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NEXT GENERATION CANCER THERAPIES



CELL GENESYS INC

CELL GENESYS

Cell Genesys is focused on developing and commercializing the next generation of biological therapies for cancer. Our lead program, GVAX® prostate cancer vaccine, is in Phase 3 human clinical trials, and we have the necessary manufacturing infrastructure in place to support potential product launch. Additional product programs are undergoing human clinical trials for leukemia, lung cancer, pancreatic cancer and myeloma; and preclinical studies are in progress for various other cancers. All are based on our novel, proprietary product platforms, the most advanced of which are GVAX® cancer vaccines and oncolytic virus therapies. For further information, please visit our website at www.cellgenesys.com.

T O O U R S T O C K H O L D E R S

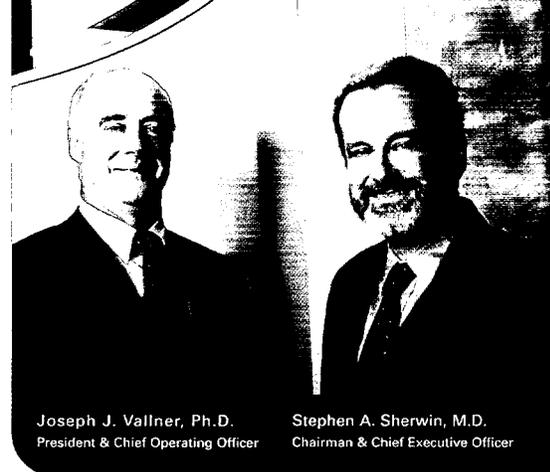
2004 MARKED ANOTHER YEAR OF SOLID ACCOMPLISHMENTS for Cell Genesys as we continued to focus on innovative biological therapies for cancer. Key milestones included the following:

- Advanced GVAX[®] prostate cancer vaccine into Phase 3 development. This study is comparing our vaccine therapy to standard chemotherapy in patients with advanced prostate cancer.
- Initiated three other important clinical trials:
 - Phase 1 trial of GVAX[®] prostate cancer vaccine in combination with MDX-010, a fully human anti-CTLA-4 antibody being developed by our collaborator, Medarex, Inc.
 - Phase 2 National Cancer Institute-sponsored trial of GVAX[®] lung cancer vaccine in patients with advanced-stage bronchoalveolar carcinoma, one of the principal subtypes of non small-cell lung cancer.
 - Phase 1/2 trial of CG7870 oncolytic virus therapy administered intravenously in combination with chemotherapy in patients with advanced prostate cancer.
- Reported favorable data across our entire pipeline of clinical products, including Phase 2 findings on various GVAX[®] vaccines for prostate cancer, pancreatic cancer, leukemia and myeloma, as well as earlier-stage Phase 1/2 results on our CG7870 oncolytic virus therapy for prostate cancer.
- Initiated development of CG0070, a second oncolytic virus therapy which is expected to begin clinical trials in 2005. Preclinical findings have demonstrated its ability to target and kill multiple cancer types.

Importantly, Cell Genesys has the financial resources to support continued product development progress. We raised over \$200 million this past year in two separate financings. As a result, we entered 2005 with a strengthened financial position. This included \$175 million in cash, cash equivalents and short-term investments as well as approximately 6.6 million shares of common stock in Abgenix, our former subsidiary, and a 25% minority position in Ceregene, our privately held former subsidiary focused on gene therapy for neurodegenerative diseases.

As we look ahead, we expect another year of progress. Among our key objectives: 1) Initiating a second Phase 3 clinical trial for GVAX[®] prostate cancer vaccine to evaluate its use in combination with chemotherapy; 2) Advancing our CG0070 oncolytic virus therapy into clinical trials for bladder cancer; 3) Reporting further Phase 2 data on prostate cancer, leukemia, lung cancer and other GVAX[®] vaccine trials.

We thank our employees for their energy and commitment and you, our stockholders, for your continued support.



Joseph J. Vallner, Ph.D.
President & Chief Operating Officer

Stephen A. Sherwin, M.D.
Chairman & Chief Executive Officer

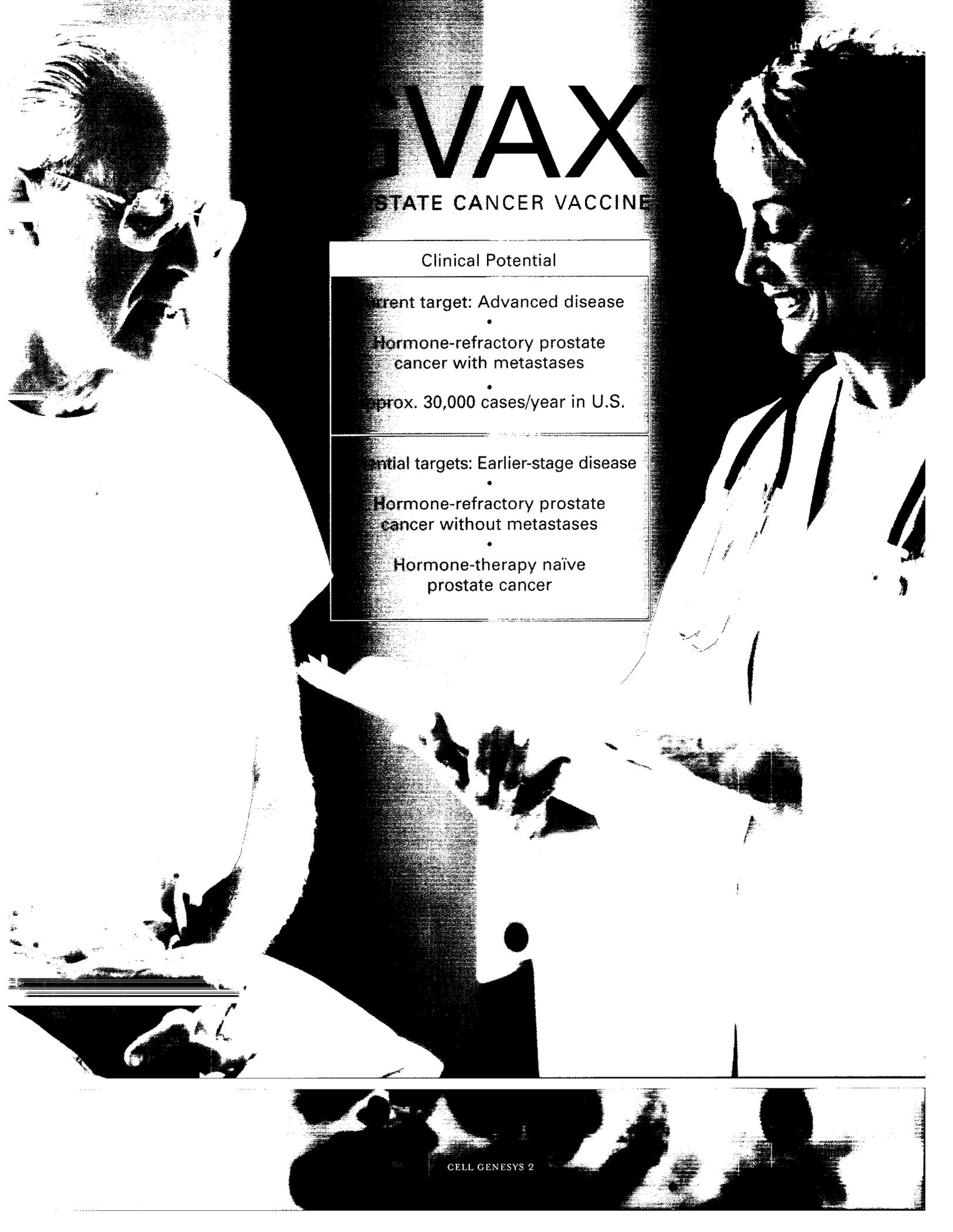
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Stephen A. Sherwin, M.D.
Chairman & Chief Executive Officer

Handwritten signature of Joseph J. Vallner in black ink.

Joseph J. Vallner, Ph.D.
President & Chief Operating Officer

March 31, 2005



GVAX

PROSTATE CANCER VACCINE

Clinical Potential

Current target: Advanced disease

•
Hormone-refractory prostate cancer with metastases

•
Approx. 30,000 cases/year in U.S.

Potential targets: Earlier-stage disease

•
Hormone-refractory prostate cancer without metastases

•
Hormone-therapy naïve prostate cancer

LEAD PROGRAM : PROSTATE CANCER

Critical Need. Major Opportunity. Our strategy with prostate cancer is to focus initially on metastatic hormone-refractory disease. At this advanced stage, patients have failed surgery, radiation therapy and hormone treatment, and the cancer has spread outside the prostate, typically to bone. The standard chemotherapy used to treat such patients extends life by only two to three months. Our Phase 3 clinical trials are designed to demonstrate longer survival and to do so with a treatment that is expected to have fewer side effects and that can be administered outside the hospital setting. We are doing everything we can to bring this potential therapy to prostate cancer patients as quickly as possible.

- The first Phase 3 trial, initiated in July 2004, will enroll about 600 patients at approximately 75 or more U.S. medical centers. Its primary objective is to assess the potential survival benefit of GVAX[®] prostate cancer vaccine compared to standard chemotherapy in patients with asymptomatic metastatic hormone-refractory prostate cancer. Patients treated with GVAX[®] vaccine receive biweekly injections over a 24-week period.
- Our second planned Phase 3 trial will target patients who have symptomatic metastatic hormone-refractory prostate cancer with cancer-related pain. In this trial, we plan to assess whether using our vaccine in combination with chemotherapy improves upon chemotherapy alone with respect to survival benefit.
- Previous studies have been encouraging. In an early 34-patient Phase 2 trial in hormone-refractory prostate cancer, the median survival was 26.2 months. Interim data from a second 80-patient Phase 2 trial demonstrated clinical activity and safety of the vaccine at the dose we have selected for Phase 3 trials.

ADVANCED TECHNOLOGY. TARGETED IMMUNOTHERAPY.

One of the reasons why cancers can spread and grow is their ability to avoid detection by the patient's immune system. All GVAX® cancer vaccines, whether for the treatment of prostate cancer or for other cancers, are designed to stimulate an immune response directed against invading cancer cells and destroy them. Our goal is to put the immune system of a cancer patient back to work, slowing down or even overcoming their disease.



In the case of GVAX® prostate cancer vaccine, we have developed a prostate cancer-specific product. The vaccine is comprised of irradiated prostate cancer cells which are designed to activate the patient's immune system to destroy prostate cancer cells. These cells have been modified to secrete GM-CSF, a potent immune hormone that drives the vaccine response. We have developed the manufacturing technology and capabilities needed to produce this cellular product at a scale sufficient for Phase 3 development and potential market launch.



GVAX® prostate cancer vaccine is a non patient-specific product that can be developed and commercialized like other “off-the-shelf” pharmaceuticals. It is manufactured at our state-of-the-art Hayward production facility.

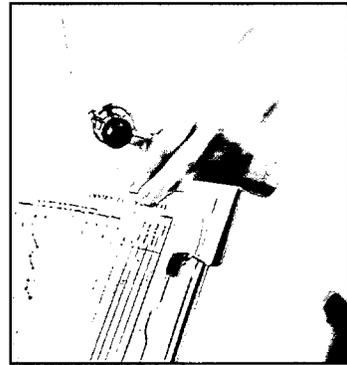
PROMISING FINDINGS. MULTIPLE CLINICAL ENDPOINTS.

GVAX® Cancer Vaccine and Oncolytic Virus Therapy Pipeline



GVAX® leukemia vaccine and GVAX® myeloma vaccine are both being studied in combination with bone marrow stem cell transplantation after induction chemotherapy, to prevent relapse. Preliminary Phase 2 findings in leukemia patients suggest a post-vaccination decrease in cancer cells persisting after chemotherapy.

GVAX® pancreatic cancer vaccine is administered following surgery to remove the primary tumor, along with adjuvant chemotherapy and radiation, to prevent disease relapse. This Phase 2 trial is fully enrolled and will begin to yield preliminary data during the next year.



In our oncolytic virus program, CG7870 for prostate cancer therapy is being developed through our alliance with Novartis. A second product, CG0070, is expected to enter clinical trials during the first half of 2005, initially for bladder cancer. These products are manufactured at our San Diego plant.

CORPORATE DIRECTORY

Corporate Officers	Board of Directors	Medical Advisory Board	Scientific Advisory Board
Stephen A. Sherwin, M.D. Chairman and Chief Executive Officer	Stephen A. Sherwin, M.D. Chairman and Chief Executive Officer Genesys, Inc.	Bruce Chabner, M.D. Clinical Director Massachusetts General Hospital Cancer Center	Bernard A. Fox, Ph.D. Chief, Laboratory of Molecular and Tumor Immunology
Joseph J. Vallner, Ph.D. President and Chief Operating Officer	David W. Carter Chairman and Chief Executive Officer Xenogen Corporation	Jordan Guterman, M.D. Professor of Medicine Harvard Medical School	Earle A. Chiles Research Institute Providence Portland Medical Center
Matthew J. Pfeiffer President and Chief Financial Officer	Nancy M. Crowell Partner Flagship Ventures	Professor of Medicine University of Texas M.D. Anderson Cancer Center	Associate Professor, Molecular Microbiology and Immunology Oregon Health and Science University
Robert J. Dow, MChB Senior Vice President, Medical Affairs	James M. Gower Chairman and Chief Executive Officer Rigel Pharmaceuticals, Inc.	Craig Henderson, M.D. Adjunct Professor of Hematology/Oncology University of California, San Francisco	Carl H. June, M.D. Professor, Pathology & Laboratory Medicine Director, Translational Research Programs The Leonard and Madlyn Abramson Family Cancer Research Institute of the University of Pennsylvania
Michael W. Ramsay Senior Vice President, Operations	John T. Potts, Jr., M.D. Physician-in-Chief and Director of Research Emeritus Massachusetts General Hospital	Ronald Levy, M.D. Robert K. Summy and Helen K. Summy Professor of Medicine Chief of the Division of Oncology Stanford University School of Medicine	John T. Potts, Jr., M.D. Physician-in-Chief and Director of Research Emeritus Massachusetts General Hospital
Peter K. Working, Ph.D. Senior Vice President, Research and Development	Thomas E. Shenk, Ph.D. Elkins Professor, Department of Molecular Biology Princeton University	William Nelson, M.D., Ph.D. Associate Professor of Oncology, Pathology, Pharmacology and Medicine, and Urology Harvard Medical School	John T. Potts, Jr., M.D. Physician-in-Chief and Director of Research Emeritus Massachusetts General Hospital
Carol C. Grundfest Vice President, Regulatory Affairs and Protect Management	Thomas E. Shenk, Ph.D. Elkins Professor, Department of Molecular Biology Princeton University	William Nelson, M.D., Ph.D. Associate Professor of Oncology, Pathology, Pharmacology and Medicine, and Urology Harvard Medical School	John T. Potts, Jr., M.D. Physician-in-Chief and Director of Research Emeritus Massachusetts General Hospital
Kristen M. Hege Vice President, Clinical Research	Eugene L. Step Retired Executive Vice President and President, Pharmaceutical Division Eli Lilly & Company	Sidney Kimmel Comprehensive Cancer Center Johns Hopkins University	Thomas E. Shenk, Ph.D. Elkins Professor Chairman, Department of Molecular Biology Princeton University
Christine McKinley Vice President, Human Resources	Inder M. Verma, Ph.D. Professor of Molecular Biology and Virology The Salk Institute	John T. Potts, Jr., M.D. Physician-in-Chief and Director of Research Emeritus Massachusetts General Hospital	Inder M. Verma, Ph.D. Professor of Molecular Biology and Virology The Salk Institute
	Dennis L. Winger Senior Vice President and Chief Financial Officer Regenera Corporation	Professor of Clinical Medicine Harvard Medical School	



CELL GENESYS

IO-K

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

- Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2004 or
- Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Period From _____ to _____

Commission File Number: 0-19986

CELL GENESYS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3061375
(I.R.S. employer
identification number)

500 Forbes Blvd., South San Francisco, CA 94080
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code:
(650) 266-3000

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

Securities registered pursuant to Section 12 (g) of the Act:
Common Stock, \$.001 Par Value
Preferred Shares Purchase Rights

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 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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes No

As of June 30, 2004, the last business day of the Registrant's most recently completed second fiscal quarter, there were 38,391,481 shares of the Registrant's voting stock outstanding, and the approximate aggregate market value of such shares held by non-affiliates of the Registrant (based on the closing sale price of such shares on the Nasdaq National Market on June 30, 2004) was \$399.0 million. Shares of Common Stock held by each executive officer and director and by each person known to the Registrant who owns 5% or more of the outstanding voting stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 10, 2005, the number of outstanding shares of the Registrant's Common Stock was 45,360,819.

Portions of the Registrant's Proxy Statement for the 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such Proxy Statement will be filed within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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PART I

Statements made in this document other than statements of historical fact, including statements about us and our subsidiaries and our respective clinical trials, research programs, product pipelines, current and potential corporate partnerships, licenses and intellectual property, the adequacy of capital reserves and anticipated operating results and cash expenditures, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. As such, they are subject to a number of uncertainties that could cause actual results to differ materially from the statements made, including risks associated with the success of research and product development programs, the issuance and validity of patents, the development and protection of proprietary technologies, the ability to raise capital, operating expense levels and the ability to establish and retain corporate partnerships. Reference is made to discussions about risks associated with product development programs, intellectual property and other risks which may affect us under "Other Factors Affecting Future Operations" below. We do not undertake any obligation to update forward-looking statements. The following should be read in conjunction with our consolidated financial statements located elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2004 and other documents filed by us from time to time with the Securities and Exchange Commission.

ITEM 1. BUSINESS

Overview

We are a biotechnology company focused on the research, development and commercialization of biological therapies for patients with cancer. We are currently developing cell-based cancer vaccines, oncolytic virus therapies and antiangiogenesis therapies to treat different types of cancer. Our clinical stage cancer programs involve cell- or viral-based products that have been genetically modified during product development to impart disease-fighting characteristics that are not found in conventional therapeutic agents. As part of our GVAX[®] cancer vaccines program, we are conducting a Phase 3 clinical trial in prostate cancer, are in ongoing Phase 2 clinical trials in lung cancer, pancreatic cancer and leukemia, and are in a Phase ½ clinical trial for multiple myeloma. We initiated our Phase 3 clinical trial for GVAX[®] prostate cancer vaccine in July 2004. In our oncolytic virus therapies program, which we are developing in part through a global alliance with Novartis AG, we initiated a Phase ½ clinical trial of CG7870 in combination with chemotherapy in advanced prostate cancer during 2004. We also expect to initiate a Phase 1 clinical trial of CG0070 in recurrent bladder cancer during the first half of 2005. We also have other preclinical oncolytic virus therapy programs as well as preclinical antiangiogenesis therapy programs evaluating potential therapies for multiple types of cancer.

Cell Genesys was incorporated in the State of Delaware in 1988. Our common stock trades on the Nasdaq National Market under the symbol "CEGE." Our principal executive offices are located at 500 Forbes Boulevard, South San Francisco, California 94080, and our phone number is (650) 266-3000. Our Internet home page is located at <http://www.cellgenesys.com>; however, the information in, or that can be accessed through, our home page is not part of this report. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to such reports are available, free of charge, on or through our Internet home page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC.

During 2004, we continued to increase our focus on developing cancer therapies and establishing our product development and manufacturing infrastructure for Phase 3 clinical trials. Our goal is to emphasize "off-the-shelf" products and, when possible, therapies that can be administered in the outpatient setting. However, we are also developing a patient-specific vaccine product for lung cancer.

We are currently evaluating cancer therapies based on biological therapy technologies in human clinical studies. These include studies of GVAX[®] cancer vaccines, which employ genetically modified tumor cells to induce an immune system response against malignant cells, as well as studies of oncolytic virus therapies, which employ genetically modified adenoviruses engineered to selectively replicate in and kill targeted cancer cells. During 2004, we obtained encouraging data from several of our GVAX[®] programs including prostate cancer, pancreatic cancer, leukemia and myeloma.

We also are currently conducting research on antiangiogenesis therapies, which may prevent tumor blood vessel growth as a strategy for the treatment of cancer. Ceregene, Inc., which was formed in January 2001 and in which we now have a minority ownership position, is continuing to develop gene therapies for the treatment of neurological disorders including Alzheimer's disease, Parkinson's disease and Amyotrophic Lateral Sclerosis (ALS), commonly known as "Lou Gehrig's disease."

We ended 2004 with approximately \$175.0 million in cash, cash equivalents and short-term investments, including approximately \$3.3 million of restricted cash and investments. We have maintained our financial position through strategic management of our resources, including our holdings of Abgenix, Inc. common stock (of which we continue to hold approximately 6.6 million shares) and by relying on funding from various corporate collaborations and licensing agreements. Additionally, in February 2003, our shelf registration statement was declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended, which initially allowed us to offer up to \$150.0 million of securities on short notice in one or more public offerings. We used this shelf registration in March 2004 to complete a public offering of 4,887,500 shares of our common stock (including the entire over-allotment option), resulting in gross proceeds of \$61.1 million. Although up to \$88.9 million may still be offered under the shelf registration, there can be no assurance that we will be able to issue any of the remaining securities under this shelf registration on acceptable terms, or at all.

In October and November 2004, we sold a total of \$145.0 million aggregate principal amount of our 3.125% Convertible Senior Notes due 2011 in a private placement. We used the net proceeds to repay bank debt totaling \$95.0 million, thereby eliminating restrictions on \$60.0 million of cash.

We may finance certain of our operations through corporate collaborations with established pharmaceutical and biotechnology companies in order to develop our technologies as broadly as possible, to fund product development and to accelerate the commercialization of certain product opportunities. Such alliances are intended to provide financial resources, research, development and manufacturing capabilities and marketing infrastructure to aid in the commercialization of potential disease therapies. We also evaluate, on an ongoing basis, opportunities to in-license or acquire products and/or technologies that complement our portfolio. There can be no assurance that we will be able to enter into additional collaborative relationships or obtain new products and/or technologies on acceptable terms, if at all, or that if such actions occur, they will lead to successful products. Failure to enter into new corporate relationships or expand our product and technological base may limit our future success.

A major portion of our operating expenses to date is related to the research and development of products either on our own behalf or under contracts, including primarily research and development of our GVAX[®] cancer vaccines and oncolytic virus therapy programs. During 2004, 2003, and 2002, our research and development expenses were \$92.1 million, \$85.3 million and \$75.1 million, respectively. We expect that our research and development expenditures and headcount will continue to increase in future years to support expanded, more advanced and more numerous clinical trials, including an anticipated second Phase 3 trial of our GVAX[®] prostate cancer vaccine in 2005, additional manufacturing and office facilities, and additional product development activities. We intend to maintain our strong commitment to research and development as an essential component of our oncology product development effort involving biological therapies for cancer. Licensed technology developed by outside parties is an additional source of potential products.

Our GVAX[®] Cancer Vaccines Program

Our GVAX[®] vaccines are cancer treatment vaccines designed to stimulate the patient's immune system to effectively fight cancer. This program was added to our product portfolio through our acquisition of Somatix Therapy Corporation in 1997. GVAX[®] vaccines are comprised of tumor cells that are genetically modified to secrete an immune-stimulating hormone known as granulocyte-macrophage colony stimulating factor, or GM-CSF, and are then irradiated for safety. Since GVAX[®] vaccines consist of whole tumor cells, the cancer patient's immune system can be activated against multiple tumor cell components (antigens), potentially resulting in greater clinical benefit than if the vaccine consisted of only a single tumor cell component. Additionally, the secretion of GM-CSF by the modified tumor cells enhances the immune response by activating dendritic cells at the vaccination site, a critical step in the optimal response by the immune system to any vaccine product. The activation of dendritic cells in turn triggers both of the key components of the immune response — the activation of antitumor immune cells and the production of antitumor antibodies. Both components of the immune response are believed to be essential for

achieving optimal benefit from treatment with a cancer vaccine product, and GVAX[®] vaccines have been shown in clinical trials to both activate immune cells and cause the production of antibodies directed against the patient's tumor. The antitumor immune response which occurs throughout the body following vaccination with a GVAX[®] product can potentially result in the destruction of tumor cells that persist or recur following surgery, radiation therapy or chemotherapy treatment.

More than 600 patients have received our GVAX[®] vaccines in multiple clinical trials to date, and the vaccines have been shown to have a favorable side effect profile that does not include the toxicities associated with conventional cancer therapies. The most consistent treatment-related side effects appear to be inflammation at the injection site and occasional flu-like symptoms. In addition, risks have been identified in connection with the surgical removal of tumor cells used to produce our patient-specific lung cancer vaccine. GVAX[®] vaccines can be conveniently administered in an outpatient setting as an injection into the skin, a site where immune cells, including in particular dendritic cells, can be optimally accessed and activated. Our GVAX[®] cancer vaccines are generally being tested in non patient-specific configurations, and we intend to develop these vaccines as "off-the-shelf" pharmaceutical products. We are also developing a lung cancer product, which is currently being tested in a patient-specific configuration that requires us to obtain a tumor sample from the patient. We are currently manufacturing GVAX[®] cancer vaccines in our Hayward, California and Memphis, Tennessee facilities, which operate in accordance with the United States Food and Drug Administration's (FDA) current Good Manufacturing Practices, or cGMP, regulations.

GVAX[®] Prostate Cancer Vaccine

Our GVAX[®] prostate cancer vaccine is a non patient-specific product comprised of two prostate cancer cell lines. We intend to develop and manufacture this vaccine initially as an "off-the-shelf" pharmaceutical for use after hormonal therapy for advanced-stage prostate cancer. Prostate cancer is the second leading cause of cancer death in men in the United States, with approximately 30,000 men dying each year from the disease. When a man is diagnosed with early-stage prostate cancer, he is treated with either a prostatectomy (surgical removal of the prostate) or radiation therapy. If the patient relapses, he is treated with hormone therapy to suppress testosterone in order to reduce the growth of the tumor. When the hormone therapy fails, the patient may or may not be treated with chemotherapy depending upon whether the disease has spread, or metastasized, to other parts of the body. We have designed our Phase 3 clinical trials to evaluate whether GVAX[®] prostate cancer vaccine can benefit patients who have become refractory to hormone therapy and have metastatic disease.

We have completed five Phase 1 and 2 clinical trials of our GVAX[®] prostate cancer vaccine in over 200 patients with various stages of recurrent prostate cancer, and the vaccine has had a favorable safety profile in each trial. These clinical trials include two Phase 2 clinical trials in hormone-refractory prostate cancer patients with radiologic evidence of metastatic disease ("metastatic HRPC"), which is the target population for current Phase 3 trial. These trials were designed to evaluate the safety and efficacy of the vaccine, as well as treatment regimens for Phase 3 clinical trials.

In September 2002, we reported final data from our first Phase 2 multicenter clinical trial of the prostate cancer vaccine in metastatic HRPC. Thirty-four patients were entered in the trial and were assigned to receive either low dose (24 patients) or high dose (10 patients) of the vaccine treatment as their only cancer therapy for up to a six-month period. In updated results reported in January 2005, patients receiving the higher dose level of the vaccine had a median survival of 34.9 months, and patients receiving the lower dose of the vaccine had a median survival of 24.0 months. The combined median survival for both dose groups was 26.2 months. These results compare favorably to those reported for Taxotere[®] (docetaxel) chemotherapy in combination with prednisone. This Taxotere[®] treatment regimen was recently approved by the FDA for the treatment of patients with this stage of prostate cancer and is now the currently approved standard of care.

Preliminary data from the second Phase 2 clinical trial were reported at the June 2004 American Society of Clinical Oncology (ASCO) meeting. The fully enrolled study includes 80 patients with metastatic HRPC with evidence of metastasis (spreading) to the bone and other sites. Patients enrolled in this Phase 2 clinical trial were monitored for safety and for evidence of vaccine activity with serial measurements of PSA, or prostate-specific antigen, a marker for prostate cancer; ICTP, or carboxy-terminal telopeptide of type I collagen, an independent biochemical marker of the bone destruction that occurs when prostate cancer spreads into the bone; bone scans; and

prostate cancer-associated antibodies induced by the vaccine. The median follow-up of patients was 12 months and median survival was not yet reached for the study. The preliminary findings indicate the safety and activity of the vaccine, and confirmed the dose for Phase 3 clinical trials. We expect to update these results during 2005.

We are planning to conduct two Phase 3 clinical trials of GVAX[®] prostate cancer vaccine in metastatic HRPC, including patients with high-risk tumors based on their Gleason score, a measure of the aggressiveness of a patient's tumor. The first Phase 3 clinical trial, referred to as the VITAL-1 trial, commenced in July 2004, and compares GVAX[®] prostate cancer vaccine to Taxotere[®] chemotherapy administered with prednisone with respect to survival benefit in metastatic HRPC patients who are asymptomatic with respect to cancer-related pain. The VITAL-1 trial is designed to demonstrate an approximately 33% improvement in median survival in the patients receiving GVAX[®] vaccine compared to patients receiving Taxotere[®] plus prednisone therapy and is expected to enroll approximately 600 patients. We received a Special Protocol Assessment, or a SPA, from the FDA for this trial in May 2004. Under this procedure, a sponsor may seek the FDA's agreement on the design and analysis of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins except in limited circumstances, such as the FDA determining that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the trial had begun. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the basis for approval with respect to effectiveness. While we have received FDA's agreement on a SPA for this Phase 3 trial assessing GVAX[®] prostate cancer vaccine, there can be no assurance that this trial will have a successful outcome or that we will ultimately receive approval for this product. The second Phase 3 clinical trial, referred to as the VITAL-2 trial, will compare GVAX[®] prostate cancer vaccine plus Taxotere[®] chemotherapy to Taxotere[®] chemotherapy alone with respect to survival benefit in metastatic HRPC patients with cancer-related pain. We are currently finalizing the protocol for this second Phase 3 clinical trial and expect to begin the trial in the first half of 2005. We plan to manufacture GVAX[®] prostate cancer vaccine for Phase 3 clinical trials and potential market launch in our Hayward, California manufacturing facility, which operates in accordance with cGMP regulations.

GVAX[®] Lung Cancer Vaccine

Our GVAX[®] lung cancer vaccine targets non small-cell lung cancer and is a patient-specific product made directly from tumor cells that are surgically removed from each treated patient. After surgical removal of a patient's tumor, the GVAX[®] lung cancer vaccine is prepared by genetically modifying the patient's tumor cells to secrete GM-CSF. The cells are then irradiated for safety prior to vaccinating the patient. The vaccines are manufactured at our Memphis, Tennessee manufacturing facility, which operates in accordance with cGMP regulations, in a semiautomated closed system designed to maximize sterility and quality control of the individualized vaccines.

Based on the encouraging results of an initial Phase ½ clinical trial of GVAX[®] lung cancer vaccine in patients with advanced non small-cell lung cancer, the majority of whom had failed radiation and/or chemotherapy, we initiated an expanded multicenter Phase 2 clinical trial of this product in advanced non small-cell lung cancer in 2003 using a new semiautomated closed system to produce the vaccine. This trial is fully enrolled with approximately 100 patients, and we expect to report preliminary results from this trial during 2005. In addition to the above Phase 2 clinical trial of GVAX[®] lung cancer vaccine, a second Phase 2 clinical trial commenced in June 2004 that is being sponsored and partially funded by the Southwest Oncology Group (SWOG), a cooperative clinical trials group of the National Cancer Institute. This clinical trial is enrolling patients with bronchoalveolar carcinoma, a subtype of non small-cell lung cancer that, based on our data, may be particularly responsive to GVAX[®] lung cancer vaccine. This trial may enroll up to approximately 100 patients. In the case of patient-specific therapies such as our GVAX[®] lung cancer vaccine, the risks of any surgical procedure that may be required to prepare the vaccine must be considered in the evaluation of the product's safety profile. All surgical procedures, particularly those in advanced disease settings, involve some element of risk to the patient, which must be evaluated in the context of the patient's condition and therapeutic alternatives. Our ongoing clinical studies are now designed to exclude patients at higher risk of post-operative complications. Nonetheless, in past and current clinical trials involving patients with very advanced stages of lung cancer, a small number of patients with progressive disease have died during the period following surgical removal of their tumors and prior to administration of GVAX[®] vaccine. Such events will continue to be included in an ongoing assessment of the overall risk/benefit profile of this product and could adversely influence the continuation of the current study and the product's future development.

An initial Phase ½ clinical trial of GVAX[®] lung cancer vaccine was conducted in advanced non small-cell lung cancer patients, the majority of whom had failed radiation and/or chemotherapy. In February 2004, final data from this trial were published in the *Journal of the National Cancer Institute*. Of the 33 patients who received vaccination, three patients (9 percent) achieved a complete response, or a complete disappearance of tumor at all disease sites, with a median duration of 17.8 months. Another seven patients (21 percent) had stable disease or minor responses with an overall median duration of 7.7 months. The median survival of all 33 treated patients was 11.6 months, measured from the initiation of vaccine manufacturing. As noted above, the results of this trial also suggested that one type of non small-cell lung cancer, bronchoalveolar carcinoma, may be more responsive to GVAX[®] lung cancer vaccine, in that two of the three patients with this type of lung cancer enrolled in the trial experienced complete responses following vaccine therapy. These results will be further evaluated in the Phase 2 clinical trial sponsored by SWOG.

GVAX[®] Pancreatic Cancer Vaccine

Our GVAX[®] pancreatic cancer vaccine is a non patient-specific product. We are currently conducting a Phase 2 clinical trial of GVAX[®] pancreatic cancer vaccine in combination with surgery and standard adjuvant radiation and chemotherapy. The targeted enrollment of 60 patients was completed in January 2005. Preliminary results from this Phase 2 trial may be available in late 2005. The trial was prompted by results from an initial Phase 1 clinical trial conducted at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. Data from this trial, which evaluated GVAX[®] pancreatic cancer vaccine in combination with surgery and standard adjuvant radiation and chemotherapy, demonstrated prolongation of disease-free survival in three of eight patients who received the two highest vaccine doses after surgical resection of their tumors followed by standard adjuvant radiation and chemotherapy. The most recently updated data revealed that these three patients remained alive and disease-free between 7 and 8 years after their respective diagnoses. In July 2004, studies were published in *The Journal of Experimental Medicine* describing the immune response to the vaccine in these three patients which indicated that patient-specific T cell immunity had been induced in these patients, but not in patients whose disease had progressed and who died. Finally, in June 2004, we reported the results of a Phase 2 clinical trial of GVAX[®] pancreatic cancer vaccine in 50 patients with inoperable metastatic pancreatic cancer. While the results of this trial demonstrate the safety and potentially enhanced clinical activity of the vaccine when administered in combination with low, immunomodulatory doses of cyclophosphamide chemotherapy, we have no current plans to conduct further studies of this vaccine in inoperable pancreatic cancer patients.

GVAX[®] Vaccines for Hematologic Malignancies

Our GVAX[®] vaccines for hematologic malignancies combine a non patient-specific GVAX[®] cancer vaccine product that we manufacture with the patient's malignant cells collected at the treatment center. We are conducting clinical trials evaluating this GVAX[®] vaccine administered after initial chemotherapy pre- and post-bone marrow stem cell transplantation in patients with newly-diagnosed acute myelogenous leukemia and multiple myeloma. A Phase 2 clinical trial of GVAX[®] leukemia vaccine and the Phase ½ clinical trial of GVAX[®] myeloma vaccine have both completed enrollment. The goal of GVAX[®] vaccine therapy in this setting is to stimulate an immune response directed against the patient's tumor cells and to prolong the remission induced by standard chemotherapy and bone marrow stem cell transplantation, and the preliminary findings from both trials indicate that vaccine treatment may reduce laboratory measures of residual disease.

Interim data from the Phase 2 clinical trial of GVAX[®] leukemia vaccine, which has enrolled 54 patients, were updated at the December 2004 meeting of the American Society of Hematology. The preliminary findings of this trial indicate that vaccine therapy is well tolerated and may reduce residual leukemic cells that persist after chemotherapy, as indicated by decreased levels of WT-1, a leukemia-associated genetic marker that is detectable in over 95 percent of patients with active acute myelogenous leukemia. Eleven of 16 patients tested to date were reported to have decreased WT-1 levels in their peripheral blood following the initiation of vaccine therapy and the median magnitude of this decrease was approximately 90%. Furthermore, relapse-free survival after a single pre-transplant vaccine was greater in these 11 patients compared to those that did not have decreases in WT-1 (80% v. 0%, p=0.02). We expect to update these results during 2005 and potentially announce further development plans for this product.

The Phase ½ clinical trial of GVAX[®] myeloma vaccine enrolled 22 patients, and 16 patients received at least one GVAX[®] vaccination. Interim data were updated at the December 2004 American Society of Hematology meeting. Combination therapy with chemotherapy followed by a transplantation and GVAX[®] vaccine resulted in six complete responses, five partial responses, three patients with stable disease and two patients with progression. Three patients with early progression after transplantation demonstrated potential antitumor activity following initiation of vaccination, as measured by reductions in the myeloma-associated circulating protein (M-spike) of 92 percent, 37 percent and 25 percent. Treatment with GVAX[®] myeloma vaccine in clinical trials to date has been safe and well tolerated. We expect to update these results in late 2005.

Our Oncolytic Virus Therapies Program

Our oncolytic virus therapies program utilizes adenovirus, one of the viruses responsible for the common cold, to create viruses that can kill cancer cells. Virus is engineered to selectively replicate in targeted cancer cells, thereby killing these cells, leaving healthy normal cells largely unharmed. The virus replicates in cancer cells until the cancer cell can no longer contain the virus and bursts. The tumor cell is destroyed and the newly created virus is believed to spread to neighboring cancer cells to continue the cycle of viral replication and tumor cell destruction. Compared with traditional therapies, oncolytic virus therapies may have a higher therapeutic index (greater specificity) with respect to their ability to kill tumor cells. We are currently manufacturing oncolytic virus therapies and other viral-based products in our San Diego, California facility, which operates in accordance with cGMP regulations.

In July 2003, we announced a global alliance with Novartis for the development and commercialization of oncolytic virus therapies. Under the agreement, we also acquired exclusive worldwide rights to the oncolytic virus therapy products and certain related intellectual property of Genetic Therapy, Inc. (GTI), an affiliate of Novartis, as well as related intellectual property of Novartis. Our alliance with Novartis thereby provided us with additional oncolytic virus therapy product opportunities at the preclinical stage of development.

CG7870 Oncolytic Virus Therapy for Prostate Cancer

CG7870, an oncolytic virus therapy for prostate cancer, has been evaluated in Phase ½ clinical trials, and has been shown to have activity following intraprostatic and intravenous administration as measured by reduction or stabilization of PSA. In December 2002, data from a Phase ½ clinical trial of intraprostatically administered CG7870 in patients with localized, recurrent prostate cancer were announced at the International Conference on Gene Therapy of Cancer. Data demonstrated reductions and stabilization of serum levels of PSA. Similar findings have also been reported for CG7870 administered as a single intravenous injection. During 2003, we initiated a Phase ½ clinical trial of intraprostatic CG7870 in combination with external beam radiation in patients with localized intermediate-risk prostate cancer. As a result of changing treatment paradigms for this stage of prostate cancer, however, we discontinued development of this combination therapy in early 2005 and elected to focus our attentions on our Phase ½ clinical trial of intravenous CG7870 in combination with Taxotere[®] chemotherapy in patients with advanced-stage prostate cancer, which was initiated in July 2004. Preclinical studies of CG7870 in combination with Taxotere[®] chemotherapy, the currently approved treatment for patients with advanced-stage prostate cancer, demonstrated significant synergistic antitumor activity in mouse tumor models of prostate cancer.

CG0070 Oncolytic Virus Therapy for Recurrent Bladder Cancer

CG0070, an oncolytic virus therapy with specificity for multiple cancers, has been evaluated in extensive preclinical studies. CG0070 is the first “armed” oncolytic virus therapy developed by Cell Genesys, so-named because it has been engineered to include the therapeutic gene for GM-CSF. As a result, CG0070 can potentially destroy cancer cells by two different mechanisms: direct cell-killing by the virus and immune-mediated cell-killing stimulated by GM-CSF. In early 2005, we announced that an Investigational New Drug (IND) application filed with the FDA for CG0070 had become effective. We expect to begin a Phase 1 clinical trial in patients with recurrent bladder cancer during the first half of 2005.

Our GVAX[®] cancer vaccines and oncolytic virus therapies are novel therapies which must undergo rigorous human testing regulated by the FDA. There is no assurance that GVAX[®] cancer vaccines or oncolytic virus therapies will be proven safe or efficacious or, if approved by the FDA, that such products can be successfully

commercialized. Although preliminary results reported to date from our clinical trials of GVAX[®] vaccines for prostate cancer, lung cancer, pancreatic cancer, leukemia and myeloma as well as clinical trials of our oncolytic virus therapy, CG7870, can be considered encouraging, our therapies may eventually be shown to have unacceptable toxicities and/or clinical efficacy may not be demonstrated in later stage testing. Any conclusion as to whether our GVAX[®] cancer vaccines and oncolytic virus therapies can potentially play a role in the treatment of multiple types of cancer will be based on both the results of ongoing clinical trials as well as future Phase 2 and Phase 3 clinical trials.

Our Preclinical Programs

Our preclinical programs are focused on additional studies of GVAX[®] cancer vaccines and the evaluation of new product opportunities in oncolytic virus therapy and antiangiogenesis therapy for multiple types of cancer. Moreover, with our increasing focus on cancer, we continue to execute our plan to pursue gene therapies for neurological disorders through our former subsidiary, Ceregene, Inc.

Oncolytic Virus Therapies

Our pipeline of preclinical oncolytic virus therapy products increased in 2003 through our global alliance with Novartis. Our current pipeline of preclinical oncolytic virus therapy products includes CG0070, which is equipped with the GM-CSF gene, as well as CG5757 and CG4030, which are equipped with a telomerase promoter, which provides the potential to target multiple types of cancer. We expect to initiate a clinical trial for CG0070, an oncolytic virus therapy with multiple cancer specificity, in bladder cancer in the first half of 2005.

Antiangiogenesis Therapy

We are conducting research on antiangiogenesis therapies that are designed to interfere with cancer cell growth or spread by either directly or indirectly blocking tumor blood vessel or lymphatic vessel growth. We are currently conducting preclinical studies to evaluate the gene-based delivery of several potential antiangiogenic proteins to determine whether this has any potential as anticancer therapy.

Government Regulations

FDA Regulation

Prescription pharmaceutical products and biologics are subject to extensive pre- and post-marketing regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of the products under the Federal Food, Drug and Cosmetic Act and the Public Health Services Act, and by comparable agencies in most foreign countries. The process required by the FDA before a new drug or biologic may be marketed in the U.S. generally involves the following: completion of preclinical laboratory and animal testing; submission of an Investigational New Drug (IND) application, which must become effective before clinical trials may begin; performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug's or biologic's intended use; and approval by the FDA of a New Drug Application (NDA), in the case of a new drug, or of a Biologics License Application (BLA) for a biologic.

The activities required before a pharmaceutical agent may be marketed in the United States begin with preclinical testing. Preclinical tests include laboratory evaluation of potential products and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies and other information including chemistry, manufacturing and controls information must be submitted to the FDA as part of an IND application, which must be reviewed and approved by the FDA before proposed clinical testing can begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution at which the study is conducted. The institutional review board considers, among other things, ethical

factors and the safety of human subjects. In addition, certain protocols involving the use of genetically modified products must also be reviewed by the Recombinant DNA Advisory Committee of the National Institutes of Health.

Typically, human clinical trials are conducted in three phases that may overlap. In Phase 1, clinical trials are conducted with a small number of subjects to determine the early safety profile and pharmacology of the new therapy. In Phase 2, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase 3, large scale, multicenter, comparative clinical trials are conducted with patients afflicted with a target disease in order to provide enough data for the statistical proof of efficacy and safety required by the FDA and other regulatory agencies. In the case of products for life-threatening diseases, the initial human testing is generally done in the target patients rather than with healthy volunteers. Since these patients are already afflicted with the target disease, it is possible that such studies may provide some results traditionally obtained in Phase 2 clinical trials. These trials are frequently referred to as Phase ½ clinical trials. Although the preliminary Phase ½ and Phase 2 clinical trials of our GVAX[®] cancer vaccines and oncolytic virus therapies have shown a generally favorable safety profile to date, there can be no assurance that such therapies or products will be tolerated at higher doses or that the clinical efficacy or safety of such therapy or product will be demonstrated in later stage testing.

The results of the preclinical and clinical testing, together with chemistry, manufacturing and controls information, are submitted to the FDA in the form of an NDA for a pharmaceutical product, and in the form of a BLA for a biologic product, in order to obtain approval to commence commercial sales. In responding to an NDA or a BLA, the FDA may grant marketing approvals, request additional information or further research, or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Patient-specific therapies such as our GVAX[®] lung cancer vaccine may be subject to additional risk with respect to the regulatory review process. FDA approval for a pharmaceutical or biologic product may not be granted on a timely basis, if at all, or if granted may not cover all the clinical indications for which approval is sought or may contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use.

We have utilized the procedure called Special Protocol Assessment (SPA) for GVAX[®] prostate cancer vaccine. Under this procedure, a sponsor may seek the FDA's agreement on the design and analysis of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins except in limited circumstances, such as the FDA determining that a substantial scientific issue essential in determining the safety or effectiveness of the product was identified after the trial had begun. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the basis for approval with respect to effectiveness. While we have received FDA's agreement on a SPA for the Phase 3 trial comparing GVAX[®] prostate cancer vaccine to Taxotere[®] chemotherapy administered with prednisone with respect to survival benefit in asymptomatic patients without cancer-related pain, there can be no assurance that this trial will have a successful outcome or that we will ultimately receive approval for this product.

Satisfaction of FDA premarket approval requirements for new drugs and biologics typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or targeted disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials or with prior versions of products does not assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of an approved product, and may limit further marketing of the product based on the results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, or withdraw approvals.

Facilities used to manufacture drugs and biologics are subject to periodic inspection by the FDA, the United States Drug Enforcement Administration (DEA) and other authorities where applicable, and must comply with the FDA's cGMP regulations. Manufacturers of biologics also must comply with FDA's general biological product

standards. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, or mandatory or voluntary recall of a product. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals and biologics, which include, among other things, standards and regulations relating to direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food, Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties including the issuance of a warning letter directing the entity to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

Other Government Regulations

We are subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the government has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us.

In addition to laws and regulations enforced by the FDA, we are also subject to regulation under National Institutes of Health guidelines, as well as under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local laws and regulations, as our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds.

Manufacturing

Manufacture of our products for clinical trials does not require an FDA license, although the FDA may at any time inspect our manufacturing facilities. We have three leased manufacturing facilities, including a 51,000 square-foot facility in Hayward, California, a 35,000 square-foot facility in Memphis, Tennessee, and a 48,000 square-foot facility in San Diego, California, all of which are operated according to cGMP regulations. We believe that our three manufacturing facilities will have the capacity to manufacture products for Phase 3 trials and market launch of our products. We are manufacturing non patient-specific GVAX[®] cancer vaccine products such as GVAX[®] prostate cancer vaccine in our Hayward facility, patient-specific GVAX[®] lung cancer vaccines in our Memphis facility and oncolytic virus therapy products in our San Diego facility.

Corporate Collaborations

Novartis AG

In July 2003, we announced a global alliance between Novartis AG and ourselves for the development and commercialization of oncolytic virus therapies. Under the agreement, we also acquired exclusive worldwide rights to the oncolytic virus therapy products and related intellectual property of Genetic Therapy, Inc. (GTI), an affiliate of Novartis, as well as certain related intellectual property of Novartis. We also received a payment of \$28.5 million from Novartis to be dedicated to the further development of several oncolytic virus therapy products by both ourselves and GTI, for which Novartis has certain marketing options. In exchange, we issued to Novartis and GTI 1,999,840 shares of our common stock, with the result that Novartis became the holder of approximately five percent (as of the time of the issuance) of our outstanding common stock. In addition, the agreement provides the basis for the sharing of future additional development costs and potential profits for certain oncolytic virus products on a worldwide basis. Upon the exercise of certain options by Novartis, development costs and profits would be

shared on an approximately equal basis in the United States. Novartis will be responsible for the development costs for markets outside the United States and pay us a royalty on potential future sales outside the United States. Novartis will also reimburse us on a cost-plus basis for products that we manufacture for them to sell outside of the United States.

In September 2004, the terms of our agreement with Novartis were amended to include the grant of a non-exclusive worldwide perpetual license to all patent rights of Novartis relating to Granulocyte Macrophage Colony Stimulating Factor ("GM-CSF"), a component of our GVAX[®] cancer vaccines, in the Field of Gene Therapy. This license bears a low single digit royalty. Also included in the agreement was acknowledgment that certain GVAX[®] vaccine products, such as our GVAX[®] prostate cancer vaccine, would not require this license and hence would not be subject to future royalty payments to Novartis.

Medarex, Inc.

In May 2003, we entered into a research and development collaboration with Medarex, Inc. to evaluate combination therapy with our GVAX[®] prostate cancer vaccine and Medarex's anti-CTLA-4 antibody. Preclinical studies indicate that anti-CTLA-4 antibody may stimulate the immune system and enhance the activity of GVAX[®] vaccines. We initiated a Phase I trial of this combination therapy in September 2004. Under the research and development collaboration agreement, both companies will share the cost of this clinical trial equally.

Abgenix, Inc.

In November 1997, we entered into a gene therapy rights agreement with Abgenix, Inc. The agreement provides us with certain rights to utilize Abgenix's XenoMouse[®] technology in the field of gene therapy. We are obligated to make certain payments to Abgenix for these rights, including license fees and royalties on future product sales. The agreement also prohibits Abgenix from granting any third-party licenses for antibody products based on antigens nominated by Abgenix for its own purposes where the primary field of use is gene therapy. In the case of third-party licenses granted by Abgenix where gene therapy is a secondary field, Abgenix is obligated to share with us a portion of the cash milestone payments and royalties resulting from any products in the field of gene therapy.

Other Collaborations

We have licensing agreements relating to our proprietary viral vector technologies. These agreements enable us to receive monetary reimbursement for providing viral vector technologies to companies that commercialize these technologies for the research market. Examples include agreements with the Clontech division of Becton, Dickinson and Company and with Invitrogen Corporation for specific vector technologies. We also have an ongoing license agreement with the Ludwig Institute for Cancer Research for gene therapy rights to vascular endothelial growth factor receptor-3 (VEGFR-3), a novel protein that we believe plays a key role in the spread of cancer to lymph glands.

Cell Genesys' Assets Outside of its Core Business

Investment in Abgenix

Abgenix is developing antibody therapies for multiple disease indications, including cancer and inflammatory diseases. Abgenix's core technology includes strains of transgenic mice capable of generating fully human antibodies. We formed Abgenix as a wholly-owned subsidiary in June 1996. Abgenix completed its initial public offering in July 1998. As of December 31, 2004, we held approximately 6.6 million shares of Abgenix common stock, or approximately 7.4 percent of outstanding shares. We expect to sell these shares of Abgenix stock over time to provide additional funding for our business.

Ceregene

In January 2001, we launched a new majority-owned subsidiary, Ceregene, located in San Diego, California, which is focused on gene therapies for central nervous system (CNS) disorders such as Alzheimer's disease, Parkinson's disease and ALS. Ceregene's goal is to use gene therapy as a "drug delivery" strategy to deliver

neurologic growth factors to specific sites in the nervous system to prevent the nerve degeneration associated with these disorders. Ceregene was formed in part through the acquisition of Neurologic Gene Therapeutics, a private San Diego-based start-up company. We initially contributed \$10.0 million to Ceregene together with access to certain of our technologies and patents in the CNS area, in exchange for approximately 60 percent ownership of the new company. Following the completion of Ceregene's recent \$32.0 million Series B financing, in which we participated through conversion of an existing bridge loan, our ownership percentage decreased to approximately 25 percent calculated on a fully diluted basis. We have the right to appoint two of the six members of Ceregene's board. Stephen A. Sherwin, M.D., our chairman and chief executive officer, has served as chairman of Ceregene since its inception, and Eugene L. Step, our director, also serves on the Ceregene board. Ceregene's operations have significantly expanded in recent years and included the appointment of Dr. Jeffrey M. Ostrove, Ph.D., as president and chief operating officer.

During 2001, the first-ever study of Alzheimer's disease gene therapy was initiated at the University of California, San Diego (UCSD) School of Medicine based on technology exclusively licensed to Ceregene. The Phase 1 clinical trial employed *ex vivo* gene therapy and is fully enrolled with eight patients. An initial report on this trial was presented at the American Academy of Neurology Meeting in April 2004. Preliminary results confirm safety and tolerability of the gene therapy, as well as biologic activity evidenced by a reduction in the rate of decline of cognitive function. Ceregene is currently developing CER-110 in its Alzheimer's disease gene therapy program, which is an *in vivo* gene therapy comprised of a nerve growth factor gene and an adeno-associated viral gene delivery system. A Phase ½ clinical trial of CER-110 was initiated in mid 2004. Ceregene is also developing CER-120 for Parkinson's disease gene therapy and CER-130 for ALS gene therapy. In 2003, Ceregene announced that it had signed a licensing agreement with Genentech, Inc. for exclusive worldwide rights to two growth factor genes for use in neurological gene therapy, including nerve growth factor and neurotrophic factor 4/5. Additionally, in August 2003, Ceregene signed an option agreement with the Salk Institute for Biological Studies for exclusive worldwide rights to the Salk Institute's ALS gene therapy technology.

Gene Activation Technology

We have developed a novel and proprietary method for protein production referred to as "gene activation." Gene activation involves the insertion of genetic regulatory elements at specific sites in cell chromosomes in order to simulate the human gene responsible for the expression of a therapeutic protein. Gene activation licensing agreements have provided us \$57.6 million in revenues to date. Since February 1997, we have had a license agreement with Hoechst Marion Roussel, now sanofi-aventis Group, for gene-activated erythropoietin (EPO). As of December 31, 2004, we have received \$23.2 million under this license agreement, which includes certain milestone payments relating to the development of gene-activated EPO, which sanofi-aventis Group is developing in collaboration with Transkaryotic Therapies, Inc. (TKT). The agreement also provides for royalties on future sales of gene-activated EPO in any territory. In June 2002, we announced the completion of a separate licensing agreement under which we exclusively licensed to TKT, our intellectual property relating to gene activation technology for certain therapeutic proteins. In exchange, we received an up-front license fee of \$26.0 million.

Patents and Trade Secrets

The patent positions of pharmaceutical and biotechnology firms, including Cell Genesys, are generally uncertain and involve complex legal and factual questions. As of December 31, 2004 we had approximately 325 patents issued or granted to us or available to us based on licensing arrangements and approximately 318 applications pending in our name or available to us based on licensing arrangements. We are currently prosecuting our patent applications, but we cannot be certain whether any given application will result in the issuance of a patent or, if any patent is issued, whether it will provide significant proprietary protection or will not be invalidated.

Our commercial success will also depend in part on not infringing the patents or proprietary rights of others and not breaching licenses granted to us. We are aware of competing intellectual property relating to both our programs in cancer vaccines and oncolytic viruses. While we currently believe that we have freedom to operate in these areas, there can be no assurance that others will not challenge our position in the future. We may be required to obtain licenses to certain third-party technologies or genes necessary in order to market our products. Any failure to license any technologies or genes required to commercialize our technologies or products at reasonable cost may have a material adverse effect on our business, results of operations or financial condition.

Litigation, which could result in substantial cost to us, may also be necessary to enforce any patents issued to us or to determine the scope and validity of other parties' proprietary rights. To determine the priority of inventions, interference proceedings are frequently declared by the U.S. Patent and Trademark Office (USPTO), which could result in substantial costs to us and may result in an adverse decision as to the priority of our inventions. We are currently involved in interference and/or opposition proceedings related to our current product portfolio and certain of our core technologies. We have filed an appeal of the final decision from the USPTO relating to an interference proceeding pending since 1996 with Applied Research Systems Holding N.V. (ARS) concerning a patent and patent application related to gene activation technology. ARS has also appealed the decision. The outcomes of these proceedings cannot be predicted. If we lose in any such proceeding, our patents or patent applications that are the subject matter of the proceeding may be invalidated or may not be permitted to issue as patents. While the current court proceeding does not involve our core technology, we may also be involved in other interference and/or opposition proceedings in the future. Consequently, we may be required to obtain a license from the prevailing party in order to continue the portion of our business that relates to the proceeding. Such license may not be available to us on acceptable terms or on any terms and we may have to discontinue that portion of our business. We believe there will continue to be significant litigation in the industry regarding patent and other intellectual property rights.

We also rely on unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our rights to our unpatented trade secrets.

We require our employees and consultants to execute confidentiality agreements upon the commencement of employment and consulting relationships with us. These agreements provide that all confidential information developed by or made known to an individual during the course of the employment or consulting relationship generally must be kept confidential. In the case of employees, the agreements provide that all inventions conceived by the individual, while employed by us, relating to our business are our exclusive property. These agreements may not provide meaningful protection for our trade secrets in the event of unauthorized use or disclosure of such information.

Competition

We face substantial competition in the development of products for cancer and other diseases. This competition, from other manufacturers of the same types of products and from manufacturers of different types of products designed for the same uses, is expected to continue in both U.S. and international markets. Cancer vaccines, oncolytic virus therapies and antiangiogenesis therapies, our three primary focus areas, are rapidly evolving areas in the biotechnology industry and are expected to undergo many changes in the coming years as a result of technological advances. We are currently aware of a number of groups that are developing cancer vaccines, oncolytic virus therapies and antiangiogenesis therapies including early-stage and established biotechnology companies, pharmaceutical companies, academic institutions, government agencies and research institutions. Examples in the cancer vaccine area include Dendreon Corporation, which has commenced Phase 3 trials in prostate cancer, and Antigenics, Inc. and CancerVax, Inc., which are developing products for kidney cancer and/or melanoma, which are types of cancer not currently targeted by us. We face competition from these groups in areas such as recruiting employees, acquiring technologies that might enhance our ability to market products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies. It is possible that our competitors could achieve earlier market commercialization, could have superior patent protection, or could have safer, more effective or more cost-effective products. These factors could render our potential products less competitive, which could have a material adverse effect on our business.

Human Resources

As of December 31, 2004, we employed 377 people, of whom 34 hold Ph.D. degrees and 11 hold M.D. degrees. Approximately 324 employees are engaged in research, development and manufacturing operations, and 53 employees support business development, intellectual property, finance and other administrative functions. Many of

our management have had prior product development experience in the biotechnology and pharmaceutical industries.

Our success will depend in large part upon our ability to attract and retain employees. We face competition in this regard from other companies, research and academic institutions, government entities and other organizations. We believe that our employee relations are good.

Executive Officers

Our executive officers and their ages as of March 1, 2005, are as follows:

Name	Age	Position
Stephen A. Sherwin, M.D.	56	Chairman of the Board and Chief Executive Officer
Joseph J. Vallner, Ph.D.	58	President and Chief Operating Officer
Matthew J. Pfeffer *.....	47	Vice President and Chief Financial Officer
Robert J. Dow, MBChB.....	54	Senior Vice President—Medical Affairs
Michael W. Ramsay.....	48	Senior Vice President—Operations
Robert H. Tidwell.....	61	Senior Vice President—Corporate Development
Peter K. Working, Ph.D.....	56	Senior Vice President—Research and Development
Carol C. Grundfest.....	50	Vice President—Regulatory Affairs and Project Management
Kristen M. Hege, M.D.....	41	Vice President—Clinical Research
Christine McKinley.....	51	Vice President—Human Resources

* On March 11, 2005, Mr. Pfeffer announced his intention to resign as our vice president and chief financial officer; however, he will remain in his position until a successor is appointed.

Dr. Sherwin, chairman of the board and chief executive officer, joined Cell Genesys in March 1990. Dr. Sherwin has served as chief executive officer since inception, and in March 1994 he was elected to the additional position of chairman of the Board of Directors. Dr. Sherwin also served as president until July 2001, at which time Dr. Vallner was appointed president. From 1983 to 1990, Dr. Sherwin held various positions at Genentech, Inc., a biotechnology company, most recently as vice president of clinical research. Prior to 1983, Dr. Sherwin was on the staff of the National Cancer Institute. Dr. Sherwin currently serves as the chairman of the board of Ceregene, Inc., a former subsidiary of Cell Genesys, which he co-founded in 2001. Dr. Sherwin was also a co-founder of Abgenix, Inc, a former subsidiary of Cell Genesys. He is also a director of Neurocrine Biosciences, Inc. and Rigel Pharmaceuticals, Inc. Dr. Sherwin, who also serves as a board member of the Biotechnology Industry Organization, holds a B.A. in biology from Yale University, an M.D. from Harvard Medical School and is board-certified in internal medicine and medical oncology.

Dr. Vallner, president and chief operating officer, joined Cell Genesys in October 1999. Dr. Vallner also served as executive vice president and chief operating officer from October 1999 to July 2001. He currently manages our research, development, clinical, regulatory, manufacturing and operations departments. Prior to joining Cell Genesys, Dr. Vallner was with SEQUUS Pharmaceuticals from 1992 to 1999 where he was instrumental in the product launch of two products including Doxil[®], a liposome-based cancer therapeutic. In addition, Dr. Vallner helped transition SEQUUS through its merger with ALZA Corporation. Prior to that, he held various positions with Syntex Corporation and G.D. Searle and Company from 1984 to 1992, and was an associate professor of pharmaceuticals at the University of Georgia. Dr. Vallner, who serves as a board member of the California Healthcare Institute, received his Ph.D. in pharmaceuticals, his M.S. in physical chemistry and his B.S. in pharmacy from the University of Wisconsin, Madison.

Mr. Pfeffer, vice president and chief financial officer, joined Cell Genesys in June 1996. Mr. Pfeffer has served as vice president since April 1999 and as chief financial officer since September 1998. Prior to that, Mr. Pfeffer also served as director of finance since June 1996. From 1989 to 1996, Mr. Pfeffer held a variety of positions at Diasonics Ultrasound, Inc., most recently as corporate controller. From 1987 to 1989, he was in the finance department at ComputerLand Corporation. From 1981 to 1987, Mr. Pfeffer was in the audit and consulting groups at Price Waterhouse, where he obtained his CPA certificate. Mr. Pfeffer graduated with a B.S. degree in business administration from the University of California, Berkeley.

Dr. Dow, senior vice president, medical affairs, joined Cell Genesys in March 2005. Prior to joining Cell Genesys, from 2002 to 2005, Dr. Dow served as chief executive officer at biolitec pharma ltd, a UK biotechnology company wholly-owned by biolitec AG of Germany. From 1997 to 2002, Dr. Dow held senior executive positions with Quantanova and Scotia Holdings, plc. From 1995 to 1997, Dr. Dow was Global Head of Global Drug Development with Hoffman la Roche, and from 1982 to 1995 he held senior executive positions in drug development with Syntex Corporation. Dr. Dow holds a B.Sc. in Medical Science from the University of St. Andrews and his medical qualification, an MBChB degree, from the University of Dundee in Scotland. He also is a Fellow of the Royal College of Physicians of Edinburgh.

Mr. Ramsay, senior vice president, operations, joined Cell Genesys in January 2002. Prior to joining Cell Genesys, Mr. Ramsay served as a vice president of manufacturing at ALZA Corporation from 1999 to 2001. Mr. Ramsay also held various positions from 1992 to 1999 with SEQUUS Pharmaceuticals, including vice president of manufacturing operations, as well as various positions at Syntex Corporation focusing on manufacturing, product development and regulatory affairs from 1978 to 1991. Mr. Ramsay holds a Bachelor of Pharmacy from the University of Nottingham in the United Kingdom.

Mr. Tidwell, senior vice president, corporate development, joined Cell Genesys in August 2000. Prior to joining Cell Genesys, Mr. Tidwell was vice president of business development at Calydon, Inc. from 1998 to 2000. Mr. Tidwell has also held various management positions with such companies as Boston Life Sciences, where he served as chief operating officer from 1993 to 1994, Genetics Institute, where he was vice president of marketing and business development from 1988 to 1993, and Eli Lilly and Company, where he held various positions including director of worldwide pharmaceutical licensing, between 1969 and 1985. Mr. Tidwell holds an M.B.A. from The Ohio State Graduate School of Business and a Bachelor of Pharmacy from The Ohio State School of Pharmacy.

Dr. Working, senior vice president, research and development, joined Cell Genesys in September 2001. Prior to joining Cell Genesys, from 1999 to 2001, Dr. Working served as vice president of analytical and non-clinical sciences and principal scientist at ALZA Corporation. From 1992 to 1999, Dr. Working was with SEQUUS Pharmaceuticals, where the last position he held was vice president of research and development. From 1988 to 1992 he was with Genentech, Inc. where he served as a senior toxicologist and head of the Experimental Toxicology Group in the Department of Safety Evaluation. Dr. Working holds Ph.D., M.S. and B.S. degrees from the University of California, Davis and an M.A. degree from the University of California, San Francisco.

Ms. Grundfest, vice president, regulatory affairs and project management, joined Cell Genesys in July 2003. Prior to joining Cell Genesys, Ms. Grundfest served as an independent consultant providing advice, analysis and recommendations regarding the regulation and approval of pharmaceutical products in the United States from 2000 to 2003. From 1998 to 2000, Ms. Grundfest served as executive director of project management and strategic planning at Systemix, Inc. and Genetic Therapy, Inc. (affiliates of Novartis AG). Ms. Grundfest also held senior regulatory positions with Roche Global Development and Syntex from 1990 to 1996, as well as served as assistant vice president, research and development at the Pharmaceutical Research and Manufacturers of America from 1982 to 1990. Ms. Grundfest received an M.H.S. in environmental health sciences from The Johns Hopkins University, School of Public Health and a B.S. in biology from Stanford University.

Dr. Hege was promoted to the position of vice president, clinical research in July 2004. Dr. Hege joined Cell Genesys in January 1994 as a medical post-doctoral research fellow, working on preclinical studies of hematopoietic stem cell gene therapy. For the past eight years, she has worked in the clinical research department, most recently as senior director, clinical research. In addition to her work at Cell Genesys, Dr. Hege has held a clinical faculty appointment at University of California, San Francisco (UCSF) since 1997 in the adult leukemia and bone marrow transplant program. Dr. Hege received a B.A. in biochemistry from Dartmouth College, an M.D. from UCSF, and is board-certified in internal medicine, medical oncology and hematology.

Ms. McKinley, vice president, human resources, joined Cell Genesys in August 1994. From 1985 to 1994, she was with Nellcor Puritan Bennett, Inc. where the last position she held was corporate human resources director. Previously, Ms. McKinley also worked at Genentech, Inc. from 1978 to 1984 in various human resource positions. She received a B.A. in psychology from the University of California, Santa Barbara.

Medical Advisory Board

We have established a Medical Advisory Board that includes several prominent leaders in the field of oncology. As of December 31, 2004, the board consisted of the following individuals:

<u>Name</u>	<u>Scientific Position</u>
Bruce Chabner, M.D.	Clinical Director Massachusetts General Hospital Cancer Center Professor of Medicine Harvard Medical School
Jordan U. Gutterman, M.D.	Department of Molecular Therapeutics Professor of Medicine University of Texas M.D. Anderson Cancer Center
Craig Henderson, M.D.	Adjunct Professor of Hematology/Oncology University of California, San Francisco
Ronald Levy, M.D.	Robert K. Summy and Helen K. Summy Professor of Medicine Chief of the Division of Oncology Stanford University School of Medicine
William Nelson, M.D., Ph.D.	Associate Professor of Oncology, Pathology, Pharmacology and Medicine, and Urology Sidney Kimmel Comprehensive Cancer Center The Johns Hopkins University
John T. Potts, Jr., M.D.	Physician-in-Chief and Director of Research Emeritus Massachusetts General Hospital Jackson Distinguished Professor of Clinical Medicine Harvard Medical School

Dr. Potts, who is also a member of our Board of Directors, serves as a liaison between the Medical Advisory Board and the Board of Directors, making periodic reports on the findings of the Medical Advisory Board to the Board of Directors.

Scientific Advisory Board

We have established a Scientific Advisory Board that includes several prominent leaders in the fields of cancer immunotherapy and gene therapy. As of December 31, 2004, the board consisted of the following individuals:

<u>Name</u>	<u>Scientific Position</u>
Bernard A. Fox, Ph.D.	Chief, Laboratory of Molecular and Tumor Immunology Earle A. Chiles Research Institute Providence Portland Medical Center Associate Professor, Molecular Microbiology Oregon Health & Science University
Carl H. June, M.D.	Professor, Pathology & Laboratory Medicine Director, Translational Research Programs The Leonard and Madlyn Abramson Family Cancer Research Institute at the University of Pennsylvania

<u>Name</u>	<u>Scientific Position</u>
John T. Potts, Jr., M.D.	Physician-in-Chief and Director of Research Emeritus Massachusetts General Hospital Jackson Distinguished Professor of Clinical Medicine Harvard Medical School
Thomas E. Shenk, Ph.D.	Elkins Professor Chairman of the Department of Molecular Biology Professor, Princeton University
Inder M. Verma, Ph.D.	Professor of Molecular Biology and Virology The Salk Institute

Dr. Verma, who is also a member of our Board of Directors, serves as a liaison between the Scientific Advisory Board and the Board of Directors, making periodic reports on the findings of the Scientific Advisory Board to the Board of Directors.

ITEM 2. PROPERTIES

We maintain our headquarters in South San Francisco, California and have three cGMP manufacturing facilities, each designed to produce one or more types of products at a scale suitable for Phase 3 trials and potential commercial market launch and all of which are now in service. We lease all of our facilities. Our Hayward, California manufacturing facility, which consists of 51,000 square feet of manufacturing space and 50,000 square feet of laboratory and office space, is currently producing our non patient-specific GVAX[®] prostate cancer vaccine. Our 48,000 square-foot viral-based product manufacturing facility in San Diego, California is manufacturing oncolytic virus therapy products for clinical trials and has also produced viral vector product for clinical trials being conducted by our minority-owned subsidiary Ceregene. Finally, our 35,000 square-foot manufacturing facility in Memphis, Tennessee is currently manufacturing patient-specific GVAX[®] lung cancer vaccines for our ongoing Phase 2 clinical trial. The Memphis facility provides us with a centrally located facility to receive and process tumor cells obtained from patient biopsies, manufacture the patient-specific vaccine products, carry out quality control testing and ship the vaccine products back to the patient treatment centers. The Memphis facility may also be used in the future as a centralized product distribution center for other products.

Our headquarters facility consists of approximately 156,000 square feet of research and development and administrative space. We moved to this location in March 2003 from our previous leased facilities in Foster City, California. We are actively pursuing the subleasing of our former headquarter facilities in Foster City until these leases expire in 2006.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on the Nasdaq National Market under the symbol "CEGE." The following table sets forth, for the periods indicated, the high and low closing prices per share of our common stock as reported by the Nasdaq National Market. We did not pay any cash dividends with respect to our common stock during any of the periods indicated below.

<u>2004</u>	<u>High</u>	<u>Low</u>
First Quarter.....	\$ 15.93	\$ 11.03
Second Quarter.....	\$ 12.98	\$ 9.45
Third Quarter.....	\$ 10.40	\$ 6.61
Fourth Quarter.....	\$ 9.34	\$ 6.38
<u>2003</u>	<u>High</u>	<u>Low</u>
First Quarter.....	\$ 11.50	\$ 6.43
Second Quarter.....	\$ 11.32	\$ 7.54
Third Quarter.....	\$ 15.10	\$ 8.87
Fourth Quarter.....	\$ 14.04	\$ 11.68

As of January 31, 2005, there were approximately 670 holders of record and approximately 24,500 beneficial holders of our common stock. On January 31, 2005, the last reported sales price on the Nasdaq National Market for our common stock was \$7.00. The market for our common stock is highly volatile.

As of December 31, 2004, we had 152 shares of Series B redeemable convertible preferred stock outstanding, held by two holders of record. As of December 31, 2004, the carrying value was approximately \$1.9 million. On January 18, 2005, all of the 152 then outstanding shares of our Series B redeemable convertible preferred stock automatically converted into an aggregate of 275,622 shares of our common stock at an effective conversion price of \$6.895 per share. For a description of the terms of the preferred stock and details regarding the recent conversion of the preferred stock into common stock, see *Note 8 of Notes to Consolidated Financial Statements* included under Item 8 of this Annual Report on Form 10-K.

We did not repurchase any shares of our equity securities during the fourth quarter of the year ended December 31, 2004.

The information required by this item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected financial information has been derived from the audited consolidated financial statements. The information set forth below is not necessarily indicative of results of future operations, and should be read in conjunction with *Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations"* and the consolidated financial statements and related notes thereto included in Item 8 of this Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

	<u>Year Ended December 31,</u>				
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenue.....	\$ 11,458	\$ 18,128	\$ 39,141	\$ 28,317	\$ 24,209
Total operating expenses.....	110,061	111,276	95,649	80,644	37,458
Gain on sale of Abgenix, Inc. common stock.....	12,160	12,638	2,246	—	239,660
Net income (loss).....	(97,411)	(56,406)	(26,599)	(28,673)	168,920

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share amounts)				
Income (loss) attributed to common stockholders	(97,511)	(56,636)	(27,301)	(29,458)	168,164
Basic income (loss) per common share.....	(2.23)	(1.48)	(0.76)	(0.85)	4.99
Diluted income (loss) per common share.....	(2.23)	(1.48)	(0.76)	(0.85)	4.55

	December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments, including restricted cash and investments.....	\$ 174,971	\$ 160,288	\$166,905	\$258,649	\$259,647
Total assets	435,139	460,502	419,197	615,310	793,716
Total current liabilities.....	77,923	94,296	76,353	149,690	239,002
Long-term obligations, excluding current portion ...	51,013	146,634	104,064	60,000	1,350
Convertible senior notes	145,000	—	—	—	—
Redeemable convertible preferred stock.....	1,897	2,706	7,632	17,970	17,185
Accumulated deficit.....	(243,973)	(146,562)	(90,156)	(63,557)	(34,883)
Stockholders' equity.....	159,306	216,866	231,148	387,554	536,179

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements made in this Item other than statements of historical fact, including statements about us and our subsidiaries and our respective clinical trials, research programs, product pipelines, current and potential corporate partnerships, licenses and intellectual property, the adequacy of capital reserves and anticipated operating results and cash expenditures, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. As such, they are subject to a number of uncertainties that could cause actual results to differ materially from the statements made, including risks associated with the success of research and product development programs, the issuance and validity of patents, the development and protection of proprietary technologies, the ability to raise capital, operating expense levels and the ability to establish and retain corporate partnerships. Reference is made to discussions about risks associated with product development programs, intellectual property and other risks which may affect us under "Other Factors Affecting Future Operations" below. We do not undertake any obligation to update forward-looking statements. The following should be read in conjunction with our consolidated financial statements located elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2004 and other documents filed by us from time to time with the Securities and Exchange Commission.

Overview

We are a biotechnology company focused on the research, development and commercialization of biological therapies for patients with cancer. We are currently developing cell-based cancer vaccines, oncolytic virus therapies and antiangiogenesis therapies to treat different types of cancer. Our clinical stage cancer programs involve cell- or viral-based products that have been genetically modified during product development to impart disease-fighting characteristics that are not found in conventional therapeutic agents. As part of our GVAX[®] cancer vaccines program, we are conducting a Phase 3 clinical trial in prostate cancer, are in ongoing Phase 2 clinical trials in lung cancer, pancreatic cancer and leukemia, and are in a Phase ½ clinical trial for multiple myeloma. We initiated our Phase 3 clinical trial for GVAX[®] prostate cancer vaccine in July 2004. In our oncolytic virus therapies program, which we are developing in part through a global alliance with Novartis AG, we are conducting a Phase ½ clinical trial in combination with Taxotere[®] chemotherapy in advanced-stage prostate cancer patients. We expect to initiate a Phase 1 clinical trial in bladder cancer using our CG0070 oncolytic adenovirus in the first half of 2005. We also have other preclinical oncolytic virus therapy programs as well as preclinical antiangiogenesis therapy programs evaluating potential therapies for multiple types of cancer.

Critical Accounting Policies

We consider certain accounting policies related to revenue recognition, lease accounting, income taxes and stock option valuation to be critical policies.

Revenue recognition

Since our inception, a substantial portion of our revenues has been generated from research and licensing agreements with collaborators. Revenue under such collaboration agreements typically includes upfront payments, cost reimbursements and milestone payments.

Revenue from non-refundable upfront license fees and other payments under collaboration agreements where we continue involvement throughout development is recognized over the development period based upon when the underlying development expenses are incurred. We recognize cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Incentive milestone payments under collaborative arrangements are recognized as revenue upon achievement of the incentive milestone events, which represent the culmination of the earnings process. Incentive milestone payments are triggered either by the results of our research efforts or by events external to us, such as regulatory approval to market a product or the achievement of specified sales levels by a marketing partner. As such, the incentive milestones are substantially at risk at the inception of the contract, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. Upon the achievement of an incentive milestone event, we have no future performance obligations related to that payment.

Amounts received under license agreements relating to our intellectual property are recognized as revenue upon execution of the technology licensing agreement, if we have no future performance obligations.

Deferred revenue represents the portion of upfront payments received that has not been earned.

Lease accounting

We record our obligations under facility operating lease agreements as rent expense. As of December 31, 2004, we have accrued approximately \$6.1 million for estimated lease exit costs associated with the move of our corporate headquarters to South San Francisco, California in March 2003 and the related vacancy in Foster City, California. This amount reflects the net remaining lease payments due under related lease contracts. We will actively pursue subleasing of our former headquarter facilities in Foster City, California until these leases expire in 2006. If we are able to sublease additional portions of our Foster City properties, our net lease costs may be less than the amount accrued as of December 31, 2004.

Income taxes

The Company establishes accruals for certain tax contingencies when, despite the belief that the Company's tax positions are fully supported, the Company believes that certain positions may be challenged and that the Company's positions may not be fully sustained. The tax contingency accruals are adjusted in light of changing facts and circumstances, such as the progress of tax audits, case law and emerging legislation. The IRS is currently examining the 2000 tax year. As of December 31, 2004, the Company's accrual for income taxes payable is sufficient to cover any expected liabilities arising from this examination. As of December 31, 2004 and 2003 respectively, we had accrued approximately \$30.0 million in tax contingencies and related interest. The Company's tax contingency accruals have been reclassified from noncurrent income tax liabilities to current liabilities within the balance sheet.

The nature of these matters is uncertain and subject to change. As a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the outcome of these matters. An outcome of such matters different than previously estimated could materially impact our financial position or results of operations in the year of resolution.

Our income tax benefits during the past three years have been based on our determination of deferred tax assets and liabilities and any valuation allowances that might be required against these deferred tax assets. We record valuation allowances to reduce deferred tax assets to the amounts that are more likely than not to be realized. We have considered anticipated future taxable income, including future taxable income that may result from future sales of holdings of our Abgenix common stock, and potential tax planning strategies in assessing the need for valuation allowances. Certain of these determinations require judgment on the part of management. If we determine that we will be able to realize our deferred tax assets in the future in excess of the carrying value of our net deferred tax assets, adjustments to the deferred tax assets will increase income by reducing tax expense in the period that we make such determination. Likewise, if we determine that we will not be able to realize all or part of the carrying value of our net deferred tax assets in the future, adjustments to the deferred tax assets will decrease income by increasing tax expense in the period that we make such determination. If our investment in Abgenix common stock were to suffer a significant decline in value, we may be required to reverse tax benefits in future periods that were previously recorded. Significant estimates are required in determining our income tax benefits. Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws and regulations, our future levels of spending for research and development, and changes in our overall level of pre-tax earnings or losses. We believe that our reserves for these uncertainties are adequate.

Stock option valuation

The preparation of the financial statement footnotes requires us to estimate the fair value of stock options granted to employees. While fair value may be readily determinable for awards of stock, market quotes are not available for long-term, nontransferable stock options because these instruments are not traded. We currently use the Black-Scholes option pricing model to estimate the fair value of employee stock options. However, the Black-Scholes model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including the stock price volatility. Because our stock options have characteristics significantly different from those of traded options and changes to the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not provide a reliable single measure of the fair value of our employee stock options. We are currently evaluating our option valuation methodologies and assumptions in light of evolving accounting standards related to employee stock options.

Results of Operations

Revenue

Revenues were \$11.5 million in 2004 compared to \$18.1 million in 2003 and \$39.1 million in 2002, as shown in the following table (in thousands):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Novartis AG.....	\$ 5,846	\$ 2,104	\$ —
Japan Tobacco Inc.	—	14,145	11,640
sanofi-aventis Group.....	3,173	1,000	1,130
Transkaryotic Therapies, Inc.	250	—	26,000
Ceregene, Inc. (since August 4, 2004).....	998	—	—
Other.....	1,191	879	371
	<u>\$ 11,458</u>	<u>\$ 18,128</u>	<u>\$ 39,141</u>

Revenues for 2004 included \$5.8 million from Novartis recognized in connection with our global alliance for the development and commercialization of oncolytic virus therapies. We received an upfront payment of \$28.5 million from Novartis in July 2003, \$10.0 million of which was initially recorded to deferred revenue, of which \$2.0 million remains as deferred revenue at December 31, 2004. We expect to recognize the remaining \$2.0 million as revenue in 2005. Revenues for 2004 also included \$3.2 million in connection with our gene activation technology license agreement with sanofi-aventis Group for gene activated erythropoietin. We have recorded contract revenue of \$0.8 million for manufacturing work performed for Ceregene since August 3, 2004, the date as of which our ownership

of Ceregene became a minority ownership position. We also recognized \$0.2 million in technology license fees from Ceregene in the fourth quarter of 2004. We recognized as other revenue in 2004 approximately \$1.0 million in grants received by Ceregene on their Alzheimer's disease and ALS research projects during the period it was a consolidated subsidiary.

In August 2003, we announced that an agreement had been reached regarding outstanding clinical and patent-related milestone and wind down payments from Japan Tobacco Inc. (JT), in connection with the termination in 2002 of a collaboration agreement for certain GVAX[®] cancer vaccines, for which we now hold all worldwide commercial rights. In connection with this final agreement, JT paid us approximately \$8.3 million in cash and waived future repayment obligations for capital expenditures associated with our manufacturing facilities in Hayward, California and in Memphis, Tennessee. We recorded \$14.1 million in revenue associated with this final agreement in 2003.

Revenues for 2002 included \$26.0 million associated with a license agreement with Transkaryotic Therapies, Inc. (TKT) for our gene activation technology and \$11.6 million from our since-terminated GVAX[®] collaboration agreement with JT. Revenues for 2002 also included \$1.1 million pursuant to the sanofi-aventis Group license agreement.

Research and development expenses

Research and development expenses were \$92.1 million in 2004 compared to \$85.3 million in 2003 and \$75.1 million in 2002. These increases can be attributed to our expanding clinical trials and other product development activities in both our GVAX[®] cancer vaccines and oncolytic virus therapy programs. In July 2004, we announced the commencement of our first Phase 3 clinical trial, which compares GVAX[®] prostate cancer vaccine to Taxotere[®] chemotherapy in patients with advanced prostate cancer without cancer-related pain. Our second Phase 3 clinical trial, planned for the first half of 2005, will compare GVAX[®] prostate cancer vaccine plus Taxotere[®] chemotherapy to Taxotere[®] chemotherapy alone in advanced prostate cancer patients with cancer-related pain. We expect that our research and development expenditures and headcount will continue to increase in future years to support expanded, more advanced and more numerous clinical trials, and associated manufacturing and product development activities. The rate of increase depends on a number of factors, including progress in research and development and clinical trials.

Biopharmaceutical products, such as those being developed by us, may take 10 to 15 years to research, develop and bring to market in the United States. Drug development in the U.S. is a process that includes several steps regulated by the FDA. The process begins with the filing of an IND application, which, if successful, allows opportunity for clinical study of the potential new medicine. Clinical development typically involves three phases of study: Phase 1, 2 and 3. Costs for each phase are generally larger than the preceding phase, as the size of the clinical trial (number of patients) grows. The most significant costs associated with clinical development are the Phase 3 trials, as they tend to be the longest and largest studies conducted during the drug development process. We currently have one product in development for which we have initiated a Phase 3 study. However, the successful development of our products is highly uncertain. Estimates of product completion dates and completion costs can vary significantly for each product and are difficult to predict. Completion of clinical trials, including the Phase 3 trials that we initiated in July 2004 and a second Phase 3 that we plan to initiate in the first half of 2005, may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product candidate. However, we estimate that clinical trials of the type we generally conduct are usually completed over the following timelines:

<u>Clinical Phase</u>	<u>Estimated Completion Period</u>
Phase 1	1-3 years
Phase 2	1-3 years
Phase 3	2-5 years

Many factors may delay our commencement and speed of completion of clinical trials, including the size and number of patients participating in the trial, the duration of patient follow-up required, the number of clinical sites at which the trial is conducted, and the length of time required to locate and enroll suitable patient subjects. Various

statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of each product. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our business. In responding to an NDA or a BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. There can be no assurance that any approval required by the FDA or other regulatory body will be obtained on a timely basis, if at all. For additional discussion of the risks and uncertainties associated with completing development of potential products, see “*Other Factors Affecting Future Operations*” below.

Included below is a summary of products and the related stage of development for each product in clinical development. The information in the column labeled “Estimated Completion of Ongoing Phase” constitutes forward-looking statements regarding timing of completion of product development phases. Our estimates of timing of completion of these trials are based on typical times of completion for trials of that type at such phases of development. The actual timing of completion of these phases of our clinical trials could differ materially from the estimates provided in the table due to the number of patients enrolled in the trial, the number of clinical trial sites involved, the time needed to fully enroll the trial, the time required for patient follow-up and other factors. Longer time frames for the completion of certain trials may be the result of requirements to measure patient survival. In addition, it is possible that any of these ongoing clinical trials may never be completed due to the occurrence of unacceptable treatment-related side effects, lack of clinical efficacy, insufficient supply of product for these clinical trials and other factors. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see “*Other Factors Affecting Future Operations*” below.

<u>Product</u>	<u>Indication</u>	<u>Phase of Development</u>	<u>Estimated Completion of Ongoing Phase</u>
GVAX [®] Prostate	Prostate cancer	Phase 3	2007-2009
GVAX [®] Lung	Non small-cell lung cancer	Phase 2	2005-2006
GVAX [®] Pancreatic	Pancreatic cancer	Phase 2	2006-2007
GVAX [®] Leukemia	Acute leukemia	Phase 2	2006-2007
GVAX [®] Myeloma	Multiple myeloma	Phase ½	2006-2007
CG7870 Oncolytic Virus	Prostate cancer	Phase ½	2006-2007

General and administrative expenses

General and administrative expenses were \$17.9 million in 2004 compared to \$26.0 million in 2003 and \$20.7 million in 2002. Excluding the lease exit costs accrual of \$1.8 million in 2004 and \$5.3 million in 2003 associated with the move of our corporate headquarters to South San Francisco, California in March 2003, the general and administrative expenses decreased by approximately \$4.6 million from 2003 to 2004. The higher expenses in 2003 reflected approximately \$2.3 million of facility costs, \$1.5 million for Ceregene, our previously majority-owned subsidiary, and approximately \$0.9 million of non-recurring facility start-up and close-down costs in connection with the move from the former headquarters in Foster City, California partially offset by increased costs associated with compliance with the Sarbanes-Oxley Act of 2002 and other corporate governance requirements. Future spending for general and administrative costs is expected to increase in order to support our growing infrastructure needs, particularly in the areas of manufacturing and other functions.

Purchased in-process technology

During 2002, we recorded a credit of \$186,000 to purchased in-process technology related to our acquisition of Calydon, Inc. in 2001. The adjustment related to the return to us of a portion of the purchase price held in escrow in accordance with the terms of the purchase agreement. We continue to conduct research using the technology acquired in the acquisition of Calydon.

Gain on sale of Abgenix common stock

During 2004, we recorded a gain of \$12.2 million associated with our sale of 819,210 shares of Abgenix common stock. At December 31, 2004, we continued to hold approximately 6.6 million shares of Abgenix common stock, which had a fair market value of approximately \$68.5 million as of that date. During 2003 we recorded a gain of \$12.6 million associated with the sale of 1,250,000 shares of Abgenix common stock. During 2002 we recorded a gain of \$2.2 million associated with the sale of approximately 260,000 shares of Abgenix common stock.

Interest and other income

Interest and other income was \$2.7 million in 2004 compared to \$4.8 million in 2003 and \$9.9 million in 2002. The decrease in 2004 compared to 2003, and compared to 2002 is attributed in each case to lower average cash balances and lower interest rates than during the prior period.

Interest expense

Interest expense was \$9.9 million in 2004 compared to \$5.4 million in 2003 and \$1.0 million in 2002. The increase in 2004 compared to 2003 and 2002 includes increased interest expense from the capital lease obligation for our headquarters facility in South San Francisco, California, which we occupied in March 2003. Interest expense associated with the facility lease was \$5.4 million in 2004 and \$5.2 million in 2003. In September 2003, the Company borrowed \$35.0 million from Silicon Valley Bank under a term-loan agreement, which was then fully paid off in late October 2004. As a result of that facility, interest expense was \$1.1 million higher in 2004 than during 2003, and the early repayment of this loan resulted in a \$0.7 million prepayment penalty in October 2004, which was accounted for as interest expense during 2004. We capitalized interest expense of \$0.8 million and \$0.8 million in 2003 and 2002, respectively, in connection with the construction of our manufacturing facility in Hayward, California.

Income taxes

We recorded a tax provision of \$3.7 million in 2004 compared to \$24.6 million tax benefit in 2003 and \$18.6 million tax benefit in 2002. The tax provision recorded in 2004 relates to the realized gain on the sale of 819,210 shares of Abgenix common stock. Net operating losses that we have concluded are realizable are based on our estimate of future taxable income, including future taxable income that may result from future sales of holdings of our Abgenix common stock. The carrying value of our deferred tax assets is based on our ability to carry-forward these net operating losses to offset that potential future taxable income. The tax benefit recorded in 2003 primarily related to net operating losses that we have concluded are realizable based on our estimate of future taxable income, including future taxable income that may result from sales of our Abgenix common stock. The tax benefit recorded in 2002 primarily related to our ability to carry-back 2002 net operating losses to the 2000 tax year. If our investment in Abgenix were to suffer a decline in value of more than 47% from the fair value as of December 31, 2004, we may be required to reverse tax benefits in future periods that were previously recorded. At December 31, 2004, we had federal net operating loss carryforwards of approximately \$266.6 million. The 2004 net operating losses will expire in the years beginning 2007 through 2024, if not utilized.

Liquidity and Capital Resources

At December 31, 2004, we had approximately \$175.0 million in cash, cash equivalents and short-term investments, of which \$3.3 million is classified as restricted cash, primarily related to a letter of credit on our corporate headquarters facility in South San Francisco, California and cGMP facilities in Hayward, California. Information regarding the classification of these assets is included in *Note 5 of Notes to Consolidated Financial Statements* included under Item 8 of this Annual Report on Form 10-K. We have maintained our financial position through strategic management of our resources including our holdings in Abgenix common stock, funding from various corporate collaborations and licensing agreements and the availability of debt financing. At December 31, 2004 we continued to hold approximately 6.6 million shares of Abgenix common stock, which had a fair market value of approximately \$68.5 million as of that date. Additionally, in February 2003, our shelf registration statement was declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended, which allowed us to offer up to \$150.0 million of securities on short notice in one or more public offerings. We used this shelf registration in March 2004 to complete a public offering of 4,887,500 shares of our common stock, resulting in gross proceeds of \$61.1 million. Although up to \$88.9 million may still be offered under the shelf

registration, there can be no assurance that we will be able to issue any of the remaining securities under this shelf registration on acceptable terms, or at all.

In October and November 2004, we sold a total of \$145.0 million aggregate principal amount of our 3.125% Convertible Senior Notes due 2011 in a private placement. We used a portion of the net proceeds of \$139.9 million to repay bank debt totaling \$95.0 million, thereby eliminating restrictions on \$60.0 million of cash.

Net cash used in operating activities was \$93.8 million in 2004 compared to \$46.7 million in 2003 and \$30.3 million in 2002. This increase in 2004 was due primarily to \$41.0 million in increased net loss. In 2003 we recorded the receipt of an aggregate of \$16.5 million in tax refunds from the Internal Revenue Service and California Franchise Tax Board from the income tax paid in 2000 and 2001 for the gain on sale of Abgenix common stock. Also, we received \$15.0 million in 2003 from a license agreement with Transkaryotic Therapies, Inc. Cash requirements for operating activities are expected to increase in future periods, due in part to significant costs related to the Phase 3 trial that we initiated in 2004 and a second Phase 3 trial that we expect to initiate in the first half of 2005, partially offset by reduced costs in other programs. The timing of these cash requirements may vary from period to period depending on our research and development activities, including our planned preclinical and clinical trials, obligations related to our existing manufacturing and headquarter facilities, and future requirements to establish manufacturing and marketing capabilities for any products that we may develop.

Net cash provided by investing activities, which includes capital expenditures, was \$39.9 million in 2004 compared to \$37.7 million net cash used by investing activities in 2003 and net cash used by investing activities of \$9.4 million in 2002. Cash provided by net short-term investments activities was \$56.5 million higher in 2004 compared to 2003. Cash flows for the 2004 period also include \$12.9 million in net proceeds from the sale of 819,210 shares of Abgenix common stock. Capital expenditures were \$5.1 million in 2004 compared to \$27.7 million in 2003 and \$66.1 million in 2002. In 2004 we completed construction of additional research areas in the corporate headquarters in South San Francisco, California. Capital expenditures for 2003 and 2002 consisted primarily of expenses incurred in connection with the construction of our cGMP manufacturing facilities for our Phase 3 trials and potential future market launch in Hayward and San Diego, California and in Memphis, Tennessee, which were completed in late 2003. Leasehold improvements for our corporate headquarters in South San Francisco, California were completed in March 2003. We currently have three cGMP manufacturing facilities located in Hayward and San Diego, California and Memphis, Tennessee. We have completed the construction necessary at our cGMP manufacturing facility for non patient-specific GVAX[®] cancer vaccines located in Hayward, California for initiation of our first Phase 3 trial, and manufacturing is currently underway at this facility. Patient-specific GVAX[®] lung cancer vaccines are being manufactured for an ongoing Phase 2 clinical trial at our cGMP manufacturing facility in Memphis, Tennessee. In 2002, we completed modifications of our cGMP manufacturing facility in San Diego, California for the manufacture of viral-based products and have since used this facility to supply product for clinical trials.

Net cash provided by financing activities was \$102.3 million in 2004 compared to \$55.2 million in 2003 and \$2.0 million in 2002. The increase includes net proceeds of \$139.9 million from the private placement of our 3.125% Convertible Senior Notes issuance in October and November 2004 and net proceeds of \$57.2 million in connection with our public offering of 4,887,500 shares of common stock in March 2004. In October, we used part of the proceeds from our note issuance to repay loans of an aggregate of \$95.0 million to Fleet Bank and Silicon Valley Bank. In July 2003, we received a \$28.5 million upfront payment from Novartis AG, of which \$18.5 million was attributed to the issuance of an aggregate of 1,999,840 shares of our common stock to Novartis and GTI, and the remaining \$10.0 million was attributed to deferred revenue. In September 2003, we borrowed \$35.0 million from Silicon Valley Bank under a five-year term loan agreement. We did not enter into any significant financing activities in 2002.

We have financed our operations primarily through the sale of equity securities, funding under collaborative arrangements, sales of Abgenix common stock, sales of convertible notes, and secured and unsecured debt financing. During 2004 and 2003, we received \$12.9 million and \$13.9 million in net proceeds from the sale of 819,210 and 1,250,000 shares of Abgenix common stock, respectively. In 2002, we sold approximately 260,000 shares of Abgenix common stock and received net proceeds of \$2.5 million. Our retained ownership of Abgenix common stock represents a material portion of our working capital. The common stock price of Abgenix has proven to be highly volatile, which has a direct impact on our liquidity and capital resources. To the extent that we continue

to hold a substantial amount of these shares, our working capital position can be expected to continue to fluctuate in future periods. The value of our investment in Abgenix common stock was \$68.5 million at December 31, 2004 and \$91.9 million at December 31, 2003.

In connection with a gain on sale of Abgenix common stock in 2000, we paid \$42.5 million in federal and state income taxes. Since 2000 we have received \$35.7 million in tax refunds from the carryback of losses. We have additional unutilized net operating loss (NOL) carryforwards, although the future utilization of these NOL carryforwards is limited by Internal Revenue Code Section 382, which imposes an annual limitation on taxable income that can be offset by NOL's following a change in control. For IRS purposes we experienced a change in control during our acquisition of Somatix in 1997. It is our current intention to minimize future tax liabilities on sales of Abgenix common stock by offsetting gains against current operating losses and the NOL carryforwards allowed under Section 382. In addition, we have certain research and development tax credits that we may utilize to offset the tax effects of such gains. However, under some circumstances we may sell more Abgenix common stock, and consequently recognize gains in excess of the amount we can offset with net operating losses and credit carryforwards.

In July 2003, we received \$28.5 million from Novartis in connection with a global alliance for the development and commercialization of oncolytic virus therapies. As a result of this agreement, we recorded \$10.0 million in deferred revenue to be recognized over the development periods of certain specified oncolytic virus programs. In 2004, we recognized revenue of \$5.8 million from the deferred revenue and \$2.0 million remained deferred as of December 31, 2004 for future recognition. We expect to spend these remaining funds in 2005. Our operating lease commitments include rent payments through January 2006 for our Foster City location of \$6.9 million, of which \$6.1 million was accrued at December 31, 2004 as part of the estimated facility exit costs associated with the move to our South San Francisco, California headquarters building in March 2003. We expect to receive \$1.1 million in aggregate future rentals under related existing subleases through January 2006.

We lease certain of our facilities and equipment under non-cancelable operating leases. These leases, including the Hayward, Foster City, San Diego and Memphis facility leases, expire at various dates through 2017, and some contain options for renewal. The South San Francisco headquarters facility lease is recorded as a capital lease as a result of certain amendments that required us to fund the costs of certain structural components of the facility.

The increase in leasehold improvements and the decrease in construction in process in 2004 reflect the completion of the corporate headquarters facility in South San Francisco, California and the completion of the cGMP manufacturing facility in Hayward, California. The Hayward facility was built to manufacture non patient-specific GVAX[®] cancer vaccines, and was placed in service during 2003. In 2003, we moved our corporate headquarters to South San Francisco from Foster City, California. As a result, we retired approximately \$14.3 million and \$1.0 million of leasehold improvements and other assets related to the former corporate headquarters in Foster City, California, and approximately \$13.6 million and \$1.0 million of related accumulated depreciation, in 2003 and in 2004, respectively. The decrease in construction in process also reflects the deconsolidation of Ceregene in August 2004 subsequent to Ceregene's Series B preferred stock financing.

Our long-term contractual obligations at December 31, 2004 were as follows (in thousands):

	<u>Total</u>	<u>Payment due</u>			
		<u>2005</u>	<u>2006 and 2007</u>	<u>2008 and 2009</u>	<u>2010 and thereafter</u>
Convertible senior notes	\$145,000	\$ —	\$ —	\$ —	\$145,000
South San Francisco facility lease obligation	99,676	6,087	12,820	13,766	67,003
Operating leases	41,399	10,294	6,192	4,768	20,145
	<u>\$286,075</u>	<u>\$16,381</u>	<u>\$19,012</u>	<u>\$18,534</u>	<u>\$232,148</u>

In October and November 2004, we issued and sold a total of \$145.0 million aggregate principal amount of 3.125% Convertible Senior Notes due 2011 in a private placement. We received approximately \$139.9 million in proceeds after deducting the initial purchasers' discount and estimated offering expenses. We used a portion of the proceeds from the sale of the notes to repay \$95.0 million of outstanding bank loans, thereby eliminating restrictions on \$60.0 million of cash. We intend to use the remainder of the proceeds for general corporate purposes.

Under certain circumstances, we may redeem some or all of the convertible senior notes on or after November 1, 2009 at a redemption price equal to 100% of the principal amount of the notes. Holders of the notes may require us to repurchase some or all of their notes if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100% of the principal amount of the notes, plus accrued and unpaid interest (and additional amounts, if any) to, but not including, the repurchase date. The notes are convertible into our common stock, initially at the conversion price of \$9.10 per share, equal to a conversion rate of approximately 109.8901 shares per \$1,000 principal amount of notes, subject to adjustment.

We estimate that our cash to be used in operating activities during 2005 will be approximately \$95.0 million. This estimated use of cash does not include capital expenditures or the cost of any potential acquisitions, nor does it reflect the potential offset by future gains on sales of Abgenix stock, equity or debt financings or major new collaborative ventures. Our capital requirements depend on numerous factors, including: the progress of our research and development programs and our preclinical and clinical trials; clinical and commercial scale manufacturing requirements; the extent of funding from collaborative partners; the acquisition of new products or technologies; and the cost and outcome of litigation, patent interference proceedings or other legal proceedings. Our ongoing development programs and any increase in the number and size of programs and trials will reduce our current cash resources and potentially create further need to raise additional capital. Therefore, we will continue to consider financing alternatives, including collaborative ventures and potential equity and debt financings in addition to periodic sales of our holdings of Abgenix stock.

While we believe that our current liquidity position will be sufficient to meet our cash needs for at least the next year, we may need to raise substantial additional funds in order to complete our pending and planned trials over their multi-year course before we will obtain product revenue, if any, from such products. Accordingly, we may entertain the possibility of raising additional capital to preserve our liquidity, depending on a number of conditions, including conditions in the capital markets. The sources of liquidity available to us include the sale of Abgenix common stock, payments from potential partners and/or licensees of our potential products and technologies, and private or public placement of Cell Genesys equity securities, warrants, debt securities or depositary shares. We regularly consider the conditions of capital markets, dilution, stockholder value and tax consequences of each type of financing on stockholders. Certain of the financing options available to us may have negative consequences to stockholders such as dilution. Given the volatile nature of the capital markets, decisions to raise capital may require actions that would impose a negative consequence in order to reduce or minimize a more significant negative consequence to stockholders.

OTHER FACTORS AFFECTING FUTURE OPERATIONS

Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our company. Additional risks not currently known to us or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline, and our ability to repay our convertible notes could be impaired, due to any of these risks, and investors may lose all or part of their investment. In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Annual Report on Form 10-K, including our consolidated financial statements and related notes.

Risks Related to Our Company

Our products are in developmental stage, are not approved for commercial sale and might not ever receive regulatory approval or become commercially viable.

All of our potential cancer vaccines, oncolytic virus therapies and antiangiogenesis therapy products are in research and development. We have not generated any revenues from the sale of products. We do not expect to generate any revenues from product sales for at least the next several years. Our products currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercial use. Our research and development efforts may not be successful, and any of our future products may not be ultimately commercially successful. Even if developed, our products may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably.

Our cancer vaccines, oncolytic virus therapies and antiangiogenesis therapy products must undergo exhaustive clinical testing and may not prove to be safe or effective. If any of our proposed products are delayed or fail, we may have to curtail our operations.

There are many reasons that potential products that appear promising at an early stage of research or development do not result in commercially successful products. Clinical trials may be suspended or terminated if safety issues are identified, if our investigators or we fail to comply with regulations governing clinical trials or for other reasons. Although we are testing some of our proposed products and therapies in human clinical trials, we cannot guarantee that we, the FDA, foreign regulatory authorities or the Institutional Review Boards at our research institutions will not suspend or terminate any of our clinical trials, that we will be permitted to undertake human clinical trials for any of our other products or that adequate numbers of patients can be recruited for our clinical trials. Also, the results of this testing might not demonstrate the safety or efficacy of these products. Even if clinical trials are successful, we might not obtain regulatory approval for any indication. Preclinical and clinical data can be interpreted in many different ways, and FDA or foreign regulatory officials could interpret data that we consider promising differently, which could halt or delay our clinical trials or prevent regulatory approval. Finally, even if our products proceed successfully through clinical trials and receive regulatory approval, there is no guarantee that an approved product can be manufactured in commercial quantities at reasonable cost or that such a product will be successfully marketed.

Our programs utilize new technologies. Existing preclinical and clinical data on the safety and efficacy of our programs are limited. Our GVAX[®] cancer vaccines and oncolytic virus therapies are currently being tested in human clinical trials to determine their safety and efficacy. None of our other products or therapies under development is in human clinical trials. The results of preclinical or earlier stage clinical trials do not necessarily predict safety or efficacy in humans. Our products in later stage clinical trials may fail to show desired safety and efficacy, despite having progressed through preclinical or early clinical trials. Serious and potentially life-threatening side effects may be discovered during preclinical and clinical testing of our potential products or thereafter, which could delay, halt or interrupt clinical trials of our products, and could result in the FDA or other regulatory authorities denying approval of our drugs for any or all indications. In the case of patient-specific therapies such as our GVAX[®] lung cancer vaccine, the risks of any surgical procedure that may be required to prepare the vaccine must be considered in the evaluation of the product's safety profile. All surgical procedures, particularly those in advanced disease settings, involve some element of risk to the patient, which must be evaluated in the context of the patient's condition and therapeutic alternatives. Our ongoing clinical studies are now designed to exclude patients at higher

risk of post-operative complications. Nonetheless, in past and current clinical trials involving patients with very advanced stages of lung cancer, a small number of patients with progressive disease have died during the period following surgical removal of their tumor and prior to administration of GVAX[®] vaccine. Such events will continue to be included in an ongoing assessment of the overall risk/benefit profile of this product and could adversely influence the continuation of the current study and the products' future development.

Clinical trials are very costly and time-consuming, especially the typically larger Phase 3 clinical trials such as the recently initiated VITAL-1 trial of our GVAX[®] prostate cancer vaccine. We cannot exactly predict if and when our current clinical trials will be completed. We also cannot exactly predict when other planned clinical trials, including additional Phase 3 clinical trials of our GVAX[®] cancer vaccines, will begin or be completed. The VITAL-1 trial of our GVAX[®] prostate cancer vaccine is our first Phase 3 clinical trial. Though we anticipate commencing our second Phase 3 clinical trial of GVAX[®] prostate cancer vaccine, the VITAL-2 trial, during the first half of 2005, we cannot guarantee that we will be able to begin the VITAL-2 Phase 3 clinical trial within that timeframe. Many factors affect patient enrollment in clinical trials, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new therapies approved for the conditions that we are investigating. In addition to delays in patient enrollment, other unforeseen developments, including delays in obtaining regulatory approvals to commence a study, delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites, lack of effectiveness during clinical trials, unforeseen safety issues, uncertain dosing issues, inability to monitor patients adequately during or after treatment, our or our investigators' failure to comply with FDA and other applicable regulations governing clinical trials, and an inability or unwillingness of medical investigators to follow our clinical protocols, could prevent or delay completion of a clinical trial and increase its costs, which could also prevent or delay any eventual commercial sale of the therapy that is the subject of the trial. Each of our two Phase 3 clinical trials of GVAX[®] prostate cancer vaccine involves a comparison to a Taxotere[®] chemotherapy regimen, which is the currently approved standard of care for this patient group. However, there can be no assurance that this chemotherapy regimen will continue to be commonly used to treat these patients in the future. Should another chemotherapy regimen be shown to be more effective than the Taxotere[®] chemotherapy regimen, we may need to conduct additional comparative clinical trials in the future.

We have not been profitable in our operations (absent the gains on sales of Abgenix common stock and certain upfront or non-recurring license fees). We expect to continue to incur substantial losses and negative cash flow from operations and may not become profitable in the future.

We have incurred an accumulated deficit since our inception. At December 31, 2004, our accumulated deficit was \$244.0 million. Our accumulated deficit would be substantially higher absent the gains we have realized on sales of our Abgenix common stock. For the year ended December 31, 2004, we recorded a net loss of \$97.4 million, which included \$12.2 million in gains on sales of our Abgenix common stock. We expect to incur substantial operating losses for at least the next several years and potentially longer. This is due primarily to the expansion of research and development programs, clinical trials and manufacturing activities and, to a lesser extent, general and administrative expenses, at a time when we have yet to realize any product revenues. We also have substantial lease obligations related to our new manufacturing and headquarter facilities. We expect that losses will fluctuate from quarter to quarter and that these fluctuations may be substantial. We cannot guarantee that we will successfully develop, manufacture, commercialize or market any products, or that we will ever achieve profitability.

We will need substantial additional funds to continue operations, and our ability to generate funds depends on many factors beyond our control.

We will need substantial additional funds for existing and planned preclinical and clinical trials, to continue research and development activities, for lease obligations related to our manufacturing and headquarter facilities, for principal and interest payments related to our debt financing obligations and to establish marketing capabilities for any products we may develop. At some point in the future, we will also need to raise additional capital to further fund our operations. Our future capital requirements will depend on, and could increase as a result of, many factors, such as:

- the progress and scope of our internally funded research, development and commercialization activities;
- our ability to establish new collaborations and the terms of those collaborations;
- competing technological and market developments;
- the time and cost of regulatory approval;
- the extent to which we choose to commercialize our future products through our own sales and marketing capabilities;
- the costs we incur in obtaining and enforcing patent and other proprietary rights or gaining the freedom to operate under the patents of others;
- our success in acquiring and integrating complementary products, technologies or businesses; and
- the extent to which we choose to expand and develop our manufacturing capacities, including manufacturing capacities necessary to meet potential commercial requirements.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research, development or clinical activities.

We plan to raise additional funds through collaborative business relationships, sales of some portion or all of our investment in Abgenix common stock, additional equity or debt financings, or otherwise, but we may not be able to do any of the foregoing on favorable terms, or at all.

Because of our long-term capital requirements, we may seek to access the public or private debt and equity markets, by selling our holdings of Abgenix common stock and/or our own debt or equity securities. Additional funding may not be available to us, and, if available, may not be on acceptable terms. Opportunities for our licensing technologies or for third-party collaborations may not be available to us on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research, development or clinical activities. In addition, we may decide to raise additional capital when conditions are favorable, even when we do not have an immediate need for additional capital at that time. If we raise additional funds by issuing equity securities, stockholders will incur immediate dilution.

Alternatively, we may need to seek funds through arrangements with collaborative partners or others that require us to relinquish rights to technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. Either of these events could have a material adverse effect on our business, results of operations, financial condition or cash flow. Currently, we do not have collaborative partners for the further development of our GVAX[®] cancer vaccines. Although we are in active discussions with potential partners for our GVAX[®] prostate cancer vaccine, we may not be successful in entering into collaborative partnerships on favorable terms, if at all. Certain of our oncolytic virus therapy products are being developed under our global strategic alliance with Novartis, and Novartis has certain future commercialization rights for these products. Also, we can give no assurance that our alliance with Novartis will continue, as Novartis periodically has the option of terminating the alliance at its discretion.

Our ability to manufacture our products is uncertain, which may delay or impair our ability to develop, test and commercialize our products.

We have built our own manufacturing facilities to operate according to the FDA's current Good Manufacturing Practices (cGMP) regulations for the manufacture of products for clinical trials and to support the potential commercial launch of our product candidates. We are under significant lease obligations for each of our facilities. We may be unable to establish and maintain our manufacturing facilities within our planned time and budget, which could have a material adverse effect on our product development timelines. Our manufacturing facilities will be subject to ongoing, periodic inspection by the FDA and state agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial use or clinical study, may result in the termination or hold on a clinical study, or may delay or prevent filing or approval of marketing applications for our products. We also may encounter problems with the following:

- achieving consistent and acceptable production yield and costs;
- meeting product release specifications;
- quality control and assurance;
- shortages of qualified manufacturing personnel;
- shortages of raw materials;
- shortages of key contractors; and
- ongoing compliance with FDA and other regulations.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our expanded facilities. The manufacturing techniques and process controls, as well as the product release specifications, required for our GVAX[®] cancer vaccines and oncolytic virus therapies are more complex and less well-established than those required for other biopharmaceutical products, including small molecules, therapeutic proteins and monoclonal antibodies. We may not be able to develop these techniques and process controls to manufacture our products effectively to meet the demands of regulatory agencies, clinical testing and commercial production.

In addition, during the course of the development and testing of our products, we may make and have made improvements to processes, formulations or manufacturing methods or employ different manufacturing facilities. Such changes may be made to improve the product's potential efficacy, make it easier to manufacture at scale, reduce variability or the chance of contamination of the product, or for other reasons. As a result, certain of the products we are currently testing in clinical trials, including our most advanced products, are not identical to those used in previous clinical trials from which we have reported clinical data. We may be required to conduct certain laboratory studies to demonstrate the comparability of our products if we introduce additional manufacturing changes. We cannot guarantee that the results of studies using the current versions of our products will be as successful as the results of earlier studies conducted using different versions of our products.

If we are unable to manufacture our products for any reason, our options for outsourcing manufacturing are currently limited. We are unaware of available contract manufacturing facilities on a worldwide basis in which our GVAX[®] product candidates can be manufactured under cGMP regulations, a requirement for all pharmaceutical products. It would take a substantial period of time for a contract manufacturing facility that has not been producing our particular products to begin producing them under cGMP regulations.

Our manufacturing facilities are subject to licensing requirements of the United States Drug Enforcement Administration (DEA), the California Department of Health Services and the Tennessee Department of Commerce and Insurance, Board of Pharmacy, referred to as the Tennessee Board of Pharmacy. While not yet subject to license by the FDA, these facilities are subject to inspection by the FDA, as well as by the DEA, the California Department of Health Services and the Tennessee Board of Pharmacy. Failure to maintain these licenses or to meet the inspection criteria of these agencies would disrupt our manufacturing processes and have a material adverse effect on our business, results of operations, financial condition and cash flow.

In order to produce our products in the quantities that we believe will be required to meet anticipated market demand, we will need to increase, or "scale up," the production process by a significant factor over the current level of production. If we are unable to do so, or if the cost of this scale up is not economically feasible for us, we may not be able to produce our products in a sufficient quantity to meet the requirements for product launch or future demand.

If our proposed products are not effectively protected by issued patents or if we are not otherwise able to protect our proprietary information, we will be more vulnerable to competitors, and our business could be adversely affected.

We rely heavily on the development and protection of our intellectual property portfolio. The patent positions of pharmaceutical and biotechnology firms, including ours, are generally uncertain and involve complex legal and factual questions. As of December 31, 2004 we had approximately 325 patents issued or granted to us or available to us based on licensing arrangements and approximately 318 applications pending in our name or available to us based on licensing arrangements. Although we are prosecuting patent applications, we cannot be certain whether any given application will result in the issuance of a patent or, if any patent is issued, whether it will provide significant proprietary protection or whether it will be invalidated. Also, depending upon their filing date, patent applications in the United States are confidential until patents are published or issued. Publication of discoveries in scientific or patent literature tends to lag behind actual discoveries by several months. Accordingly, we cannot be sure that we were the first creator of inventions covered by pending patent applications or that we were the first to file patent applications for these inventions. In addition, to the extent we license our intellectual property to other parties, we may incur expenses as a result of contractual agreements in which we indemnify these licensing parties against losses incurred if our intellectual property infringes upon the rights of others.

Our intellectual property may be challenged by our competitors in the future, which may have a material adverse effect on our business, results of operations, financial condition and cash flow.

Our commercial success depends in part on not infringing the patents or proprietary rights of others and not breaching licenses granted to us. We are aware of competing intellectual property relating to both our programs in cancer vaccines and oncolytic virus therapies. While we currently believe we have freedom to operate in these areas, others may challenge our position in the future. We may be required to obtain licenses to third-party technologies or genes necessary in order to market our products. Any failure to license any technologies or genes required to commercialize our technologies or products at reasonable cost may have a material adverse effect on our business, results of operations, financial condition and cash flow.

We may have to engage in litigation, which could result in substantial cost, to enforce our patents or to determine the scope and validity of other parties' proprietary rights.

To determine the priority of inventions, the United States Patent and Trademark Office (USPTO) frequently declares interference proceedings. In Europe, patents can be revoked through opposition proceedings. These proceedings could result in an adverse decision as to the priority of our inventions.

We are involved in one interference and several opposition proceedings related to our current product portfolio and certain of our technologies. We have filed an appeal of the final decision from the USPTO relating to an interference proceeding pending since 1996 with Applied Research Systems Holding N.V. (ARS) concerning a patent and patent application related to gene activation technology. ARS has also appealed the decision. The result of the appeal is uncertain at this time. We are not currently involved in any other interference proceedings. We are

also currently involved in European opposition proceedings, some of which relate to our current product portfolio and certain of our core technologies.

We cannot predict the outcome of these proceedings. An adverse result in any of these proceedings could have an adverse effect on our intellectual property position in these areas and on our business as a whole. If we lose in any such proceeding, our patents or patent applications that are the subject matter of the proceeding may be invalidated or may not be permitted to issue as patents. Consequently, we may be required to obtain a license from the prevailing party in order to continue the portion of our business that relates to the proceeding. Such license may not be available to us on acceptable terms or on any terms, and we may have to discontinue that portion of our business. We may be involved in other interference and/or opposition proceedings in the future. We believe that there will continue to be significant litigation in the industry regarding patent and other intellectual property rights.

Our competitive position may be adversely affected by our limited ability to protect and control unpatented trade secrets, know-how and other technological innovation.

Our competitors may independently develop similar or better proprietary information and techniques and disclose them publicly. Also, others may gain access to our trade secrets, and we may not be able to meaningfully protect our rights to our unpatented trade secrets.

We require our employees and consultants to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed by or made known to an individual during the course of the employment or consulting relationship generally must be kept confidential. In the case of employees, the agreements provide that all inventions relating to our business conceived by the employee while employed by us are our exclusive property. These agreements may not provide meaningful protection for our trade secrets in the event of unauthorized use or disclosure of such information.

Our competitors may develop therapies for the diseases that we are targeting that are more advanced or more effective than ours, which could adversely affect our competitive position, or they may commercialize products more rapidly than we do, which may adversely affect our competitive position.

There are many companies pursuing programs for the treatment of cancer. Some of these competitors are large pharmaceutical companies, such as Bristol-Myers Squibb, Novartis, Roche, and sanofi-aventis Group, which have greater experience and resources than we do in developing products, in undertaking preclinical testing and human clinical trials of new pharmaceutical products, in obtaining FDA and other regulatory approvals of products, and in manufacturing and marketing new therapies. We are also competing with other biotechnology companies with similar experience and resources to ours, but which may have programs that are in a later stage of clinical testing than ours, such as Dendreon Corporation, Antigenics, Inc. and CancerVax, Inc.

Some competitors are pursuing product development strategies that are similar to ours, particularly with respect to our cancer vaccine and oncolytic virus therapy programs. Certain of these competitors' products are in more advanced stages of product development and clinical trials. We compete with other clinical-stage companies and institutions for clinical trial participants, which could reduce our ability to recruit participants for our clinical trials. Delay in recruiting clinical trial participants could adversely affect our ability to bring a product to market prior to our competitors. Our competitors may develop technologies and products that are more effective than ours, or that would render our technology and products less competitive or obsolete.

Our competitive position and those of our competitors can vary based on the performance of products in clinical trials. In addition, our competitors may obtain patent protection or FDA approval and commercialize products more rapidly than we do, which may impact future sales of our products. We also may not have the access that some of our competitors have to biological materials necessary to support the research, development or manufacturing of planned therapies. If we are permitted by the FDA to commence commercial sales of products, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on:

- product efficacy;
- price;
- safety;
- reliability;
- availability;
- patent protection; and
- sales, marketing and distribution capabilities.

Our competitive position also depends upon our ability to attract and retain qualified personnel, develop proprietary products or processes, and secure sufficient funding for the often-lengthy period between product conception and commercial sales.

To the extent we depend on strategic partners to sell, market or distribute our products, we will have reduced control over the success of the sales, marketing and distribution of our future products.

We have no experience in sales, marketing or distribution of biopharmaceutical products. We may in the future rely on sales, marketing and distribution expertise of potential corporate partners for our initial products. The decision to market future products directly or through corporate partners will be based on a number of factors, including:

- market size and concentration;
- size and expertise of the partner's sales force in a particular market; and
- our overall strategic objectives.

If we choose to rely on strategic partners for the sale, marketing or distribution of our future products, we will have less control over the success of our products and will depend heavily upon our partners' abilities and dedication to our products. We cannot assure you that these future strategic partnerships will be available on favorable terms, if at all, nor can we assure you that they will enhance our business.

We may in the future be exposed to product liability claims, which could adversely affect our business, results of operations, financial condition and cash flow.

Clinical trials or marketing of any of our potential products may expose us to liability claims resulting from the use of our products. These claims might be made by clinical trial participants, consumers, health care providers or sellers of our products. We currently maintain product liability insurance with respect to each of our clinical trials. We may not be able to maintain insurance or obtain sufficient coverage at a reasonable cost, given the increasing cost of insurance in today's insurance market. An inability to maintain insurance at an acceptable cost, or at all, could prevent or inhibit the clinical testing or commercialization of our products or otherwise affect our financial condition. A claim, particularly resulting from a clinical trial, on any of our insurance policies or a product recall could have a material adverse effect on our business, results of operations, financial condition and cash flow.

Our business, financial condition and results of operations could suffer as a result of future strategic acquisitions and investments.

We may engage in future acquisitions or investments that could dilute our existing stockholders or cause us to incur contingent liabilities, commitments, debt or significant expense. From time to time, in the ordinary course of business, we may evaluate potential acquisitions or investments in related businesses, products or technologies, although we currently have no commitments or agreements for any such acquisitions or investments. We may not be successful with any strategic acquisition or investment. Any future acquisition or investment could harm our business, financial condition and results of operations.

If we engage in future acquisitions, we may not be able to fully integrate the acquired companies and their intellectual property or personnel. Our attempts to do so may place additional burdens on our management and infrastructure. Future acquisitions will also subject us to a number of risks, including:

- the loss of key personnel and business relationships;
- difficulties associated with assimilating and integrating the new personnel and operations of the acquired companies;
- the potential disruption of our ongoing business;
- the expense associated with maintenance of diverse standards, controls, procedures, employees and clients;
- the diversion of resources from the development of our own proprietary technology; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could result in a material adverse effect on our business.

Our facilities in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power. Future blackouts could disrupt the operations of our facilities. In addition, we do not carry sufficient business interruption insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could have a material adverse effect on our business. We are vulnerable to a major earthquake and other calamities. Most of our facilities are located in seismically active regions. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake and do not have a recovery plan for fire, earthquake, power loss, terrorist activity or similar disasters. We are unable to predict the effects of any such event, but the effects could be seriously harmful to our business.

We depend on our key technical and management personnel to advance our technology, and the loss of these personnel could impair the development of our products.

We rely and will continue to rely on our key management and scientific staff, all of whom are employed at-will. The loss of key personnel or the failure to recruit necessary additional qualified personnel could have a material adverse effect on our business and results of operations. There is intense competition from other companies, research and academic institutions and other organizations for qualified personnel. We may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. We will need to continue to recruit experts in the areas of clinical testing, manufacturing, marketing and distribution and to develop additional expertise in our existing personnel. If we do not succeed in recruiting necessary personnel or developing this expertise, our business could suffer significantly.

We depend on clinical trial arrangements with public and private medical institutions to advance our technology, and the loss of these arrangements could impair the development of our products.

We have arrangements with a number of public and private medical institutions for the conduct of human clinical trials for our GVAX[®] cancer vaccine programs and oncolytic virus therapies. The early termination of any of these clinical trial arrangements or the failure of these institutions to comply with the regulations and requirements governing clinical trials would hinder the progress of our clinical trial program. If any of these relationships are terminated, the clinical trials might not be completed, and the results might not be evaluable.

Inventions or processes discovered by our outside scientific collaborators may not become our property, which may affect our competitive position.

We rely on the continued availability of outside scientific collaborators performing research. These relationships generally may be terminated at any time by the collaborator, typically by giving 30 days notice. These scientific collaborators are not our employees. As a result, we have limited control over their activities and can expect that only limited amounts of their time will be dedicated to our activities. Our arrangements with these collaborators, as well as those with our scientific consultants, provide that any rights we obtain as a result of their research efforts will be subject to the rights of the research institutions for which they work. In addition, some of these collaborators have consulting or other advisory arrangements with other entities that may conflict with their obligations to us. For these reasons, inventions or processes discovered by our scientific collaborators or consultants may not become our property.

Our stock price is influenced by the market price of Abgenix stock, which has been highly volatile.

Our retained ownership of Abgenix common stock represents a material portion of the total assets on our balance sheet. The common stock price of Abgenix has proven to be highly volatile. During the year ended December 31, 2004, the per share price of Abgenix common stock fluctuated between a high closing price of \$18.55 and low closing price of \$7.77. The value of our holdings of Abgenix common stock was \$68.5 million at December 31, 2004 compared to \$91.9 million at December 31, 2003. Movements in the price of Abgenix common stock, up or down, may exert corresponding influences on the market price of our stock.

The prices of our common stock and convertible senior notes are likely to continue to be volatile in the future.

The stock prices of biopharmaceutical and biotechnology companies, including ours, have historically been highly volatile. Since January 1, 2002, our stock price has fluctuated between a high closing price of \$22.99 on January 3, 2002 and a low closing price of \$5.27 on March 10, 2005. The market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition, as our convertible senior notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of the notes. The following factors, among others, may affect the prices of our common stock and notes:

- announcements of data from, or material developments in, our clinical trials or those of our competitors, including delays in the commencement of a clinical trial;
- fluctuations in our financial results;
- announcements of technological innovations or new therapeutic products by us or our competitors, including innovations or products by our competitors that may require us to redesign, and therefore delay, our clinical trials to account for those innovations or products;
- announcements of changes in governmental regulation affecting us or our competitors;
- announcements of regulatory approval or disapproval of our or our competitors' products;
- announcements of new collaborative relationships by us or our competitors;

- developments in patent or other proprietary rights affecting us or our competitors;
- public concern as to the safety of products developed by us or other biotechnology and pharmaceutical companies;
- general market conditions;
- fluctuations in the price of Abgenix common stock;
- material developments related to our minority interest in Ceregene, Inc.;
- fluctuations in price and volume in the stock market in general, or in the trading of the stock of biopharmaceutical and biotechnology companies in particular, that are unrelated to our operating performance;
- issuances of securities in equity, debt or other financings or issuances of common stock upon conversion of our convertible senior notes;
- sales of common stock by existing stockholders; and
- the perception that such issuances or sales could occur.

Our stockholders may be diluted by the conversion of outstanding senior notes.

In October and November 2004, we issued and sold \$145.0 million aggregate principal amount of senior notes, which are convertible into our common stock, initially at the conversion price of \$9.10 per share, equal to a conversion rate of approximately 109.8901 shares per \$1,000 principal amount of notes, subject to adjustment. The holders of the notes may choose at any time to convert their notes into common stock. The number of shares of common stock issuable upon conversion of the notes, and therefore the dilution of existing common stockholders, could increase as a result of an event triggering the antidilution rights of the notes, including certain acquisitions in which 10% or more of the consideration paid for our common stock in the transaction is in the form of cash or securities that are not freely tradable.

Our stockholders may be diluted, or our common stock price may be adversely affected by, the exercise of outstanding stock options or other issuances of our securities.

We may issue additional common stock, preferred stock, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of common stock, preferred stock or securities convertible into or exchangeable for our common stock or the exercise of stock options would dilute existing investors and could adversely affect the price of our common stock and, in turn, the price of our convertible senior notes.

We have adopted anti-takeover defenses that could make it difficult for another company to acquire control of us or could limit the price investors might be willing to pay for our stock.

Certain provisions of our certificate of incorporation, bylaws, debt instruments and Delaware law could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions include the adoption of a Stockholder Rights Plan, commonly known as a "poison pill." Under the Stockholder Rights Plan, we made a dividend distribution of one preferred share purchase right for each share of our common stock outstanding as of August 21, 1995 and each share of our common stock issued after that date. In July 2000, we made certain technical changes to amend the plan and extended the term of such plan until 2010. The rights are exercisable only if an acquirer purchases 15 percent or more of our common stock or announces a tender offer for 15 percent or more of our common stock. Upon exercise, holders other than the acquirer may purchase our stock at a discount. Our Board of Directors may terminate the rights plan at any time or under certain circumstances redeem the rights. Because the rights may substantially dilute the stock ownership of a person or group attempting to take us

over without the approval of our Board of Directors, the plan could make it more difficult for a third party to acquire us (or a significant percentage of our outstanding capital stock) without first negotiating with our Board of Directors regarding such acquisition. These provisions and certain provisions of the Delaware General Corporation Law may have the effect of deterring hostile takeovers or otherwise delaying or preventing changes in our management or in the control of our company, including transactions in which our stockholders might otherwise receive a premium over the fair market value of our common stock.

Due to the potential value of our strategic investments, we could be determined to be an investment company, and if such a determination were made, we would become subject to significant regulation that would adversely affect our business.

Our non-controlling positions in Abgenix and Ceregene, along with investments of our available cash resources in certain types of fixed-income securities, could be considered “investment securities” under the Investment Company Act of 1940, raising a question of whether we are an investment company required to register and be regulated under the Investment Company Act. Regulation under the Investment Company Act, or a determination that we failed to register when required to do so, could materially and adversely affect our business. We believe that we are primarily engaged in the research, development and commercialization of biological cancer therapies and that any investment securities are ancillary to our primary business. Nevertheless, to address any uncertainty in this regard, we have invested a portion of our portfolio in money market funds and U.S. government securities and limited the level of investment in corporate bonds and other instruments that could be considered “investment securities.” In addition, over time we plan to reduce the level of our investment securities by periodic sales of our holdings in Abgenix. These dispositions may be effected under unfavorable market conditions. The lower rates of return realized after the reinvestment of our investment portfolio, and any required dispositions of non-controlling investments, could adversely affect our future reported results.

Risks Related to Our Industry

In order for our products to be offered to the public, they must undergo extensive clinical testing and receive approval from the FDA, which could delay or prevent the commercialization of our products.

Human therapeutic products must undergo rigorous preclinical and clinical testing and other premarket approval procedures by the FDA and similar authorities in foreign countries. Preclinical tests include laboratory evaluation of potential products and animal studies to assess the potential safety and efficacy of the product and its formulations. Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with FDA Good Clinical Practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. The developer of the drug must provide information relating to the characterization and controls of the product before administration to the patients participating in the clinical trials. This requires developing approved assays of the product to test before and after administration to the patient. In addition, developers of pharmaceutical products must provide periodic data regarding clinical trials to the FDA, and foreign regulatory authorities, as appropriate. These health authorities may issue a clinical hold upon a trial if they do not believe, or cannot confirm, that the trial can be conducted without unreasonable risk to the trial participants. We cannot assure you that these regulatory authorities will not issue a clinical hold with respect to any of our clinical trials in the future. The results of the preclinical testing and clinical testing, together with chemistry, manufacturing and controls information, are submitted to the FDA and other health authorities in the form of a new drug application for a pharmaceutical product, and in the form of a biologics license application for a biological product, requesting approval to commence commercial sales.

In responding to a new drug application or a biologics license application, the FDA and other health authorities may grant marketing approvals, request additional information or further research, or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Regulatory approval of a new drug application, new drug application supplement or biologics license application is never guaranteed, and the approval process typically takes several years and is extremely expensive. Regulatory authorities have substantial discretion in the drug and biologics approval processes. Despite the time and expense incurred, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical or clinical studies. Approvals may not be granted on a timely basis, if at all, and if granted may not cover

all the clinical indications for which we may seek approval. Also, an approval might contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use.

Even if our products are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products including unanticipated adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures or detention, injunctions or the imposition of civil or criminal penalties.

We are subject to federal, state and local laws and regulations, and complying with these may cause us to incur significant costs.

We are subject to laws and regulations enforced by the FDA, the DEA, the California Department of Health Services, the Tennessee Board of Pharmacy and other regulatory statutes including:

- the Occupational Safety and Health Act;
- the Environmental Protection Act;
- the Toxic Substances Control Act;
- the Resource Conservation and Recovery Act; and
- other current and potential future federal, state or local laws and regulations.

In particular with respect to environmental laws, product development activities involve the use of hazardous materials, and we may incur significant costs as a result of the need to comply with these laws. Our research and development activities involve the controlled use of hazardous materials, chemicals, viruses and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts of terrorism, from these materials. In the event of an accident, we could be held liable for any damages that result, and any resulting liability could exceed our resources. We may also be required to incur significant costs to comply with environmental laws and regulations in the future.

Failure to comply with foreign regulatory requirements governing human clinical trials and marketing approval for drugs and devices could prevent us from selling our products in foreign markets, which may adversely affect our operating results and financial condition.

For marketing drugs and biologics outside the United States, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country and may require additional testing. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these

regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

Reimbursement from third-party payors may become more restricted in the future, which may reduce demand for our products.

There is uncertainty related to the extent to which third-party payors will cover and pay for newly approved drugs. Sales of our future products will be influenced by the willingness of third-party payors to provide reimbursement. In both domestic and foreign markets, sales of our potential products will depend in part upon coverage and payment amounts from third-party payors, including:

- government agencies;
- private health care insurers and other health care payors such as health maintenance organizations;
- self-insured employee plans; and
- Blue Cross/Blue Shield and similar plans.

There is considerable pressure to reduce the cost of biotechnology and pharmaceutical products. Reimbursement from government agencies, insurers and large health organizations may become more restricted in the future. Our potential products represent a new mode of therapy, and while the cost-benefit ratio of the products may be favorable, we expect that the costs associated with our products will be substantial. Our proposed products, if successfully developed, may not be considered cost-effective by third-party payors. Insurance coverage might not be provided by third-party payors at all or may be provided only after substantial delay. Even if such coverage is provided, the approved third-party payment amounts might not be sufficient to permit widespread acceptance of our products.

The continuing efforts of governmental and third-party payors to contain or reduce the costs of healthcare may impair our future revenues and profitability.

The pricing of our future products may be influenced in part by government controls. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement more rigorous provisions relating to government payment levels. While we cannot predict whether the government will adopt any such legislative or regulatory proposals, the announcement or adoption of these proposals could have a material adverse effect on our business, results of operations, financial condition and cash flow.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Equity Price Risk

We are subject to risk associated with our retained ownership in Abgenix common stock. The value of our holdings of Abgenix common stock was \$68.5 million at December 31, 2004 compared to \$91.9 million at December 31, 2003. Each 10% decrease in market value of these securities would result in a decrease in value of approximately \$6.9 million and \$9.2 million from the fair value of those investments at December 31, 2004 and 2003, respectively.

Interest Rate Risk

We are exposed to interest rate sensitivity on our investments in debt securities and our outstanding fixed rate debt. The objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid, investment grade and government debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short-term securities and our goal is to maintain an average maturity of less than one year. The following table provides information about our financial instruments that are sensitive to changes in interest rates.

Interest Rate Sensitivity
Principal Amount by Expected Maturity and Average Interest Rate
(dollars in thousands)

<u>As of December 31, 2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u> <u>Thereafter</u>	<u>Total</u>	<u>Fair Value</u> <u>December 31,</u> <u>2004</u>
Total Investment Securities.....	\$ 115,112	\$ 37,340	\$ 10,976	\$ —	\$ —	\$163,428	\$162,779
Average Interest Rate	2.39%	2.27%	2.46%	—	—	2.37%	—
Fixed Interest Rate							
Convertible Senior Notes ⁽¹⁾	\$ 4,531	\$ 4,531	\$ 4,531	\$ 4,531	\$157,838	\$175,962	\$145,000
Average Interest Rate	3.125%	3.125%	3.125%	3.125%	3.125%	3.125%	—
<u>As of December 31, 2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u> <u>Thereafter</u>	<u>Total</u>	<u>Fair Value</u> <u>December 31,</u> <u>2003</u>
Total Investment Securities.....	\$ 44,666	\$ 72,232	\$ 14,358	\$ 1,950	\$ 14,573	\$ 147,779	\$148,339
Average Interest Rate	1.53%	2.19%	2.64%	5.55%	1.35%	1.99%	—
Variable Interest Rate Debt							
Financing, including							
Current Portion	\$ —	\$ —	\$ —	\$ —	\$ 60,000	\$ 60,000	\$ 60,000
Average Interest Rate ⁽²⁾	—	—	—	—	1.80%	1.80%	—
Fixed interest Rate Debt							
Financing, including							
Current Portion	\$ 961	\$ 4,323	\$ 4,475	\$ 4,639	\$ 21,398	\$ 35,796	\$ 35,796
Average Interest Rate	6.86%	6.75%	6.73%	6.73%	6.73%	6.74%	—

- (1) In connection with our issuance of our 3.125% convertible senior notes due 2011, we fully repaid both our variable interest rate debt financing and our fixed interest rate debt financing concurrent with the initial closing on October 20, 2004.
- (2) Interest rate was based upon LIBOR rate index plus a spread of 0.625 percent, and can be reset on a quarterly or semi-annual basis.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Statements

The Board of Directors and Stockholders
Cell Genesys, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting included in Item 9A, that Cell Genesys, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Cell Genesys, Inc's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process 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. A company's 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 the transactions and dispositions of the assets of the company; (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 receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

In our opinion, management's assessment that Cell Genesys maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Cell Genesys maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cell Genesys as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004 and our report dated February 24, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 24, 2005

Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements

The Board of Directors and Stockholders
Cell Genesys, Inc,

We have audited the accompanying consolidated balance sheets of Cell Genesys, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of Cell Genesys, Inc.'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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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 Cell Genesys at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Cell Genesys's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 24, 2005

CELL GENESYS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	<u>December 31,</u>	
	<u>2004</u>	<u>2003</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 58,324	\$ 9,867
Short-term investments	113,347	87,062
Current portion of restricted cash and investments	3,300	3,359
Investment in Abgenix, Inc. common stock	68,503	91,936
Prepaid expenses and other current assets	1,184	1,173
Total current assets	<u>244,658</u>	<u>193,397</u>
Restricted cash and investments	—	60,000
Property and equipment, net	159,663	172,102
Noncurrent deferred tax assets	25,177	34,247
Deposits and other assets	5,641	756
	<u>\$ 435,139</u>	<u>\$ 460,502</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,888	\$ 2,567
Accrued compensation and benefits	5,071	4,106
Deferred revenue	2,031	7,877
Accrued facility exit costs	6,092	9,459
Other accrued liabilities	5,924	4,610
Accrued income taxes	29,954	29,954
Deferred tax liabilities	25,177	34,247
Current portion of debt financings	—	961
Current portion of facility lease obligation	786	515
Total current liabilities	<u>77,923</u>	<u>94,296</u>
Noncurrent portion of debt financings	—	94,835
Noncurrent portion of facility lease obligation	51,013	51,799
Convertible senior notes	145,000	—
Redeemable convertible preferred stock, \$.001 par value: 5,000,000 shares authorized; 152 and 226 shares issued and outstanding in 2004 and 2003, respectively	1,897	2,706
Commitments		
Stockholders' equity:		
Common stock, \$.001 par value: 75,000,000 shares authorized; 44,978,226 and 39,671,521 shares issued and outstanding in 2004 and 2003, respectively	45	40
Additional paid-in capital	372,014	312,017
Accumulated other comprehensive income	31,220	51,371
Accumulated deficit	<u>(243,973)</u>	<u>(146,562)</u>
Total stockholders' equity	<u>159,306</u>	<u>216,866</u>
	<u>\$ 435,139</u>	<u>\$ 460,502</u>

See accompanying notes

CELL GENESYS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year ended December 31,		
	2004	2003	2002
Revenue	\$ 11,458	\$ 18,128	\$ 39,141
Operating expenses:			
Research and development	92,133	85,296	75,138
General and administrative	17,928	25,980	20,697
Credit for purchased in-process technology.....	—	—	(186)
Total operating expenses	<u>110,061</u>	<u>111,276</u>	<u>95,649</u>
Loss from operations	(98,603)	(93,148)	(56,508)
Gain on sale of Abgenix, Inc. common stock	12,160	12,638	2,246
Interest and other income.....	2,662	4,832	9,942
Interest expense	(9,885)	(5,360)	(1,011)
Loss before minority interest and income taxes.....	(93,666)	(81,038)	(45,331)
Loss attributed to minority interest.....	—	—	96
Loss before income taxes.....	(93,666)	(81,038)	(45,235)
Income tax benefit (provision).....	(3,745)	24,632	18,636
Net loss	(97,411)	(56,406)	(26,599)
Dividend in kind to preferred stockholders.....	100	230	702
Loss attributed to common stockholders.....	<u>\$ (97,511)</u>	<u>\$ (56,636)</u>	<u>\$ (27,301)</u>
Basic and diluted loss per common share	<u>\$ (2.23)</u>	<u>\$ (1.48)</u>	<u>\$ (0.76)</u>
Weighted average shares of common stock outstanding-basic and diluted.....	<u>43,682</u>	<u>38,177</u>	<u>35,889</u>

See accompanying notes

CELL GENESYS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	\$ (97,411)	\$ (56,406)	\$ (26,599)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	16,773	12,159	4,366
Loss (gain) on disposal of property and equipment	(19)	634	50
Gain on sale of Abgenix, Inc. common stock	(12,160)	(12,638)	(2,246)
Issuance of common stock related to Somatix acquisition			
Non-employee stock based compensation	105	81	238
Credit for purchased in-process technology	—	—	(186)
Changes to:			
Prepaid expenses and other assets	788	636	9,489
Receivable from Transkaryotic Therapies, Inc.	—	15,000	(15,000)
Noncurrent deferred tax assets	3,745	(20,682)	(13,153)
Accounts payable	411	(1,413)	2,002
Accrued compensation and benefits	1,134	495	974
Deferred revenue	(5,846)	2,006	2,115
Accrued facility exit costs	(3,367)	3,281	6,178
Other accrued liabilities	2,064	(2,260)	(3,334)
Minority interest in equity of subsidiary	—	—	(96)
Noncurrent income tax liabilities	—	12,386	4,476
Net cash used in operating activities	<u>(93,783)</u>	<u>(46,721)</u>	<u>(30,330)</u>
Cash flows from investing activities:			
Purchases of short-term investments	(227,651)	(265,905)	(235,669)
Maturities of short-term investments	8,543	15,520	—
Sales of short-term investments	251,661	226,468	290,741
Purchases of restricted cash and investments	—	—	(945)
Capital expenditures	(5,087)	(27,658)	(66,074)
Proceeds from disposal of property and equipment	67	65	107
Proceeds from sale of Abgenix, Inc. common stock	12,918	13,859	2,487
Cash effect related to the deconsolidation of Ceregene	(521)	—	—
Net cash provided by (used in) investing activities	<u>39,930</u>	<u>(37,651)</u>	<u>(9,353)</u>
Cash flows from financing activities:			
Proceeds from issuances of common stock	59,088	20,249	1,202
Net proceeds from convertible senior note-financing	139,912	—	—
Proceeds from term loan financings	—	35,237	926
Payments under Ceregene financing	(482)	(272)	(95)
Payments under facility lease obligation	(515)	(47)	—
Payments under debt financings	(95,693)	—	—
Net cash provided by financing activities	<u>102,310</u>	<u>55,167</u>	<u>2,033</u>
Net increase (decrease) in cash and cash equivalents	48,457	(29,205)	(37,650)
Cash and cash equivalents at the beginning of the year	9,867	39,072	76,722
Cash and cash equivalents at the end of the year	<u>\$ 58,324</u>	<u>\$ 9,867</u>	<u>\$ 39,072</u>

See accompanying notes

CELL GENESYS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balances at December 31, 2001	35,596	36	274,365	176,710	(63,557)	387,554
Comprehensive loss:						
Net loss	—	—	—	—	(26,599)	(26,599)
Change in net unrealized holding gain on available for sale securities	—	—	—	(141,991)	—	(141,991)
Total comprehensive loss						(168,590)
Cancellation of common stock upon settlement of the outstanding Calydon acquisition	(10)	—	(186)	—	—	(186)
Issuance of common stock upon exercise of stock options and pursuant to the Employee Stock Purchase Plan	149	—	1,202	—	—	1,202
Issuance of common stock related to the 1997 Somatix acquisition	99	—	396	—	—	396
Income tax benefit from stock option deductions	—	—	196	—	—	196
Non-employee stock-based compensation expense	—	—	238	—	—	238
Conversion of 904 preferred shares into common shares	1,048	1	11,039	—	—	11,040
Dividend to preferred stockholders	—	—	(702)	—	—	(702)
Balances at December 31, 2002	36,882	37	286,548	34,719	(90,156)	231,148
Comprehensive loss:						
Net loss	—	—	—	—	(56,406)	(56,406)
Change in net unrealized holding gain on available for sale securities	—	—	—	16,652	—	16,652
Total comprehensive loss						(39,754)
Issuance of common stock upon exercise of stock options and pursuant to the Employee Stock Purchase Plan	223	—	1,730	—	—	1,730
Income tax benefit from stock option deductions	—	—	216	—	—	216
Non-employee stock-based compensation expense	—	—	81	—	—	81
Conversion of 439 preferred shares into common shares	567	1	5,155	—	—	5,156
Issuance of common stock to Novartis/GTI	2,000	2	18,517	—	—	18,519
Dividend to preferred stockholders	—	—	(230)	—	—	(230)
Balances at December 31, 2003	39,672	40	312,017	51,371	(146,562)	216,866
Comprehensive loss:						
Net loss	—	—	—	—	(97,411)	(97,411)
Change in net unrealized holding gain on available for sale securities	—	—	—	(20,151)	—	(20,151)
Total comprehensive loss						(117,562)
Issuance of common stock upon exercise of stock options and pursuant to the Employee Stock Purchase Plan	284	—	1,897	—	—	1,897
Issuance of common stock in follow on offering, net of issuance costs of \$3.9 million	4,887	5	57,186	—	—	57,191
Non-employee stock-based compensation expense	—	—	105	—	—	105
Conversion of 74 preferred shares into common shares	135	—	909	—	—	909
Dividend to preferred stockholders	—	—	(100)	—	—	(100)
Balances at December 31, 2004	<u>44,978</u>	<u>\$45</u>	<u>\$ 372,014</u>	<u>\$31,220</u>	<u>\$(243,973)</u>	<u>\$ 159,306</u>

See accompanying notes

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization and basis of presentation

Cell Genesys, Inc. (“Cell Genesys” or “the Company”) has focused its research and product development efforts on biological therapies for patients with cancer. The Company’s objective is to develop and commercialize cell-based cancer vaccines, oncolytic virus therapies and antiangiogenesis therapies to treat different types of cancer. Cell Genesys’ current clinical-stage programs include GVAX[®] cancer vaccines and oncolytic virus therapies.

The consolidated financial statements include the accounts of Cell Genesys and its majority-owned subsidiary, Ceregene, Inc. through August 3, 2004, after which, as a result of a decline in ownership, Ceregene was no longer consolidated, but is accounted for under the equity method. All significant intercompany balances and transactions have been eliminated.

Concentration of risk

Cash and cash equivalents, short-term investments and accounts receivables are financial instruments, which potentially subject the Company to concentrations of credit risk. The Company maintains and invests in high credit quality investment-grade securities that bear minimal credit risk. The Company has not experienced any significant credit losses and does not generally require collateral on receivables.

Revenue recognition

The Company’s revenues are derived principally from research and licensing agreements with collaborators. Revenue under such collaboration agreements typically includes upfront payments, cost reimbursements and milestone payments. We evaluate whether the delivered element under these arrangements has value to our customer on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered item exists. Deliverables that do not meet these criteria are treated as one unit of accounting for the purposes of revenue recognition.

Revenue from non-refundable upfront license fees and other payments under collaboration agreements where the Company continues involvement throughout development is recognized over the development period based upon when the underlying development expenses are incurred. The Company recognizes cost reimbursement revenue under collaborative agreements as the related research and development costs are incurred, as provided for under the terms of these agreements.

Incentive milestone payments under collaborative arrangements are recognized as revenue upon achievement of the incentive milestone events, which represent the culmination of the earnings process. Incentive milestone payments are triggered either by the results of the Company’s research efforts or by events external to the Company, such as regulatory approval to market a product or the achievement of specified sales levels by a marketing partner. As such, the incentive milestones are substantially at risk at the inception of the contract, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. Upon the achievement of an incentive milestone event, the Company has no future performance obligations related to that payment.

Amounts received under license agreements relating to the Company’s intellectual property are recognized as revenue upon execution of the technology licensing agreement, if the Company has no future performance obligations.

Deferred revenue represents the portion of upfront payments received that has not been earned.

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Depreciation and amortization

Cell Genesys records property and equipment at cost and depreciates it using the straight-line method over the estimated useful lives of the assets, generally five years. Computer equipment is depreciated over a life of three years.

Furniture and equipment leased under capital leases is amortized over the shorter of the useful lives or the lease term. Leasehold improvements are amortized over the shorter of the useful lives or the lease term, generally 15 to 17 years. Amortization of leased assets is included in depreciation and amortization expense and is combined with accumulated depreciation and amortization of the Company's owned assets. Intangible assets, which consist of patents, are amortized using the straight-line method over the estimated useful lives of the assets, generally 10 years.

Cash, cash equivalents and short-term investments

Cell Genesys places its cash, cash equivalents and short-term investments, including restricted cash and investments, with high credit quality United States and foreign financial institutions, government and corporate issuers and limits the amount of credit exposure to any one issuer. The Company considers all highly liquid investments with insignificant interest rate risk with a maturity of less than three months when purchased to be cash equivalents. All investments are denominated in U.S. dollars. Short-term investments include equity securities classified as available-for-sale. The Company records its investments at fair market value, based on quoted market prices.

The Company's debt and marketable equity securities are classified as available-for-sale and carried at fair value. Management considers the investments in debt securities to be available for use in current operations. As a result, all investments in debt securities are classified as current assets, even if the remaining maturity of the investment is more than one year beyond the balance sheet date. The cost of securities sold is based on the specific identification method. Realized gains and losses and declines in value, judged to be other than temporary, on available-for-sale securities are included in interest and other income (loss). Unrealized holding gains and losses on securities classified as available-for-sale are recorded in accumulated other comprehensive income, net of tax. The Company determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date.

Restricted cash and investments relate to the Company's \$3.3 million letter of credit on the Company's corporate headquarters facility in South San Francisco, California, and its cGMP manufacturing facility in Hayward, California.

Reclassifications

Certain prior year balances, relating to income tax liabilities, have been reclassified to current from long term taxes payable to conform to the current year presentation.

Stock-based compensation

In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), the Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations and to adopt the "disclosure only" alternative described in SFAS 123. Under APB 25, when the exercise price of the Company's employee stock options equals or exceeds the fair market value on the date of the grant or the fair value of the underlying stock on the date of the grant as determined by the Company's Board of Directors, no compensation expense is recognized.

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

The following table illustrates, pursuant to SFAS 123, as amended by SFAS No. 148, the effect on net loss and loss per common share, had compensation costs for stock-based employee compensation plans been determined based upon the fair value method prescribed under SFAS 123 using the straight-line method of accounting for vesting (see *Note 9 of Notes to Consolidated Financial Statements*):

	<u>Year ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(in thousands except per share data)		
Loss attributed to common stockholders.....	\$ (97,511)	\$ (56,636)	\$ (27,301)
Deduct:			
Stock-based employee compensation expense determined under SFAS 123, net of related taxes.....	(13,516)	(12,700)	(11,836)
Pro forma net loss.....	<u>\$ (111,027)</u>	<u>\$ (69,336)</u>	<u>\$ (39,137)</u>
Basic and diluted loss per share, as reported.....	\$ (2.23)	\$ (1.48)	\$ (0.76)
Basic and diluted pro forma loss per share.....	\$ (2.54)	\$ (1.82)	\$ (1.09)

Loss per share

Basic loss per share is calculated using the weighted average number of shares of common stock outstanding during the period. Diluted loss per share includes the impact of potentially dilutive securities. As the Company's potentially dilutive securities (stock options, redeemable convertible preferred stock and convertible debt) were anti-dilutive for all periods presented, they have been excluded from the computation of shares used in computing diluted loss per share.

The Company had securities outstanding which could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive. These outstanding securities consisted of the following (in thousands, except per share data):

	<u>2004</u>
<u>Year Ended December 31,</u>	
Convertible senior notes.....	<u>15,934</u>
Redeemable convertible preferred stock.....	<u>253</u>
Outstanding stock options.....	<u>7,822</u>
Weighted average exercise price of stock options.....	<u>\$ 12.23</u>

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. Management makes estimates when preparing the financial statements which affect revenue recognition, accrued but unbilled expenses for clinical trials, accrued facility exit costs and lease accounting, expenses for certain outside experts and consultants, useful lives of property and equipment, income taxes, stock option valuation and other items.

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Comprehensive income (loss)

Comprehensive income (loss) is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes to stockholders' equity of the Company that are excluded from net loss. Other comprehensive income (loss) includes solely unrealized gains or losses on the Company's available-for-sale securities, including the Company's holdings of Abgenix, Inc. common stock, net of tax. The following table presents the calculation of comprehensive income (loss) (in thousands):

	<u>Year ended December 31.</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net loss	\$ (97,411)	\$ (56,406)	\$ (26,599)
Other comprehensive income (loss):			
Increase (decrease) in unrealized gain on investments, net of tax benefit/(provision) of \$(9.6) million, \$11.1 million and \$(94.7) million in 2004, 2003, and 2002, respectively	(12,779)	25,411	(138,627)
Less: reclassification adjustment for gains recognized in net loss, net of related tax of \$4.9 million, \$5.8 million, and \$2.2 million in 2004, 2003, and 2002, respectively	<u>(7,372)</u>	<u>(8,759)</u>	<u>(3,364)</u>
Comprehensive loss	<u>\$ (117,562)</u>	<u>\$ (39,754)</u>	<u>\$ (168,590)</u>

Segment reporting

The Company's operations are treated as one operating segment, as it reports profit and loss information only on an aggregate basis to the chief operating decision-makers.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123R, "Share-Based Payment," which is a revision of SFAS 123. SFAS 123R supersedes APB 25 and amends SFAS No. 95, "Statement of Cash Flows." Generally, the approach in SFAS 123R is similar to the approach described in FASB Statement 123. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. SFAS 123R must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS 123R on July 1, 2005.

SFAS 123R permits public companies to adopt its requirement using one of two methods: 1) A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123R for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date; or 2) A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company plans to adopt SFAS 123R using the modified prospective method.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of Statement 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of Statement 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted Statement 123R in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net loss and loss per share in Note 9 to our

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

consolidated financial statements. Statement 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. The Company cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options, and whether the Company will be in a taxable position). There is no tax impact related to the prior periods since the Company is in a net loss position.

2. Statement of Cash Flows

Supplemental disclosure to the Consolidated Statements of Cash Flows is as follows (in thousands):

	Year ended December 31,		
	2004	2003	2002
Cash paid for interest.....	\$ 9,155	\$ 5,887	\$ 1,762
Cash refunded for income taxes.....	\$ —	\$ (16,532)	\$ (10,161)

The Company capitalized interest expense of \$0.8 million in each of 2003 and 2002 in connection with the construction of its manufacturing facility in Hayward, California. In 2002, the Company capitalized \$52.4 million of property and equipment in connection with the classification of the South San Francisco, California headquarters facility as a capital lease.

3. Acquisitions

In 2002, Cell Genesys recorded a credit of \$186,000 to the original purchased in-process technology charge in 2001 related to the Company's acquisition of Calydon, Inc., a private biotechnology company focused on the treatment of cancer using genetically engineered oncolytic virus therapies. The credit recorded in 2002 related to a claim made by Cell Genesys against the portion of the Calydon purchase price held in escrow. The claim resulted from undisclosed liabilities assumed in the purchase. Additionally in 2002, Cell Genesys recorded a non-cash purchase price adjustment in the amount of \$396,000 related to common stock issued to former shareholders of a subsidiary of Somatix, Inc., an entity acquired by Cell Genesys in 1997.

4. Collaborative and License Agreements

The Company derives substantially all of its revenues from collaborative and license agreements, as shown in the following table (in thousands):

	Year ended December 31,		
	2004	2003	2002
Novartis AG.....	\$ 5,846	\$ 2,104	\$ —
Japan Tobacco Inc.	—	14,145	11,640
sanofi-aventis Group.....	3,173	1,000	1,130
Transkaryotic Therapies, Inc.	250	—	26,000
Ceregene, Inc.	998	—	—
Other.....	1,191	879	371
	\$ 11,458	\$ 18,128	\$ 39,141

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Global alliance with Novartis AG

On July 23, 2003, the Company announced a global alliance with Novartis AG for the development and commercialization of oncolytic virus therapies. Under the agreement, the Company acquired exclusive worldwide rights to the oncolytic virus therapy products and related intellectual property of Genetic Therapy, Inc. (GTI), an affiliate of Novartis, as well as certain related intellectual property of Novartis, and received an upfront payment of \$28.5 million from Novartis. This payment is to be dedicated to the further development of certain existing oncolytic virus therapy products of the Company and those acquired from GTI, in each case for which the Company and Novartis both have future commercialization rights. In exchange, the Company issued to Novartis and GTI 1,999,840 shares of Cell Genesys, Inc. common stock. Of the \$28.5 million upfront payment received from Novartis, the Company recorded approximately \$18.5 million to the 1,999,840 common shares issued, based upon the market value of such shares, and approximately \$10.0 million to deferred revenue, which the Company will recognize as revenue over the related development period. The agreement also provides the basis for the sharing of future additional development costs and profits related to the potential products on a worldwide basis. The Company recognized \$5.8 million and \$2.1 million in revenue under this agreement in 2004 and 2003, respectively, and \$2.0 million remained as deferred revenue at December 31, 2004. The Company expects to recognize the remaining \$2.0 million as revenue in 2005.

Collaborative agreement with Japan Tobacco Inc.

On December 17, 1998, Cell Genesys entered into a worldwide collaboration agreement with the pharmaceutical division of Japan Tobacco Inc. ("JT") for certain of the Company's GVAX[®] cancer vaccines. In October 2002, the remaining portion of the agreement with JT was terminated with the result that Cell Genesys reacquired full commercial rights to the entire GVAX[®] cancer vaccine portfolio. In August 2003, the Company announced that an agreement had been reached regarding outstanding clinical and patent-related milestone and wind down payments arising from this terminated collaboration agreement. In connection with this final agreement, JT paid Cell Genesys approximately \$8.3 million in cash and waived future repayment obligations for capital expenditures associated with Cell Genesys' manufacturing facilities in Hayward, California and Memphis, Tennessee, resulting in revenue of \$14.1 million for 2003. The Company did not record any revenue associated with this agreement in 2004.

Gene activation technology licenses

Cell Genesys executed a license agreement with Aventis, now sanofi-aventis Group, in February 1997 for gene-activated erythropoietin ("EPO") and a second undisclosed protein. In late 2000, sanofi-aventis Group informed the Company of its intention to terminate this license agreement as it relates to the second undisclosed protein. The agreement provides for up to \$26 million in milestone payments and fees, in addition to any royalties on future sales of gene-activated EPO anywhere in the world. As of December 31, 2004, Cell Genesys had received approximately \$23.2 million under this license agreement, which included certain milestone payments relating to the development of gene-activated EPO which sanofi-aventis Group is developing in collaboration with Transkaryotic Therapies, Inc ("TKT"). The Company recognized revenues of \$3.2 million, \$1.0 million and \$1.1 million in 2004, 2003 and 2002, respectively, pursuant to the agreement.

In June 2002, Cell Genesys completed a license agreement with TKT under which Cell Genesys exclusively licensed intellectual property relating to the development of gene-activated EPO. In exchange, Cell Genesys received an upfront license fee of \$26.0 million, which was to have been comprised of \$11.0 million in cash and \$15.0 million in shares of TKT common stock. An amendment to the original license agreement provided for the substitution of a cash payment in lieu of the TKT stock, and in January 2003, Cell Genesys received a cash payment of \$15.0 million from TKT. In addition, Cell Genesys may receive additional payments, in an aggregate amount of up to \$17.0 million in cash and TKT common stock, upon the achievement of certain patent-related milestones, but Cell Genesys can make no assurances that any of these patent-related milestones will ever be achieved or that any additional payments will be received. No ongoing royalty payments will be made by TKT to Cell Genesys under the

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

terms of this agreement. In 2004, the Company received and recorded \$0.3 million in revenue as a result of patent-related milestones achieved under this agreement.

Gene therapy rights agreement with Abgenix

In November 1997, Cell Genesys entered into a gene therapy rights agreement (the "GTRA") with Abgenix. The GTRA provides Cell Genesys with certain rights to Abgenix's XenoMouse[®] technology in the field of gene therapy. Cell Genesys is obligated to make certain payments to Abgenix for these rights including reimbursement of license fees and royalties on future product sales. The GTRA also prohibits Abgenix from granting any third-party licenses for antibody products based on antigens nominated by Abgenix for its own purposes where the primary field of use is gene therapy. In the case of third-party licenses granted by Abgenix where gene therapy is a secondary field, Abgenix is obligated to share with Cell Genesys a portion of the cash milestone payments and royalties resulting from any products in the field of gene therapy.

Other collaborations

Cell Genesys has licensing agreements relating to its proprietary viral vector technologies. These collaborations enable Cell Genesys to receive monetary reimbursement for providing viral vector technologies to companies that commercialize these technologies for the research market. Examples include agreements with the Clontech division of Becton, Dickinson and Company and Invitrogen Corporation.

5. Investments

The following is a summary of the Company's available-for-sale securities at December 31, 2004 and 2003 (in thousands):

December 31, 2004	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Money market funds	\$ 2,744	\$ —	\$ —	\$ 2,744
Corporate notes	11,743	—	(3)	11,740
U.S. government and its agencies	148,941	6	(652)	148,295
Abgenix common stock	6,131	62,372	—	68,503
	<u>\$ 169,559</u>	<u>\$ 62,378</u>	<u>\$ (655)</u>	<u>\$ 231,282</u>
Classified as:				
Cash equivalents				\$ 49,432
Short-term investments				113,347
Abgenix common stock				68,503
				<u>\$ 231,282</u>
December 31, 2003	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Money market funds	\$ 2,040	\$ —	\$ —	\$ 2,040
Corporate notes	87,230	368	(41)	87,557
Municipal bonds	12,506	75	—	12,581
U.S. government and its agencies	46,003	168	(10)	46,161
Abgenix common stock	6,889	85,047	—	91,936
	<u>\$ 154,668</u>	<u>\$ 85,658</u>	<u>\$ (51)</u>	<u>\$ 240,275</u>
Classified as:				
Cash equivalents				\$ 1,277
Restricted cash and investments				60,000
Short-term investments				87,062
Abgenix common stock				91,936
				<u>\$ 240,275</u>

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

As of December 31, 2004, unrealized losses set forth above were primarily due to increases in interest rates. The gross unrealized losses in our portfolio of investments represent less than 0.3% of the total fair value of the portfolio. We have concluded that unrealized losses in our investment securities are other-than-temporary, and we have the intent and ability to hold impaired securities to maturity or call date. Gross realized gains on the sale of investment securities were \$12.3 million, \$14.6 million, and \$5.6 million for the years ended December 31, 2004, 2003 and 2002, respectively. The Company sold 819,210, 1,250,000, and 260,000 shares of Abgenix stock resulting in net proceeds of \$12.9 million, \$13.9 million and \$2.5 million in 2004, 2003 and 2002, respectively.

The amortized cost and estimated fair value of the Company's available-for-sale debt securities by contractual maturity are shown below (in thousands):

<u>December 31, 2004</u>	<u>Amortized Cost</u>	<u>Estimated Fair Value</u>
Due in one year or less.....	\$ 115,112	\$ 114,900
Due in one to three years	<u>48,316</u>	<u>47,879</u>
	<u>\$ 163,428</u>	<u>\$ 162,779</u>

6. Property and Equipment

Property and equipment consists of the following (in thousands):

	<u>December 31,</u>	
	<u>2004</u>	<u>2003</u>
Machinery, furniture and equipment.....	27,111	24,947
Leasehold improvements	119,811	116,590
Property and equipment under facility lease obligation.....	52,361	53,343
Construction in process.....	<u>3,864</u>	<u>5,673</u>
	203,147	200,553
Accumulated depreciation and amortization.....	<u>(43,484)</u>	<u>(28,451)</u>
	<u>\$ 159,663</u>	<u>\$ 172,102</u>

7. Leases and Debt

Operating leases

The Company leases certain of its facilities and equipment under non-cancelable operating leases. These leases, including the Hayward, Foster City, San Diego and Memphis facility leases, expire at various dates through 2017 and some contain options for renewal. Rent expense under operating leases was \$5.0 million in 2004, \$9.1 million in 2003 and \$9.6 million in 2002.

In 2002, the Company recorded accrued expense for estimated lease exit costs associated with the planned move of its corporate headquarters to South San Francisco, California in March 2003 and the related vacancy in Foster City, California. Based upon updated estimates of the rental market for comparable laboratory and office space, the Company subsequently revised its estimate of accrued lease exit costs and recorded an additional \$5.3 million of general and administrative expense in 2003 and further recorded another \$1.8 million in 2004 based on the continuing decline in market conditions related to subleasing this space. As of December 31, 2004, the Company has approximately \$6.1 million accrued related to lease exit costs.

Debt financing

In October 2004, the Company entered into a purchase agreement with initial purchasers relating to the private placement of \$110.0 million aggregate principal amount of its 3.125% Convertible Senior Notes due 2011. The

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Company granted the initial purchasers a 30-day option to purchase up to an additional \$35.0 million principal amount of the notes, which the purchasers elected to exercise in full in November 2004. We received approximately \$139.9 million in net proceeds after deducting the initial purchasers' discount and estimated offering expenses. The Company used a portion of the net proceeds to repay bank debt of \$60.0 million in asset-backed debt financing obligation acquired from Fleet Bank in December 2001 in connection with the construction of the Company's manufacturing facility in Hayward, California. Liquid financial instruments, including cash and marketable securities, which are classified as restricted cash and investments on the consolidated balance sheet, secured the debt financing, which bore interest based on LIBOR (London Interbank Offering Rate) plus 0.625 percent and was scheduled to mature in January 2008. The repayment eliminated restrictions on \$60.0 million of cash. In addition, the Company used the net proceeds of the note issuance to repay \$35.0 million in term loans acquired in September 2003 from Silicon Valley Bank, which bore interest at 6.73 percent and was scheduled to mature in September 2008. The loan was secured by certain of the Company's assets, excluding the Company's intellectual property assets, deposits in certain investment accounts and the Company's holdings of Abgenix, Inc. common stock. As of December 31, 2004, the Company recorded accrued interest expense of \$0.8 million under the convertible senior notes. Interest on the notes is payable in May of 2005 and every six months thereafter until the notes are due in 2011.

Under certain circumstances, the Company may redeem some or all of the notes on or after November 1, 2009 at a redemption price equal to 100% of the principal amount of the notes. Holders of the notes may require the Company to repurchase some or all of their notes if a fundamental change (as defined in the indenture governing the notes) occurs, at a repurchase price equal to 100% of the principal amount of the notes, plus accrued and unpaid interest (and additional amounts, if any) to, but not including, the repurchase date.

Facility lease obligation

During 2002, the Company amended the lease for its headquarters facility in South San Francisco, California to fund the costs of certain structural components of the facility. As a result of this lease amendment, the Company is required to account for the lease as a capital lease obligation. At December 31, 2004, the Company had approximately \$51.8 million of facility lease obligations and \$38.8 million of related leasehold improvement assets, net of accumulated amortization.

Future minimum payments under non-cancelable operating leases and facility lease obligation at December 31, 2004 were as follows (in thousands), net of sublease rental amounts expected to be received:

	<u>Operating Leases *</u>	<u>Facility Lease Obligation</u>
Years ending December 31:		
2005	\$ 10,294	\$ 6,087
2006	3,856	6,300
2007	2,336	6,520
2008	2,430	6,748
2009	2,338	7,017
2010 and beyond.....	<u>20,145</u>	<u>67,003</u>
Total minimum payments	<u>\$ 41,399</u>	99,675
Less: Amount representing interest and executory costs.....		<u>(47,876)</u>
Present value of future debt payments		51,799
Less: Current portion of future payments.		<u>(786)</u>
Noncurrent portion of future payments.....		<u>\$ 51,013</u>

* Total operating lease commitments include rent payments for the Foster City location of \$6.9 million, of which \$6.1 million was accrued at December 31, 2004 as part of the estimated facility exit costs associated with the move to the South San Francisco, California headquarters building in March 2003. The Company expects to receive \$1.1 million in aggregate future rentals under related subleases through January 2006.

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

8. Redeemable Convertible Preferred Stock

In January 2000, the Company issued shares of Series B redeemable convertible preferred stock pursuant to a call option granted in connection with a previous offering. The number of shares of common stock issuable upon conversion of the shares of Series B preferred stock issued in January 2000 was determined by dividing the market value of the shares to be converted by the lower of a fixed conversion price of \$14.53 per share (subject to antidilution provisions), or the average of certain trading prices during the 10 trading days preceding such date of conversion.

As of December 31, 2004, 152 shares of the Series B redeemable convertible preferred stock remained outstanding by two holders of record and were convertible into 252,917 shares of the Company's common stock based on an effective conversion price of \$7.50 per share. As of December 31, 2004, the carrying value of the outstanding Series B redeemable convertible preferred stock, including imputed dividends, was approximately \$1.9 million.

On January 18, 2005, all of the 152 then-outstanding shares of our Series B redeemable convertible preferred stock automatically converted into an aggregate of 275,622 shares of our common stock at a conversion price of \$6.895 per share. This conversion occurred in accordance with their terms on the five-year anniversary of their issuance, according to a predetermined formula. Following the conversion, no shares of the Company's Series B preferred stock remained outstanding.

9. Stockholders' Equity

Common Stock

In March 2004, the Company completed a public offering of its common stock. In the offering, the Company sold 4,250,000 shares along with an additional 637,500 shares pursuant to the exercise over-allotment option by the underwriters, resulting in gross proceeds of \$61.1 million. The offering was pursuant to the Company's shelf registration statement filed in February 2003, which allows the Company to sell shares of its common stock up to a total dollar amount of an additional \$88.9 million, although there can be no assurance that we will be able to issue any of the remaining securities under this shelf registration on acceptable terms, or at all.

Stock Option Plans

Under the Cell Genesys 1998 Incentive Stock Option Plan ("the 1998 Plan"), 3,760,000 shares of common stock were authorized for issuance as of December 31, 2004. The 1998 Plan provides for the issuance of common stock and granting of options for common stock to employees, officers and consultants of the Company. Cell Genesys grants options to purchase shares of common stock for issuance under the 1998 Plan with exercise prices at no less than the fair market value of the underlying common stock as of the date of grant. Options granted under the 1998 Plan have a maximum term of 10 years and generally vest over four years at the rate of 25 percent one year from the grant date and 1/48 monthly thereafter. Cell Genesys previously sponsored the 1989 Incentive Stock Option Plan, which expired and was retired in 1999, and the 1992 Incentive Stock Option Plan, which expired and was retired in 2002. As of December 31, 2004, there were 2,681,154, 787,740 and 31,000 options outstanding under the 1998, 1989 and 1992 Incentive Stock Option Plans, respectively, and 746,668 options available for grant under the 1998 Incentive Stock Option Plan.

Under the Company's 2001 Nonstatutory Option Plan ("the 2001 Plan"), 5,500,000 shares of common stock have been authorized for issuance as of December 31, 2004. The 2001 Plan provides for the issuance of common stock and granting of options for common stock to employees (excluding executive officers) and consultants of the Company. The Company generally grants options to purchase shares of common stock for issuance under the 2001 Plan at no less than the fair market value of the stock as of the date of grant. Options granted under the 2001 Plan

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

have a maximum term of 10 years and generally vest over four years at the rate of 25 percent one year from the grant date and 1/48 monthly thereafter. As of December 31, 2004, there were 4,074,979 options outstanding and 1,355,227 options available for grant under the 2001 Plan.

Under the Company's 2001 Non-Employee Directors Stock Option Plan ("the Directors Plan"), 300,000 shares of common stock have been authorized for issuance as of December 31, 2004. The Directors Plan provides for the issuance of common stock and granting of options for common stock to non-employee directors of the Company. The Company grants options to purchase common stock for issuance under the Directors Plan at no less than the fair market value of the stock as of the date of grant. Options granted under the Directors Plan have a maximum term of 10 years. Each non-employee director is automatically granted an option to purchase 30,000 shares upon initial appointment or election to the Board and an option to purchase 7,500 shares each year thereafter. Stock options granted upon appointment or election to the Board vest at the rate of 25 percent annually on each anniversary of the date of grant. Subsequent grants for continued service on the Board vest fully on the date of grant. As of December 31, 2004, there were 247,500 options outstanding and 52,500 options available for grant under the Directors Plan.

The following table summarizes information about the plans (share numbers in thousands):

	Shares Available	Outstanding Stock Options	
		Number of Shares	Weighted Average Exercise Price
Balances, December 31, 2001	6,168	4,446	\$ 13.91
Authorized	3,000	—	—
Granted	(1,807)	1,807	\$ 14.14
Exercised	—	(83)	\$ 5.16
Expired	(4,273)	—	—
Forfeited	<u>408</u>	<u>(408)</u>	\$ 18.09
Balances, December 31, 2002	3,496	5,762	\$ 13.82
Authorized	500	—	—
Granted	(1,674)	1,674	\$ 9.85
Exercised	—	(97)	\$ 7.41
Expired	(31)	—	—
Forfeited	<u>704</u>	<u>(704)</u>	\$ 16.70
Balances, December 31, 2003	2,995	6,635	\$ 12.62
Authorized	500	—	—
Granted	(2,131)	2,131	\$ 11.50
Exercised	—	(123)	\$ 6.33
Expired	(31)	—	—
Forfeited	<u>821</u>	<u>(821)</u>	\$ 14.44
Balances, December 31, 2004	<u>2,154</u>	<u>7,822</u>	\$ 12.23
Exercisable at December 31, 2004		<u>4,951</u>	\$ 12.68
Exercisable at December 31, 2003		<u>4,056</u>	\$ 12.22
Exercisable at December 31, 2002		<u>3,114</u>	\$ 11.66
Weighted average fair value of options granted during 2004*			\$ 11.50
Weighted average fair value of options granted during 2003*			\$ 5.66
Weighted average fair value of options granted during 2002*			\$ 8.21

*Fair value of the stock options was based on the Black-Scholes model. See below for information regarding the assumptions applied to the model in each of the years.

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

The following table summarizes information about stock options outstanding at December 31, 2004:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding (in thousands)	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable (in thousands)	Weighted-Average Exercise Price
\$3.50-7.21.....	1,566	5.4	\$ 5.59	1,069	\$ 5.05
\$7.34-9.50.....	1,642	6.7	\$ 8.77	1,103	\$ 8.69
\$9.95-14.04.....	2,278	8.7	\$ 12.77	838	\$ 12.51
\$14.07-19.63.....	1,812	6.8	\$ 16.90	1,455	\$ 17.21
\$19.88-42.63.....	524	6.2	\$ 24.40	486	\$ 25.54
	<u>7,822</u>			<u>4,951</u>	

Employee Stock Purchase Plans

The 2002 Employee Stock Purchase Plan (“the Purchase Plan”) was approved by stockholders in June 2002. The Purchase Plan allows eligible employees to purchase common stock at 85 percent of its fair value at certain specified dates. Employee contributions are limited to 10 percent of compensation or \$25,000, whichever is less. As of December 31, 2004, a total of 400,000 shares of common stock have been authorized for issuance under the Purchase Plan. The Purchase Plan also allows for annual increases in the number of shares authorized for issuance under the Purchase Plan to be added on the first day of each of the Company’s fiscal years beginning in 2003, equal to the lesser amount of (a) 100,000 shares, (b) ½ percent of the outstanding additional shares on such date, or (c) an amount determined by the Board of Directors. Pursuant to this annual provision, 100,000 shares were authorized for issuance effective January 1, 2004, and an additional 100,000 shares were authorized for issuance effective January 1, 2005. As of December 31, 2004, 286,727 shares have been issued pursuant to the Purchase Plan.

The 1992 Employee Stock Purchase Plan (“1992 Plan”) expired in 2002. A total of 650,000 shares of common stock had been authorized for issuance under the 1992 Plan. As of December 31, 2002, 620,411 shares had been issued pursuant to the 1992 Plan.

Pro forma information

Pro forma information regarding net loss and net loss per share is required by SFAS 123, and has been determined as if the Company had accounted for options granted under its employee stock option plans and the Purchase Plan under the fair value method of SFAS 123. The fair value of options granted in 2004, 2003 and 2002 was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2004	2003	2002
Risk free interest rates.....	2.67%	1.53%	1.70%
Volatility factors.....	0.68	0.76	0.79
Expected life.....	3.9	3.9	3.9

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company’s employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management’s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

A reconciliation of the Company's recorded income tax benefit (provision) to the U.S. statutory rate follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Tax benefit at U.S. statutory rate of 35%	\$ 32,783	\$ 28,363	\$ 15,832
Change in valuation allowance	(45,789)	(11,826)	(1,594)
Research and development tax credits	4,180	4,396	4,350
Tax effect of unrealized losses on available-for-sale-securities recorded in other comprehensive income	5,094	—	—
In-process research and development	—	—	74
Prior year items	—	3,726	—
Other	(13)	(27)	(26)
Benefit (provision) for income taxes	<u>\$ (3,745)</u>	<u>\$ 24,632</u>	<u>\$ 18,636</u>

As of December 31, 2004, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$266.6 million, which will expire on various dates between 2007 and 2024, if not utilized. As of December 31, 2004, the Company had federal R&D tax credits of \$13.4 million, which will expire on various dates between 2018 and 2024. As of December 31, 2004, the Company had net operating loss carryforwards for California state income tax purposes of \$71.4 million, which will expire on various dates between 2005 and 2014. As of December 31, 2004, the Company had California state R&D tax credits of \$12.6 million, which do not expire. The Company also had Manufacturer Investment Credits of \$149 thousand which expire in 2010 and 2011. Utilization of the net operating loss and credit carryforwards may be subject to substantial annual limitation due to ownership change provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. Prior year items relate to changes in estimates to the net operating loss carrybacks to the 2000 year tax returns that were filed during 2003.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	\$ 96,895	\$ 57,464
Research credit carryforwards	21,673	17,675
Capitalized research and development, net of amortization	8,405	2,526
Other accruals and reserves	(452)	4,617
Net deferred tax assets	126,521	82,282
Valuation allowance	(101,344)	(48,035)
	<u>25,177</u>	<u>34,247</u>
Deferred tax liabilities:		
Unrealized gain on investments, including Abgenix, Inc.	(25,177)	(34,247)
Net deferred tax	<u>\$ —</u>	<u>\$ —</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. The valuation allowance increased by \$53.3 million, \$24.9 million and \$9.2 million in 2004, 2003 and 2002 respectively.

The Company establishes accruals for certain tax contingencies when, despite the belief that the Company's tax positions are fully supported, the Company believes that certain positions may be challenged and that the Company's positions may not be fully sustained. The tax contingency accruals are adjusted in light of changing facts and circumstances, such as the progress of tax audits, case law and emerging legislation. The IRS is currently

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

examining the 2000 tax year. As of December 31, 2004, the Company's accrual for income taxes payable is sufficient to cover any expected liabilities arising from this examination. As of December 31, 2004 and 2003 respectively, we had accrued approximately \$30.0 million in tax contingencies and related interest. The Company's tax contingency accruals have been reclassified from noncurrent income tax liabilities to current liabilities within the balance sheet.

The nature of these matters is uncertain and subject to change. As a result, the amount of our liability for certain of these matters could exceed or be less than the amount of our current estimates, depending on the outcome of these matters. An outcome of such matters different than previously estimated could materially impact our financial position or results of operations in the year of resolution.

11. 401(k) Plan

Cell Genesys sponsors a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code covering all full time employees ("the Cell Genesys 401K Plan"). Participating employees may contribute up to the annual Internal Revenue Service contribution limit. The Cell Genesys 401K Plan also provides for employer matching contributions up to an annual limit of \$3,000. The Cell Genesys 401K Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by the employees and by Cell Genesys, and income earned on the contributions, are not taxable to employees until withdrawn from the plan. Contributions by Cell Genesys are tax deductible by Cell Genesys when made. At the discretion of each participant, the assets of the Cell Genesys 401K Plan are invested in any of twelve different investment options.

The employer matching contribution is invested in the same investment options selected by the employee for their individual contributions. The employer matching contributions vest ratably over three years. The Company contributed \$942,050, \$843,000 and \$777,000 in employer matching contributions in 2004, 2003 and 2002, respectively.

12. Selected Quarterly Financial Information (Unaudited)

<u>Quarterly Results of Operations</u> (Unaudited)	<u>Quarter Ended</u>			
	<u>March 31,</u> <u>2004</u>	<u>June 30,</u> <u>2004</u>	<u>September 30,</u> <u>2004</u>	<u>December 31,</u> <u>2004</u>
	(in thousands, except per share amounts)			
Revenues.....	\$ 2,584	\$ 2,462	\$ 3,228	\$ 3,184
Research and development	22,644	24,097	21,686	23,706
General and administrative ⁽¹⁾	5,549	5,115	3,772	3,492
Net loss ⁽²⁾	(20,919)	(26,019)	(24,049)	(26,424)
Basic and diluted loss per share.....	(0.52)	(0.58)	(0.54)	(0.59)

(1) The quarters ended March 31 and June 30, 2004 include facility exit costs of \$1.0 million and \$0.8 million, respectively.

(2) The quarters ended March 31, June 30 and September 30, 2004 include gains on sales of Abgenix, Inc. common stock of \$5.5 million, \$6.5 million and \$0.2 million, respectively.

CELL GENESYS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

Quarterly Results of Operations (Unaudited)	Quarter Ended			
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
	(in thousands, except per share amounts)			
Revenues ⁽¹⁾	\$ 1,038	\$ 13	\$ 15,710	\$ 1,367
Research and development	21,058	22,578	20,371	21,289
General and administrative ⁽²⁾	5,041	6,930	6,439	7,570
Net loss ⁽³⁾	(17,375)	(19,096)	(2,914)	(17,021)
Basic and diluted loss per share.....	(0.47)	(0.51)	(0.07)	(0.43)

(1) The quarter ended September 30, 2003 includes \$14.1 million in connection with a terminated collaboration agreement with Japan Tobacco Inc.

(2) The quarters ended June 30, September 30 and December 31, 2003 include facility exit costs of \$1.6 million, \$1.2 million and \$2.5 million, respectively.

(3) The quarters ended June 30, September 30 and December 31, 2003 include gains on sales of Abgenix, Inc. common stock of \$7.3 million, \$2.6 million and \$2.7 million, respectively.

Basic and diluted loss per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly basic and diluted per share amounts may not equal annual basic and diluted loss per share amounts.

13. Related Party

In August 2004, Ceregene, Inc., previously a majority-owned subsidiary of the Company, announced an initial closing of a \$32.0 million Series B preferred stock financing. The Company participated in the financing through the conversion of a bridge loan into shares of Ceregene's Series B preferred stock. Immediately following that financing, the Company owned approximately 25% of Ceregene's capital stock on a fully diluted basis. Neither the financial position nor operating results for Ceregene have been consolidated by Cell Genesys subsequent to August 3, 2004. As of and for the four months ended December 31, 2004, the Company's investment in Ceregene was accounted for under the equity method of accounting as a result of the Company's reduced ownership position in Ceregene. As of December 31, 2004, the Company's cost basis in its investment in Ceregene had been reduced to zero; consequently, the Company does not expect to recognize future losses from Ceregene under the equity method of accounting. At the time of the deconsolidation, the Company recorded a liability of approximately \$0.2 million for a Cell Genesys guarantee of certain secured indebtedness of Ceregene. The guarantee extends into the year 2006. The liability that the Company initially recognized for the guarantee will be reduced, by a credit in the statement of operations, as the Company and as the risk of payment under the guarantee decreases.

Commencing August 4, 2004, Ceregene is considered to be a related party. For the four months ended December 31, 2004, the Company recorded revenue of \$0.8 million from Ceregene under a contract manufacturing arrangement and technology license revenue of \$0.2 million under the same agreement.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management team, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that our disclosure controls and procedures were effective as of December 31, 2004 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over the Company's financial reporting.

The Company's internal control over financial reporting is 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. Internal control over financial reporting includes those policies and procedures that:

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on the assessment using those criteria, management believes that, as of December 31, 2004, our internal control over financial reporting was effective.

Our independent registered public accountants, Ernst & Young LLP, audited the consolidated financial statements included in this Annual Report on Form 10-K and have issued an audit report on management's assessment of our internal control over financial reporting as well as on the effectiveness of the Company's internal control over financial reporting. Their report on the audit of internal control over financial reporting appears on page 38 of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no significant changes in our internal control over financial reporting that occurred during the year ended December 31, 2004, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

(a) The information required by this Item concerning our directors is incorporated by reference to our Definitive Proxy Statement for the 2005 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2004 fiscal year (the "2005 Proxy Statement").

(b) The information required by this Item concerning our executive officers is set forth in the section entitled "*Executive Officers*" in Part I of this Form 10-K and is incorporated by reference into this section.

We have adopted a code of ethics that applies to all of our employees, including our principal executive officer, our principal financial officer and our principal accounting officer. This code of ethics, which is part of our Code of Business Conduct and Ethics that applies to all of our employees, is posted on our website and can be accessed from the following link: *Cell Genesys Code of Business Conduct and Ethics-Corporate Governance*.

We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding any amendment to, or waiver from, a provision of this code of ethics by posting such information on our website, at the address and location specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to our 2005 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management, as well as equity compensation plans, is incorporated by reference to the information set forth in the sections "Beneficial Owners and Management's Ownership of Cell Genesys Stock" and "Equity Compensation Plan Information" in our 2005 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated by reference to our 2005 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to our 2005 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 1. Index to Financial Statements

	<u>Page</u>
Consolidated Balance Sheets at December 31, 2004 and 2003	45
Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002	46
Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002	47
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2004, 2003 and 2002	48
Notes to Consolidated Financial Statements.....	49

2. Index to Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or not required or because the required information is included in the financial statements or notes thereto.

(b) Exhibits

Number	Note	Description
2.1	(1)	Agreement and plan of merger and reorganization, dated as of January 12, 1997, among Cell Genesys, S Merger Corp. and Somatix Therapy Corporation.
2.2	(2)	Asset Purchase Agreement dated January 8, 2001 between Cell Genesys and Chiron Corporation, pursuant to which Cell Genesys purchased operating assets of Chiron Corporation's gene therapy operations.
2.3	(3)	Series A Preferred Stock Purchase Agreement dated January 10, 2001, pursuant to which Cell Genesys purchased shares of Series A Preferred Stock of Ceregene, Inc.
2.4	(4)	Agreement and Plan of Reorganization dated as of August 1, 2001 by and among Cell Genesys, Satellite Acquisition Corporation, Calydon, Inc., Kenneth Socha as shareholder representative (with respect to Articles VII and IX only) and Chase Manhattan Bank and Trust Company, N.A., as escrow agent.
3.1	(5)	Restated Certificate of Incorporation.
3.2	(5)	Certificate of Amendment to Restated Certificate of Incorporation.
3.3	(5)	Certificate of Designation of Series A Participating Preferred Stock.
3.4	(5)	Certificate of Amendment to Certificate of Designation of Series A Participating Preferred Stock.
3.5	(5)	Certificate of Designation of Series B Redeemable Convertible Preferred Stock.
3.6	(28)	Bylaws.
4.1	(6)	Amended and Restated Preferred Shares Rights Agreement, dated as of July 26, 2000 between Cell Genesys and Fleet National Bank.
4.2	(29)	Indenture dated as of October 20, 2004 by and between Cell Genesys and U.S. Bank National Association.
10.1†	(7)	Form of Indemnification Agreement for Directors and Officers.
10.2†	(8)	Amended 1989 Incentive Stock Plan.
10.3†	(8)	Amended 1992 Employee Stock Purchase Plan.
10.4	(7)	Representative Preferred Stock Purchase Agreement.
10.5	(9)	Fourth Amended and Restated Stockholder Rights Agreement.
10.6	(7)	License Agreement dated August 13, 1990 between Cell Genesys and the University of North Carolina at Chapel Hill.
10.8	(10)	License Agreement dated June 28, 1991 between Cell Genesys and the University of Utah Research Foundation.
10.9†	(11)	Amended Employment Agreement with Stephen A. Sherwin, M.D.
10.10	(11)	Research and Development Leases dated November 1, 1994 between Cell Genesys and Vintage Park Associates and Addendums thereto.
10.11*	(12)	Amendment No. 1 dated June 7, 1996 to Vintage Park Research and Development Lease.
10.12†	(13)	Amended 1998 Incentive Stock Plan.

<u>Number</u>	<u>Note</u>	<u>Description</u>
10.13	(14)	Research and Development Leases Amendment dated February 12, 2001 between Cell Genesys and Vintage Park Associates.
10.14	(15)	Research and Development Leases between Cell Genesys and Drawbridge/Forbes LLC, dated March 3, 2001.
10.15	(16)	Lease Agreement dated June 21, 2001, between Alexandria Real Estate Equities, Inc., and Cell Genesys for property located at 11055 Roselle Street in San Diego, California.
10.16	(17)	Lease Agreement dated June 21, 2001, between Alexandria Real Estate Equities, Inc., and Cell Genesys for property located at 11075 Roselle Street in San Diego, California.
10.17*	(18)	Amended and Restated GVAX [®] Agreement by and between Japan Tobacco Inc. and Cell Genesys dated November 26, 2001.
10.18	(18)	Credit Agreement between Cell Genesys and Fleet National Bank dated as of December 27, 2001.
10.19	(18)	Industrial Lease Agreement dated February 1, 2002, between Shelby Drive Corporation, and Cell Genesys for property located at 4600 Shelby Drive, Suite 108, Memphis, Tennessee.
10.20	(18)	Lease Agreement dated January 7, 2002, between F & S Hayward, LLC, and Cell Genesys for property located at the Adjacent Park of Bridgeview Tech Park of 24570 Clawiter Road, Hayward, California.
10.21*	(19)	License Agreement dated June 7, 2002 between Transkaryotic Therapies, Inc. and Cell Genesys, Inc.
10.22†	(20)	2002 Employee Stock Purchase Plan.
10.23†	(20)	2001 Nonstatutory Stock Option Plan.
10.24†	(21)	Change of Control Severance Agreement.
10.25	(22)	Amendment No. 2 dated June 12, 2003 to the Credit Agreement between Cell Genesys and Fleet National Bank.
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10.28*	(25)	Product Development and Option Agreement dated July 23, 2003 between Cell Genesys and Novartis Pharma AG.
10.29	(26)	Standstill and Registration
10.30	(27)	Rights Agreement dated July 23, 2003 between Cell Genesys, Novartis AG and Genetic Therapy, Inc. Loan and Security Agreement dated September 29, 2003 between Cell Genesys, Inc. and Silicon Valley Bank.
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12.1		Computation of Ratio of Earnings to Fixed Charges and Ratio of Earnings to Combined Fixed Charges and Preferred Stock Dividend Requirements. Consent of Independent Registered Public Accounting Firm.
31.1		Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1		Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished, not filed).

* Confidential treatment has been granted with respect to specific portions of this exhibit.

† Management compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 15(c) of Form 10-K.

(1) Incorporated by reference to Exhibit 2.1 filed with the Company's Form 8-K dated January 12, 1997. (2) Incorporated by reference to Exhibit 10.3 filed with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.

- (3) Incorporated by reference to Exhibit 10.4 filed with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
- (4) Incorporated by reference to Exhibit 10.1 filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
- (5) Incorporated by reference to the same numbered exhibit filed with the Company's Registration Statement on Form S-3/A (Reg. No. 333-102122) filed with the SEC on January 30, 2003.
- (6) Incorporated by reference to the Company's Form 8-A12G/A dated July 28, 2000.
- (7) Incorporated by reference to the same numbered exhibit filed with the Company's Registration Statement on Form S-1 (Reg. No. 33-46452) as amended.
- (8) Incorporated by reference to the same numbered exhibit filed with the Company's Annual Report on Form 10-K for the year ended December 31, 1995.
- (9) Incorporated by reference to the same numbered exhibit filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995.
- (10) Incorporated by reference to the same numbered exhibit filed with the Company's Annual Report on Form 10-K for the year ended December 31, 1992.
- (11) Incorporated by reference to the same numbered exhibit filed with the Company's Annual Report on Form 10-K for the year ended December 31, 1994.
- (12) Incorporated by reference to Exhibit 10.40 filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- (13) Incorporated by reference to Exhibit 4.1 filed with the Company's Registration Statement Form S-8 filed July 31, 2000.
- (14) Incorporated by reference to Exhibit 10.1 filed with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
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- (19) Incorporated by reference to the same numbered exhibit filed with the Company's Quarterly Report on Form 10-Q/A for the quarter ended June 30, 2002 (filed July 30, 2003).
- (20) Incorporated by reference to Exhibit 4 filed with the Company's Registration Statement on Form S-8 filed with the SEC on July 2, 2002.
- (21) Incorporated by reference to Exhibit 10.26 filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2002.

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- (28) Incorporated by reference to the same numbered exhibit filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2003.
- (29) Incorporated by reference to Exhibit 4.1 filed with the Company's Registration Statement on Form S-3 (Reg. No. 333-121732) filed with the SEC on December 29, 2004.
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31.1		Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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**Computation of Ratio of Earnings to Fixed Charges and Ratio of Earnings to Combined
Fixed Charges and Preferred Stock Dividend Requirements**
(in thousands, except for ratios)

Ratio of Earnings to Fixed Charges

	<u>Year Ended December 31,</u>				
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
Income (loss) before income taxes and cumulative effect of accounting change	\$(93,666)	\$(81,038)	\$(45,235)	\$(34,185)	\$239,583
Add: Fixed charges	13,433	10,743	6,576	4,450	1,386
Less: Capitalized interest	—	(832)	(765)	—	—
Earnings, as defined	<u>\$(80,233)</u>	<u>\$(71,127)</u>	<u>\$(39,424)</u>	<u>\$(29,735)</u>	<u>\$240,969</u>
Interest expense	\$ 9,885	\$ 5,360	\$ 1,011	\$ 500	\$ 386
Capitalized interest	—	832	765	—	—
Estimated interest portion of rental expense	3,548	4,551	4,800	3,950	1,000
Fixed charges	<u>\$ 13,433</u>	<u>\$ 10,743</u>	<u>\$ 6,576</u>	<u>\$ 4,450</u>	<u>\$ 1,386</u>
Excess (deficiency) of earnings to fixed charges	<u>\$(93,666)</u>	<u>\$(81,870)</u>	<u>\$(46,000)</u>	<u>\$(34,185)</u>	<u>\$239,583</u>
Ratio of earnings to fixed charges	N/A	N/A	N/A	N/A	173.9

Ratio of Earnings to Combined Fixed Charges and Preferred Stock Dividend Requirements

	<u>Year Ended December 31,</u>				
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
Earnings, as defined (from above)	\$(80,233)	\$(71,127)	\$(39,424)	\$(29,735)	\$240,969
Preferred stock dividend requirements	100	230	702	785	756
Earnings, as defined	<u>\$(80,133)</u>	<u>\$(70,897)</u>	<u>\$(38,722)</u>	<u>\$(28,950)</u>	<u>\$241,725</u>
Fixed charges (from above)	\$ 13,433	\$ 10,743	\$ 6,576	\$ 4,450	\$ 1,386
Preferred stock dividend requirements	100	230	702	785	756
Combined fixed charges and preferred stock dividend requirements	<u>\$ 13,533</u>	<u>\$ 10,973</u>	<u>\$ 7,278</u>	<u>\$ 5,235</u>	<u>\$ 2,142</u>
Excess (deficiency) of earnings to combined fixed charges and preferred stock dividend requirements	<u>\$(93,666)</u>	<u>\$(81,870)</u>	<u>\$(46,000)</u>	<u>\$(34,185)</u>	<u>\$239,583</u>
Ratio of earnings to combined fixed charges and preferred stock dividend requirements	N/A	N/A	N/A	N/A	100.2

For the purpose of calculating the ratio of earnings to fixed charges, earnings are defined as consolidated income from continuing operations before income taxes plus fixed charges. Fixed charges are the sum of interest of all indebtedness, and estimated interest within rental expense. We have no amortization of debt issuance costs or preference securities. The ratio of earnings to combined fixed charges and preferred stock dividend requirements includes the tax adjusted deemed dividend to preferred stockholders.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-102122 333-71608, and 333-121732) and in the related Prospectuses, and on Form S-8 pertaining to the 1989 Incentive Stock Plan and the 1992 Employee Stock Purchase Plan (No. 333-07707), the 1998 Incentive Stock Plan (No. 333-59633), the 2001 Nonstatutory Stock Plan and Employee Stock Purchase Plan (No. 333-42644), the 2001 Director Option Plan (No. 333-63398), the Calydon, Inc. Management Incentive and Retention Plan, as amended (No. 333- 71606), the 2001 Nonstatutory Stock Option Plan and the 2002 Employee Stock Purchase Plan (No. 333-91796), and the 2002 Employee Stock Purchase Plan and the 1998 Incentive Stock Plan (No. 333-1087) of Cell Genesys, Inc. of our reports dated February 24, 2005, with respect to the consolidated financial statements, management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Cell Genesys, Inc, included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 11, 2005

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Stephen A. Sherwin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cell Genesys, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 14, 2005

By: /s/ STEPHEN A. SHERWIN, M.D.

Name: Stephen A. Sherwin, M.D.
Title: Chairman of the Board and Chief
Executive Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Stephen A. Sherwin, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Cell Genesys, Inc. on Form 10-K for the year ended December 31, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of Cell Genesys, Inc.

Dated: March 14, 2005

By: /s/ STEPHEN A. SHERWIN, M.D
Name: Stephen A. Sherwin, M.D.
Title: Chairman of the Board and Chief
Executive Officer

I, Matthew J. Pfeffer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Cell Genesys, Inc. on Form 10-K for the year period ended December 31, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of Cell Genesys, Inc.

Dated: March 14, 2005

By: /s/ MATTHEW J. PFEFFER
Name: Matthew J. Pfeffer
Title: Vice President and Chief Financial Officer

SHAREHOLDER INFORMATION

Annual Meeting

The Annual Meeting of Stockholders will be held at 10:00 a.m., Tuesday, May 3, 2005, at the company's corporate headquarters.

Corporate Headquarters

500 Forbes Boulevard
South San Francisco,
California 94080
Tel: 650.266.3000
Fax: 650.266.3010

Corporate Website

For further information, the company's website provides current and historical information on Cell Genesys, its research and development programs, its clinical trials, investor relations, and career opportunities. This site is located at: www.cellgenesys.com

Investor Relations

General stockholder inquiries, including requests for the company's Annual Report to the SEC on Form 10-K should be directed to:

Investor Relations
Cell Genesys, Inc.
500 Forbes Boulevard
South San Francisco,
California 94080
Tel: 650-266-3200
Fax: 650-266-3010
E-mail: ir@cellgenesys.com

Transfer Agent and Registrar

Communications concerning stock transfer requirements, lost certificates and change of address should be directed to:
Equiserve Trust Company, N.A.
P.O. Box 43010
Providence,
Rhode Island 02940-3010
Tel: 816.843.4299

General Counsel

Wilson Sonsini Goodrich & Rosati
Professional Corporation
Palo Alto, California

Independent Auditors

Ernst & Young LLP
Palo Alto, California

Stock Listing

The company's common stock is traded over-the-counter on the Nasdaq National Market under the symbol: CEGE.

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Statements made about Cell Genesys and its subsidiaries herein other than statements of historical fact, including statements about the companies' progress and results of clinical trials, marketability of potential products and nature of product pipelines, technology, availability of financing and adequacy of capital resources, corporate partnerships, licenses and intellectual property, are forward-looking statements and are subject to a number of uncertainties that could cause actual results to differ materially from the statements made, including risks associated with the success of research, development and clinical programs, the regulatory approval process, competitive technologies and products, patents, corporate partnerships and the availability of additional financings. For additional information about these and other risks which may affect Cell Genesys and its subsidiaries, please see Cell Genesys' Annual Report on form 10-K for the year ended December 31, 2004 dated March 14, 2005, as well as Cell Genesys reports on Form 10-Q and 8-K and other reports filed from time to time with the Securities and Exchange Commission.



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