financial officer (who is both our principal financial and principal accounting officer). Our Code of Conduct is available free of charge through our website at <http://www.targetedgenetics.com>, in the *Corporate Governance* section of our Investor Relations home page. We intend to post on our website any amendment to, or waiver from, a provision of our Code of Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller that relates to any element of the definition of *code of ethics* provided in Item 406 of Regulation S-K.

**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 14, 2009.

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

The information required by this Item is incorporated by reference to the sections captioned *Executive Compensation*, *Equity Compensation Plan Information* and *Security Ownership of Certain Beneficial Owners and Management* in the proxy statement for our annual meeting of shareholders to be held on May 14, 2009.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this Item with respect to certain relationships and related-party transactions and director independence is incorporated by reference to the sections captioned *Related-Person Transactions* and *Proposal One Election of Directors Director Independence* in the proxy statement for our annual meeting of shareholders to be held on May 14, 2009.

**Item 14. Principal Accountant Fees and Services.**

The information required by this Item with respect to principal accountant fees and services is incorporated by reference to the section captioned *Proposal Four Ratification of the Selection of Independent Registered Public Accounting Firm Fees* in the proxy statement for our annual meeting of shareholders to be held on May 14, 2009.

**Table of Contents****PART IV****Item 15. Exhibits and Financial Statement Schedules.****1. Financial Statements**

The following consolidated financial statements are submitted in Part II, Item 8 of this annual report:

|   |                   |
|---|-------------------|
| <u>Report of Independent Registered Public Accounting Firm</u>  | <b>Page</b><br>52 |
| <u>Consolidated Balance Sheets as of December 31, 2008 and 2007</u>   | 53                |
| <u>Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006</u>           | 54                |
| <u>Consolidated Statements of Shareholders' Equity for the years ended December 31, 2008, 2007 and 2006</u> | 55                |
| <u>Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006</u>           | 56                |
| <u>Notes to Consolidated Financial Statements</u>   | 57                |

**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**

| Exhibit Number | Exhibit Description  | Incorporated by Reference |                      |                | Filed Herewith |
|----------------|--|---------------------------|----------------------|----------------|----------------|
|                |  | Form                      | Date of First Filing | Exhibit Number |                |
| 3.1            | Restated Articles of Incorporation   | 8-K                       | 1/30/08              | 3.1            |                |
| 3.2            | Amended and Restated Bylaws  | 8-K                       | 12/28/07             | 3.1            |                |
| 4.1            | Registration Rights Agreement among Targeted Genetics Corporation and certain investors dated as of January 8, 2007                                    | 8-K                       | 1/8/07               | 10.2           |                |
| 4.2            | Registration Rights Agreement among Targeted Genetics Corporation and certain purchasers dated as of June 22, 2007                                     | 8-K                       | 6/25/07              | 10.2           |                |
| 10.1           | Form of Indemnification Agreement between Targeted Genetics Corporation and its officers and directors   | 10-K                      | 3/23/00              | 10.1           |                |
| 10.2           | Amended and Restated Senior Management Employment Agreement, dated as of March 27, 2009, between Targeted Genetics Corporation and B.G. Susan Robinson |                           |                      |                | X              |
| 10.3           | Amended and Restated Senior Management Employment Agreement, dated as of March 11, 2008, between Targeted Genetics Corporation and David J. Poston     | 8-K                       | 3/12/08              | 10.3           |                |

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| Exhibit Number | Exhibit Description   | Incorporated by Reference |                      |                | Filed Herewith |
|----------------|---|---------------------------|----------------------|----------------|----------------|
|                |   | Form                      | Date of First Filing | Exhibit Number |                |
| 10.4           | Gene Transfer Technology License Agreement, dated as of February 18, 1992, between Immunex Corporation and Targeted Genetics Corporation*       | 10-K                      | 3/23/00              | 10.3           |                |
| 10.5           | Exclusive Sublicense Agreement, dated June 9, 1999, between Targeted Genetics Corporation and Alkermes, Inc.*                                   | 10-Q                      | 8/5/99               | 10.36          |                |
| 10.5(a)        | Amendment Agreement to Exclusive Sublicense Agreement, dated as of March 12, 2002, between Targeted Genetics Corporation and Alkermes, Inc.     | 10-K                      | 3/12/04              | 10.52          |                |
| 10.5(b)        | Amendment No. 2 to Exclusive Sublicense Agreement, dated as of May 29, 2003, between Targeted Genetics Corporation and Alkermes, Inc.*          | 8-K                       | 7/22/03              | 10.01          |                |
| 10.5(c)        | Amendment No. 3 to Exclusive Sublicense Agreement, dated as of March 9, 2007, between Targeted Genetics Corporation and Alkermes, Inc.*         | 10-K                      | 3/29/07              | 10.5(c)        |                |
| 10.6           | Common Stock Purchase Agreement, dated December 31, 2004, by and among Targeted Genetics Corporation, Enterprise Partners and Venrock Partners  | 10-K                      | 3/4/05               | 10.58          |                |
| 10.7           | Agreement Under an NIH Prime Award, dated February 10, 2006, between The Children s Hospital of Philadelphia and Targeted Genetics Corporation* | 10-K                      | 3/16/06              | 10.36          |                |
| 10.7(a)        | Modification of Agreement, dated October 27, 2006, between The Children s Hospital of Philadelphia and Targeted Genetics Corporation            | 8-K                       | 11/1/06              | 10.1           |                |
| 10.8           | Securities Purchase Agreement, dated January 8, 2007, among Targeted Genetics Corporation and certain investors                                 | 8-K                       | 1/8/07               | 10.1           |                |
| 10.9           | Securities Purchase Agreement, dated June 22, 2007, among Targeted Genetics Corporation and certain purchasers                                  | 8-K                       | 6/25/07              | 10.1           |                |
| 10.10          | Form of Warrant to Purchase Shares of Common Stock of Targeted Genetics Corporation dated January 11, 2007                                      | 8-K                       | 1/8/07               | 10.3           |                |
| 10.11          | Form of Warrant to Purchase Shares of Common Stock of Targeted Genetics Corporation dated June 27, 2007   | 8-K                       | 6/25/07              | 10.3           |                |
| 10.12          | License Agreement, effective June 1, 2002, by and between The Trustees of the University of Pennsylvania and Targeted Genetics Corporation*     | 10-K                      | 3/29/07              | 10.16          |                |
| 10.13          | License Agreement, effective December 5, 2006, by and between Amsterdam Molecular Therapeutics B.V. and Targeted Genetics Corporation*          | 10-K                      | 3/29/07              | 10.17          |                |

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| Exhibit Number | Exhibit Description   | Incorporated by Reference |                      |                | Filed Herewith |
|----------------|---|---------------------------|----------------------|----------------|----------------|
|                |   | Form                      | Date of First Filing | Exhibit Number |                |
| 10.14          | Patent License Agreement Exclusive, dated April 29, 2004, between the National Institutes for Health and Targeted Genetics Corporation*   | 10-K                      | 3/29/07              | 10.18          |                |
| 10.14(a)       | Amendment No. 1 to OTT License Agreement Number L-086-2000/0, dated August 14, 2006, between the National Institutes for Health and Targeted Genetics Corporation*  | 10-K                      | 3/29/07              | 10.18(a)       |                |
| 10.15          | Office Lease, dated as of October 7, 1996, between Benaroya Capital Company, LLC and Targeted Genetics Corporation  | 10-K                      | 3/17/97              | 10.26          |                |
| 10.15(a)       | Fifth Lease Amendment, dated January 8, 2004, between Targeted Genetics Corporation and Benaroya Capital Company, LLC   |                           |                      |                | X              |
| 10.15(b)       | Sixth Lease Amendment, dated as of April 1, 2006, between Met Park West IV, LLC (successor in interest to Benaroya Capital Company, LLC) and Targeted Genetics Corporation  | 10-Q                      | 5/4/06               | 10.4           |                |
| 10.15(c)       | Seventh Lease Amendment, dated as of June 7, 2006, between Met Park West IV, LLC (successor in interest to Benaroya Capital Company, LLC) and Targeted Genetics Corporation   | 8-K                       | 6/21/06              | 10.1           |                |
| 10.16          | Canyon Park Building Lease, dated as of June 30, 2000, between Targeted Genetics Corporation and CarrAmerica Corporation  | 10-Q                      | 8/11/00              | 10.1           |                |
| 10.17          | Olive Way Building Lease, dated as of November 20, 1993, as amended, between Targeted Genetics Corporation and Ironwood Apartments, Inc. (successor in interest to Metropolitan Federal Savings and Loan Association) | 10-K                      | 3/23/00              | 10.29          |                |
| 10.17(a)       | Fifth Amendment to Lease Agreement, dated as of June 20, 2003, between Targeted Genetics Corporation and Ironwood Apartments, Inc.  | 8-K                       | 7/22/03              | 10.02          |                |
| 10.17(b)       | Sixth Amendment to Lease Agreement, dated as of November 1, 2003, between Targeted Genetics and Ironwood Apartments, Inc.*  | 8-K                       | 1/13/04              | 10.1           |                |
| 10.18          | 1992 Restated Stock Option Plan   | S-8                       | 7/10/98              | 99.1           |                |
| 10.19          | 1999 Stock Option Plan, as amended and restated March 22, 2004  | S-8                       | 6/17/04              | 10.1           |                |
| 10.20          | 2000 Genovo Inc. Roll-Over Stock Option Plan  | S-8                       | 10/19/00             | 99.1           |                |
| 10.21          | Targeted Genetics Corporation Stock Incentive Plan  | 8-K                       | 5/22/07              | 10.1           |                |
| 10.22          | Form of Restricted Stock Unit Agreement   | 8-K                       | 5/22/07              | 10.2           |                |

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| Exhibit<br>Number | Exhibit Description   | Incorporated by Reference |                         |                   | Filed<br>Herewith |
|-------------------|---|---------------------------|-------------------------|-------------------|-------------------|
|                   |   | Form                      | Date of<br>First Filing | Exhibit<br>Number |                   |
| 21.1              | Subsidiaries of Targeted Genetics Corporation   |                           |                         |                   | X                 |
| 23.1              | Consent of Independent Registered Public Accounting Firm  |                           |                         |                   | X                 |
| 31.1              | Certification of Chief Executive Officer pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended          |                           |                         |                   | X                 |
| 31.2              | Certification of Chief Financial Officer pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended          |                           |                         |                   | X                 |
| 32.1              | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |                           |                         |                   | X                 |
| 32.2              | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |                           |                         |                   | X                 |

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

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

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized in the city of Seattle, state of Washington, on March 31, 2009.

**TARGETED GENETICS CORPORATION**

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

**POWER OF ATTORNEY**

Each person whose individual signature appears below hereby authorizes and appoints B.G. Susan Robinson and David J. Poston, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature  | Title  | Date           |
|--|--|----------------|
| /s/ B.G. Susan Robinson<br>B.G. Susan Robinson                   | President, Chief Executive Officer and Director<br>(Principal Executive Officer)   | March 31, 2009 |
| /s/ David J. Poston<br>David J. Poston                           | Vice President, Finance, Chief Financial Officer,<br>Treasurer and Secretary (Principal Financial and<br>Principal Accounting Officer) | March 31, 2009 |
| /s/ Jeremy L. Curnock Cook<br>Jeremy L. Curnock Cook             | Chairman of the Board  | March 31, 2009 |
| /s/ Joseph M. Davie, Ph.D., M.D.<br>Joseph M. Davie, Ph.D., M.D. | Director   | March 31, 2009 |
| /s/ Roger L. Hawley<br>Roger L. Hawley                           | Director   | March 31, 2009 |
| /s/ Nelson L. Levy, Ph.D., M.D.<br>Nelson L. Levy, Ph.D., M.D.   | Director   | March 31, 2009 |

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/s/ Michael S. Perry, D.V.M., Ph.D

Director

March 31, 2009

Michael S. Perry, D.V.M., Ph.D.