

# REGULATING GENE EXPRESSION TO TREAT DISEASE

Corgentech is focused on transcription factor decoys initially for the treatment of cardiovascular disease, cancer and inflammatory disease.



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Squibb agreed to fund a majority of the development expenses associated with E2F Decoy. Corgentech and Bristol-Myers Squibb will co-develop and co-promote E2F Decoy in the U.S., sharing profits equally. Bristol-Myers Squibb will register and sell E2F Decoy outside the U.S.

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### **Progress in Developing TF Decoys for Cancer and Inflammatory Diseases**

Corgentech has a pipeline of TF Decoys rapidly emerging from our proprietary technology and for which we have retained the rights. Our growing Decoy Bank enables us to identify target TFs, and design and optimize additional TF Decoys.

In 2003, Corgentech began preclinical study of HIF Decoys for treatment of cancer and continued preclinical investigation of NF-kB Decoy for inflammatory diseases, such as rheumatoid arthritis and dermatitis.

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### **Outlook on the Future**

The next year promises to be an exciting time for Corgentech, particularly in the area of advancing the clinical development and commercialization of E2F Decoy. We expect results from the pivotal Phase 3 trials of E2F Decoy for prevention of failure of bypass graft by early 2005. During 2004, we will initiate Phase 1/2 trials of E2F Decoy to prevent arterio-venous (AV) graft failure. These grafts are the physical connections between patients with end-stage renal disease and the dialysis machines required to cleanse their blood. Preclinical data suggests that E2F Decoy treatment can also reduce the high failure rate in AV grafts. Our clinical trial will initially enroll approximately 60 patients.

Our R&D plans for 2004 include preparing for clinical development of NF-kB Decoy for inflammatory diseases; demonstrating proof of concept of HIF Decoy for cancer; and utilizing the Decoy Bank to design and optimize more TF Decoys. In addition, we will pursue business development partnerships for our TF Decoys for inflammatory diseases and in-licensing opportunities for hospital-based and specialty therapeutics in cardiovascular, inflammation and oncology markets.

The innovation, expertise and dedication of our employees have made profound contributions to our swift progress. We want to thank our private stockholders for their support in the past and welcome all of our new public stockholders. We appreciate your continued support and look forward to this exciting year at Corgentech.

Sincerely,



John P. McLaughlin  
*President and Chief Executive Officer*

during bypass surgery. The therapy binds to and inhibits the E2F transcription factor, which is responsible for turning on genes that cause proliferation of smooth muscle cells. The build up of smooth muscle cells and cholesterol leads to arterial blockage and failure of bypass vein grafts.

Our program for E2F Decoy has strong preclinical and Phase 1 and Phase 2 clinical data on feasibility during cardiovascular and vascular surgery, as well as on safety and efficacy. For example, a statistically significant reduction of graft blockage was observed in a Phase 2 trial of E2F Decoy in CABG patients. Moreover, a Phase 1 trial of E2F Decoys in peripheral bypass graft patients showed significant inhibition of smooth muscle cell proliferation that leads to vascular graft failure.

Both of our large pivotal Phase 3 trials of E2F Decoy to prevent vein graft failure were fully enrolled in 2003 and are currently in the 12-month follow-up period. The PREVENT III trial is a Phase 3 study of E2F Decoy to prevent PBG failure in 1400 patients. The PREVENT IV trial is a Phase 3 study of E2F

### CORGENTECH'S PRODUCT PIPELINE



	Preclinical	Phase I	Phase II	Phase III
<b>CARDIOVASCULAR</b>				
<b>E2F Decoy</b>				
Peripheral Bypass Graft				
Coronary Bypass Graft				
Arterio-Venous Graft				
<b>INFLAMMATORY</b>				
<b>NF-kB Decoy</b>				
Rheumatoid Arthritis				
Dermatitis				
<b>ONCOLOGY</b>				
<b>HIF Decoy</b>				
Solid Tumors				

Decoy for the prevention of CABG failure in 2400 patients; an additional 600 CABG patients were enrolled as part of a post-approval follow-up study. Corgentech has received Fast Track status from the U.S. Food and Drug Administration (FDA) for E2F Decoys for the prevention of bypass graft failure. The Fast Track status affords expedited review by FDA.

In October 2003, we entered a world-wide collaborative agreement with Bristol-Myers Squibb for the development and commercialization of E2F Decoy. Under the terms of the arrangement, Bristol-Myers Squibb paid Corgentech \$45 million (\$25 million in cash and \$20 million in equity), with the potential for an additional \$205 million in clinical and regulatory milestone payments and up to \$320 million in milestone payments for attainment of agreed upon sales levels of E2F Decoy. In addition, Bristol-Myers


**LETTER TO  
STOCKHOLDERS**



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**To Our Stockholders,**

At Corgentech Inc. (Nasdaq: CGTK), we are proud of the remarkable scientific, clinical, business and financial achievements we have made over the past 12 months. Our lead therapeutic candidate, E2F Decoy, is in late-stage clinical development for an important cardiovascular indication, prevention of bypass graft failure, which is a significant unmet medical need and market opportunity. During 2003, we completed a significant collaborative agreement with Bristol-Myers Squibb for the joint development and commercialization of E2F Decoy worldwide. Furthermore, we concluded an initial public offering in February 2004, raising more than \$100 million of net cash proceeds, which was well received by the marketplace.

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**Innovative Technology and Experienced Leadership**

Corgentech is a biopharmaceutical company focused on discovering, developing and commercializing therapies that regulate gene expression to treat serious diseases characterized by large unmet medical needs. Our robust and versatile platform technology, Transcription Factor (TF) Decoys, is a potentially powerful new class of therapeutics that blocks the activity of multiple genes linked to a disease. Because abnormal gene expression is a fundamental cause of many diseases and because many diseases involve multiple genes, controlling the regulators of functionally related genes — the transcription factors — offers an attractive therapeutic approach. While our technology is capable of treating multiple diseases, our initial focus is on cardiovascular disease, inflammatory disease and cancer.

As of December 31, 2003, we had 37 issued patents, 37 pending patent applications and exclusive trade secrets covering our TF Decoy and delivery technology.

Our seasoned management team, experienced in successfully discovering, developing, registering, manufacturing and commercializing pharmaceuticals, biological therapeutics and medical devices, was enhanced with the additions of Dr. Daniel Gennevois as vice president of medical affairs, Thomas Yonker as vice president to manage product development and oversee our relationship with Bristol-Myers Squibb, and Nancy Donahue as vice president of cardiovascular marketing. Renowned thought-leaders and highly respected cardiovascular and vascular surgeons comprise our scientific and clinical advisory boards. During 2003, we moved to our new headquarters in South San Francisco, a larger facility at approximately 50,000 square feet at a lower cost per square foot than our previous building.

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**Advancing Clinical Development of E2F Decoys for Cardiovascular Indications**

Our innovative lead product candidate, E2F Decoy, is being studied in two pivotal Phase 3 clinical trials for preventing vein graft failure in patients undergoing coronary artery bypass grafts (CABG) in the heart and peripheral bypass grafts (PBG) in the leg. E2F Decoy therapy is a one-time treatment that occurs

**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, 2003

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NO. 000-50573

**CORGENTECH INC.**

(Exact Name of Registrant as specified in its Charter)

Delaware

(State or Other Jurisdiction of  
Incorporation or Organization)

77-0503399

(IRS Employer Identification Number)

650 Gateway Boulevard  
South San Francisco, California 94080  
(650) 624-9600

(Address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

**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 Per Share  
(Title of Class)

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 Exchange Act Rule 12b-2). Yes  No

The aggregate market value of the voting stock held by non-affiliates of the Registrant based upon the closing price of the common stock listed on the Nasdaq National Market on February 27, 2004 was \$226,504,875, based on a closing price of \$19.25 per share, excluding 15,963,805 shares of the Registrant's common stock held by current executive officers, directors and stockholders whose ownership exceeds 5% of the common stock outstanding at February 27, 2004. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant. The Registrant has elected to use February 27, 2004 as the calculation date, as on June 30, 2003 (the last business day of the Registrant's second fiscal quarter) the Registrant was a privately held concern.

The total number of shares outstanding of the Registrant's common stock as of February 27, 2004 was 27,730,292.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Definitive Proxy Statement, to be filed with the Commission pursuant to Regulation 14A in connection with the 2004 Annual Meeting of Stockholders, are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

Certain exhibits are incorporated herein by reference into Part IV of this Annual Report on Form 10-K.

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## PART I

### Forward-Looking Statements

This Annual Report on Form 10-K, including particularly the sections entitled "Business Risks," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipates," "believes," "continue," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," or the negative of these terms or other comparable terminology. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10-K is filed with the Securities and Exchange Commission.

### Item 1. Business

#### Overview

Corgentech is focused on the discovery, development and commercialization of a new class of therapeutics called transcription factor decoys, or TF decoys. Our TF decoys are synthetically manufactured short strands of DNA that specifically bind to and block the activity of their target transcription factors. Transcription factors are specialized DNA-binding proteins and are widely recognized as excellent therapeutic targets because they control gene expression and biological processes. Because abnormal gene expression is a fundamental cause of many diseases, controlling the regulators, the transcription factors, offers an attractive therapeutic approach. We believe that TF decoys may offer advantages over existing therapeutic approaches because a single TF decoy can target multiple genes involved in a specific disease process. We are focused on TF decoys initially for the treatment of cardiovascular disease, inflammatory disease, such as arthritis, and cancer.

We are creating a pipeline of novel therapeutics based on our proprietary TF decoy technology. Our lead product candidate, E2F Decoy, a combination drug and delivery device, is currently in two Phase 3 clinical trials for the prevention of vein graft failure. In September 2003, we completed patient enrollment for both of our Phase 3 clinical trials. We are also developing E2F Decoy for the prevention of arterio-venous, or AV, graft failure and intend to begin Phase 1/2 clinical trials for this indication in the first half of 2004. E2F Decoy has received Fast Track designation from the U.S. Food and Drug Administration, or FDA, for both the prevention of vein graft failure and AV graft failure. We have entered into a world-wide collaborative agreement with Bristol-Myers Squibb Company, or BMS, for the development and commercialization of E2F Decoy for all indications. We also have additional TF decoys in pre-clinical development for the treatment of inflammatory diseases and cancer.

As part of our collaboration with BMS, we retain the right to co-promote E2F Decoy in the United States and we intend to build a specialty sales force with BMS to support the sales of E2F Decoy in the United States. Because E2F Decoy will be used by physicians in a relatively concentrated market, we believe this market can be effectively covered with a specialty sales force of approximately 75 to 100 representatives. We will share 50% of the profits or losses from the sale of E2F Decoy in the United States and will receive royalties on all E2F Decoy sales outside of the United States. We have retained the commercialization rights to our other product candidates.

## **Scientific Background**

### *Transcription Factors Regulate Gene Expression*

The human genome is the complete set of DNA-encoded instructions that serves as the blueprint for all cellular structures and activities. The human genome is estimated to comprise approximately 30,000 genes. Genes are segments of DNA with specific sequences that direct the production of proteins which carry out critical biological functions.

The protein-coding instructions from genes are not transmitted directly from DNA to proteins. Instead, the information is transmitted indirectly through messenger RNA, or mRNA. mRNA is a transient intermediary molecule similar to a single strand of DNA that serves as the template for protein production. mRNA is produced in a highly regulated and essential process called transcription. Transcription plays a central role in gene expression and therefore represents an attractive control point for regulating the expression of genes.

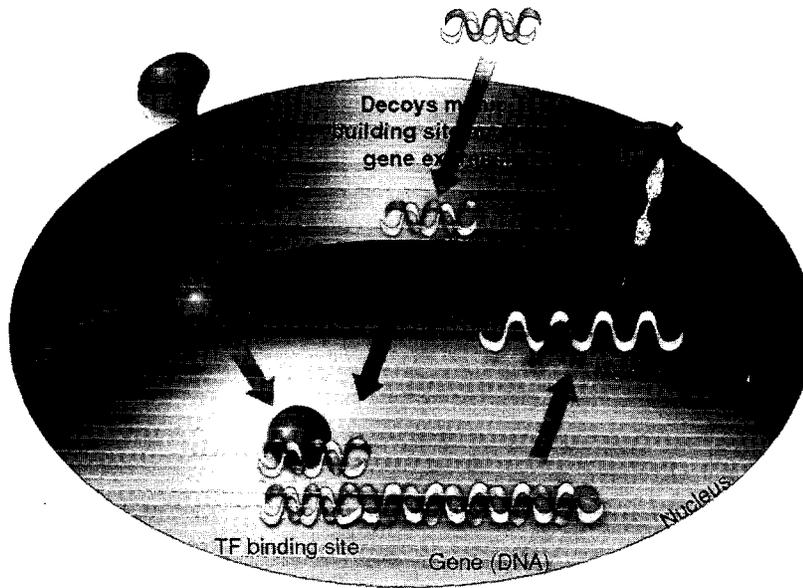
Transcription factors regulate gene expression by recognizing and binding to short stretches of a specific DNA sequence in the regulatory region of genes and controlling the transcription of RNA. Some transcription factors selectively regulate one or a few genes, whereas other transcription factors act more like master switches that activate multiple genes in a functional pathway. A set of genes activated by a single transcription factor share a similar DNA sequence called a transcription factor consensus sequence in their regulatory region. When a transcription factor is activated, it interacts with a specific binding site in its target genes, thereby initiating expression of an entire set of genes. Hundreds of transcription factors have been identified and characterized to date. There are estimated to be approximately 2,000 human transcription factors.

### *Gene Expression in Disease*

The human body is made up of specialized cells that perform different functions. Every cell in the body possesses approximately 30,000 genes that constitute the human genome. However, different subsets of genes are activated or turned on in different cell types, depending on the specific function of that cell type. In other words, the function or activity of a cell is controlled by the regulation of the expression of specific genes in that cell. Tight control of gene expression is paramount for the normal function of cells. Inappropriate gene activation, resulting in overexpression or underexpression of a protein or group of proteins, is an underlying cause of many diseases.

### **TF Decoys: A New Class of Therapeutics**

We have developed a novel and proprietary method for regulating gene expression through the inhibition of specific transcription factors. Our core technology involves the delivery of small strands of synthetically manufactured DNA called TF decoys as therapeutic agents. TF decoys mimic the binding site of the transcription factor. As a result, the transcription factor binds to the TF decoy, thereby preventing the transcription factor from binding to and activating the genes it regulates as illustrated below.



We have developed a proprietary method for the highly efficient delivery of TF decoys into cells and tissues without the use of potentially hazardous substances, using controlled uniform pressure. The delivery of these TF decoys can be adjusted by controlling three variables: pressure, duration of treatment and concentration of TF decoy. Our tests have demonstrated that we are able to deliver TF decoys to approximately 90% of the cells and tissues treated at a modest pressure of six pounds per square inch for ten minutes.

We believe that pressure treatment is a safe and highly effective method for delivery of TF decoys into cells; however, alternative delivery methods will expand the potential therapeutic indications for which TF decoys can be utilized. For use with future TF decoys, we are evaluating a number of different delivery technologies including several that rely upon peptides. The peptides are chemically linked to TF decoys, actively transporting the TF decoy and peptide constructs into the cell. Early work with peptide delivery has produced promising results.

#### **The Advantages of Our TF Decoy Platform**

We believe our TF decoys may offer several advantages over existing therapeutic approaches:

- *Broadly Applicable to a Variety of Diseases.* Because inappropriate expression of genes plays an important role in most diseases, our TF decoy technology allows us to address a wide range of diseases.
- *Potentially More Effective Treatment.* Many diseases are caused by the inappropriate expression of multiple functionally related genes. By intervening at the transcription factor level, TF decoys prevent the expression of multiple, related genes that are turned on when they should not be, thereby potentially providing more effective treatment than therapeutics that target a single gene.
- *Short Development Cycle.* In contrast to the year or more required to discover and optimize small molecule therapeutics, TF decoys can be designed based on known transcription factor binding site information and be ready for preclinical testing in a matter of one or two months.

- *Ease of Manufacturing.* In contrast to the typical biotechnology therapeutic product, TF decoys can be easily synthesized and purified at a reasonable cost. Our synthesis technology renders TF decoys resistant to degradation which simplifies the storage and distribution of these products.

## Product Pipeline

Our lead product candidate, E2F Decoy, is in Phase 3 clinical trials for the prevention of bypass graft failure. We are conducting two Phase 3 clinical trials to support this indication: one in Coronary Artery Bypass Graft, or CABG, and one in Peripheral Artery Bypass Graft, or PBG. In addition, we intend to initiate a Phase 1/2 clinical trial evaluating E2F Decoy for the prevention of AV graft failure in the first half of 2004. Our second TF decoy, NF- $\kappa$ B Decoy, has shown that it can reduce inflammation in preclinical models. In addition, we are studying TF decoys in various oncology indications and have initiated preclinical studies in several cancer models.

Product Candidate	Clinical Indications	Development Status	Corgentech Commercialization Rights
E2F Decoy	Bypass Graft Failure	Phase 3 CABG enrollment completed Phase 3 PBG enrollment completed	50%-50% co-promote with BMS in the United States and royalties outside the United States
E2F Decoy	AV Graft Failure	Phase 1/2 trial planned for the first half of 2004	Same as above
NF- B Decoy	Inflammatory Diseases	Preclinical	100% Worldwide
Cancer Decoys	Cancer	Preclinical	100% Worldwide

### *E2F Decoy for the Prevention of Bypass Graft Failure*

#### *Bypass Surgery and Bypass Graft Failure*

The arteries that transport blood to the heart muscle and legs can become clogged by plaque which is a build up of smooth muscle cells, fat and cholesterol on the inside walls of arteries. This build-up blocks or narrows arteries and prevents blood and oxygen from reaching the heart or limb. Bypass surgery is performed to reroute blood around clogged arteries thereby improving the flow of blood and oxygen to the heart in the case of CABG or leg in the case of PBG. Bypass surgery is one of the most common surgical procedures in the United States.

While CABG and PBG surgeries are very effective procedures for restoring blood flow to otherwise oxygen starved tissue, these grafts often fail. The veins typically used in bypass surgery are thin walled vessels that are designed for a low-pressure environment. Arteries are thick walled vessels that have evolved to handle the high pressure flow of blood from the heart. When the vein grafts used to bypass a blocked artery are exposed to the high pressure of arterial flow, there is significant stress on the thin wall of the veins. The vein responds to this perceived injury by causing its walls to thicken. Unfortunately, the vein does so in a manner that often leads to failure of the bypass graft. Smooth muscle cells proliferate in the middle layer of the vein wall and migrate to the inner surface of the vein over a two-week period following surgery, in a process known as neointimal hyperplasia. The resulting accumulation of activated smooth muscle cells secrete inflammatory and growth factors leading to plaque build up and graft failure over time. Currently, there is no approved pharmacologic therapy for the prevention of vein graft failure.

In 2000, approximately 375,000 coronary bypass graft procedures were performed in the United States with an additional 280,000 performed in Europe and 15,000 in Japan. Approximately 19% of bypass grafts fail at one year with the failure rate climbing to about 50% between years ten and fifteen.

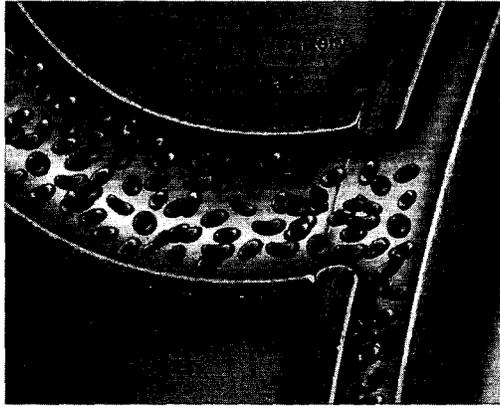
The ramifications of failure for CABG patients include heart attack, chest pain, congestive heart failure, irregular heartbeat and death. A repeat of a CABG procedure to repair a failing or failed graft is a technically more difficult procedure with mortality rates of three to five times higher than the original CABG procedure. During 2002, in the United States, the average hospital charge for a repeat CABG surgery was about \$80,000.

In 2000, approximately 120,000 peripheral bypass graft procedures were performed in the United States with an additional 106,000 performed in Europe and 55,000 in Japan. Approximately 20% to 30% of vein grafts fail within one year and up to 50% fail by five years. The consequences of PBG failure for the patients are grave disability and discomfort, poor wound healing, gangrene, amputation of some or all of the limb and death. The surgery to repair a failed or failing peripheral graft is a technically more difficult procedure with an increased risk of complications following the repair surgery. In 2002, typical hospital charges for surgery to repair a failed or failing peripheral graft averaged \$34,000 in the United States.

*E2F Decoy: Our Solution for the Prevention of Bypass Graft Failure*

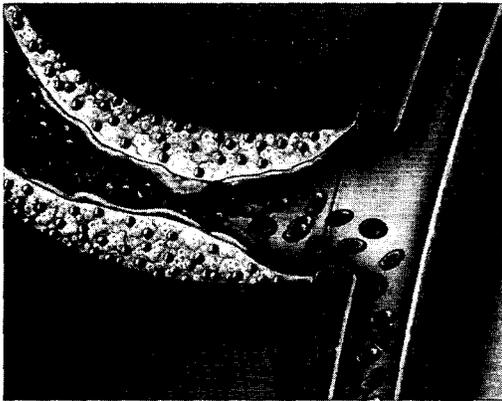
E2F Decoy prevents bypass vein graft failure by binding to and inactivating the E2F transcription factor. E2F is responsible for the activation of numerous genes involved in the growth and proliferation of certain cells, including the smooth muscle cells that comprise neointimal hyperplasia. E2F Decoy treatment, by blocking the E2F transcription factor, prevents the activation of the genes responsible for the proliferation of the smooth muscle cells that cause neointimal hyperplasia. E2F Decoy also causes the graft biology to adapt to the high-pressure environment of arterial blood flow in a more favorable manner. Rather than the formation of neointimal hyperplasia on the inner surface of the vein, the cells in the middle layer of the vein lengthen and thicken, creating a new and stronger architecture in the vein that more closely resembles an artery, the blood vessel that the graft is designed to replace.

The following graphics present a conceptual rendering of the effect of E2F Decoy on vein grafts.



*Thin walled vein used in bypass graft procedures immediately after the surgery*

Untreated



*Bypass vein graft with neointimal hyperplasia and plaque build up leading to blockage or failure of the graft*

E2F Decoy Treated



*E2F Decoy prevents the formation of neointimal hyperplasia and instead causes the vein wall to thicken and become stronger, looking more like the artery that the graft is designed to bypass*

E2F Decoy treatment involves only a single administration and is easily integrated into current surgical practice. Typically in bypass surgery, the vein that will serve as the bypass graft is harvested from the leg and checked for holes and lesions. The surgeon then sets the vein aside and prepares the bypass site, the chest or leg, for implantation of the bypass graft. E2F Decoy treatment occurs in the operating room after the vein is harvested and before implantation. After harvest and inspection, the vein is placed in the treatment chamber of our delivery device, the chamber is filled with E2F Decoy, and uniform pressure is introduced for ten minutes. This pressure causes E2F Decoy to enter into the cells of the vein. After ten minutes of treatment, the vein graft is removed from the chamber, excess E2F Decoy is rinsed off, and the treated vein is ready for surgical implantation at the appropriate

peripheral or coronary site using traditional surgical techniques. There are no further treatments. We believe that E2F Decoy will be viewed as an attractive and convenient therapy by surgeons for several reasons, including:

- *Safety:* Because the treatment of the vein occurs outside the body and the vein is rinsed before use as a bypass graft, the amount of systemic exposure to E2F Decoy is minimal. To date, the safety profile of E2F Decoy treatment have been excellent. Our data and safety monitoring boards for each Phase 3 clinical trial has reviewed the safety data from more than 1,000 patients in each trial and recommended proceeding with the trial.
- *One-time Treatment:* Neointimal hyperplasia, the major underlying cause of graft failure, occurs primarily during the first two weeks following surgery. Because E2F Decoy is present during this period, a one time treatment is sufficient.
- *No Change in Surgical Technique:* The treatment does not require any alteration of surgical technique during vein harvest or implantation.
- *No Change in Standard Operating Room Equipment:* There is no change with respect to other standard equipment in the operating room. E2F Decoy treatment can be administered whether the bypass patient is on a heart-lung bypass machine or not.

#### ***E2F Decoy: U.S. Regulatory Status***

We are seeking FDA approval and have received Fast Track status for the use of E2F Decoy to prevent the failure of bypass grafts. We have discussed with the FDA, and the FDA has agreed, that satisfactory results from the two Phase 3 clinical trials will be sufficient to support an approval for prevention of bypass graft failure, provided that after approval we monitor CABG patients for five years after enrollment to track major cardiac events to confirm a positive treatment effect. In addition, we intend to submit a 510(k) premarket notification to the FDA for review and clearance of the pressure delivery device.

#### ***E2F Decoy Clinical Trials for CABG***

##### ***E2F Decoy: Phase 3 CABG Trial***

We are conducting a randomized, double blind, placebo-controlled Phase 3 clinical trial involving 2,400 patients undergoing CABG at over 100 centers. Each patient must require at least two vein grafts during their CABG surgery. Patients are randomized to undergo a one-time vein graft treatment with E2F Decoy or placebo. Patients will be evaluated for clinical signs and safety at 30 days. The primary endpoint is the percent reduction in the incidence of critical graft stenosis between the E2F Decoy treated and placebo groups. Critical graft stenosis is defined in the trial as blockage of the graft of 75% or greater as measured by quantitative coronary angiography at 12 months. E2F Decoy's Fast Track status allows us to use the angiographic results as the primary endpoint. Safety will be assessed by monitoring adverse events, post-operative complications and laboratory abnormalities. This Phase 3 clinical trial completed patient enrollment in August 2003 and is expected to conclude in the first quarter of 2005.

##### ***E2F Decoy: Post-Approval CABG Confirmatory Trial***

The FDA is requiring us to conduct a post-approval confirmatory trial. This trial will include the 2,400 patients in the Phase 3 CABG trial plus an additional 600 CABG patients. We completed enrollment of the additional 600 CABG patients in October 2003. We will follow these 3,000 CABG patients for up to five years monitoring annually the incidence of death, heart attack and repeat CABG surgery.

### *E2F Decoy: Phase 2 CABG Trial*

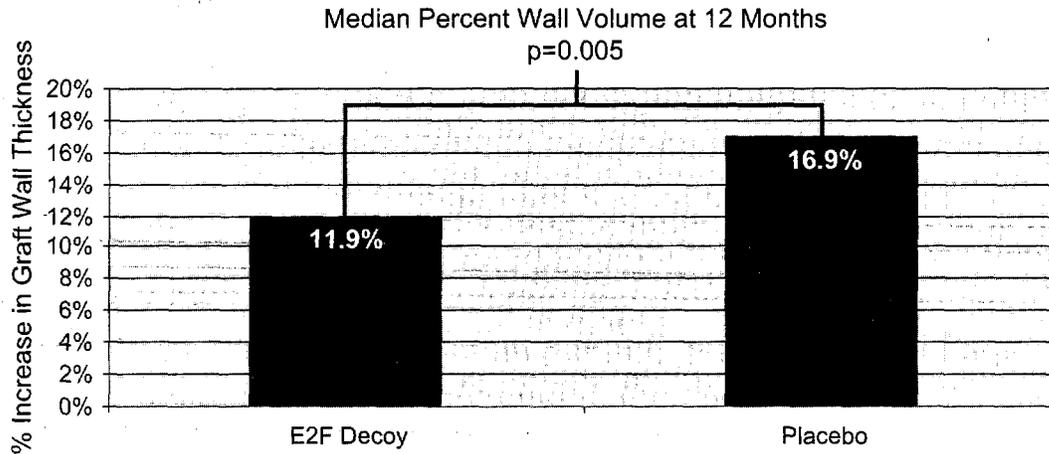
In 2001, we completed a randomized, double-blind, placebo-controlled Phase 2 clinical trial investigating the safety and ease of incorporation of E2F Decoy treatment into the procedure. Two hundred patients were enrolled and were randomized evenly between the E2F Decoy-treated arm and the placebo group. Among the entry criteria, each patient must have required two or more vein grafts. An efficacy endpoint in the study was the incidence of critical graft stenosis at 12 months after CABG surgery as measured by quantitative coronary angiography. The Stanford University School of Medicine Core Cardiology Laboratory analyzed our results in a blinded fashion.

In this Phase 2 clinical trial we observed a statistically significant relative reduction in graft failure in a per graft analysis defined as graft stenosis of 75% or more in the E2F Decoy-treated group compared to the untreated patients. A number of patients returned for an angiogram earlier than the specified 12-month timeframe because they experienced adverse symptoms. When those patients returning early for an angiogram are included in the analysis, as they will be for our analysis of the Phase 3 clinical trial, the relative reduction in graft failure increased from 30% to 32% and the p-value improved from 0.03 to 0.02. A p-value is a measure of the probability that a value greater than or equal to the observed value occurred strictly by chance. A lower p-value indicates greater confidence in the result. The results of this study, as shown in the table below, demonstrate a statistically significant reduction in the blockages that lead to graft failure. We believe these results, if confirmed in Phase 3 clinical trials, will result in adoption of E2F Decoy for the prevention of bypass graft failure.

<i>Per Graft Analysis</i>				
<b>Endpoint</b>	<b>Placebo</b>	<b>E2F Decoy</b>	<b>Relative Risk Reduction</b>	<b>p-Value</b>
75% or more stenosis	38.7%	27.3%	30%	0.03
75% or more stenosis including early angiograms	40.0%	27.7%	32%	0.02

We subsequently performed an analysis of the angiographic results in which patients were categorized by quartile (i.e., 0% to 25%, 25% to 50%, 50% to 75% or 75% to 100% blockage) according to their graft with the most blockage. The purpose of this more sensitive analysis was to examine the benefit of E2F Decoy on a per patient basis. This analysis revealed a statistically significant difference in favor of E2F Decoy treatment ( $p=0.006$ ).

In addition, in a subgroup of patients we measured the overall thickening of the vein graft wall as an index of graft remodeling using intravascular ultrasound, or IVUS. Because IVUS can be dangerous to patients with grafts that are diseased, only grafts without disease were selected for this subgroup to minimize any risk to the patient. Excluding diseased grafts from this analysis imposes a bias against seeing a treatment effect by E2F Decoy, because the greatest treatment benefit between the E2F Decoy and placebo groups should be observed in the most diseased grafts. Notwithstanding this adverse bias, the results show a statistically significant reduction in graft wall volume in the E2F Decoy group ( $p=0.005$ ) at 12 months after surgery, suggesting that E2F Decoy has a potent inhibitory effect on the formation of neointimal hyperplasia.



In summary, this Phase 2 clinical trial demonstrated a statistically significant reduction of critical graft stenosis in E2F Decoy treated patients in a per graft analysis of angiograms obtained 12 months after treatment. Further, the angiographic data, when analyzed on a per patient basis by quartile, showed a highly statistically significant difference in favor of E2F Decoy treatment. These two analyses support that E2F Decoy treatment can prevent the pathology that causes graft failure. The IVUS data, which demonstrated a significant reduction in graft wall volume among E2F Decoy treated patients, supports that E2F Decoy acts by redirecting the graft biology away from a build up of neointimal hyperplasia and toward arterialization of the vein graft creating a bypass vein graft that will last longer. In addition, in this Phase 2 clinical trial, E2F Decoy was shown to be safe.

#### ***E2F Decoy: Clinical Trials for PBG***

##### *E2F Decoy: Phase 3 PBG Trial*

We are conducting a randomized, double blind, placebo-controlled Phase 3 clinical trial involving 1,400 patients undergoing PBG surgery at approximately 80 centers. Patients are randomized to undergo a one-time treatment with E2F Decoy or placebo. The primary endpoint is the time to the first procedure performed to improve blood flow through a failed or failing graft or an amputation of the treated limb within the 12 months following surgery. To determine if and when a graft fails, patients will be assessed at 1, 3, 6, and 12 months after bypass surgery.

In this trial, we have excluded technical failures from the primary endpoint analysis. Technical failures sometimes occur during or shortly after the bypass graft surgery and are associated with limitations of the vein graft, insufficient blood flow into and out of the graft, or the surgical procedure. These types of failures occur before neointimal hyperplasia develops and are therefore not expected to be impacted by E2F Decoy treatment. A panel of vascular surgeons is reviewing in a blinded manner all cases where the graft is repaired to determine which are technical failures.

Safety will be assessed by monitoring adverse events, post-operative complications, and laboratory abnormalities. This trial enrolled its last patient in September 2003. It is expected to conclude in the fourth quarter of 2004.

### *E2F Decoy: Phase 1/2 PBG Trial*

We have completed a randomized, blinded, placebo-controlled Phase 1/2 PBG clinical trial investigating the safety and ease of incorporation of E2F Decoy treatment into the bypass surgical procedure. Initially, five patients were enrolled in a non-blinded fashion. Upon analysis of laboratory and safety data that showed no drug-related adverse events in these patients, 41 additional patients were enrolled at Harvard's Brigham and Women's Hospital under blinded conditions. Prior to operation, patients were randomly assigned to receive either an untreated graft or an E2F Decoy-treated graft.

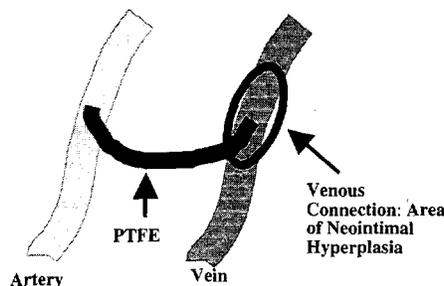
The primary endpoints of the Phase 1/2 clinical trial were safety and the ease with which E2F Decoy treatment could be incorporated into the bypass surgical procedure. All patients randomized into the trial were included in the safety analysis. Post-operative complications were comparable among the three study arms. There were no E2F Decoy treatment-related adverse events. No significant differences in complete blood count or blood chemistry measurements were detected among the three study groups either during the first post-operative week or at one month following surgery. E2F Decoy treatment was easily integrated into current surgical practice.

The results of our Phase 2 CABG clinical trial and Phase 1/2 PBG clinical trial do not necessarily predict future clinical trial results and our Phase 3 clinical trials may fail to produce results satisfactory to the FDA or foreign regulatory authorities.

### *E2F Decoy for the Prevention of AV Graft Failure*

#### *AV Graft Failure*

In 2001, there were more than 300,000 patients in the United States with severe kidney disease known as end stage renal disease, who require vascular access for dialysis treatment. Approximately 100,000 patients per year receive new or revised AV grafts. An AV graft composed of a synthetic material, a plastic known as polytetrafluoroethylene, or PTFE, is used to connect an artery and vein in the arm of the dialysis patient, as illustrated below. The dialysis machine is connected via a catheter to the PTFE conduit.



Over half of these AV grafts fail within six months and 95% fail within 24 months. The majority of these failures are due to narrowing and blockage at the venous connection. The primary cause of failure of these grafts is neointimal hyperplasia, similar to that seen in bypass vein grafts. According to the 1999 Annual Report of the United States Renal Data System, the leading cause of morbidity in these patients is related to vascular access placement and the resulting complications. Failure of vascular access conduits accounts for 25% of the hospitalizations of these patients and costs an estimated \$1 billion annually in the United States alone.

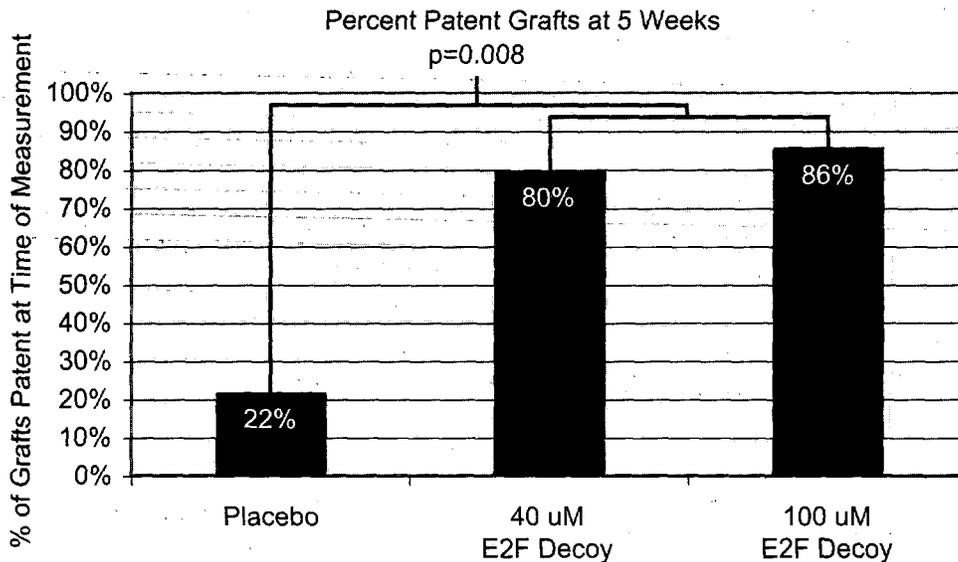
### *E2F Decoy: Phase 1/2 AV Graft Trial*

We intend to initiate a Phase 1/2 clinical trial investigating the use of E2F Decoy to prevent the failure of AV grafts in the first half of 2004. The FDA reviewed the protocol and we are proceeding

with this trial. It will be a 60 patient placebo-controlled trial with the patients evenly divided between E2F Decoy treated and untreated groups. We believe the high and rapid failure rate of AV grafts should permit us to conduct smaller and faster clinical trials than is typically required for other indications.

*Preclinical Data*

We have conducted preclinical studies showing that treatment with E2F Decoy can prevent the build up of neointimal hyperplasia that leads to the failure of these grafts. In a porcine animal model, PTFE conduits were surgically engrafted to the carotid artery and jugular vein. Before the PTFE was sewn to the venous connection, the most common point of failure in these grafts, the venous connection was treated either with placebo, 40 micromolar concentration of E2F Decoy or 100 micromolar concentration of E2F Decoy. As shown in the chart, 80% and 86% of the E2F Decoy treated grafts were patent, meaning blood was flowing through them, at five weeks after surgery compared to 22% of the placebo treated grafts. This result was statistically significant ( $p=0.008$ ).



**Our Preclinical Programs**

*NF-κB Decoy*

The transcription factor Nuclear Factor Kappa B, or NF-κB, is an important regulator of many genes involved in the control of inflammation, immune response, and cell apoptosis or cell death. There is scientific data in literature indicating that interruption of the NF-κB signaling pathway inhibits rheumatoid arthritis, osteoarthritis, dermatitis and interstitial cystitis.

The family members of NF-κB fall into two major groups: complexes which are capable of turning on the inflammation genes, and a complex which is not capable of turning on the inflammation genes regulated by this transcription factor and has an anti-inflammatory effect. Blockade of both groups of NF-κB halts not only the inflammatory response but also the anti-inflammatory response.

We have developed a TF decoy that binds to the NF-κB transcription factor with a high degree of specificity. In addition, our NF-κB Decoy preferentially blocks the complexes responsible for turning on the inflammatory genes. We have studied in numerous preclinical animal models the efficacy of this NF-κB Decoy. The decoy that blocks preferentially the complexes of NF-κB most responsible for turning on the pro-inflammatory genes reduces swelling significantly compared to a control decoy or a decoy that blocks both complexes of NF-κB. These results demonstrate the greater potential efficacy of

our NF- $\kappa$ B Decoy. We are currently optimizing the dosing and administration of the selective NF- $\kappa$ B Decoy.

### ***Cancer Decoys***

It is well established scientifically that cancer cells have abnormal gene expression patterns compared with normal cells. Many gene-expression analyses are undertaken with the notion that the key target genes will be abnormal or over expressed, and that inhibition of these over-expressed genes will be beneficial. However, we believe that the very large number of genes related to cancer are controlled by a limited number of transcription factors that are overactive in many human cancers. We believe that these transcription factors offer the most direct and promising targets for treating cancer.

We have focused our cancer decoy efforts on the transcription factor, Hypoxia-inducible factor, or HIF, which has been identified as an excellent target in oncology. HIF is a key transcription factor regulator of the response to hypoxia, or a lack of sufficient oxygen, that is activated in a broad range of cancers including brain, breast, cervical, esophageal and ovarian cancers. Chronic hypoxia is associated with angiogenesis (growth of blood vessels to feed the tumors) and tumor progression. Moreover, HIF activity is correlated with treatment failure and mortality. HIF plays a key role in tumor progression, turning on not only the genes required for angiogenesis, such as vascular endothelial growth factor, or VEGF (a validated target for anti-tumor therapy), but also the genes that allow the cell to adapt to hypoxia and survive, such as growth factors and energy/metabolism genes. Thus, blockade of HIF will inhibit not only angiogenesis but also tumor growth and survival making it an attractive target for certain cancers.

While not currently the focus of our cancer program, we believe that both E2F and NF- $\kappa$ B are also excellent targets for anticancer drugs.

### **Our Research Programs**

#### ***E2F Decoy Treatment to Prevent Restenosis in Arteries***

Restenosis is a re-narrowing or blockage of an artery at the same site where treatment, such as an angioplasty or stent procedure, has already taken place. There are two properties that make E2F Decoy an attractive pharmaceutical to prevent restenosis. First, E2F Decoy treatment prevents the proliferation of smooth muscle cells that cause restenosis without causing the cells to die. Most drugs that inhibit the proliferation of smooth muscle cells cause some cell death. Second, E2F Decoy targets the proliferation of smooth muscle cells that cause restenosis, but does not block the proliferation of endothelial cells, thereby allowing normal endothelial healing. Rapid, successful endothelial healing is critical because it prevents smooth muscle proliferation and lines the vessel with a surface that reduces the risk of formation of blood clots.

Using an animal model of restenosis, we have shown that a one-time treatment with E2F Decoy helped keep the artery open and reduced the build up of plaque when compared to treatment with a control as measured using ultrasound at 30 days. The properties of E2F Decoy and this data suggest that it could be useful as a coating on stents or balloons used in angioplasty. These markets represent a substantial commercial opportunity.

#### ***Corgentech Decoy Trust***

Our research group has established a unique and proprietary approach to rapidly identify and analyze the expression patterns and regulatory regions of human genes in order to identify key target transcription factors, transcription factor binding sites and to design potential TF decoys. This continuously expanding and updated dataset is our Decoy Trust that enables us to rapidly generate and

optimize TF decoys. We have filed several patent applications on this improved method for target selection and decoy design and optimization.

### **Corporate Strategy**

Our objective is to create a fully-integrated biopharmaceutical company focused on the discovery, development and commercialization of TF decoys. Our initial focus is in the areas of cardiovascular disease, inflammatory disease, such as arthritis, and cancer which we believe represent large market opportunities with unmet medical needs. Key elements of our strategy include:

- *Maximize Commercial Potential of E2F Decoy.* We are devoting most of our efforts to completing the clinical development of E2F Decoy and, assuming satisfactory clinical data, preparing for the registration and commercial launch of the product. We are also preparing to conduct clinical trials studying E2F Decoy treatment to prevent the failure of arterio-venous grafts.
- *Develop Additional TF Decoys.* We have already designed TF decoys for inflammatory disease and cancer. We will conduct additional preclinical testing to ready one or more of these TF decoys for clinical testing. Leveraging our proprietary technologies, we will develop additional TF decoys.
- *Establish Specialized Sales and Marketing Capabilities.* We intend to build a sales force with BMS of approximately 75 to 100 sales representatives to commercialize E2F Decoy to cardiothoracic and vascular surgeons in the United States.

### **Sales and Marketing**

Our plan is to develop our own specialized domestic sales and marketing infrastructure to commercialize E2F Decoy and other products that we develop in the future. We have hired a Vice President for Business Development and Commercial Operations with significant experience in sales and marketing roles at large pharmaceutical companies to lead our commercialization efforts. We will begin to recruit our domestic sales force in late 2004.

As part of our collaboration with BMS, we expect to focus our sales and marketing efforts for E2F Decoy on cardiothoracic and vascular surgeons. These two surgical specialties in the United States are relatively small. We estimate that there are approximately 6,300 cardiothoracic and vascular surgeons in the United States. These surgeons perform most of the CABG and PBG surgeries as well as the placement of AV grafts. Equally important, these surgeons are concentrated in a small group of hospitals. For example, we estimate that CABG surgery is performed at approximately 1,200 hospitals in the United States, yet about 700 of those hospitals account for 90% of the patients. While slightly more diverse, PBG surgery is performed at an estimated 2,900 hospitals in the United States, with 90% of those patients treated in about 1,500 hospitals. Because of the small size of our target professional audience in the United States and their location in hospitals, we believe that we can best serve this market through a relatively small, dedicated specialty sales force. We expect that this sales force will consist of approximately 75 to 100 representatives.

Outside the United States, we currently plan to market and sell our products that receive regulatory approval through established industry participants. We have granted BMS exclusive commercialization rights with respect to E2F Decoy outside the United States. However, we may establish our own sales and marketing organization for future products in key markets, including the European Union.

In the future, we expect some of our products will compete in markets with larger physician audiences requiring a more sizable sales force. We will form partnerships with other companies where partnering offers advantages in marketing reach and leverages existing physician relationships. In

hospital-based sales markets and other markets that involve a physician audience that can be served by a specialty sales force, we expect to reserve a significant role in marketing for ourselves.

## **Manufacturing**

We do not own facilities for the manufacture of material for clinical or commercial use and intend to rely on contract manufacturers to produce such products initially. We have personnel experienced in outsourced manufacturing to oversee the production of E2F Decoy and future products that we may develop.

The manufacturing process for E2F Decoy consists of the chemical synthesis and purification of each of the two short strands of DNA and the combination of these two strands to form the active pharmaceutical ingredient, E2F Decoy. Each of these steps involves a relatively common chemical engineering process similar to small molecule manufacture. The raw materials that are required to manufacture E2F Decoy are generally available from a number of suppliers.

We rely on third parties to supply us with E2F Decoy and its related device. We do not have agreements with these third parties which obligate them to provide us with any products for future clinical trials or future commercial sales.

The manufacture of the two strands comprising E2F Decoy is currently performed by Avecia Biotechnology. Most of the clinical supply of the two strands comprising E2F Decoy was synthesized at Avecia's facility in Milford, Massachusetts. More recent supplies of clinical material and commercial materials have been and will be sourced from Avecia's plant in Grangemouth, Scotland. We are in the process of negotiating an agreement with Avecia to supply us with our commercial requirements for E2F Decoy.

The two strands that comprise E2F Decoy are combined and filled into vials by Hollister-Stier at its facility in Spokane, Washington. We are also negotiating with Hollister-Stier to supply our commercial needs.

With respect to the drug delivery device, most of the components are fabricated for us by third parties. The pressure syringe component of our delivery device, the most complex component, is manufactured by Merit Medical Systems. This component is approved on a worldwide basis. We are also negotiating with Merit Medical Systems to supply our commercial needs. We have contracted for the manufacture of the other components of the device, the provision of sterilization services, and the assembly of our products' components into a final kit.

It is possible that either we or BMS may perform some of these functions in the future.

## **License Agreements**

### ***Bristol-Myers Squibb Company***

In October 2003, we entered into agreements with BMS to develop, manufacture and commercialize E2F Decoy for the prevention of bypass graft failure, AV graft failure and for other animal and human uses. Under the terms of the agreements:

- Upon execution of the collaboration arrangement in October 2003, BMS paid us \$45 million, consisting of \$25 million in consideration for license and distribution rights granted to BMS and \$20 million for 2,079,002 shares of our Series D preferred stock;
- BMS will co-promote E2F Decoy with us in the United States and will share equally with us in profits and losses from the commercialization of E2F Decoy products in the United States, with BMS having the right to record all United States product sales;

- BMS will commercialize E2F Decoy outside the United States pursuant to an exclusive license and pay us a royalty on net sales;
- BMS will fund a majority of the ongoing costs of developing E2F Decoy for CABG, PBG and AV graft failure, including costs incurred in connection with performing nonclinical and clinical studies of E2F Decoy for these indications as well as costs of certain related manufacturing, supply and other activities;
- BMS is potentially obligated to pay us up to \$205 million in milestone payments based on the achievement of worldwide regulatory submissions and approvals for the initial indications of E2F Decoy;
- BMS is potentially obligated to pay us up to \$320 million in milestone payments based upon attainment of agreed upon sales levels of E2F Decoy; and
- BMS may terminate the collaboration relationship in whole or in part upon six months prior notice.

Under the agreements, each party will report its development costs incurred on a quarterly basis and the parties will make reconciling payments to effect the agreed apportionment of such costs after the end of each quarter. During the three months and the year ended December 31, 2003, we incurred research and development expenses for E2F Decoy of approximately \$10 million and \$41.2 million, respectively. In October 2003, we entered into our collaboration agreement with BMS, under which BMS is obligated to fund a majority of the ongoing costs of developing E2F Decoy for CABG, PBG and AV graft failure. During the three months ended December 31, 2003, we recorded approximately \$6.9 million in reimbursable expenses due from BMS, as contract revenue from related party.

Under the agreements, the parties' sharing of profits and losses from the commercialization of E2F Decoy in the United States and the payment of royalties to us by BMS based on net sales of E2F Decoy outside the United States extends, on a country-by-country basis, until the later of 10 years after commercial launch or the expiration of the patent rights licensed to BMS in each particular country.

The collaboration is governed by a joint steering committee, consisting of an equal number of our representatives and BMS representatives. There are also working groups with representation from both parties that have responsibility over development and regulatory, manufacturing, finance and commercialization matters. Ultimate decision-making authority is vested in us as to some matters and in BMS as to other matters. A third category of decisions require the approval of both us and BMS. Outside the United States, ultimate decision-making authority as to most matters is vested in BMS.

***The Board of Trustees of the Leland Stanford Junior University***

We have an agreement with The Board of Trustees of the Leland Stanford Junior University, or Stanford, for an exclusive worldwide license under patents concerning the use of pressure to deliver TF decoys and other therapeutics into cells. We have the right to grant sublicenses under this agreement. In exchange for the rights licensed from Stanford, we paid Stanford an up-front license fee of \$50,000 and issued Stanford 38,315 shares of our common stock. In addition, through December 31, 2003 we have paid Stanford \$1,622,500 in royalty payments, for the achievement of milestones and sublicense revenue. We also agreed to pay Stanford an additional \$150,000 upon FDA approval of a pressure delivery device. We further agreed to pay Stanford an annual minimum royalty of \$20,000 per year for the life of the agreement. We also agreed to pay royalties to Stanford based on net sales of TF decoys and other products using pressure technology sold by us, our affiliates or sublicensees. Our royalty obligation extends on a country-by-country basis until the later of seven years, if no licensed patent issues, or expiration of the last-to-expire patent licensed from Stanford. In addition, we agreed to pay sublicense revenues to Stanford with respect to any upfront payments and research, development, or regulatory milestone payments, which includes such payments from BMS, that we receive for TF decoys and other products using pressure technology. There are no other milestone payments due to Stanford

under this agreement. Upon the expiration of the last-to-expire patent, the agreement expires and we have no further royalty obligation to Stanford.

#### ***The Brigham and Women's Hospital, Inc.***

We have an agreement with The Brigham and Women's Hospital, Inc., or BWH, for an exclusive worldwide license under patents and know-how concerning TF decoys and other therapeutics to treat and prevent diseases. Subject to the prior approval of BWH, we have the right to grant sublicenses under this agreement. In exchange for the rights licensed from BWH, we paid BWH an up-front license fee of \$50,000 and issued BWH 56,250 shares of our common stock. In addition, through December 31, 2003 we have paid BWH \$1,622,500 in royalty payments, for the achievement of milestones and sublicense revenue. We also agreed to pay BWH an additional \$150,000 upon FDA approval of E2F Decoy. We further agreed to pay BWH an annual minimum royalty of \$20,000 per year for the life of the agreement. We also agreed to pay royalties to BWH based on net sales of TF decoys sold by us, our affiliates or sublicensees. Our royalty obligation extends on a country-by-country basis until the later of seven years, if no licensed patent issues, or the expiration of the last-to-expire patent licensed from BWH. In addition, we agreed to pay sublicense revenues to BWH with respect to any upfront payments and research, development or regulatory filing milestones payments, which includes such payments from BMS, or license maintenance fees that we receive for TF decoys. There are no other milestone payments due to BWH under this agreement. Upon the expiration of the last-to-expire patent, the agreement expires and we have no further royalty obligation to BWH.

#### **Intellectual Property**

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of December 31, 2003, we had 37 issued United States and foreign patents and 37 pending United States and foreign patent applications. Most patents and patent applications can be roughly grouped into two families: pressure-mediated delivery of TF decoys, and *in vivo* use of TF decoys, licensed from Stanford and BWH, respectively. The patents in these families expire between 2013 and 2016.

Specifically, our patent portfolio includes four issued United States patents, two of which provide broad coverage for the delivery of TF decoys, including our E2F Decoy, to tissues using pressure. The pressure-mediated delivery technology is also protected by issued patents in Europe (covering 16 countries), Australia, China, Hong Kong, and Singapore, and claimed in pending patent applications in several additional countries, including Canada and Japan.

The patent family directed to the *in vivo* use of TF decoy technology includes four pending United States patent applications, one of which has received a Notice of Allowance which is issued after examination of a patent filing and determination that the applicant appears to be entitled to such patent. Foreign patent applications are pending in Europe. Although the sequence of our E2F Decoy was earlier disclosed in the scientific literature and therefore a composition of matter claim is not available, these pending patent applications, if issued with claims substantially similar to those currently pending, will provide broad rights encompassing the prevention of bypass and AV graft failure with any E2F Decoy regardless of its sequence.

In addition, we have filed two patent applications claiming the use of proprietary statistical methods to correlate transcription factors and their target genes, allowing the creation of a TF Decoy

Trust and the use of proprietary statistical methods to identify novel transcription factor targets based on their target genes being inappropriately turned on and causing a medical condition. We have also filed patent applications for decoy molecules targeting various transcription factors, pursuing composition of matter claims.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We rely on trade secrets to protect our technology in addition to patents, especially where patent protection is believed not to be appropriate or obtainable. However, trade secrets are difficult to protect. We attempt to protect our proprietary technology, in part, with appropriate agreements with our employees, consultants and collaborators. There can be no assurance that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party. Our commercial success will depend in part on not infringing upon the proprietary rights of third parties and on not breaching the technology licenses pursuant to which we have obtained certain of our proprietary rights, but we may be infringing on third party rights. It is uncertain whether the issuance of any third party patent would require us to alter our products or processes, obtain licenses or cease certain activities. Our breach of our license agreements or failure to obtain a license to technology that we may require to discover, develop or commercialize our future products may have a material adverse impact on us. One or more third party patents or patent applications may conflict with patent applications to which we have rights. Any such conflict may substantially reduce the coverage of any rights that may issue from the patent applications to which we have rights. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office to determine priority of invention.

### **Competition**

The development and commercialization of new drugs is highly competitive. We will face competition with respect to E2F Decoy, NF- $\kappa$ B Decoy, cancer decoys and any products we may develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

The key competitive factors affecting the success of E2F Decoy treatment are likely to be the efficacy, safety profile and price of E2F Decoy as well as existing therapies for the prevention or treatment of cardiovascular disease. The commercial success of E2F Decoy will depend upon the results of the clinical trials of the product, the product label and experience with the product in the commercial marketplace. We have not yet determined the price for E2F Decoy treatment and do not expect to do so before commercial launch.

If E2F Decoy receives marketing approval for the prevention of bypass graft failure or AV graft failure, there will be indirect and direct competition.

### ***CABG and PBG***

With respect to indirect competition, there are alternative procedures and/or treatments that could affect the size of the CABG and PBG markets. The use of drug eluting stents could reduce the number of patients requiring CABG or PBG surgery. The use of internal mammary arteries and radial arteries could reduce the number of patients requiring E2F Decoy. The use of grafts composed of synthetic materials could reduce the number of patients requiring E2F Decoy. In addition, the use of drugs to control cholesterol and similar agents may reduce the number of patients who suffer from cardiovascular disease and thus require CABG or PBG surgery. Further, a number of drugs are being tested to reduce restenosis in arteries that, if proven safe and effective, could reduce the number of patients who suffer from cardiovascular disease and thus require CABG or PBG surgery.

With respect to direct competition, there are no pharmaceuticals currently approved to prevent the failure of bypass vein grafts. In some instances, surgical interventions such as angioplasty, atherectomy or drugs to dissolve blood clots may be used to revise or fix a failing bypass graft. In other instances, a subsequent bypass grafting operation may be possible to ameliorate the effects of the failing bypass graft. A few companies may be conducting or are contemplating conducting clinical trials to prevent the failure of bypass grafts. If the commercialization of E2F Decoy is successful for this indication, it can be expected that other pharmaceutical and biotechnology companies will seek to enter into this market by introducing alternative therapies.

### ***AV Grafts***

With respect to indirect competition, there are a number of therapies approved or being studied that could reduce the rate of kidney failure or improve renal function thereby delaying or obviating the need for dialysis and an AV graft. For example, angiotensin converting enzyme, or ACE, inhibitors, and possibly angiotensin receptor blockers, are medications that may decrease the rate of decline in renal function. An alternative procedure to hemodialysis is peritoneal dialysis in which fluids are pumped into the abdominal cavity of the patient avoiding the need for an AV graft.

With respect to direct competition, there are a number of medical devices approved or being studied that provide alternative access for dialysis. Hemodialysis can also be achieved using a direct connection between an artery and a vein, called an arteriovenous fistula. The National Kidney Foundation has recommended that 40% to 50% of these patients receive an AV fistula because they have a lower failure rate than AV graft. AV fistula rates have increased by 35% since the National Kidney Foundation initiative was introduced in 1997; however, AV fistulas still represent only 24% of all vascular access procedures in the United States, largely due to the extended time required for fistulas to mature before they can be used for dialysis and the failure of many fistulas to mature. Unlike AV grafts which can often be used in two to three weeks, AV fistula access requires a minimum of four weeks to mature before it can be used and it is highly recommended that they be allowed to mature 12 to 16 weeks prior to use. Furthermore, 30% to 50% of AV fistulas fail to mature and can never be used for dialysis. Other types of access that avoid an AV graft are catheters near the collarbone or internal jugular catheters. Both are generally temporary access conduits. There are also a number of drug-based therapies under investigation by other companies. If the commercialization of E2F Decoy is successful for this indication, it can be expected that other pharmaceutical and biotechnology companies will seek to enter into this market by introducing alternative therapies.

### **Government Regulation**

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the safety, efficacy, research, development, testing, manufacture, storage, record-keeping, labeling, promotion, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing.

### *United States Government Regulation*

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations. If we fail to comply with the applicable United States requirements at any time during the product development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

Our products are considered by FDA to be combinations of a drug and a device. Both the drug and the device are subject to separate FDA review and approval or clearance. If FDA denies approval or clearance of either component, our ability to market our products could be significantly delayed or precluded.

The steps required before a drug may be marketed in the United States include:

- completion of preclinical laboratory tests, animal studies and formulation studies under FDA's good laboratory practices regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the FDA of a New Drug Application, or NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP; and
- FDA review and approval of the NDA before any commercial marketing, sale or shipment of the product.

Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The FDA requires a 30-day waiting period after the filing of each IND application before clinical tests may begin, in order to ensure that human research subjects will not be exposed to unreasonable health risks. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA has placed the IND on clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing the trial to commence on the terms originally specified in the IND.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Each trial must be reviewed and approved by an independent Institutional Review Board, or IRB, before it can begin and the trial is subject to IRB oversight. FDA, the IRB or we may discontinue a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice requirements and the requirements for informed consent.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase 1 trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness.

Phase 2 trials usually involve controlled trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- evaluate preliminarily the efficacy of the drug for specific indications.

Phase 3 trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including extensive manufacturing information and information on the composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use.

As part of the Food and Drug Modernization Act of 1997, Congress established a statutory program for the approval of Fast Track products in order to ensure the availability of safe and effective drugs, biologics and medical devices by expediting the FDA review process for new products. A Fast Track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for that condition. Under the Fast Track program, the sponsor of a new drug or biologic may request the FDA to designate the product as a Fast Track product at any time during the clinical development of the product. The FDA can base approval of a marketing application for a Fast Track product, on a clinical endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. Fast Track status may enable accelerated approval and allows for a "rolling submission" of a marketing application. We have received a Fast Track designation for the use of E2F Decoy to prevent the failure of bypass grafts and the use of E2F Decoy to prevent the failure of hemodialysis access grafts.

Before approving an application, the FDA will inspect the facility or the facilities at which the product is manufactured, and will not approve the product unless cGMP compliance is satisfactory. FDA will also inspect the clinical sites at which the trials were conducted to assess their compliance, and will not approve the product unless compliance with Good Clinical Practice requirements is satisfactory. If the FDA determines the application demonstrates that the product is safe and effective for the proposed indication and that the manufacturing process and the manufacturing facilities are acceptable, the FDA will issue an approval letter. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and may deny the application, limit the indication for which the drug is approved or require additional post-approval testing in other requirements.

The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We

may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

If and when regulatory approval of a product is obtained, we will be required to comply with a number of post-approval requirements. For example, if the FDA approves our initial application for E2F Decoy, the FDA has required and we are conducting a post-approval confirmatory trial monitoring the CABG patients for up to five years tracking events such as death, heart attack, repeat CABG and other interventions using a catheter. We also must comply with other regulatory requirements, including cGMP regulations and adverse event reporting. Holders of an approved NDA are required to report certain adverse reactions and production problems, if any, to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We use, and will continue to use in at least the near term, third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

The FDA has advised that the use of E2F Decoy to prevent the failure of hemodialysis access grafts can be studied under the existing IND covering the study of E2F Decoy for the prevention of bypass graft failure. In addition, the FDA has determined that the failure of hemodialysis grafts represents a serious medical condition, that there are no adequate pharmaceuticals to prevent the failure of such grafts and that there is evidence of the potential for E2F Decoy treatment to treat this serious and unmet medical need. Consequently, the FDA has granted Fast Track status to this new indication for our lead product, affording it the benefits of close consultation with the FDA and expedited review.

#### *510(k)*

FDA's Center for Drug Evaluation and Research will have primary responsibility for reviewing E2F Decoy. The pressure device used to deliver the drug is subject to separate review as a medical device by FDA's Center of Devices and Radiological Health.

The FDA classifies medical devices into three classes based on the regulatory control deemed necessary by the FDA to reasonably ensure safety and effectiveness. From lowest to highest level of regulatory control, the three classes are:

- *Class I*: Subject to general controls, which include: company registration; device listing; manufacturing devices in accordance with the FDA's Good Manufacturing Practices Quality System Regulation (which cover quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging

and labeling control, device evaluation, distribution, installation, complaint handling, servicing and records); labeling devices in accordance with FDA labeling regulations; and submission of a 510(k) premarket notification before marketing a device.

- *Class II*: Subject to general controls (described in Class I above) and special controls. Special controls may include special labeling requirements, mandatory performance standards and post-market surveillance.
- *Class III*: Subject to premarket approval, which includes filing a premarket approval application (PMA) requiring the independent demonstration that the new medical device is safe and effective, typically by collecting human clinical data for the medical device.

The FDA has informed us that we must obtain marketing clearance for the pressure device as a "device" before it can be marketed in the United States. We intend to pursue clearance through the submission of a 510(k) premarket notification. A 510(k) premarket notification is a pre-marketing application submitted to the FDA to demonstrate that a medical device is substantially equivalent to one or more devices that were cleared through a 510(k) notification or to devices that were marketed prior to May 28, 1976 and for which the FDA has not required a premarket approval application. The FDA has 90 days to review and act on our 510(k) notification, although the actual time for FDA review may be significantly longer. We will submit a 510(k) notification to the Center of Devices and Radiological Health (medical devices) for review and clearance based on the substantial equivalence of our pressure delivery device to legally marketed predicates including Merit Medical's pressure syringe and DMC Saphenous Vein Distension system. We expect to file this notification in 2004. If the FDA determines that our device is not substantially equivalent to one or more pre-existing predicate devices, it could deny our 510(k) application. Under these circumstances, we would need to request the FDA to classify the pressure device as a Class I or Class II device that can be marketed without premarket approval or, failing that, obtain premarket approval of the pressure device as a Class III device.

#### ***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products, including E2F Decoy. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our products, including E2F Decoy.

## **Third Party Reimbursement and Pricing**

### *General*

In the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. In determining payment rates, third party payors are increasingly scrutinizing the prices charged for medical products and services. Our products may not be reimbursed by these third party payors at rates sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental 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 limit payments for pharmaceuticals by governmental payors. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

### *Medicare and Medicaid*

Subject to obtaining required marketing approvals from the FDA and other required State approvals, E2F Decoy may be used by surgeons to prevent the failure of bypass grafts and hemodialysis access conduits. We expect that in the United States a majority of the bypass graft patients who are treated with E2F Decoy will be Medicare beneficiaries. In addition, private payors many times look to the Medicare program's treatment of medical technologies when developing their policies. The Centers for Medicare and Medicaid Services, or CMS, is the agency within the Department of Health and Human Services that administers Medicare and will be responsible for both coverage and reimbursement decisions for E2F Decoy when administered to Medicare beneficiaries during CABG and PBG surgery.

In general, Medicare makes a flat pre-determined payment amount for beneficiaries receiving covered inpatient services in an acute care hospital. This is part of the prospective payment system, known as "PPS." For acute care hospitals, under PPS, payment for a patient's stay is based on diagnosis-related groups (DRGs), which include reimbursement for all of the covered services and drugs that are provided during that stay. For each DRG, a relative weight is calculated representing the average resources required to care for cases in that particular DRG relative to the average resources used to treat cases in all DRGs. DRG relative weights are recalculated every year to reflect changes in technology and medical practice in a budget neutral manner. We are currently seeking either to gain additional reimbursement for an existing DRG applicable to CABG and PBG or to have a new DRG with higher reimbursement amount established for CABG and PBG when E2F Decoy treatment is used. Under revisions to Medicare law, CMS provides for an add-on payment for a new medical technology when the existing DRG payment rate is inadequate. To obtain an add-on payment, a company would be required to show that the technology is "new," that it provides a substantial improvement to existing treatments and that certain applied payment thresholds have been exceeded. Add-on payments are made for a period of two to three years. Before additional payments may be made or CMS decides to create a new DRG for CABG and PBG surgery utilizing E2F Decoy treatment, we must demonstrate the safety and effectiveness of E2F Decoy treatment to the FDA. Further, Medicare coverage is based on our ability to demonstrate that the treatment is "reasonable and necessary" for Medicare patients. In addition, Congress approved the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Reform Act), which liberalizes eligibility criteria for add-on payments and eliminates budget neutrality requirements for such payments. The Medicare Reform Act, would require CMS first to assign a new technology to an appropriate DRG where the average cost of care most closely approximates the relative costs of the new technology. Even

upon implementation of the legislation, there may continue to be significant delays in obtaining adequate reimbursement which will adversely affect market acceptance.

People with severe kidney disease, known as End Stage Renal Disease, or ESRD, also receive Medicare benefits. Medicare covers about 90% of the patients with chronic renal failure who would require dialysis. Under this program, Medicare pays a fixed fee for the provision of certain services. Certain drugs needed by these patients are also reimbursed by Medicare under this program. It is our expectation that we will seek coverage for our treatment of patients requiring hemodialysis access grafts. We expect that such treatment may be performed in an inpatient or outpatient setting for ESRD patients. To the extent coverage is obtained, we expect to seek payment for services performed in both settings. The decision by Medicare to reimburse for the use of E2F Decoy to treat these patients will depend on our ability to demonstrate that the E2F Decoy treatment is "reasonable and necessary" for the treatment of these grafts. In addition, there may be significant delays in obtaining adequate reimbursement amounts, which will adversely affect market acceptance.

For classification of physician services, the American Medical Association has developed a coding system known as the Current Procedural Terminology, or CPT. CPT codes are established by the American Medical Association and adopted by the Medicare program to describe and develop payment amounts for certain physician services. The Medicare physician fee schedule uses CPT codes (and other codes) as part of the determination of allowable payment amounts to physicians. In determining appropriate payment amounts for surgeons, CMS is likely to seek guidance from the appropriate surgical societies regarding the relative technical skill level and complexity of a new surgical procedure. Generally, the designation of a new procedure code for a new procedure using a new product does not occur until after FDA approval of the product used in the surgery. Codes are assigned by either the AMA (for CPT codes) or CMS (for Medicare-specific codes) and new codes usually become effective on January 1st of each year.

CMS is considering various proposals to change the methods and levels of reimbursement in Medicare. At this point, it is unclear whether the CMS proposals or Congressional legislation will become effective or the extent to which CMS' proposed changes or the recently approved Congressional legislation will affect reimbursement for E2F Decoy.

#### ***Commercial Insurers' Payment***

In most private insurance plans, the medical benefits provisions include reimbursement for drugs administered during a medical procedure in the payment amount for the procedure itself. We expect the same reimbursement methodology to be used for E2F Decoy treatment during CABG or PBG surgery. If private insurers decide to cover E2F Decoy treatment as part of CABG or PBG surgery, they likely will reimburse for the drug in a variety of ways depending on the particular insurance plan and the contract they have negotiated with surgeons, hospitals and drug suppliers. Like Medicare, commercial insurers have the authority to place coverage limitations (for example, limitations on indications for use and utilization limits) on drugs like E2F Decoy.

#### **Financial Information by Business Segment and Geographic Data**

We operate in one segment, the discovery, development and commercialization of TF Decoys. During 2001 and 2002 we did not have any revenues, and during 2003 our only revenue was from our collaboration agreement with BMS. All of our long-lived assets are located in the United States.

#### **Employees**

As of December 31, 2003, we had 72 full time employees, 15 of whom hold Ph.D., M.D. or comparable degrees and 24 of whom hold other advanced degrees. Approximately 60 employees are engaged in research and development and 12 in business development, finance and other administrative functions. Our employees are not represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

## Executive Officers and Key Employees

Our executive officers and other key employees and their respective ages as of December 31, 2003 are:

Name	Age	Position
<b>Executive Officers:</b>		
John P. McLaughlin	52	President, Chief Executive Officer and Director
Richard P. Powers	58	Vice President and Chief Financial Officer
Todd J. Lorenz, M.D.	50	Chief Medical Officer
Leslie M. McEvoy, Ph.D.	43	Vice President, Research
James Z. Huang	38	Vice President, Business Development and Commercial Operations
<b>Key Employees:</b>		
Lynn Seely, M.D.	44	Vice President, Clinical Research
Daniel Gennevois, M.D.	49	Vice President, Medical Affairs
John X. Regan	48	Vice President, Manufacturing
Patricia Oto, R.Ph.	43	Vice President, Regulatory & Quality Assurance

### Executive Officers

*John P. McLaughlin* has been our President and Chief Executive Officer, and a member of our board of directors since January 2000. From December 1997 to September 1999, Mr. McLaughlin was President of Tularik Inc., a biopharmaceutical company. From September 1987 to December 1997, Mr. McLaughlin held a number of senior management positions at Genentech, Inc., a biopharmaceutical company, including Executive Vice President with responsibility for many commercial functions. From January 1985 to September 1987, Mr. McLaughlin was a partner at a Washington, D.C. law firm specializing in food and drug law. Mr. McLaughlin served as counsel to various subcommittees in the United States House of Representatives, where he drafted numerous measures that became FDA laws. Mr. McLaughlin is a co-founder and Chairman of the Board of Directors of Eyetech Pharmaceuticals, Inc., a biopharmaceutical company. He received a B.A. in Government from the University of Notre Dame and a J.D. from the Catholic University of America.

*Richard P. Powers* has been our Vice President and Chief Financial Officer since October 2001. From March 1999 to August 2000, Mr. Powers served as Executive Vice President and Chief Financial Officer of Eclipse Surgical Technologies, Inc., a medical device company. From February 1996 to March 1999, Mr. Powers served as Executive Vice President and Chief Financial Officer of CardioGenesis Corporation, a medical device company. From January 1981 to August 1995, Mr. Powers held a number of senior management positions at Syntex Corporation, a biopharmaceutical company, including Senior Vice President and Chief Financial Officer. Mr. Powers also currently serves on the board of directors of Airlease Management Services, Inc. Mr. Powers received a B.S. in Accounting from Canisius College and an M.B.A. from the University of Rochester, New York.

*Todd J. Lorenz, M.D.* has been our Chief Medical Officer since May 2001. From 1994 to 2001, he was Vice President of Medical Affairs at Cor Therapeutics, a biopharmaceutical company where he managed clinical development activities. From 1990 to 1994, he served as Director of Clinical Development of Xoma Corporation, a biopharmaceutical company. From 1985 to 1990, he was in private practice, and also served as a clinical consultant for Highland General Hospital's Department of Endocrinology in Oakland, California. Dr. Lorenz has a clinical appointment at the University of California, San Francisco School of Medicine. Dr. Lorenz received a B.A. in Chemistry and an M.D. from Case Western Reserve School of Medicine. Dr. Lorenz completed his residency in internal

medicine at the University of Texas, Southwestern and a fellowship in endocrinology at the University of California, San Francisco.

*Leslie M. McEvoy, Ph.D.* has been our Vice President of Research since November 2000. From October 1997 to October 2000, Dr. McEvoy was Program Director of chemokine research and development and Senior Principal Scientist in the Department of Immunobiology at DNAX Research Institute of Molecular and Cellular Biology, Inc. From 1992 to 1997, Dr. McEvoy was a Senior Research Scientist and Principal Investigator at the Stanford University School of Medicine. Prior to 1992, Dr. McEvoy held research positions at Stanford School of Medicine, Lilly Research Laboratories, Pennsylvania State University and Clarkson University. Dr. McEvoy received a B.S. in Biology from Clarkson University and a Ph.D. in Molecular and Cell Biology from Pennsylvania State University.

*James Z. Huang* has been our Vice President of Business Development and Commercial Operations since September 2002. From June 2000 to August 2002, Mr. Huang was Vice President of Business Development and Commercial Operations of Tularik Inc., a biopharmaceutical company. From July 1995 to May 2000, Mr. Huang was Product Director of Avandia and Diabetes and held positions in new product development and Worldwide Business Development at SmithKline Beecham PLC, now GlaxoSmithKline, a pharmaceutical company. From July 1992 to June 1995, Mr. Huang held various positions in Bristol-Myers Squibb Company's Strategic Product Planning, Managed Care and Sales and Marketing organizations, and research and development positions at Alza Corporation, now part of Johnson & Johnson Company, a pharmaceutical company. Mr. Huang received a B.S. in Chemical Engineering from the University of California, Berkeley and an M.B.A. from the Stanford University Graduate School of Business.

#### **Key Employees**

*Lynn Seely, M.D.* has been our Vice President of Clinical Research since September 2002. From December 2001 to June 2002, Dr. Seely served as Vice President of Clinical Development of Cytec Health Corporation, a medical diagnostic company. From September 2000 to November 2001, Dr. Seely was Vice President of Clinical Development at Pro-Duct Health, Inc., a medical device company. From December 1996 to September 2000, she was Director of Clinical Development at Chiron Corporation, a biopharmaceutical company. From July 1992 to November 1996, Dr. Seely was an Assistant Professor of Medicine at the University of California, San Diego. Dr. Seely received a B.A. in Journalism from the University of Oklahoma and an M.D. from the University of Oklahoma College of Medicine. Dr. Seely completed her residency in internal medicine at Yale-New Haven Hospital in New Haven, Connecticut, where she served as Chief Resident. Dr. Seely completed a postdoctoral fellowship in Endocrinology and Metabolism at the University of California, San Diego.

*Daniel Gennevois, M.D.* has been our Vice President of Medical Affairs since August 2003. From June 2003 to July 2003, Dr. Gennevois served as Senior Medical Director for Xoma Corporation. From June 2001 to June 2003, Dr. Gennevois served as Executive Director and Vice President of Clinical Operations at Dynavax Technologies, a biopharmaceutical company. From March 1997 to May 2001, he was Senior Director of Clinical Research of Roche Bioscience, a subsidiary of F. Hoffmann-La Roche Ltd., a pharmaceutical company. From November 1995 to March 1997, he served as Director of Clinical Research of Chiron Vaccines, a business unit of Chiron Corporation, a biopharmaceutical company. From June 1991 to November 1995, Dr. Gennevois served as Director of Medical Research of Syntex Corporation, a biopharmaceutical company. From 1985 to 1991, he served as Associate Director of Clinical and Business Development for American Bioproducts Co., and Scientific Manager for Porton Products. Dr. Gennevois received a Bachelor degree in Mathematics from Lycee Ampere (Lyon, France) and a Doctor of Medicine degree from the University of Lyon, Claude Bernard School of Medicine in Lyon, France. Dr. Gennevois completed clinical training in infectious disease at the Hospital Edouard Herriot, also in Lyon.

*John X. Regan* has been our Vice President of Manufacturing since December 2002. From January 1983 to December 2002, Mr. Regan held a number of management positions at Genentech, Inc., including Senior Director of Manufacturing. From 1979 to 1983, Mr. Regan served as Formulating Chemist of SmithKline Diagnostics, a diagnostics company. Mr. Regan received a B.S. in Biology from the University of Massachusetts.

*Patricia Oto, R.Ph.* has been our Vice President of Regulatory & Quality Assurance since July 2001. From June 1997 to June 2001, Ms. Oto was Senior Director of Regulatory Affairs at Corixa, Inc., a biopharmaceutical company. From 1990 to 1997, Ms. Oto held various positions in the Regulatory Affairs and Quality Assurance departments at Genentech, Inc., including Regulatory Manager. From January 1984 to January 1990, Ms. Oto held various Quality and Manufacturing positions at Syntex Corporation and Summa Manufacturing Corporation. Ms. Oto received a B.S. in Pharmacy from the University of New Mexico College of Pharmacy, Albuquerque, New Mexico.

#### **Available Information**

We make available, free of charge, through our Internet website, <http://www.corgentech.com>, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

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

As of December 31, 2003, we leased an approximately 50,000 square foot facility in South San Francisco, California for our headquarters and as the base for marketing and product support operations and research and development activities. This lease expires in June 2006 and we have an option to extend this lease for an additional four years. We also lease an approximately 3,000 square foot facility in South San Francisco, California. This lease expires in March 2005. We believe that our current facilities will be sufficient to meet our needs through 2004.

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

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings.

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

In October 2003, we submitted the following matters to our stockholders for their approval. On October 10, 2003, our stockholders approved each of these matters, as set forth below. We did not receive written consents from each stockholder. As of the record date for taking such action, we had 13,802,955 shares of common stock outstanding (on an as-if-converted basis). The results of the voting from the stockholders that returned written consents to us are as follows:

1. The approval of the sale of secured convertible promissory notes and warrants for an aggregate of \$20,000,000;

For: 12,560,258

Against: 0

2. The amendment and restatement of our Amended and Restated Certificate of Incorporation to (a) increase our common stock by 5,875,000 shares from 16,057,500 to 21,932,500, (b) increase our preferred stock by 6,016,502 shares from 12,350,758 to 18,367,260, (c) increase our Series C preferred stock by 3,937,500 shares from 8,062,500 to 12,000,000, and (d) designate 2,079,002 shares as Series D preferred stock; and

For: 12,560,258

Against: 0

3. The approval of the terms of the sale of additional shares of Series C preferred stock.

For: 12,560,258

Against: 0

In December 2003, we submitted certain matters to our stockholders for their approval in connection with our initial public offering. On January 9, 2004, our stockholders approved each of these matters, as set forth below. We did not receive written consents from each stockholder. As of the record date for taking such action, we had 20,113,656 shares of common stock outstanding (on an as-if-converted basis). The results of the voting from the stockholders that returned written consents to us is as follows:

1. The amendment to our Amended and Restated Certificate of Incorporation increasing the total authorized number of shares of our capital stock by 5,000,000, from 161,199,040 to 166,199,040;

For: 19,456,122

Against: 0

2. The amendment and restatement of our Amended and Restated Certificate of Incorporation following our initial public offering;

For: 19,456,122

Against: 0

3. The amendment and restatement of our Bylaws following our initial public offering;

For: 19,456,122

Against: 0

4. The amendment and restatement of our 1999 Equity Incentive Plan to increase the number of shares authorized thereunder from 1,729,824 to 2,969,949;

For: 19,456,122

Against: 0

5. The amendment and restatement of the 1999 Equity Incentive Plan as the 2003 Equity Incentive Plan;

For: 19,456,122

Against: 0

6. The approval of our 2003 Employee Stock Purchase Plan;

For: 19,456,122

Against: 0

7. The approval of our 2003 Non-Employee Directors' Stock Option Plan; and

For: 19,456,122

Against: 0

8. The approval of our form of Indemnity Agreement.

For: 19,456,122

Against: 0

## PART II

### **Item 5. Market for the Registrant's Common Stock and Related Stockholder Matters**

Our common stock has traded on the Nasdaq National Market under the symbol "CGTK" since February 12, 2004. On March 23, 2004, the last reported sale price on the Nasdaq National Market for our common stock was \$19.50 per share.

#### **Holdings**

As of March 1, 2004 there were approximately 170 stockholders of record of our common stock.

#### **Dividends**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to finance the growth and development of our business and therefore do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our board of directors and will depend upon our financial condition, operating results, capital requirements, covenants in our debt instruments, and such other factors as the board of directors deems relevant.

#### **Equity Compensation Plans**

The information regarding securities authorized for issuance under our equity compensation plans required by this item will be contained in our definitive Proxy Statement with respect to our 2004 Annual Meeting of Stockholders, to be held on May 13, 2004, under the caption "Securities Authorized for Issuance Under Equity Compensation Plans," and is incorporated herein by reference.

#### **Use of Proceeds from the Sale of Registered Securities**

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-110923) that was declared effective by the Securities and Exchange Commission on February 11, 2004 and a Registration Statement on Form S-1 filed pursuant to Rule 462 (File No. 333-112734) on February 12, 2004, pursuant to which we sold all 6,900,000 shares of our common stock registered. We expect to use the net proceeds of \$100.8 million in our research and development efforts, product development activities, and general corporate activities.

Our initial public offering of common stock commenced on February 12, 2004 and was completed after all of the shares of common stock that were registered were sold. The managing underwriters in our initial public offering were Credit Suisse First Boston LLC, Lehman Brothers Inc., CIBC World Markets Corp. and Piper Jaffray & Co. The aggregate offering price of the 6,900,000 shares registered and sold was \$110.4 million. Of this amount, \$7.7 million was paid in underwriting discounts and commissions, and an additional \$1.7 million of expenses was incurred, of which approximately \$900,000 was incurred during the year ended December 31, 2003. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning 10% or more of our common stock, or to our affiliates.

#### **Recent Sales of Unregistered Securities**

From January 1, 2003 to December 31, 2003, Corgentech sold and issued the following unregistered securities:

(1) From January 1, 2003 through December 31, 2003, we granted stock options to purchase an aggregate of 1,721,746 shares of our common stock, at exercise prices ranging from \$1.20 to \$5.00 per share, to employees, consultants and directors, pursuant to our 1999 Equity Incentive Plan. Our 1999

Equity Incentive Plan was amended and restated as our 2003 Equity Incentive Plan in connection with our initial public offering. During this period, stock options to purchase an aggregate of 64,553 shares of our common stock were cancelled without being exercised.

(2) From January 1, 2003 through December 31, 2003, we issued 488,988 shares of our common stock at exercise prices ranging from \$0.24 to \$5.00 per share, for an aggregate of \$678,625, pursuant to the exercise of outstanding stock options. During this period, 7,773 shares were repurchased at their original exercise price.

(3) In October 2003, we issued a stock award covering 100,000 shares of our common stock, at a price of \$1.20 per share, and stock options to purchase an aggregate of 200,000 shares of our common stock, at an exercise price of \$1.20 per share. Both the stock award and stock options were granted outside of our 1999 Equity Incentive Plan to our directors.

(4) In February, April, August and October 2003, we issued warrants exercisable into 4,455 share of our Series C preferred stock to an investor in connection with a credit facility. The warrants had an exercise price of \$7.40 per share. The warrants were exercised in connection with our initial public offering for 2,394 shares. The shares of our Series C preferred stock converted into shares of our common stock at the rate of one share of common stock for each share of Series C preferred stock immediately prior to the closing of our initial public offering.

(5) In September and October 2003, we issued convertible promissory notes in the aggregate principal amount of \$20,000,000 convertible into Series C preferred stock to 16 investors in connection with a bridge loan. The convertible promissory notes converted at a rate of \$7.40 per share.

(6) In October 2003, we issued 1,351,347 shares of our Series C preferred stock to 21 purchasers, at \$7.40 per share, for an aggregate purchase price of \$10,000,000.

(7) In October 2003, we issued 2,079,002 shares of our Series D preferred stock to one purchaser, at \$9.62 per share, for an aggregate purchase price of \$20,000,000. The shares of our Series D preferred stock converted into shares of our common stock at the rate of one share of common stock for each share of Series D preferred stock immediately prior to the closing of our initial public offering.

(8) In October 2003, we issued 2,702,697 shares of our Series C preferred stock in connection with the voluntary conversion of convertible promissory notes in the aggregate principal amount of \$20,000,000. We further issued warrants to purchase an aggregate of 810,801 shares of Series C preferred stock, at a purchase price of \$0.004 per share, for an aggregate purchase price of \$3,243.23. The warrants had an exercise price of \$7.40 per share. The warrants to purchase 810,801 shares of Series C preferred stock and the warrants to purchase 152,024 shares of Series C preferred stock previously issued in February 2002 were exercised in connection with our initial public offering for 681,574 shares.

The sales and issuances of securities described in paragraphs (1) and (2) above were deemed to be exempt from registration under the Securities Act by virtue of Rule 701 promulgated thereunder in that they were offered and sold either pursuant to a written compensatory benefit plan or pursuant to a written contract relating to compensation, as provided by Rule 701.

The sale and issuance of securities described in paragraph (3) through (8) above were deemed to be exempt from registration under the Securities Act by virtue of Section 4(2) and/or Regulation D promulgated thereunder.

## Item 6. Selected Financial Data

The following Selected Financial Data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K.

	Period from January 19, 1999 (inception) to December 31, 1999	Year Ended December 31,				
		2000	2001	2002	2003	
(in thousands, except share and per share data)						
<b>Statements of Operations Data:</b>						
Contract revenue, related party . . . . .	\$ —	\$ —	\$ —	\$ —	\$ 8,678	
Operating expenses:						
Research and development . . . . .	550	1,333	8,068	21,536	46,004	
General and administrative . . . . .	515	781	2,374	3,206	6,067	
Total operating expenses . . . . .	1,065	2,114	10,442	24,742	52,071	
Loss from operations . . . . .	(1,065)	(2,114)	(10,442)	(24,742)	(43,393)	
Interest and other income . . . . .	73	57	349	471	416	
Interest and other expense . . . . .	—	—	—	(1,376)	(20,190)	
Net loss . . . . .	\$ (992)	\$ (2,057)	\$ (10,093)	\$ (25,647)	\$ (63,167)	
Preferred stock deemed dividend . . . . .	—	—	—	—	(14,407)	
Net loss attributable to common stockholders . . . . .	\$ (992)	\$ (2,057)	\$ (10,093)	\$ (25,647)	\$ (77,574)	
Basic and diluted net loss per common share . . . . .	\$ (2.69)	\$ (2.69)	\$ (6.10)	\$ (14.38)	\$ (37.90)	
Shares used in computing basic and diluted net loss per common share . . . . .	369,362	765,290	1,653,631	1,783,564	2,046,944	
Year Ended December 31,						
		1999	2000	2001	2002	2003
(in thousands)						
<b>Balance Sheet Data:</b>						
Cash, cash equivalents and short-term investments . . . . .		\$1,568	\$ 4,626	\$ 2,718	\$ 28,586	\$ 54,590
Working capital . . . . .		1,499	4,183	1,931	24,424	47,016
Total assets . . . . .		1,588	5,014	4,102	31,238	69,323
Long-term debt . . . . .		—	—	—	—	628
Convertible preferred stock . . . . .		2,485	7,456	15,370	64,351	114,332
Accumulated deficit . . . . .		(992)	(3,050)	(13,143)	(38,790)	(101,957)
Total stockholders' equity (deficit) . . . . .		(986)	(2,960)	(12,863)	(38,253)	(78,818)

See Note 2 to our financial statements for a description of the method used to compute pro forma basic and diluted net loss per common share and shares used in computing pro forma basic and diluted net loss per common share.

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

*You should read the following discussion and analysis in conjunction with "Item 6. Selected Financial Data," and "Item 8. Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K.*

### **Overview**

Corgentech is a biopharmaceutical company focused on the discovery, development and commercialization of a novel class of therapeutics called transcription factor decoys, or TF decoys, that treat disease through the regulation of gene expression. Transcription factor decoys bind to and inactivate transcription factors which regulate gene expression and control biological processes. We are initially focusing our TF decoy discovery efforts on diseases with unmet needs including cardiovascular disease, inflammatory disease, such as arthritis, and cancer. Our most advanced TF decoy, E2F Decoy, a combination drug and delivery device, is in two Phase 3 clinical trials for the prevention of vein graft failure. In September 2003, we completed patient enrollment for both of our Phase 3 clinical trials. We expect results from our CABG trial in the first quarter of 2005 and results from our PBG trial in the fourth quarter of 2004. In addition, in the first half of 2004, we expect to initiate a Phase 1/2 clinical trial for our E2F Decoy in a new indication, the prevention of arterio-venous, or AV, graft failure.

We were incorporated in January 1999. Since our inception, our only revenues have been derived from our recent collaboration with Bristol-Myers Squibb Company, or BMS, and we have incurred significant losses each year. We have funded our operations since inception primarily through the private placement of equity securities. We generated net losses of \$63.2 million, \$25.6 million and \$10.1 million in the years ended December 31, 2003, 2002 and 2001, respectively. We had an accumulated deficit of \$102.0 million as of December 31, 2003 and will need to generate significant revenues to achieve and then maintain profitability.

In October 2003, we entered into global collaboration agreements with BMS for the development and commercialization of E2F Decoy for all indications. We and BMS will co-promote E2F Decoy in the United States and share equally in profits and losses. We have granted BMS the exclusive right to commercialize E2F Decoy outside the United States pursuant to a royalty-bearing license. Under our agreements with BMS, BMS is obligated to fund a majority of the ongoing development costs associated with E2F Decoy incurred pursuant to a development budget.

### **Financial Operations Overview**

#### ***Revenues***

We have not generated any revenues from sales of commercial products since our inception and do not expect to generate any revenue, other than contract revenues and milestone payments, until at least 2005. BMS will have the right to record all United States product sales.

#### ***Research and Development Expenses***

Research and development expenses represent costs incurred for the discovery of novel TF decoys, our preclinical and clinical trials, activities relating to regulatory filings and manufacturing development efforts. We utilize a combination of internal resources and independent contractors to manage our clinical trials. The manufacturing activities related to product for clinical trials are conducted by third parties. We expense our research and development costs as they are incurred.

From inception to December 31, 2000, we incurred research and development expenses of approximately \$1.9 million to conduct our Phase 2 clinical trial of E2F Decoy for CABG and to conduct additional research. We are unable to estimate the portion of costs incurred that are allocable to the individual research activities we conducted during the periods prior to December 31, 2000 because we did not segregate costs among our research programs for either management or external

reporting. The following table shows the allocation of research and development expenses to E2F Decoy and all other activities.

	Year Ended December 31,		
	2001	2002	2003
	(in thousands)		
E2F Decoy . . . . .	\$ 5,680	\$17,182	\$41,218
Other activities . . . . .	2,388	4,354	4,786
Total research and development expenses . . . . .	<u>\$ 8,068</u>	<u>\$21,536</u>	<u>\$46,004</u>

During the years ended December 31, 2001 and 2002 and 2003, we incurred research and development expenses totaling \$75.6 million. Of this amount, approximately \$64.1 million was spent on activities required to advance the development of our clinical product candidate, E2F Decoy, through full enrollment of Phase 3 clinical trials. The remaining amount of \$11.5 million was expended primarily on employee costs, supplies and materials and infrastructure related to chemistry and related functions associated with our early stage research activities.

During the three months and the year ended December 31, 2003, we incurred research and development expenses for E2F Decoy of approximately \$10.0 million and \$41.2 million, respectively. In October 2003, we entered into our collaboration agreement with BMS, under which BMS is obligated to fund a majority of the ongoing costs of developing E2F Decoy for CABG, PBG and AV graft failure. During the three months ended December 31, 2003, we recorded approximately \$6.9 million in reimbursable expenses due from BMS, as contract revenue, related party.

We currently have one clinical product candidate, E2F Decoy. We expect to incur expenses of approximately \$49.0 million to complete our two Phase 3 clinical trials and post-approval trials for E2F Decoy. A majority of these expenses will be reimbursed by BMS pursuant to our collaboration agreement. Due to the significant risks and uncertainties inherent in the clinical development, manufacturing and regulatory approval process, the cost to complete our development of E2F Decoy for AV graft failure and other product candidates is not accurately predictable. Results from clinical trials and manufacturing development may not be favorable. Further data from clinical trials is subject to varying interpretation, and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, accounting, facilities, other general corporate activities and non-cash stock compensation.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies relating to revenue recognition, stock compensation and clinical trial accounting are most critical to a full understanding and evaluation of our reported financial results.

### ***Revenue Recognition***

Revenues associated with our collaboration with BMS consist of non-refundable, up-front license fees and reimbursement of development expenses.

We use revenue recognition criteria outlined in Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" and Emerging Issues Task Force, or EITF Issue 00-21 "Revenue Arrangements with Multiple Deliverables," or EITF 00-21. Accordingly, we recognize revenues from licensing agreements based on the performance requirements of the agreement. Non-refundable up-front fees, where we have an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into license fees in the statements of operations over the estimated term of the performance obligation.

To date we have received \$25.0 million from BMS in non-refundable up-front fees in consideration for license and distribution rights of E2F Decoy. In determining the term of performance obligation, we took into account the estimated period to complete clinical trials and receive regulatory approvals for commercialization of E2F Decoy in CABG, PBG and AV grafts based upon the most recent development plans for each product. If such plans are modified, the timing of recognition of deferred revenue will change. In addition, the manufacturing and co-promotion arrangements were not considered to be deliverables as defined under EITF 00-21.

### ***Stock Compensation***

We account for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, an interpretation of APB No. 25, and related interpretations and have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*, or SFAS No. 123.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. We have elected to continue to follow the intrinsic value method of accounting as prescribed by APB No. 25. The information regarding net loss as required by SFAS No. 123, presented in Note 1 to our financial statements, has been determined as if we had accounted for our employee stock options under the fair value method of that statement. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

Stock compensation expense, which is a non-cash charge, results from stock option grants at exercise prices below the deemed fair value of the underlying common. Stock compensation is amortized on a straight line basis over the vesting period of the underlying option, generally four years. From inception through December 31, 2003, we recorded deferred stock compensation expense of \$19.6 million which is amortized over the vesting period of the options. At December 31, 2003, we had a total of \$18.3 million remaining to be amortized.

The total unamortized deferred stock compensation recorded for all option grants through December 31, 2003, is expected to be amortized as follows: \$4.8 million during the year ending

December 31, 2004, \$4.8 million during the year ending December 31, 2005, \$4.8 million during the year ending December 31, 2006 and \$3.9 million during the year ending December 31, 2007.

### *Clinical Trial Accounting*

We record accruals for estimated clinical study costs, comprising payments for work performed by contract research organizations and participating hospitals. These costs are a significant component of research and development expenses. We accrue costs for clinical studies performed by contract research organizations based on estimates of work performed under the contracts. Costs of setting up hospital sites for participation in trials are accrued immediately. Hospital costs related to patient enrollment are accrued as patients are entered in the trial. Payments to hospitals for post-surgery patient angiograms are accrued at the time of the performance of the angiogram.

### **Results of Operations**

#### *Year Ended December 31, 2002 Compared to Year Ended December 31, 2003*

*Contract Revenue, Related Party.* Contract revenue, related party was \$0 for the year ended December 31, 2002 and \$8.7 million for the year ended December 31, 2003. The increase in revenue was primarily attributable to the reimbursement by BMS of \$6.9 million in expenses associated with E2F Decoy research and development and the recognition of \$1.7 million of deferred revenue.

*Research and Development Expenses.* Research and development expenses increased from \$21.5 million for the year ended December 31, 2002 to \$46.0 million for the year ended December 31, 2003. The increase in research and development of \$24.5 million was primarily the result of an increase of \$10.3 million in expenses associated with the expansion of our clinical development programs relating to E2F Decoy, \$10.0 million in expenses associated with manufacturing development activities, and higher payroll and non-cash stock compensation expenses of \$2.8 million as we increased our personnel. We anticipate that these expenses will continue to increase as we further advance E2F Decoy to commercialization and other TF decoys into clinical testing.

*General and Administrative Expenses.* General and administrative expenses increased from \$3.2 million for the year ended December 31, 2002 to \$6.1 million for the year ended December 31, 2003. The increase of \$2.9 million was primarily attributable to higher payroll and non-cash stock compensation expenses and related expenses of \$2.2 million as we increased our personnel and \$617,000 related to increased legal and patent expenses.

We expect our general and administrative expenses to increase substantially due to the costs associated with being a publicly traded company and the infrastructure necessary to support the potential commercialization of E2F Decoy. We also expect to incur marketing expenses during the year ending December 31, 2004 related to pre-launch activities associated with E2F Decoy. Assuming we receive regulatory approval for E2F Decoy, we would expect to incur significant sales and marketing expenses which would be shared with BMS.

*Interest and Other Income.* Interest and other income decreased from \$471,000 for the year ended December 31, 2002 to \$417,000 for the year ended December 31, 2003 as a result of lower average cash balances.

*Interest and Other Expense.* Interest and other expense increased from \$1.4 million for the year ended December 31, 2002 to \$20.2 million for the year ended December 31, 2003. Interest expense for the year ended December 31, 2003 included a charge of \$5.5 million related to the estimated fair value of warrants issued in conjunction with convertible notes issued in September and October 2003 and an associated beneficial conversion feature on these notes of \$14.5 million.

## ***Year Ended December 31, 2001 Compared to Year Ended December 31, 2002***

***Research and Development Expenses.*** Research and development expenses increased from \$8.1 million for the year ended December 31, 2001 to \$21.5 million for the year ended December 31, 2002. The increase of \$13.4 million was primarily attributable to \$11.5 million in increased expenses associated with the expansion of our clinical development programs relating to E2F Decoy, and higher payroll expenses of \$2.0 million as we increased our personnel.

***General and Administrative Expenses.*** General and administrative expenses increased from \$2.4 million for the year ended December 31, 2001 to \$3.2 million for the year ended December 31, 2002. The increase of \$832,000 was primarily attributable to higher payroll expenses of \$845,000 as we increased our personnel.

***Interest and Other Income.*** Interest and other income increased from \$349,000 for the year ended December 31, 2001 to \$471,000 for the year ended December 31, 2002 as a result of higher average cash balances.

***Interest and Other Expense.*** Interest and other expense increased from \$0 for the year ended December 31, 2001 to \$1.4 million for the year ended December 31, 2002. Interest expense for the year ended December 31, 2002 included a charge of \$748,000 related to the estimated fair value of warrants issued in conjunction with convertible notes we issued in February and May 2002 and an associated beneficial conversion feature on these notes of \$537,000.

### **Income Taxes**

At December 31, 2003, we had net operating loss carryforwards for federal income taxes of \$56.7 million. If not utilized, federal net operating loss carryforwards will begin to expire in 2007. Our utilization of the net operating loss and tax credit carryforwards may be subject to annual limitations pursuant to Section 382 of the Internal Revenue Code, and similar state provisions, as a result of changes in our ownership structure. The annual limitations may result in the expiration of net operating losses and credits prior to utilization.

At December 31, 2001, 2002 and 2003, we had deferred tax assets representing the benefit of net operating loss carryforwards and certain start-up costs capitalized for tax purposes. We did not record a benefit for the deferred tax assets because realization of the benefit was uncertain and, accordingly, a valuation allowance is provided to offset the deferred tax assets.

### **Liquidity and Capital Resources**

#### ***Sources of Liquidity***

Since our inception, we have financed our operations primarily through the issuance of equity securities, capital equipment financing and payments from BMS pursuant to our recent collaboration. Through December 31, 2003, we had received net proceeds of \$113.3 million from the issuance of shares of common stock and preferred stock, \$1.4 million from capital equipment financing and \$25.0 million from BMS. At December 31, 2003, we had \$54.6 million in cash, cash equivalents and short-term investments and had \$638,000 of restricted cash pledged as collateral for letters of credit for our leased facilities. In February 2004, we issued 6,900,000 shares of common stock at \$16.00 per share upon the closing of our initial public offering in which we raised approximately \$100.8 million, net of underwriting discounts and commissions and estimated expenses.

Pursuant to our collaboration agreement, BMS has agreed to fund a majority of ongoing development costs incurred towards the development of E2F Decoy for the prevention of bypass graft failure and prevention of AV graft failure. We believe that our available cash, cash equivalents and short-term investments, net proceeds from our initial public offering, expected reimbursements of

development costs from BMS and the first regulatory milestone payment, will be sufficient to fund anticipated levels of operations through at least mid-2005.

### *Cash Flows*

Net cash used in operating activities was \$25.8 million for 2003. This consisted primarily of a net loss for the period of \$63.2 million plus increases in current assets, long term assets and restricted cash of \$11.4 million, partially offset by an increase in deferred revenue, accounts payable and accrued expenses of \$25.8 million, non-cash charges for depreciation and amortization of \$482,000, issuance of equity for services rendered of \$1.3 million, and non-cash compensation and interest expense of \$21.2 million. Net cash provided by investing activities of \$14.8 million in 2003, consisted primarily of net sales of marketable securities of \$15.9 million, offset by purchases of property and equipment of \$1.2 million. Net cash provided by financing activities of \$52.4 million during 2003 was due primarily to the issuance of promissory notes of \$20.0 million, issuance of shares of preferred stock and common stock of \$30.6 million, equipment loans of \$1.4 million, and a bank overdraft of \$712,000. These proceeds were offset by repayments of debt of \$328,000.

Net cash used in operating activities increased from \$9.1 million in 2001 to \$20.0 million in 2002 and \$25.8 million in 2003. The increase in cash used in operating activities from 2001 to 2002 and from 2002 to 2003 was due to continued expansion of research and development activities and clinical trial costs.

Net cash provided by/used in investing activities changed from cash provided of \$600,000 in 2001 to a usage of \$14.8 million for 2002 to cash provided of \$14.8 million in 2003. The decrease in net cash provided by investing activities from 2001 to 2002 was primarily due to increased purchases of short-term investments and property and equipment. The increase in net cash provided by investing activities from 2002 to 2003 is primarily due to net sales of short term investments of \$17.0 million.

Net cash provided by financing activities increased from \$7.9 million in 2001 to \$47.5 million in 2002 and \$52.4 million in 2003. The increase in net cash provided by financing activities from 2001 to 2002 was primarily due to incremental proceeds of \$34.5 million from the sale of preferred stock and proceeds from the issuance of promissory notes of \$4.5 million. The increase in cash provided by financing activities from 2002 to 2003 was primarily due to incremental proceeds of \$15.5 million from the issuance of bridge loans, issuances of preferred stock and issuances of equipment loans.

### *Credit Facility*

In February 2003, we entered into an equipment line of credit with GE Capital Corporation providing funding of up to \$1.5 million. At December 31, 2003, we had drawn down \$1.4 million on the line of credit. Amounts under the line of credit are secured by the equipment purchased.

### *Operating Capital and Capital Expenditure Requirements*

We expect to devote substantial resources to continue our research and development efforts and to expand our sales, marketing and manufacturing programs associated with the commercialization and launch of E2F Decoy and our future products.

We do not expect to generate significant additional funds, other than reimbursements and milestone payments that we receive from our collaboration with BMS, until we successfully obtain marketing approval for, and begin selling, E2F Decoy. We believe that the key factors that will affect our internal and external sources of cash are:

- our ability to successfully obtain marketing approval for and to commercially launch E2F Decoy;
- the success of our other clinical and preclinical development programs;
- the receptivity of the capital markets to financings by biotechnology companies; and

- our ability to maintain our collaboration with BMS and enter into other strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

If our available cash, cash equivalents and short-term investments, net proceeds from our initial public offering, expected reimbursements of development costs and the first regulatory milestone payment from BMS (payable upon our first U.S. New Drug Application filing for E2F Decoy) are insufficient to satisfy our liquidity requirements or if we develop or acquire additional product candidates, we may need to raise additional external funds through the sale of additional equity or debt securities. The sale of additional equity and debt securities may result in additional dilution to our stockholders. Additional financing may not be available in amounts or on terms acceptable to us or at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

### ***Contractual Obligations***

Our outstanding contractual obligations relate to our equipment debt financings, facilities leases, and obligations under our agreement with our third-party contract manufacturer. Our contractual obligations as of December 31, 2003 were as follows (in millions):

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than One Year</u>	<u>One to Three Years</u>	<u>Four to Five Years</u>	<u>After Five Years</u>
Equipment financing . . . . .	\$1.2	\$0.5	\$0.7	\$—	\$—
Operating leases . . . . .	4.1	1.4	2.7	—	—
Manufacturing development agreement . . . . .	4.1	3.2	0.9	—	—
Total contractual cash obligations . . . . .	<u>\$9.4</u>	<u>\$5.1</u>	<u>\$4.3</u>	<u>\$—</u>	<u>\$—</u>

The contractual summary above reflects only payment obligations that are fixed and determinable. We also have contractual payment obligations, the timing of which are contingent on future events. We are obligated to make certain payments under our license agreements with The Board of Trustees of the Leland Stanford Junior University and The Brigham and Women's Hospital, Inc. if milestones relating to the development and regulatory approval of E2F Decoy are achieved. In addition, if E2F Decoy is successfully commercialized we will pay royalties and pursuant to these license agreements. These royalty rates are in the low single digits. Please see "Business—License Agreements" for a further description of these agreements.

We have also entered into letters of credit totaling \$608,000 securing our operating lease obligations.

### **Recent Accounting Pronouncements**

In November 2002, the FASB issued Financial Interpretation, or FIN, No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, or FIN No. 45. FIN No. 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The adoption of FIN No. 45 did not have a material impact on our financial statements.

In December 2002, the EITF issued EITF Issue 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). EITF 00-21 provides guidance on determining whether a revenue arrangement contains multiple deliverable items and if so, requires that revenue be allocated among the different items based on fair value. EITF 00-21 also requires that revenue on any item in a revenue arrangement with multiple deliverables not delivered completely must be deferred until delivery of the item is completed. The guidance in EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Corgentech's agreements with BMS have been accounted for under the provisions of EITF 00-21.

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities*. This interpretation requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. It explains how to identify variable interest entities and how an enterprise assesses its interest in a variable interest entity to decide whether to consolidate that entity. This interpretation applies in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN No. 46 did not have a material impact on our financial position or results of operations.

#### **Item 7A. Qualitative and Quantitative Disclosures About Market Risk**

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds and corporate debt securities. Our cash and cash equivalents through December 31, 2003 included liquid money market accounts. Our short-term investments included readily marketable debt securities. Due to the short-term nature of these instruments, a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio as of December 31, 2003.

#### **BUSINESS RISKS**

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

*We will depend heavily on the success of our lead product candidate, E2F Decoy, which is still in development. If we are unable to commercialize E2F Decoy or experience significant delays in doing so, we may have to cease operations.*

We have invested a significant portion of our time and financial resources since our inception in the development of E2F Decoy. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development, approval and commercialization of E2F Decoy. If we are not successful in the completion of clinical trials for the development, approval and commercialization of E2F Decoy, we may never generate any revenues and may be forced to cease operations. All of our other product candidates are in preclinical development, and we do not expect to seek regulatory approval of these products for many years, if at all.

The commercial success of E2F Decoy will depend upon successful completion of clinical trials, manufacturing commercial supplies, obtaining marketing approval, successfully launching the product and acceptance of the product by the medical community and third party payors as clinically useful, cost-effective and safe. If the data from one or both of our Phase 3 clinical trials is not satisfactory, we may not proceed with our planned filing of an application for approval or we may be forced to delay the filing or narrow the indication for which we are seeking marketing approval.

Our E2F Decoy consists of a drug and a delivery device, both of which must be approved to commercialize E2F Decoy. Even if we file an application for approval with satisfactory clinical data, the

FDA may not accept our filing, or may request additional information, including data from additional clinical trials. The FDA may also approve the device but not the drug or vice versa, may approve E2F Decoy for very limited purposes with many restrictions on its use, may delay approval, or ultimately, may not grant marketing approval for E2F Decoy. Even if we do receive the approval of the FDA, we may be unable to gain market acceptance by the medical community and third-party payors.

***If BMS terminates our collaboration, or if there are any adverse developments in our relationship with BMS, we could be prevented from successfully commercializing E2F Decoy.***

In October 2003, we entered into agreements with BMS relating to the development, regulatory approval and commercialization of E2F Decoy. Based on the terms of our collaboration, we expect to receive significant development funding and milestone payments from BMS. BMS may terminate the collaborative agreement upon six months prior notice, after which BMS will not be obligated to fund our development and commercialization costs or make milestone payments. The collaboration is governed by a joint steering committee, consisting of an equal number of representatives of us and BMS. There are also working groups with representation from both parties that have responsibility over development and regulatory, manufacturing, finance and commercialization matters. Ultimate decision-making authority is vested in us as to some matters and in BMS as to other matters. A third category of decisions require the approval of both us and BMS. Outside the United States, ultimate decision-making authority as to most matters is vested in BMS. Any loss of BMS as a commercial partner for E2F Decoy, dispute over the terms of the collaboration, disagreements over decisions made with respect to the collaboration or other adverse developments in our relationship with BMS would harm our business and would require us to seek additional capital.

***We have limited manufacturing capabilities and manufacturing personnel and expect to depend on third parties to manufacture E2F Decoy and any future products. We are dependent on single suppliers for E2F Decoy intermediates and components of the pressure device used to administer E2F Decoy.***

We have limited personnel with experience in, and we do not own facilities for, manufacturing any clinical or commercial products. We rely on third parties to supply us with E2F Decoy and its related device for our clinical trials. We do not have agreements with these third parties which obligate them to provide us with any products for future clinical trials or future commercial sales. We are in the process of negotiating agreements with these third parties for the production of the active pharmaceutical ingredient of E2F Decoy, for the filling, finishing, labeling and distribution of the final E2F Decoy product, and for the manufacture of the pressure device, for clinical supply and commercial sale. These manufacturers will be our single suppliers. There are a limited number of manufacturers that are capable of manufacturing the active ingredient of E2F Decoy or its related device and are willing to do so. If we are unable, for whatever reason, to obtain E2F Decoy and its related device from these suppliers, we may not be able to obtain alternate manufacturers in a timely manner, if at all, to meet our requirements for clinical trials and, subject to receipt of regulatory approvals, commercial sale. We also depend on third-party contract laboratories to perform quality control testing of E2F Decoy and its device.

The third-party manufacturer of the active pharmaceutical ingredient of E2F Decoy plans to produce commercial quantities of E2F Decoy at a different site than the sites used to manufacture this ingredient for clinical trial use. Because of this change of site, the FDA may require us to conduct a study to demonstrate that changing the manufacturing location has not affected the product. If we cannot establish that the products are equivalent or if the FDA disagrees with the results of our study, commercial launch of E2F Decoy would be delayed.

In order to produce E2F Decoy in the quantities that we anticipate will be required to meet anticipated market demand, we need to increase, or "scale up," the production process by a significant factor over the current level of production of the active pharmaceutical ingredient. If we are unable to do so, we may not be able to produce E2F Decoy in sufficient quantities to meet the requirements for

the launch of the product or to meet future demand. In addition, if the scaled up production process is not efficient, our gross margins may be reduced.

We may in the future elect to manufacture certain of our products in our own manufacturing facilities. We would need to invest additional funds and recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

***If our third-party manufacturers' facilities do not follow current good manufacturing practices, our product development and commercialization efforts may be harmed.***

There are a limited number of manufacturers that operate under the FDA's and European Union's good manufacturing practices regulations and are capable of manufacturing E2F Decoy. Our third-party manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. A failure of our third-party manufacturers to follow current good manufacturing practices or other regulatory requirements and to document their adherence to such practices may lead to significant delays in the availability of products for commercial use or clinical study, the termination of, or hold on a clinical study, or may delay or prevent filing or approval of marketing applications for our products. In addition we could be subject to sanctions being imposed on us, including fines, injunctions and civil penalties. Changing manufacturers may require revalidation of the manufacturing process and procedures in accordance with FDA mandated current good manufacturing practices and will require FDA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development of our products, including E2F Decoy, or market them.

***Our competitors currently offer and may develop therapies that reduce the size of our markets.***

There are a growing number of approved therapies for the prevention or treatment of cardiovascular disease. These include cholesterol lowering agents, agents to prevent or disrupt blood clots, drug eluting stents, balloon angioplasty, arterial bypass grafts and synthetic conduits used for bypass. Some or all of these treatments could reduce the size of the CABG, PBG and AV graft markets. These treatments are marketed by major pharmaceutical and/or medical device companies. In particular, drug eluting stents were only approved for use in 2003 and could potentially result in a significant decrease in bypass graft procedure volumes. Two drug eluting stents have been approved in the United States and are being marketed by Johnson & Johnson and Boston Scientific Corporation, two companies with significant financial and marketing resources. In addition, various other treatments for cardiovascular disease are in various stages of preclinical or clinical testing by other companies. These therapies could also affect the size of the CABG, PBG and/or AV graft markets or could result in pricing pressure if we receive marketing approval for E2F Decoy.

***If we fail to obtain an adequate level of reimbursement for our products by third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.***

The availability and levels of reimbursement by governmental and other third party payors affect the market for our products. The efficacy, safety and cost-effectiveness of our products as well as the efficacy, safety and cost-effectiveness of any competing products will determine the availability and level of reimbursement. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including E2F Decoy, to other available

therapies. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenues would be reduced.

Because E2F Decoy treatment occurs during bypass graft surgery, and most of these patients are over 65 years of age and likely to be covered by Medicare, we will seek to have the level of reimbursement for bypass surgery incorporating E2F Decoy treatment increased by the Centers for Medicaid and Medicare Services, or CMS. CMS is the federal agency that administers Medicare and makes coverage and reimbursement decisions for Medicare beneficiaries. This is a time consuming and expensive process. In addition, many private insurers adopt CMS' coverage and reimbursement decisions for their insureds. If CMS does not increase the level of reimbursement to hospitals associated with E2F Decoy treatment on a timely basis, or at all, or establishes an unsatisfactory level of reimbursement, E2F Decoy may never obtain market acceptance or generate meaningful revenues.

***The Fast Track designation for development of E2F Decoy may not actually lead to a faster development or regulatory review or approval process.***

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. Marketing applications filed by sponsors of products in fast track development may qualify for expedited review under policies or procedures offered by the FDA, but the Fast Track designation does not assure such qualification. We have been granted Fast Track designation from the FDA for E2F Decoy for the prevention of bypass graft failure and AV graft failure. E2F Decoy's Fast Track designation may be withdrawn by the FDA if the FDA believes that it is no longer supported by data from our clinical development program. In addition, E2F Decoy's Fast Track designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that the FDA will ultimately approve E2F Decoy.

***If our preclinical tests or clinical trials with respect to our TF decoys for bypass graft failure, AV graft failure, inflammatory diseases or cancer do not meet safety or efficacy endpoints in these evaluations, or if we experience significant delays in these tests or trials, our ability to commercialize products and our financial position will be impaired.***

Clinical development, including preclinical testing, is a long, expensive and uncertain process and is subject to delays. It may take us several years to complete our testing, and failure can occur at any stage of testing. Patient enrollment in future clinical trials and completion of patient follow-up in our current Phase 3 clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study and patient compliance. Delays in patient enrollment or failure of patients to continue to participate in a study may cause an increase in costs and delays, or result in the failure of the trial.

The results of preclinical or clinical studies do not necessarily predict future clinical trial results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Drug-related adverse events during a clinical trial could cause us to repeat a trial, terminate a trial or cancel the program. In addition, we are required by the FDA to conduct additional preclinical studies, including toxicology, while our clinical studies are ongoing.

***We have a limited operating history and if we do not generate significant revenues, we will not be able to achieve profitability.***

We do not have any products approved for marketing. We have a limited history of operations and have focused primarily on clinical trials of E2F Decoy. We have incurred net losses since our inception, including net losses of approximately \$63.2 million for the year ended December 31, 2003. As of

December 31, 2003, we had an accumulated deficit of approximately \$102.0 million. In 2003, net cash used in operating activities was approximately \$2.1 million per month. We expect to incur substantial net losses to further develop and commercialize E2F Decoy and do not know whether or when we will become profitable. If we are unable to generate significant revenues from E2F Decoy or attain profitability, we will not be able to sustain our operations.

*We will need additional financing, which may be difficult to obtain. If we fail to obtain necessary financing or do so on unattractive terms, our development programs and other operations could be harmed.*

We will require substantial funds to conduct development, including preclinical testing and clinical trials of our potential products including E2F Decoy. We expect that our existing cash, cash equivalents and short-term investments, the net proceeds from our initial public offering plus expected reimbursements of E2F Decoy development costs of approximately \$23.2 million in aggregate from BMS during fiscal 2004 and the first half of fiscal 2005 and our first regulatory milestone payment from BMS of \$20.0 million (payable upon our first U.S. New Drug Application filing for E2F Decoy) will be sufficient to fund our planned operations through at least mid-2005. BMS will fund a majority of the ongoing development costs we incur for the development of E2F Decoy for CABG, PBG and AV graft failure. We expect to increase our spending significantly as we expand our infrastructure, development programs and commercialization activities and our future capital requirements will depend on many factors, including:

- the success of our collaboration with BMS;
- the scope and results of our E2F Decoy clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for E2F Decoy;
- the cost of E2F Decoy manufacturing activities;
- the cost of E2F Decoy commercialization activities, including marketing, sales and distribution;
- the advancement of our NF- $\kappa$ B Decoy and cancer decoys into development; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation.

Additional financing may not be available when we need it or may not be available on favorable terms. If we are unable to obtain adequate funding on a timely basis, we may be required to significantly curtail one or more of our research, development or commercial programs. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience dilution and the terms of any new equity securities may have preference over our common stock.

*Our products are based on a new technology, TF decoys, and we have only limited experience in regulatory affairs, which may affect our ability or the time required to obtain necessary regulatory approvals.*

All of our product candidates, including E2F Decoy, are based on our TF decoy technology. Because there are currently no approved products based on this technology, the regulatory requirements governing this type of product may be more rigorous or less clearly established than for already approved classes of therapeutics. We must provide the FDA and foreign regulatory authorities with preclinical and clinical data that demonstrate that our products are safe and effective before they can be approved for commercial sale. We, not BMS, have primary responsibility for compiling this data and submitting the application for regulatory approval of E2F Decoy in the United States. We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals.

As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals for our product candidates.

***If our post-approval follow up trial of CABG patients does not show a difference in major cardiac events between treated and untreated patients the FDA could withdraw or limit the approval of E2F Decoy.***

If E2F Decoy is approved by the FDA, we will be required by the FDA to monitor the CABG patients for up to five years after enrollment to track major cardiac events such as death, heart attack, the need for a repeat CABG surgery or the need for surgical intervention to rescue a failed or failing graft. Even if E2F Decoy is approved for the prevention of bypass graft failure, the FDA may subsequently withdraw or limit such approval if we cannot show a difference in major cardiac events between CABG patients treated with E2F Decoy and CABG patients receiving a placebo.

***If third-party clinical research organizations do not perform in an acceptable and timely manner, our clinical trials could be delayed or unsuccessful.***

We do not have the ability to conduct all of our clinical trials independently. We rely on clinical investigators, third-party clinical research organizations and consultants to perform substantially all of these functions. If we cannot locate acceptable contractors to run our clinical trials or enter into favorable agreements with them, or if these third parties do not successfully carry out their contractual duties, satisfy FDA requirements for the conduct of clinical trials or meet expected deadlines, we will be unable to obtain required approvals and will be unable to commercialize our products, including E2F Decoy, on a timely basis, if at all. Our agreements are generally cancelable by either party with 30 to 90 days notice, with or without cause.

***We may fail to obtain FDA clearance or approval of the pressure device used to deliver E2F Decoy.***

We will need to obtain clearance of the pressure device used to deliver the drug by the FDA's Center for Devices and Radiological Health, or CDRH, under a 510(k) premarket notification establishing that the pressure device is substantially equivalent to one or more marketed predicate devices. We expect to file such notification in 2004. In the event we cannot establish such substantial equivalence, we will need to request that the FDA classify the pressure device as a Class I or Class II device that can be marketed without premarket approval or, failing that, obtain premarket approval of the pressure device by CDRH. The FDA classifies medical devices into three classes based on the regulatory control deemed necessary by the FDA to reasonably ensure safety and effectiveness. A Class I device is subject to general controls, including compliance with the FDA's good manufacturing practices regulations and labeling regulations. A Class II device is subject to general controls and special controls, which may include special labeling requirements, mandatory performance standards and post-market surveillance. A Class III device is subject to pre-market approval requiring the independent demonstration that the new medical device is safe and effective. If we are unable to obtain clearance or approval of the pressure device, the commercialization of E2F Decoy could be delayed or possibly prevented.

***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 or 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, injunctions or the imposition of civil or criminal penalties.

***Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.***

We intend to market our products in international markets. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. In the case of E2F Decoy, we have had limited interactions with foreign regulatory authorities, and BMS has responsibility to obtain regulatory approvals outside the United States. We will be dependent on BMS to obtain these approvals. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining 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 foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

***If we do not find collaborators for our other product candidates, we may have to reduce or delay our rate of product development and/or increase our expenditures.***

Our strategy to develop, manufacture and commercialize our products includes entering into various relationships with pharmaceutical companies to advance our programs and reduce our expenditures on each program. To date, we have entered into one collaboration agreement regarding E2F Decoy. Our other product candidates will target highly competitive therapeutic markets in which we have limited experience and expertise. If we are unable to develop this expertise ourselves, we will need to enter into agreements with a larger biotechnology or pharmaceutical company to provide us with the necessary resources and experience for the development and commercialization of products in these markets. There are a limited number of companies with the resources necessary to develop our future products commercially, and we may be unable to attract any of these firms. A company that has entered into a collaboration agreement with one of our competitors may choose not to enter into a collaboration agreement with us. We may not be able to negotiate any collaborations on acceptable terms or at all. If we are not able to establish collaborative arrangements, we may have to reduce or delay further development of some of our programs and/or increase our expenditures and undertake the development activities at our own expense. If we elect to increase our expenditures to fund our development programs, we will need to obtain additional capital, which may not be available on acceptable terms or at all.

In addition, there have been a significant number of recent business combinations among large biotechnology and pharmaceutical companies that have reduced the number of potential future collaborators. If business combinations involving BMS or other potential collaborators were to occur, the effect could be to diminish, terminate or cause delays in one or more of our product development programs.

***We depend on our officers and key employees, and if we are not able to retain them or recruit additional qualified personnel, our business will suffer.***

We are highly dependent on our President and Chief Executive Officer, John P. McLaughlin and other officers and key employees. Due to the specialized knowledge each of our officers and key employees possesses with respect to E2F Decoy and our operations, the loss of service of any of our officers or key employees could delay or prevent the successful completion of our Phase 3 clinical trials

or the commercialization of E2F Decoy. We do not carry key man life insurance on our officers or key employees except for Mr. McLaughlin.

We have employment agreements with Mr. McLaughlin, Richard P. Powers, our Vice President and Chief Financial Officer, Todd J. Lorenz, our Chief Medical Officer, Leslie M. McEvoy, our Vice President, Research and James Z. Huang, our Vice President, Business Development and Commercial Operations. Each of our officers and key employees may terminate their employment without notice and without cause or good reason. We currently are not aware that any officer or key employee is planning to leave or retire.

In addition, our growth will require hiring a significant number of qualified scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. Our offices are located in the San Francisco Bay Area, where competition for personnel with biopharmaceutical skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

*If we are unable to manage our expected growth, we may not be able to commercialize our product candidates, including E2F Decoy.*

We are rapidly expanding our operations and expect to continue to grow our research and development, product development and administrative operations. In 2003, we relocated to a larger facility in South San Francisco, California, in order to expand our research and development efforts and to further develop E2F Decoy. This expansion has placed, and is expected to continue to place, a significant strain on our management, operational and financial resources. In particular, the commencement of our two Phase 3 clinical trials has consumed a significant portion of management's time and our financial resources. To manage any further growth and to commercialize E2F Decoy, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. There can be no assurance that our current and planned personnel, systems, procedures and controls will be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

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

*We face the risk of product liability claims and may not be able to obtain insurance.*

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing, and marketing of drugs and related devices. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. In addition, if any of our product candidates are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity or reduced acceptance of our products in the market.

*Our operations involve hazardous materials and we must comply with environmental laws and regulations, which can be expensive.*

Our research and development activities involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous

waste products. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. We generally contract with third parties for the disposal of such substances and store certain low-level radioactive waste at our facility until the materials are no longer considered radioactive. We cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs associated with civil penalties or criminal fines and in complying with environmental laws and regulations. We do not have any insurance for liabilities arising from hazardous materials. Compliance with environmental laws and regulations is expensive, and current or future environmental regulation may impair our research, development or production efforts.

***The life sciences industry is highly competitive and subject to rapid technological change.***

The life sciences industry is highly competitive and subject to rapid and profound technological change. Our present and potential competitors include major pharmaceutical companies, as well as specialized biotechnology and life sciences firms in the United States and in other countries. Most of these companies have considerably greater financial, technical and marketing resources than we do. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in our competitors. Our existing or prospective competitors may develop processes or products that are more effective than ours or be more effective at implementing their technologies to develop commercial products faster. Our competitors may succeed in obtaining patent protection and/or receiving regulatory approval for commercializing products before us. Developments by our competitors may render our product candidates obsolete or non-competitive.

We also experience competition from universities and other research institutions, and we frequently compete with others in acquiring technology from those sources. These industries have undergone, and are expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. There can be no assurance that others will not develop technologies with significant advantages over those that we are seeking to develop. Any such development could harm our business.

***Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact upon our ability to sell our products profitably. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system, either nationally or at the state level. These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Legislation creating a prescription drug benefit and making certain changes in Medicare reimbursement has recently been enacted by Congress. Given this legislation's recent enactment, it is still too early to determine its impact on the pharmaceutical industry and our business. Further federal and state proposals are likely. The potential for adoption of these proposals may affect our ability to raise capital, obtain additional collaborators or market our products. Such proposals, if enacted, may reduce our revenues, increase our expenses or limit the markets for our products. In particular, we expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

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

*If we are unable to obtain and maintain protection for the intellectual property incorporated into our products, the value of our technology and products will be adversely affected.*

Our success will depend in large part on our ability or the ability of our licensors to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into our products. As of December 31, 2003, we had 37 issued United States and foreign patents and 37 pending United States and foreign patent applications. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. Neither we nor our licensors may be able to obtain additional issued patents relating to our technology. Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of the term of patent protection we may have for our products. In addition, our patents and our licensors' patents may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any leak of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets.

*If we lose our licenses from Stanford University or Brigham and Women's Hospital we will not be able to continue our business.*

We hold licenses from The Board of Trustees of the Leland Stanford Junior University and The Brigham and Women's Hospital, Inc. for patents, patent applications and know-how covering our technology generally and E2F Decoy specifically. These license agreements impose various diligence, commercialization, sublicensing, royalty, insurance, and other obligations on us. If we fail to comply with the obligations in the license agreements, the licensor may have the right to terminate the license and we may not be able to market products that were covered by the license including E2F Decoy. To date, we have met all of our obligations under these agreements.

*We may incur substantial costs enforcing our patents, defending against third-party patents, invalidating third-party patents or licensing third-party intellectual property, as a result of litigation or other proceedings relating to patent and other intellectual property rights.*

We may not have rights under some patents or patent applications that would be infringed by technologies that we use in our research, drug targets that we select, or product candidates that we seek to develop and commercialize. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We or our collaborators therefore may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may

be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of patent infringement claims, which could harm our business.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Although we are not currently a party to any patent litigation or any other adversarial proceeding, including any interference proceeding declared before the United States Patent and Trademark Office, regarding intellectual property rights with respect to our products and technology, we may become so in the future. We are not currently aware of any actual or potential infringement claim involving our intellectual property rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent or other proceeding is resolved against us, we may be enjoined from researching, developing, manufacturing or commercializing our products without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

*We may not be successful in our efforts to expand our portfolio of products and develop additional delivery technologies.*

A key element of our strategy is to discover, develop and commercialize a portfolio of new drugs in addition to E2F Decoy, and technologies to deliver those drugs safely and efficiently. We are seeking to do so through our internal research programs and in-licensing. A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify new disease targets, product candidates and delivery technologies require substantial technical, financial and human resources whether or not any candidates or technologies are ultimately identified. Our research programs may initially show promise in identifying potential product candidates or delivery technologies, yet fail to yield product candidates or delivery technologies for clinical development for any of the following reasons:

- research methodology used may not be successful in identifying potential product candidates;
- potential delivery technologies may not safely or efficiently deliver our drugs; and
- product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

If we are unable to discover suitable potential product candidates or develop additional delivery technologies through internal research programs or in-license suitable products or delivery technologies on acceptable business terms, our business prospects will suffer.

#### **Other Risks**

*Changes in, or interpretations of, accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.*

Accounting methods and policies for biopharmaceutical companies, including policies governing revenue recognition, expenses, accounting for stock options and in-process research and development

costs are subject to further review, interpretation and guidance from relevant accounting authorities, including the Securities and Exchange Commission. Changes to, or interpretations of, accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this prospectus. We currently are not required to record stock-based compensation charges if the employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. Although the standards have not been finalized and the timing of a final statement has not been established, the Financial Accounting Standards Board has announced their support for recording expense for the fair value of stock options granted. If we were to change our accounting policy to record expense for the fair value of stock options granted and retroactively restate all prior periods presented, then our operating expenses would increase. We rely heavily on stock options to motivate existing employees and attract new employees. If we are required to expense stock options, we may then choose to reduce our reliance on stock options as a motivation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. If we did not reduce our reliance on stock options, our reported losses would increase.

***Anti-takeover defenses that we have in place could prevent or frustrate attempts by stockholders to change the direction or management of the company.***

Provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our board of directors. These provisions:

- establish a classified board of directors, so that not all members of our board may be elected at one time;
- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirors at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence.***

Our (a) executive officers and (b) directors and principal stockholders, together with their affiliates, as of February 27, 2004, beneficially owned approximately 6.6% and 55.2% of our voting stock, respectively, including shares subject to outstanding options. Our executive officers are not affiliated with any of our directors, principal stockholders or their affiliates. These stockholders will likely be able to determine the composition of our board of directors, possess the voting power to approve all matters requiring stockholder approval, and continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

*If our stock price is volatile, purchasers of our common stock could incur substantial losses.*

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The price for our common stock may be influenced by many factors, including:

- results of our clinical trials;
- failure of any of our product candidates, if approved, to achieve commercial success;
- developments concerning our collaboration with BMS;
- regulatory developments in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- ability to manufacture our products to commercial standards;
- public concern over our products;
- litigation;
- the departure of key personnel;
- future sales of our common stock;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- investors' perceptions of us; and
- general economic, industry and market conditions.

*If there are substantial sales of our common stock, our stock price could decline.*

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Upon the closing of our initial public offering on February 18, 2004, we had 27,730,292 shares of common stock outstanding, including 6,900,000 shares sold in our initial public offering. Of the remaining 20,830,292 shares outstanding upon the closing of our initial public offering, approximately 15,019,134 shares may be sold pursuant to Rule 144, 144(k) and 701 upon the expiration of 180-day lock-up agreements.

Existing stockholders holding an aggregate of 17,912,685 shares of common stock and 12,500 shares underlying a warrant, have rights with respect to the registration of these shares of common stock with the Securities and Exchange Commission. If we register their shares of common stock following the expiration of the lock-up agreements, they can sell those shares in the public market.

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

The financial statements required by this item are submitted as a separate section of this Annual Report on Form 10-K. See Item 15 of Part IV.

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

None.

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

#### *Evaluation of disclosure controls and procedures.*

Based on their evaluation as of December 31, 2003, our chief executive officer and chief financial officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were sufficiently effective to ensure that the information required to be disclosed by us in this Annual Report on Form 10-K was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-K.

#### *Changes in internal controls.*

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

#### *Limitations on the effectiveness of controls.*

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Corgentech have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## PART III

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

Information concerning our directors will be contained in our definitive Proxy Statement with respect to our 2004 Annual Meeting of Stockholders, to be held on May 13, 2004, under the caption "Proposal 1—Election of Directors" and is incorporated by reference into this Annual Report on Form 10-K. Information concerning our Executive Officers is set forth under "Executive Officers and Key Employees" in Part I of this Annual Report on Form 10-K and is incorporated herein by reference. Information concerning compliance with Section 16(a) of the Securities and Exchange Act of 1934 is incorporated by reference to the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance," to be contained in our definitive Proxy Statement. Information concerning our code of conduct is incorporated by reference to the section entitled "Code of Conduct," to be contained in our definitive Proxy Statement.

### **Item 11. Executive Compensation**

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2004 Annual Meeting of Stockholders, to be held on May 13, 2004, under the caption "Executive Compensation," and is hereby incorporated by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2004 Annual Meeting of Stockholders, to be held on May 13, 2004, under the caption "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans," and is hereby incorporated by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2004 Annual Meeting of Stockholders, to be held on May 13, 2004, under the caption "Certain Transactions," and is hereby incorporated by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2004 Annual Meeting of Stockholders, to be held on May 13, 2004, under the caption "Proposal 2—Ratification of Selection of Independent Accountants," and is hereby incorporated by reference.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

	<u>Page</u>
1. Financial Statements and Report of Independent Auditors .....	55
2. Notes to Financial Statements .....	63
3. Financial Statement Schedules—None.	
4. Exhibits.—See Exhibit Index	

(b) Reports on Form 8-K

We did not file any reports on Form 8-K during the fourth quarter ended December 31, 2003.

(c) Exhibits

See Item 15(a) above.

(d) Financial Statement Schedule

See Item 15(a) above.

**Corgentech Inc.**  
**Index to Financial Statements**

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## REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders  
Corgentech Inc.

We have audited the accompanying balance sheets of Corgentech Inc. as of December 31, 2002 and 2003 and the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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 financial position of Corgentech Inc. at December 31, 2002 and 2003 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
January 23, 2004 except for Note 11 as to  
which the date is February 12, 2004

**Corgentech Inc.**

**Balance Sheets**

	<u>December 31,</u>	
	<u>2002</u>	<u>2003</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents . . . . .	\$ 13,184,713	\$ 54,589,874
Short-term investments . . . . .	16,010,640	—
Contract revenue receivable, related party . . . . .	—	6,940,713
Prepaid expenses and other current assets . . . . .	747,849	2,695,520
Notes receivable from employees . . . . .	79,167	79,167
<b>Total current assets . . . . .</b>	<b>30,022,369</b>	<b>64,305,274</b>
Property and equipment, net . . . . .	1,596,840	2,278,471
Restricted cash . . . . .	—	638,298
Notes receivable from employees . . . . .	191,333	168,167
Other long-term assets . . . . .	36,660	1,933,215
<b>Total assets . . . . .</b>	<b>\$ 31,847,202</b>	<b>\$ 69,323,425</b>
<b>Liabilities, convertible preferred stock and stockholders' deficit</b>		
<b>Current liabilities:</b>		
Bank overdraft . . . . .	\$ 609,559	\$ 1,321,542
Accounts payable . . . . .	1,661,418	3,333,833
Current portion of deferred revenue, related party . . . . .	—	7,692,307
Current portion of long-term debt . . . . .	—	453,898
Accrued clinical trial liabilities . . . . .	1,913,307	2,592,321
Other accrued liabilities . . . . .	1,401,773	1,375,730
Refundable exercise price . . . . .	11,814	519,340
<b>Total current liabilities . . . . .</b>	<b>5,597,871</b>	<b>17,288,971</b>
Deferred revenue, related party, net of current portion . . . . .	—	15,570,720
Long-term debt, less current portion . . . . .	—	627,581
Deferred rent and accrued loss on sublease . . . . .	151,411	321,905
<b>Commitments</b>		
<b>Convertible preferred stock, \$0.001 par value:</b>		
Series A: 4,325,254 shares authorized; 1,081,304 shares designated, issued, and outstanding at December 31, 2002 and 2003; aggregate liquidation preference of \$2,500,000 at December 31, 2002 and 2003, respectively . . . . .	2,484,993	2,484,993
Series B and B-1: 12,827,778 shares authorized; 3,194,444 shares designated, issued, and outstanding at December 31, 2002 and 2003; aggregate liquidation preference of \$13,000,000 at December 31, 2002 and 2003, respectively . . . . .	12,884,968	12,884,968
Series C: 32,250,000 and 48,000,000 shares authorized at December 31, 2002 and 2003, respectively; 6,918,345 and 10,972,389 shares designated, issued, and outstanding at December 31, 2002 and 2003, respectively; aggregate liquidation preference of \$51,195,753 and \$81,195,679 at December 31, 2002 and 2003, respectively . . . . .	48,980,948	78,986,812
Series D: 8,316,008 shares authorized; 2,079,002 designated, issued, and outstanding at December 31, 2003, no shares designated, issued, and outstanding at December 31, 2002; aggregate liquidation preference of \$0 and \$20,000,000 at December 31, 2002 and 2003, respectively . . . . .	—	19,975,538
<b>Stockholders' deficit:</b>		
Common stock, \$0.001 par value: 64,230,000 and 87,730,000 shares authorized at December 31, 2002 and 2003, respectively; 2,182,406 and 2,441,570 shares issued and outstanding at December 31, 2002, and 2003 . . . . .	2,182	2,441
Additional paid-in capital . . . . .	797,601	41,480,029
Notes receivable from officers . . . . .	(121,315)	(43,238)
Deferred stock compensation . . . . .	(221,979)	(18,300,081)
Accumulated other comprehensive income . . . . .	81,001	(50)
Accumulated deficit . . . . .	(38,790,479)	(101,957,164)
<b>Total stockholders' deficit . . . . .</b>	<b>(38,252,989)</b>	<b>(78,818,063)</b>
<b>Total liabilities and stockholders' deficit . . . . .</b>	<b>\$ 31,847,202</b>	<b>\$ 69,323,425</b>

See accompanying notes.

**Corgentech Inc.**  
**Statements of Operations**

	Year ended December 31,		
	2001	2002	2003
Contract revenue, related party .....	\$ —	\$ —	\$ 8,677,686
Operating expenses:			
Research and development .....	8,068,493	21,536,194	46,004,355
General and administrative .....	2,373,776	3,205,653	6,066,634
Total operating expenses .....	<u>(10,442,269)</u>	<u>(24,741,847)</u>	<u>(52,070,989)</u>
Loss from operations .....	(10,442,269)	(24,741,847)	(43,393,303)
Interest and other income .....	348,820	470,806	416,666
Interest and other expense .....	—	(1,376,114)	(20,190,048)
Net loss .....	(10,093,449)	(25,647,155)	(63,166,685)
Preferred stock deemed dividend .....	—	—	(14,407,484)
Net loss attributable to common stockholders .....	<u>\$(10,093,449)</u>	<u>\$(25,647,155)</u>	<u>\$(77,574,169)</u>
Basic and diluted net loss per common share .....	<u>\$ (6.10)</u>	<u>\$ (14.38)</u>	<u>\$ (37.90)</u>
Shares used to compute basic and diluted net loss per common share .....	<u>1,653,631</u>	<u>1,783,564</u>	<u>2,046,944</u>

See accompanying notes.

**Corgentech Inc.**  
**Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit)**

	Convertible Preferred Stock		Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Notes Receivable from Officers	Deferred Stock Compensation	Accumulated Other Comprehensive Income	Accumulated Stockholders' Deficit	Total
	Shares	Amount								
<b>Balances at December 31, 2000</b> .....	2,350,053	\$ 7,455,821	1,808,966	\$ 1,809	\$ 437,845	\$ (70,800)	\$ (322,320)	\$ 43,320	\$ (3,049,875)	\$ (2,960,021)
Issuance of Series B and B-1 convertible preferred stock at \$4.00 to \$4.32 per share to investors for cash, net of issuance costs of \$56,359 .....	1,925,695	7,868,640	—	—	—	—	—	—	—	—
Issuance of common stock at \$0.24 per share for licenses in January 2001 .....	—	—	23,750	24	5,676	—	—	—	—	5,700
Issuance of common stock at \$0.24 to \$0.40 per share for cash and notes receivable upon exercise of stock options .....	—	—	146,250	146	50,954	(50,515)	—	—	—	585
Issuance of common stock at \$0.24 to \$0.40 per share for cash upon exercise of stock options .....	—	—	106,125	106	41,044	—	—	—	—	41,150
Issuance of stock options for consulting services .....	—	—	—	—	20,533	—	—	—	—	20,533
Issuance of Series B-1 warrants granted for bank line of credit .....	—	45,500	—	—	—	—	—	—	—	—
Deferred stock compensation .....	—	—	—	—	155,100	—	(155,100)	—	—	—
Amortization of deferred stock compensation .....	—	—	—	—	—	—	158,278	—	—	158,278
Unrealized loss on available-for-sale securities .....	—	—	—	—	—	—	—	(35,451)	—	(35,451)
Net loss .....	—	—	—	—	—	—	—	—	(10,093,449)	(10,093,449)
Net and comprehensive loss .....	—	—	—	—	—	—	—	—	—	(10,128,900)
<b>Balances at December 31, 2001</b> .....	4,275,748	15,369,961	2,085,091	2,085	711,152	(121,315)	(319,142)	7,869	(13,143,324)	(12,862,675)
<b>(carried forward)</b> .....										

See accompanying notes.

**Corgentech Inc.**  
**Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit) (continued)**

	Convertible Preferred Stock		Common Stock Shares Amount	Additional Paid-in Capital	Notes Receivable from Officers	Deferred Stock Compensation	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount							
<b>Balances at December 31, 2001 (brought forward)</b> . . . . .	4,275,748	\$15,369,961	2,085,091	\$ 711,152	\$(121,315)	\$ (319,142)	\$ 7,869	\$(13,143,324)	\$(12,862,675)
Issuance of Series C convertible preferred stock at \$7.40 per share to investors for cash and notes, net of issuance costs of \$3,500,015 . . . . .	6,807,423	46,875,135	—	—	—	—	—	—	—
Issuance of Series C preferred stock at \$7.40 per share for financing fees . . . . .	109,121	807,499	—	—	—	—	—	—	—
Issuance of Series C preferred stock at \$7.40 per share for professional services . . . . .	1,801	13,333	—	—	—	—	—	—	—
Beneficial conversion feature on convertible notes payable and fair value of warrants issued with notes . . . . .	—	1,284,981	—	—	—	—	—	—	—
Issuance of common stock at \$0.24 to \$1.20 per share for cash upon exercise of stock options, net of repurchases . . . . .	—	—	97,315	37,655	—	—	—	—	37,752
Issuance of stock options for consulting services . . . . .	—	—	—	16,437	—	—	—	—	16,437
Deferred stock compensation . . . . .	—	—	—	37,811	—	(37,811)	—	—	—
Adjustment to deferred stock compensation for cancellation of options . . . . .	—	—	—	(5,454)	—	5,454	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	129,520	—	—	129,520
Unrealized gain on available-for-sale securities . . . . .	—	—	—	—	—	—	73,132	—	73,132
Net loss . . . . .	—	—	—	—	—	—	—	(25,647,155)	(25,647,155)
Net and comprehensive loss . . . . .	—	—	—	—	—	—	—	(25,574,023)	(25,574,023)
<b>Balances at December 31, 2002 (carried forward)</b> . . . . .	11,194,093	64,350,909	2,182,406	797,601	(121,315)	(221,979)	81,001	(38,790,479)	(38,252,989)

See accompanying notes.

**Corgentech Inc.**

**Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit) (continued)**

	Convertible Preferred Stock		Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Stock Compensation	Accumulated Other Comprehensive Income	Accumulated Stockholders' Deficit	Total Stockholders' Deficit
	Shares	Amount								
<b>Balances at December 31, 2002 (brought forward)</b>	11,194,093	\$ 64,350,909	2,182,406	\$ 2,182	\$ 797,601	\$(121,315)	\$ (221,979)	\$ 81,001	\$ (38,790,479)	\$(38,252,989)
Issuance of Series C convertible preferred stock at \$7.40 per share to investors for cash, net of issuance costs of \$21,612	4,054,044	29,978,378	—	—	—	—	—	—	—	—
Issuance of Series D convertible preferred stock at \$9.62 per share to investors for cash, net of issuance costs of \$24,462	2,079,002	19,975,538	—	—	—	—	—	—	—	—
Issuance of common stock at \$0.24 - \$5.00 per share for cash upon exercise of stock options net of repurchases & unvested refundable shares	—	—	159,164	159	167,581	—	—	—	—	167,740
Issuance of common stock at \$1.20 per share for services	—	—	100,000	100	119,900	—	—	—	—	120,000
Stock compensation related to issuance of stock for services	—	—	—	—	1,174,545	—	—	—	—	1,174,545
Compensation related to certain options granted to consultants	—	—	—	—	176,997	—	—	—	—	176,997
Deferred stock compensation	—	—	—	—	19,057,371	—	(19,057,371)	—	—	—
Adjustment to deferred compensation for cancellation of options	—	—	—	—	(3,724)	—	3,724	—	—	—
Adjustment to deferred compensation for employee converted to consultant	—	—	—	—	(10,242)	—	10,242	—	—	—
Amortization deferred stock compensation	—	—	—	—	—	—	965,303	—	—	-965,303
Compensation related to certain warrants granted for line of credit arrangements	—	—	—	—	—	—	—	—	—	—
Repayment notes receivable from Stockholders	—	27,486	—	—	—	—	—	—	—	—
Beneficial conversion feature of bridge loan	—	—	—	—	—	7,277	—	—	—	7,277
Warrants issued in conjunction with debt	—	—	—	—	14,521,485	—	—	—	—	14,521,485
Beneficial conversion feature of Series C and Series D preferred stock	—	—	—	—	5,478,515	—	—	—	—	5,478,515
Deemed dividend for Series C and Series D convertible preferred stock	—	—	—	—	14,407,484	—	—	—	—	14,407,484
Forgiveness of note receivable from Stockholders	—	—	—	—	(14,407,484)	—	—	—	—	(14,407,484)
Change in unrealized gain on available-for-sale securities	—	—	—	—	—	70,800	—	(81,051)	—	70,800
Net loss	—	—	—	—	—	—	—	—	(63,166,685)	(63,166,685)
Comprehensive loss	—	—	—	—	—	—	—	—	—	(63,247,736)
<b>Balances at December 31, 2003</b>	17,327,139	\$114,332,311	2,441,570	\$2,441	\$41,480,029	\$ (43,238)	\$ (18,300,081)	\$ (50)	\$ (101,957,164)	\$(78,818,063)

See accompanying notes.

**Corgentech Inc.**  
**Statements of Cash Flows**

	Year ended December 31,		
	2001	2002	2003
<b>Operating activities</b>			
Net loss	\$(10,093,449)	\$(25,647,155)	\$(63,166,685)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	104,167	261,208	482,418
Non-cash compensation expense	178,811	145,957	1,169,785
Non-cash interest expense	—	1,284,981	20,000,000
Issuance of equity for services rendered and licenses, net	51,200	820,832	1,294,545
Forgiveness of note receivable	—	—	70,800
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(272,121)	(399,948)	(1,947,671)
Contract revenue receivable, related party	—	—	(6,940,713)
Notes receivable from employees	(75,000)	(195,500)	23,166
Restricted cash	(7,850)	172,955	(638,047)
Other long-term assets	(81,733)	45,073	(1,896,555)
Accounts payable	132,122	1,302,294	1,672,415
Accrued clinical trial liabilities	—	1,913,307	679,013
Other accrued liabilities	484,377	625,968	(26,042)
Deferred revenue, related party	—	—	23,263,027
Long-term liabilities	108,000	(108,000)	—
Deferred rent and accrual for loss on subleased property	351,366	(199,955)	170,494
Net cash used in operating activities	<u>(9,120,110)</u>	<u>(19,977,983)</u>	<u>(25,790,050)</u>
<b>Investing activities</b>			
Purchase of property and equipment	(662,623)	(1,152,347)	(1,164,049)
Purchase of short-term investments	(3,261,002)	(22,429,131)	(1,000,207)
Sale of short-term investments	4,495,503	8,760,492	16,929,545
Net cash provided by (used in) investing activities	<u>571,878</u>	<u>(14,820,986)</u>	<u>14,765,289</u>
<b>Financing activities</b>			
Proceeds from issuance of convertible preferred stock, net of share issuance costs	7,868,640	42,375,135	29,953,917
Proceeds from issuance of bridge loans	—	4,500,000	20,000,000
Proceeds from issuance of equipment loans	—	—	1,409,105
Repayment of equipment loans	—	—	(327,626)
Proceeds from issuance of common stock	41,735	49,566	682,543
Bank overdraft	—	609,559	711,983
Net cash provided by financing activities	<u>7,910,375</u>	<u>47,534,260</u>	<u>52,429,922</u>
Net increase (decrease) in cash and cash equivalents	(637,857)	12,735,291	41,405,161
Cash and cash equivalents at beginning of period	1,087,279	449,422	13,184,713
Cash and cash equivalents at end of period	<u>\$ 449,422</u>	<u>\$ 13,184,713</u>	<u>\$ 54,589,874</u>
<b>Supplemental schedule of cash flow information</b>			
Interest paid	\$ —	\$ 82,945	\$ 184,312
<b>Supplemental schedule of noncash investing and financing activities</b>			
Issuance of common stock for notes receivable	\$ 50,515	\$ —	\$ —
Issuance of warrants for bridge loan	\$ —	\$ 1,284,981	\$ 5,478,515
Issuance of preferred stock for professional services	\$ —	\$ 820,832	\$ —
Issuance of preferred stock as repayment of bridge loans	\$ —	\$ 4,500,000	\$ 20,000,000
Bridge loan interest paid with preferred stock	\$ —	\$ 55,890	\$ —

See accompanying notes.

**Corgentech Inc.**  
**Notes to Financial Statements**

**1. Summary of Significant Accounting Policies**

**Organization, Business, and Basis of Presentation**

Corgentech Inc. (the "Company") is a biopharmaceutical company focused on the discovery, development and commercialization of a new class of therapeutics called transcription factor decoys, or TF decoys. The Company is focused on TF decoys initially for the treatment of cardiovascular disease, inflammatory disease, such as arthritis, and cancer.

The Company is creating a pipeline of novel therapeutics based on its proprietary TF decoy technology. The Company's lead product candidate, E2F Decoy, is currently in two Phase 3 clinical trials for the prevention of vein graft failure. The Company has entered into a world-wide collaborative agreement with Bristol-Myers Squibb Company, or BMS, for the development and commercialization of E2F Decoy for all indications. The Company also has additional TF decoys in pre-clinical development for the treatment of inflammatory diseases and cancer.

The Company anticipates working on a number of long-term development projects which will involve experimental and unproven technology. The projects may require many years and substantial expenditures to complete, and may ultimately be unsuccessful. The Company will need to obtain additional funds from outside sources to continue its research and development activities, fund operating expenses, pursue regulatory approvals, and build production, sales, and marketing capabilities, as necessary. If the Company is unable to develop, receive approval for or successfully commercialize E2F Decoy, it may never be profitable and have to cease operations.

As a result of the Company's collaborative arrangement with BMS and its movement toward commercial launch of its product candidates, the Company was removed from the development stage for reporting purposes.

**Need to Raise Additional Capital**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred significant net losses and negative cash flows from operations since its inception. At December 31, 2002 and 2003, the Company had an accumulated deficit of \$38,790,479 and \$101,957,164, respectively.

If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its development programs or obtain funds through collaborative arrangements with others that may require the Company to relinquish rights to certain of its technologies, product candidates, or products that the Company would otherwise seek to develop or commercialize itself. The Company intends to raise additional funds through the issuance of equity securities, if available on terms acceptable to the Company.

**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 financial statements and accompanying notes. Actual results could differ from these estimates.

**Corgentech Inc.**  
**Notes to Financial Statements (Continued)**

**1. Summary of Significant Accounting Policies (Continued)**

**Reclassifications**

Certain reclassifications have been made to the prior year to conform to the current year presentation. These reclassifications have no impact on net loss previously recorded.

**Clinical Trials Accounting**

The Company records accruals for estimated clinical study costs, comprising work performed by contract research organizations and participating hospitals. These costs are a significant component of research and development expenses. The Company accrues costs for clinical studies performed by contract research organizations based on estimates of work performed under the contracts. Costs of setting up hospital sites for participation in the trials are accrued immediately. Hospital costs related to patient enrollment are accrued as patients are entered in the trial. Payments to hospitals for post-surgery patient angiograms are accrued at the time of the performance of the angiogram.

**Revenue Recognition**

Revenues associated with the Company's collaboration with BMS consist of non-refundable, up-front license fees and reimbursement of development expenses.

The Company uses revenue recognition criteria outlined in Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" and Emerging Issues Task Force ("EITF") Issue 00-21 "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into license fees in the statements of operations over the estimated term of the performance obligation.

**Cash Equivalents and Short-Term Investments**

The Company considers all highly liquid securities with maturities of three months or less from the date of purchase to be cash equivalents, which consist of short-term municipal and money market funds.

Management determines the appropriate classification of securities at the time of purchase. The Company has classified its entire investment portfolio as available-for-sale. The Company views its available-for-sale portfolio as available for use in current operations. Accordingly, the Company has classified all investments as short-term, even though the stated maturity may be one year or more beyond the current balance sheet date. Available-for-sale securities are carried at fair value based on quoted market prices, with unrealized gains and losses reported in accumulated other comprehensive income (loss), as a separate component of stockholders' equity (deficit).

Realized gains and losses and declines in value, if any, judged to be other than temporary on available-for-sale securities are reported in other income or expense. When securities are sold, any associated unrealized gain or loss recorded as a separate component of stockholders' equity is reclassified out of stockholders' equity on a specific-identification basis and recorded in earnings for the period.

**Corgentech Inc.**  
**Notes to Financial Statements (Continued)**

**1. Summary of Significant Accounting Policies (Continued)**

**Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments and accounts receivable. The Company places its cash and cash equivalents with two high-credit quality financial institutions. Such investments are generally in excess of FDIC insurance limits. The Company is exposed to credit risk in the event of default by the financial institutions holding the cash and cash equivalents to the extent of the amount recorded on the balance sheets. Short-term investments are invested in high-credit quality commercial paper and government agency securities.

**Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized using the straight-line method over the estimated useful lives of the assets or the term of the lease, whichever is shorter.

**Impairment of Long-Lived Assets**

In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ("SFAS No. 144"), the Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under SFAS No. 144, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value. Through December 31, 2003, there have been no such losses.

**Research and Development**

Research and development costs include related salaries, contractor fees, administrative expenses, and allocations of research related overhead costs. In accordance with SFAS No. 2, *Accounting for Research and Development Costs*, such costs are expensed as incurred.

**Stock-Based Compensation**

The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board Interpretation ("FIN") No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25*, and related interpretations and has adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*.

In December 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, *Interim Financial Reporting*, to require

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**1. Summary of Significant Accounting Policies (Continued)**

disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to employee stock compensation on reported net loss. The Company has elected to continue to follow the intrinsic-value method of accounting as prescribed by APB Opinion No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement. The resulting effect on net losses to date pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

The following table illustrates the weighted-average assumptions for the Black-Scholes model used in determining the fair value of options granted to employees:

	Year ended December 31		
	2001	2002	2003
Dividend yield . . . . .	—	—	—
Risk-free interest rate . . . . .	4.3%	3.8%	2.9%
Volatility . . . . .	80%	80%	80%
Expected life . . . . .	4 years	4 years	4 years

The Company has recorded deferred stock compensation with respect to options granted to employees of \$155,100 and \$32,357 during the years ended December 31, 2001 and 2002, respectively, representing the difference between the exercise price of the options and the deemed fair value of the common stock. The deemed fair value of the common stock amounted to \$1.00 and \$1.20 for the years ended December 31, 2001 and 2002, respectively. The deferred stock compensation is being amortized on a straight line basis over the related vesting terms of the options. Such amortization expense amounted to \$129,520 and \$114,282 for the years ended December 31, 2002 and 2003, respectively.

During the year ended December 31, 2003, certain stock options were granted with exercise prices that were below the deemed fair value of the common stock at the date of grant. Deferred stock compensation of \$19,057,371 was recorded during the year ended December 31, 2003 and will be amortized on a straight-line basis over the related vesting terms of the options. The Company recorded employee stock compensation expense of \$851,021 for the year ended December 31, 2003.

The expected future amortization expense for deferred compensation as of December 31, 2003 is as follows.

2004 . . . . .	\$ 4,823,456
2005 . . . . .	4,794,736
2006 . . . . .	4,766,360
2007 . . . . .	3,915,529
	<u>\$18,300,081</u>

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**1. Summary of Significant Accounting Policies (Continued)**

The following table illustrates the effect on net loss and net loss per common share had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation:

	Year ended December 31,		
	2001	2002	2003
Net loss attributable to common stockholders, as reported . . . . .	\$ (10,093,449)	\$ (25,647,155)	\$ (77,574,169)
Plus: Employee stock compensation expense based on intrinsic value method . . . . .	158,278	129,520	965,303
Less: Employee stock compensation expense determined under the fair value method for all awards . . . . .	(99,493)	(159,383)	(1,292,201)
Pro forma net loss . . . . .	<u>\$ (10,034,664)</u>	<u>\$ (25,677,018)</u>	<u>\$ (77,901,067)</u>
Net loss per common share attributable to common stockholders:			
Basic and diluted, as reported . . . . .	\$ (6.10)	\$ (14.38)	\$ (37.90)
Basic and diluted, pro forma . . . . .	<u>\$ (6.07)</u>	<u>\$ (14.40)</u>	<u>\$ (38.06)</u>

Stock compensation arrangements to nonemployees are accounted for in accordance with SFAS No. 123, as amended by SFAS No. 148, and EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

**Comprehensive Loss**

Comprehensive loss is comprised of net loss and unrealized gains/losses on available-for-sale securities, in accordance with SFAS No. 130, *Reporting Comprehensive Income*.

**Income Taxes**

The Company uses the liability method for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Currently there is no provision for income taxes as the Company has incurred net losses to date.

**Fair Value of Financial Instruments**

Financial instruments, including cash and cash equivalents, accounts payable, debt obligations and other accrued liabilities but excluding short-term investments, are carried at cost, which management believes approximates fair value given their short-term nature.

**Recent Accounting Pronouncements**

In November 2002, the FASB issued FASB Interpretation No. 45 (FIN 45), *Guarantor's Disclosure Requirements for Guarantees, Including Indirect Guarantees of Others*. FIN 45 clarifies the guarantor's requirements relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees and requires the guarantor to recognize at the inception of a guarantee a liability for the fair value of the guarantee obligation. FIN 45 also requires additional disclosures by a guarantor in its

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**1. Summary of Significant Accounting Policies (Continued)**

financial statements about the obligation associated with guarantees issued. The provisions for the initial recognition and measurement of guarantees are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of periods ending after December 15, 2002. The Company adopted the disclosure and accounting requirements for its financial statements as of December 31, 2003 and to date, the adoption of FIN 45 has not had a material effect on its operations or on its financial condition.

In December 2002, the EITF issued EITF Issue 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). EITF 00-21 provides guidance on determining whether a revenue arrangement contains multiple deliverable items and if so, requires that revenue be allocated among the different items based on fair value. EITF 00-21 also requires that revenue on any item in a revenue arrangement with multiple deliverables not delivered completely must be deferred until delivery of the item is completed. The guidance in EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company's agreements with BMS have been accounted for under the provisions of EITF 00-21.

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities* ("FIN No. 46"). This interpretation requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. It explains how to identify variable interest entities and how an enterprise assesses its interest in a variable interest entity to decide whether to consolidate that entity. As amended, this interpretation applies in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN No. 46 did not have a material impact on the Company's financial statements.

**2. Net Loss Per Common Share**

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration of additional potential common shares. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding and dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, preferred stock, options, and warrants are considered to be potential common shares and are only included in the calculation of diluted net loss per common share when their effect is dilutive.

**Corgentech Inc.**  
**Notes to Financial Statements (Continued)**

**2. Net Loss Per Common Share (Continued)**

	Year ended December 31,		
	2001	2002	2003
<b>Historical</b>			
<b>Numerator:</b>			
Net loss attributable to common stockholders . . . . .	\$(10,093,449)	\$(25,647,155)	\$(77,574,169)
<b>Denominator:</b>			
Weighted-average common shares outstanding . . . . .	1,866,100	2,151,954	2,332,330
Less: Weighted-average unvested common shares subject to repurchase . . . . .	(212,469)	(368,390)	(285,386)
Denominator for basic and diluted net loss per common share attributable to common stockholders . . . . .	<u>1,653,631</u>	<u>1,783,564</u>	<u>2,046,944</u>
Basic and diluted net loss per common share attributable to common stockholders . . . . .	<u>\$ (6.10)</u>	<u>\$ (14.38)</u>	<u>\$ (37.90)</u>
<b>Historical outstanding dilutive securities not included in diluted net loss per share attributable to common stockholders calculation</b>			
Preferred stock . . . . .	4,275,748	11,194,093	17,327,139
Options to purchase common stock . . . . .	110,626	449,951	1,820,654
Warrants . . . . .	12,500	164,524	979,780
	<u>4,398,874</u>	<u>11,808,568</u>	<u>20,127,573</u>

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**3. Cash Equivalents and Short-Term Investments**

The following is a summary of the fair value of available-for-sale securities as at December 31, 2002 and December 31, 2003.

	December 31, 2002			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Corporate Securities . . . . .	\$ 8,729,639	\$ 72,496	\$ —	\$ 8,802,135
Mortgage Securities . . . . .	10,350,000	—	—	10,350,000
U.S. Government Securities . . . . .	7,200,000	8,505	—	7,208,505
Total . . . . .	<u>\$26,279,639</u>	<u>\$ 81,001</u>	<u>\$ —</u>	<u>\$26,360,640</u>
Reported as:				
Cash and cash equivalents . . . . .	\$10,350,000	—	—	\$10,350,000
Short-term investments . . . . .	<u>\$15,929,639</u>	<u>\$ 81,001</u>	<u>—</u>	<u>\$16,010,640</u>
	<u>\$26,279,639</u>	<u>\$ 81,001</u>	<u>\$ —</u>	<u>\$26,360,640</u>
	December 31, 2003			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mortgage Securities . . . . .	\$53,450,000	\$ —	\$ —	\$53,450,000
Total . . . . .	<u>\$53,450,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$53,450,000</u>
Reported as:				
Cash and cash equivalents . . . . .	<u>\$53,450,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$53,450,000</u>

**4. License and Collaboration Agreements**

***Collaboration Agreement***

In October 2003, the Company entered into agreements with Bristol-Myers Squibb Company (“BMS”) to develop, manufacture and commercialize E2F Decoy. In connection with the agreements, BMS will co-promote E2F Decoy in the United States and share equally in profits and losses. Additionally, the Company has granted BMS the exclusive right to commercialize E2F Decoy outside the United States pursuant to a royalty-bearing license. BMS has the right to record all product sales.

In connection with the collaboration, BMS paid the Company \$45,000,000, consisting of a non-refundable, up-front license fees of \$25,000,000 and an additional \$20,000,000 for the purchase of 2,079,002 shares of Series D convertible preferred stock at \$9.62 per share. The rights and features of Series D convertible preferred stock are substantially the same as Series C preferred stock. The collaboration also provides additional funding including payment for the majority of ongoing costs of developing E2F Decoy for CABG, PBG and AV graft failure including costs incurred in connection with performing nonclinical and clinical studies of the product for these indications as well as costs of certain related manufacturing, supply and other activities and substantial regulatory and sales milestones. In addition, BMS is potentially obligated to pay up to \$205 million in milestone payments based on the achievement of worldwide regulatory submissions and approvals and up to \$320 million in milestone payments based upon attainment of agreed upon sales levels of E2F Decoy. BMS has the

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**4. License and Collaboration Agreements (Continued)**

right to terminate this collaboration, in whole or in part, for convenience with six months advance notice.

The Company recorded revenues associated with the Company's collaboration with BMS consisting of \$6.9 million in respect of the reimbursement of development expenses and \$1.8 million in respect of the amortization of non-refundable, upfront license fees. The Company also recorded a deemed dividend of \$6,913,627 in October 2003 associated with the issuance of the Series D convertible preferred stock to reflect the value of the beneficial conversion feature embedded therein. The deemed dividend will increase the net loss attributable to common stockholders in the calculation of basic and diluted net loss per common share.

***The Board of Trustees of the Leland Stanford Junior University***

The Company has an agreement with The Board of Trustees of the Leland Stanford Junior University, ("Stanford"), for an exclusive worldwide license under patents concerning the use of pressure to deliver TF decoys and other therapeutics into cells. The Company has the right to grant sublicenses under this agreement. In exchange for the rights licensed from Stanford, the Company paid Stanford an up-front license fee of \$50,000 and issued Stanford 38,315 shares of common stock. In addition, through December 31, 2003, the Company has paid Stanford \$1,622,500 in royalty payments. The Company has also agreed to pay Stanford an additional \$150,000 upon FDA approval of a pressure delivery device. The Company pays Stanford an annual minimum royalty of \$20,000 per year for the life of the agreement. All license fees and milestone payments were charged to research and development. The Company further agreed to pay royalties to Stanford based on net sales of TF decoys and other products using pressure technology sold. The royalty obligation extends on a country-by-country basis until the later of seven years, if no licensed patent issues, or expiration of the last-to-expire patent licensed from Stanford. The Company will also pay sublicense revenues to Stanford with respect to any upfront payments and research, development, or regulatory milestone payments, which includes such payments from BMS, that it receives for TF decoys and other products using pressure technology. There are no other milestone payments due to Stanford under this agreement. Upon the expiration of the last-to-expire patent, the agreement expires and there is no further royalty obligation to Stanford.

***The Brigham and Women's Hospital, Inc.***

The Company has an agreement with The Brigham and Women's Hospital, Inc., ("BWH"), for an exclusive worldwide license under patents and know-how concerning TF decoys and other therapeutics to treat and prevent diseases. Subject to the prior approval of BWH, the Company has the right to grant sublicenses under this agreement. In exchange for the rights licensed from BWH, the Company paid BWH an up-front license fee of \$50,000 and issued BWH 56,250 shares of our common stock. In addition, through December 31, 2003, the Company has paid BWH \$1,622,500 in royalty payments. In addition, the Company agreed to pay BWH an additional \$150,000 upon FDA approval of E2F Decoy. The Company also agreed to pay BWH an annual minimum royalty of \$20,000 per year for the life of the agreement. All license fees and milestone payments were charged to research and development. The Company further agreed to pay royalties to BWH based on net sales of TF decoys. The royalty obligation extends on a country-by-country basis until the later of seven years, if no licensed patent issues, or the expiration of the last-to-expire patent licensed from BWH. The Company will also pay sublicense revenues to BWH with respect to any upfront payments and research, development or

**Corgentech Inc.**  
**Notes to Financial Statements (Continued)**

**4. License and Collaboration Agreements (Continued)**

regulatory filing milestones payments, which includes such payments from BMS, or license maintenance fees that it receives for TF decoys. There are no other milestone payments due to BWH under this agreement. Upon the expiration of the last-to-expire patent, the agreement expires and there is no further royalty obligation to BWH.

**5. Property and Equipment**

Property and equipment consists of the following:

	December 31,	
	2002	2003
Computer equipment and software . . . . .	\$ 350,385	\$ 574,637
Lab equipment . . . . .	1,320,519	1,844,588
Leasehold improvements . . . . .	51,217	312,052
Office furniture and fixtures . . . . .	245,449	400,342
	1,967,570	3,131,619
Less accumulated depreciation and amortization . . . . .	(370,730)	(853,148)
Property and equipment, net . . . . .	\$1,596,840	\$2,278,471

**6. Related Party Transactions**

**Notes Receivable from Employees**

In 2002, the Company loaned \$200,000 in the form of a recourse note to an officer. The note is secured by shares of the Company's common stock held by the officer and bears an interest rate of 4.50% per annum, with a three-year term. The Company also entered into a bonus plan with the officer to which the officer is entitled to three cash bonus payments of \$75,667, \$72,667 and \$69,667 in October 2003, October 2004 and October 2005, respectively, or a pro rata portion thereof calculated based upon the number of days in the applicable year for which the officer remains employed by the Company. For the year ended December 31, 2002 and 2003 loan repayments were made out of bonuses paid to the officer totaling \$16,667 and \$66,667, respectively, and were recorded as compensation expense.

In 2001, the Company loaned \$75,000 in the form of a recourse note to an officer. The note bears an interest rate of 7.75% per annum, with a four-year term and is due in three annual installments of \$12,500 with the remaining \$37,500 coming due on the one year anniversary of the effective date of a registration statement of the Company's common stock. The Company also entered into a bonus plan with the officer to which the officer is entitled to three cash bonus payments, each equal to \$13,469, payable in June 2002, June 2003 and June 2004. For the years ended December 31, 2001, 2002 and 2003 loan repayments were made out of bonuses paid to the officer totaling \$6,250, \$12,500 and \$12,500 and were recorded as compensation expense, respectively.

**Private Placement Fees**

The Company engaged an affiliate of a major investor in the 2002 private placement, to act as sole placement agent for the transaction. The Chairman of the Board is a general partner of the major investor. The affiliate received total fees of \$3.2 million in connection with the private placement, of which \$2.4 million was settled in cash, and \$807,499 settled in exchange for 109,121 shares of Series C convertible preferred stock.

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**6. Related Party Transactions (Continued)**

**BMS Contract**

In 2003, the Company entered into a collaboration agreement with BMS as described in Note 4. BMS became a significant stockholder in the Company as part of the transaction. As such, all balance sheet and income statement amounts with BMS have been classified as related party.

**7. Convertible Notes Payable**

In January 2002, the Company signed a Note and Warrant Purchase Agreement with several investors to provide the Company with an aggregate amount of up to \$10,000,000 in return for convertible notes ("notes") in one or more disbursements at any time prior to July 31, 2002.

The Company drew down \$3,000,000 in February 2002 and \$1,500,000 in May 2002. The notes earned simple interest at 8% per annum, and were converted to Series C preferred stock at \$7.40 per share, upon completion of the private placement in June 2002. Interest expense related to the notes was \$82,849 for the year ended December 31, 2002, of which \$26,598 was paid in cash, and \$55,891 was paid with Series C preferred stock at \$7.40 per share.

In connection with the notes, the Company issued 152,024 warrants to purchase Series C preferred stock at an exercise price of \$7.40 per share. The warrants have a five-year exercise period, subject to earlier termination upon an initial public offering of the Company's securities, and were purchased for total cash consideration of \$135.

After considering the fair value of the warrants, it was determined that the notes converted into preferred stock at a conversion price less than the fair value of the preferred stock. A beneficial conversion feature valued at approximately \$642,000 was recorded as a discount to notes payable. As the notes were converted to preferred stock during 2002, the total amount of this discount was amortized in 2002 and is reflected in interest expense.

The fair value of the issued warrants was established utilizing the Black-Scholes pricing model using the following weighted-average assumptions: a volatility of 80%, a risk-free interest rate of 2.78%, a contractual life of five years, and no annual dividends. The relative fair market value of the warrants was estimated as \$642,491, recorded in convertible preferred stock and fully amortized to interest expense during 2002.

In September 2003, the Company signed another Note and Warrant Purchase Agreement with several investors to provide the Company with an aggregate of \$20,000,000 in return for convertible notes in one or more disbursements at any time prior to March 15, 2004.

The Company drew down \$8,000,000 in September 2003 and \$12,000,000 in October 2003. The notes earned simple interest at 8% per annum, and converted into preferred stock in October 2003. Notes interest expense was \$47,332 for the year ended December 31, 2003.

In connection with these notes, the Company issued 324,320 and 486,481 warrants to purchase Series C preferred stock at an exercise price of \$7.40 per share related to the September and October 2003 draw downs, respectively. The warrants have a five-year exercise period, subject to earlier termination upon an initial public offering of the Company's securities.

After considering the fair value of the warrants, it was determined that the notes converted into preferred stock at a conversion price less than the fair value of the preferred stock. The Company

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**7. Convertible Notes Payable (Continued)**

recorded a beneficial conversion feature of \$5,903,471 in September 2003 and \$8,618,014 in October 2003 associated with these issuances to reflect the value of the beneficial conversion feature embedded in the Series C preferred stock.

The Company recorded \$19,918,375 as interest expense upon conversion of the notes in October 2003 comprising the relative fair market value of the warrants issued in September and October 2003 and the associated beneficial conversion features, net of recorded interest expense. The guidelines set forth in EITF Consensus No. 98-5 limit the amount of the beneficial conversion feature to the amount of the proceeds of the related financing.

The fair value of the issued warrants was established utilizing the Black-Scholes pricing model using the following weighted-average assumptions: a volatility of 80%, a risk-free interest rate of 2.78%, a contractual life of five years, and no annual dividends.

The relative fair market value of the warrants was estimated as \$2,096,529 and \$3,381,986 for the warrants issued in September 2003 and October 2003, respectively. During the year ended December 31, 2003 the Company amortized \$34,293 to interest expense. Upon conversion of the notes into preferred stock in October 2003 the Company recorded \$4,840,547 in preferred stock and fully amortized the remaining amount to interest expense.

**8. Leases and Commitments**

The Company entered into lease agreements in May 2001 and July 2003 for office space under noncancelable operating leases through April 2005 and June 2006, respectively. The noncancelable operating lease through April 2005 was subleased during 2001 and the Company recorded a provision for the net future lease costs at a lower amount. The provision amounted to \$204,622 and \$112,141 at December 31, 2002 and 2003, respectively. The lease expires in February 2005. The future minimum payments under the lease, by year, are as follows:

	<u>Lease Payments</u>	<u>Sublease Income</u>	<u>Net</u>
Year ending December 31,			
2004 .....	\$170,166	\$ (80,325)	\$ 89,841
2005 .....	42,955	(20,655)	22,300
	<u>\$213,121</u>	<u>\$(100,980)</u>	<u>\$112,141</u>

The future minimum payments under the lease that expires in June 2006, by year, are as follows:

<u>Year ending December 31,</u>	
2004 .....	\$1,347,504
2005 .....	1,698,444
2006 .....	952,284
	<u>\$3,998,232</u>

Rent expense under the operating leases amounted to \$1,714,305, \$1,894,244, and \$1,734,224 for the years ended December 31, 2001, 2002 and 2003, respectively. Deferred rent under the operating leases amounted to \$151,411 and \$321,905 at December 31, 2002 and 2003, respectively.

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**8. Leases and Commitments (Continued)**

As part of the lease agreements, the Company entered into letters of credit aggregating to \$607,500 held by the Company's landlords. These letters of credit are secured by the Company's cash and as such are reflected in restricted cash.

**Terms of Loan Agreement with Comerica Bank**

In July 2001, the Company entered in a Loan and Security Agreement ("Loan Agreement") with Comerica bank for a line of credit. Pursuant to the Loan Agreement, the Company may request advances, equipment advances, and letters of credit (as such terms are defined in the Loan Agreement) up to an aggregate outstanding amount not to exceed \$1,000,000. The Company had used \$500,000 to secure a letter of credit in connection to the office space lease agreements. The Loan Agreement was terminated in September 2002.

In consideration of the line of credit, the Company issued warrants exercisable for an aggregate of 12,500 shares of Series B-1 preferred stock at an exercise price of \$4.32 per share. The fair value for these warrants was established utilizing the Black-Scholes pricing method using the following weighted-average assumptions: a volatility of 80%, a risk-free interest rate of 5.09%, a contractual life of 10 years, and no annual dividends. The fair value of the warrants estimated to be \$45,500, was recorded as prepaid interest and amortized over the term of the loan, which terminated in September 2002. Interest expense relating to these warrants amounted to \$6,319 for the year ended December 31, 2001 and \$39,181 for the year ended December 31, 2002.

**Equipment Loan Agreement**

In February 2003, the Company entered in a Loan Agreement with a lender for an equipment loan. Pursuant to the Loan Agreement, the Company may receive loan proceeds up to an aggregate of \$1,500,000. The Company has drawn down approximately \$1,400,000 of the loan through December 31, 2003. The loan bears interest at 8.25% per annum and is repayable in 36 monthly installments through 2006. The Company's obligations under the Loan Agreement are secured by a security interest in equipment specified in the Loan Agreement. In consideration of the equipment loan, the Company issued warrants exercisable for an aggregate of 4,455 shares of the Series C preferred stock at an exercise price of \$7.40 per share. The fair value of these warrants was established utilizing the Black-Scholes pricing method using the following weighted-average assumptions: a volatility of 80%, a risk-free interest rate of 3.9%, a contractual life of 10 years, and no annual dividends. The fair market value of the warrants was estimated to be \$19,800 and will be amortized to expense over the life of the loan.

**9. Stockholders' Equity (Deficit)**

**Common Stock**

In January 1999, the Company issued 1,388,750 shares of common stock to the founders, original contributors, and attorneys at \$0.004 per share, with 1,093,750 of the shares subject to repurchase rights which lapse over a 48-month period from the date of issuance. The Company has an irrevocable option to repurchase, only when the relationship of the founder with the Company is terminated with cause, as defined in the agreement. At December 31, 2001, 2002 and 2003, 296,224, 22,786 and zero shares, respectively, remained subject to repurchase.

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**9. Stockholders' Equity (Deficit) (Continued)**

In December 1999, the Company issued 3,750 shares of common stock to a consultant at \$0.24 per share, the fair value of common stock at the date of issuance. During 2000, the Company issued 33,966 shares of common stock to consultants at \$0.24 per share, the fair value of common stock at the date of issuance.

In January 2000, the Company issued 300,000 shares of common stock to an employee at \$0.24 per share, the fair value of common stock at the date of issuance as deemed by the board of directors. In the event the employee's employment with the Company is terminated, the Company has the right to repurchase all unvested shares from the employee at the original purchase price for a period of 90 days after termination. These repurchase rights lapse with respect to 75,000 shares on the first anniversary of the date of grant, and for the remainder, ratably over the following 36 months. At December 31, 2002 and 2003, 81,250 and 6,250 shares, respectively, of common stock were subject to repurchase.

During 2002, the Company issued 6,000 options to consultants at \$1.20 per share, the estimated fair value of common stock at the date of issuance. These options were exercised in 2002.

During 2003, the Company issued 42,250 options to consultants at a price range of \$1.20 - \$5.00 per share, the estimated fair value of common stock at the date of issuance. Of these options, 29,850 shares were exercised in 2003.

**Convertible Preferred Stock**

At December 31, 2002 and 2003, the Company was authorized to issue up to 49,403,032 and 73,469,040 shares of convertible preferred stock, respectively, issuable in series. Through December 31, 2003, 1,081,304 shares have been designated as Series A convertible preferred stock, 2,500,000 shares have been designated as Series B convertible preferred stock, 694,444 shares have been designated as Series B-1 convertible preferred stock, 10,972,389 shares have been designated as Series C convertible preferred stock and 2,079,002 shares have been designated as Series D convertible preferred stock.

The Company initially recorded the Series A, B, B-1, C and D convertible preferred stock at their fair values on the date of issuance in 1999, 2000, 2001, 2002 and 2003, respectively, net of issuance costs of \$15,004, \$104,172, \$56,359, \$3,499,854 and \$0, respectively. A redemption event will only occur upon the liquidation, winding up or change in control or sale of substantially all of the assets of the Company. As the redemption event is outside the control of the Company, all shares of convertible preferred stock have been presented outside of permanent equity in accordance with EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. Further, the Company has also elected not to adjust the carrying values of the Preferred Stock to the redemption value of such shares, since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying values to the redemption values will be made if it becomes probable that such redemption will occur.

In June and July 2002, the Company completed a private placement for the sale of 6,807,423 shares of Series C convertible preferred stock at \$7.40 per share, resulting in gross cash proceeds of \$45,819,099 and conversion of \$4,555,890 of notes and accrued interest.

Issuance costs incurred totaled \$3,499,854, of which \$807,499 was the estimated fair value of 109,121 shares of Series C convertible preferred stock issued for related professional services in lieu of cash. The fair value was estimated based on the closing exercise price for Series C convertible preferred stock in the private placement.

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**9. Stockholders' Equity (Deficit) (Continued)**

In June 2002, the Company issued 1,801 shares of Series C convertible preferred stock to consultants for professional services. The estimated fair value of the shares issued was \$13,333, based on the issue price in the private placement of \$7.40 per share, and was expensed immediately.

In October 2003, the Company issued 1,351,347 shares of Series C convertible preferred stock at \$7.40 per share resulting in gross cash proceeds of \$10,000,000. The Company recorded a deemed dividend of \$7,493,857 associated with the issuance to reflect the value of the beneficial conversion feature embedded therein. The deemed dividend will increase the net loss attributable to common stockholders in the calculation of basic and diluted net loss per common share.

The rights and features of the Company's convertible preferred stock are as follows:

*Dividends*

Holders of shares of convertible preferred stock are entitled to noncumulative dividends of 8% per share if and when declared by the Board of Directors. These dividends are to be paid in advance of any distributions to common stockholders. No dividends have been declared or paid by the Company through December 31, 2003.

*Conversion*

Each share of convertible preferred stock is convertible, at the option of the holder, into shares of common stock on a one-for-one basis, subject to adjustment for anti-dilution. Conversion is automatic upon the closing of an underwritten public offering with aggregate gross proceeds of at least \$40,000,000 and an offering price of at least \$12.00 (as adjusted for any stock splits, stock dividends, recapitalizations and the like) or upon the approval of the holders of at least two-thirds of the outstanding shares of the Series C convertible preferred stock. The Company has reserved sufficient shares of common stock for issuance upon conversion of the outstanding preferred stock. The preferred stock has voting rights on an as-if-converted to common stock basis.

*Voting*

Each holder of the shares of convertible preferred stock is entitled to voting rights equivalent to the number of shares of common stock into which their respective shares are convertible.

*Liquidation Preference*

In the event of liquidation, dissolution or winding up of the Company, holders of Series A, B, B-1, and C and D preferred stocks shall have a liquidation preference of \$2.312, \$4.00, \$4.32, \$7.40 and \$9.62 per share, respectively, plus any declared but unpaid dividends. After payment of these preferential amounts, the remaining assets of the Company shall be distributed among the holders of Series B and B-1 preferred stock, who shall have a liquidation preference of \$4.00 and \$4.32 per share, respectively, plus any declared but unpaid dividends. After payment of these preferential amounts, the remaining assets of the Company shall be distributed among the holders of Series A preferred stock, who shall have a liquidation preference of \$2.312 per share, plus any declared but unpaid dividends. After payment of these preferential amounts, the remaining assets of the Company shall be distributed among the holders of the preferred and common stock pro rata based on the number of shares of common stock held (as if the preferred stock had converted.) If upon liquidation, the assets of the

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**9. Stockholders' Equity (Deficit) (Continued)**

Company are insufficient to provide for the preferential amounts, then the entire assets of the Company shall be distributed first to the holders of Series C and D preferred stock and then to the holders of Series A, B and B-1 preferred stock on a pari passu basis, in proportion to the full preferential amount of the respective preferred shares. A change of control or sale of substantially all of the assets of the Company is considered to be a liquidation event.

**Stock Options**

The 1999 Equity Incentive Plan (the "Plan") was adopted in July 1999 and provides for the issuance of stock options. As of December 31, 2002, 2003, the Company had reserved 1,033,415 and 1,784,825 shares of common stock for issuance under the Plan, respectively. The Board of Directors adopted in December 2003 and the stockholders approved in January 2004 the reservation of an additional 1,000,000 shares of common stock for issuance under the Plan and to rename the Plan the 2003 Equity Incentive Plan, to become effective upon the effective date of this registration statement.

Stock options granted under the Plan may be either incentive stock options, nonstatutory stock options, stock bonuses, or rights to acquire restricted stock. Incentive stock options may be granted to employees with exercise prices of no less than the fair value of the common stock on the grant date and nonstatutory options may be granted to employees, directors, or consultants at exercise prices of no less than 85% of the fair value of the common stock on the grant date, as determined by the board of directors. If, at the time the Company grants an option, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options may be granted with vesting terms as determined by the board of directors. Except as noted above, options expire no more than 10 years after the date of grant or earlier if employment is terminated.

Common stock options may include a provision whereby the holder, while an employee, director, or consultant, may elect at any time to exercise the option as to any part or all of the shares subject to the option prior to the full vesting of the option. Any unvested shares so purchased are subject to repurchase by the Company at a price equal to the original purchase price of the stock. This right of repurchase will lapse with respect to the option shares, and each optionee shall vest in his or her option shares, as follows: a minimum of 20% of the option shares upon completion of one year of service measured from the vesting commencement date, and the balance of the option shares in a series of successive equal monthly installments upon the optionee's completion of each of the next 36 months of service thereafter. At December 31, 2002 and 2003, 309,331 and 478,766 shares, respectively, of common stock acquired through the exercise of options are subject to the Company's right of repurchase.

**Corgentech Inc.**  
**Notes to Financial Statements (Continued)**

**9. Stockholders' Equity (Deficit) (Continued)**

A summary of activity under the Plan is as follows:

	Shares Available for Grant	Outstanding Options	
		Number of Shares	Weighted-Average Exercise Price Per Share
Balances at December 31, 2000	767,639	110,500	\$0.24
Options granted	(276,875)	276,875	\$0.40
Options exercised	—	(252,375)	\$0.37
Options canceled	24,375	(24,375)	\$0.25
Balances at December 31, 2001	515,139	110,625	\$0.35
Additional shares authorized	527,500	—	—
Options granted	(499,449)	499,449	\$1.08
Options exercised	—	(123,750)	\$0.42
Options canceled	36,375	(36,375)	\$0.84
Shares repurchased	3,901	—	\$0.46
Balances at December 31, 2002	583,466	449,949	\$1.10
Additional shares authorized	1,232,625	—	—
Options granted	(1,721,746)	1,721,746	\$1.90
Options exercised	—	(488,988)	\$1.39
Options canceled	64,553	(64,553)	\$1.20
Shares repurchased	7,773	—	\$0.43
Balances at December 31, 2003	166,671	1,618,154	\$1.86

The following table summarizes information about the stock options outstanding at December 31, 2003:

Exercise Prices	Options Outstanding		
	Number Outstanding at Dec. 31, 2003	Weighted-Avg. Remaining Contract Life	Options Vested at Dec. 31, 2003
\$0.24	10,500	6.70	10,500
\$0.40	13,950	7.36	13,315
\$1.20	458,187	9.21	86,647
\$2.00	1,075,724	9.88	22,621
\$5.00	59,793	9.97	—
	1,618,154	9.65	133,083

The weighted-average fair value of options granted during the year ended December 31, 2002 and 2003 were \$0.72 and \$10.72, respectively.

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**9. Stockholders' Equity (Deficit) (Continued)**

**Notes Receivable From Officers**

During 2000, the Company issued a note receivable to an officer to finance the purchase of shares of the Company's common stock. The principal amount of the note was \$70,800 and bore interest at 5.88% per annum and was full recourse. As of December 31, 2002, the note receivable balance was \$70,800 plus accrued interest of approximately \$12,700, of which the principal was recorded in stockholders' equity (deficit). The accrued interest was recorded in other long-term assets. In accordance with the officer's employment agreement, this note was forgiven in November 2003.

During 2001, the Company issued a note receivable to an officer to finance the purchase of shares of the Company's common stock. The principal amount of the note is \$11,100 and bears interest at 7.75% per annum, is full recourse and matures in 2004. The note is due in three annual installments of \$3,700. For the years ended December 31, 2003, 2002, and 2001, loan repayments were made out of bonuses paid to the officer totaling \$3,700, \$3,700 and \$1,850 and were recorded as compensation expense, respectively.

During 2001, the Company issued a note receivable to an officer to finance the purchase of shares of the Company's common stock. The principal amount of the note is \$39,600 and bears interest at 10% per annum, is full recourse, and matures in 2005. As of December 31, 2002 and 2003 the note receivable balance is \$39,600 plus accrued interest of approximately \$4,100 and \$8,100, respectively, of which the principal is recorded in stockholders' equity (deficit).

**2003 Employee Stock Purchase Plan**

The Board of Directors adopted the 2003 Employee Stock Purchase Plan, or the 2003 Purchase Plan, in December 2003 and the stockholders approved it in January 2004 to become effective upon the effective date of this registration statement.

The 2003 Purchase Plan authorizes the issuance of 250,000 shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its affiliates, which amount will be increased on January 1, from 2005 until 2024, by 2% of the number of shares of common stock outstanding on that date or such lesser amount as the Board of Directors may determine. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased on that date. The 2003 Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. As of December 31, 2003, no shares of common stock have been purchased under the 2003 Purchase Plan.

**2003 Non-Employee Directors' Stock Option Plan**

The Board of Directors adopted the 2003 Non-Employee Directors' Stock Option Plan, or the 2003 Directors' Plan, in December 2003 and the stockholders approved it in January 2004 to become effective upon the effective date of this registration statement. The 2003 Directors' Plan will provide for the automatic grant of nonstatutory stock options to purchase shares of common stock to non-employee directors.

The aggregate number of shares of common stock that may be issued pursuant to options granted under the 2003 Directors' Plan is 150,000 shares which amount will be increased annually on January 1, from 2005 until 2014, by the number of shares of common stock subject to options granted during the

**Corgentech Inc.**

**Notes to Financial Statements (Continued)**

**9. Stockholders' Equity (Deficit) (Continued)**

prior calendar year. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased. As of December 31, 2003, no shares of common stock have been issued under the 2003 Directors' Plan.

**Shares Reserved for Issuance**

The Company has reserved shares of common stock for future issuance at December 31, 2003 as follows:

	<b>December 31, 2003</b>
Options outside Plan .....	202,500
Stock option plan .....	1,784,825
Conversion of outstanding convertible preferred stock .....	17,327,139
Conversion of outstanding convertible debt .....	—
Conversion of outstanding convertible preferred stock warrants .....	979,780
	<u>20,294,244</u>

**10. Income Taxes**

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 are as follows:

	<b>December 31,</b>	
	<b>2002</b>	<b>2003</b>
Deferred tax assets:		
Federal and state net operating losses .....	\$ 14,680,640	\$ 21,924,717
Federal and state research credits .....	1,989,212	2,363,817
Other .....	446,758	10,616,504
	17,116,610	34,905,038
Valuation allowance .....	(17,116,610)	(34,905,038)
Net deferred tax assets .....	\$ —	\$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$4,294,398, \$11,575,582, and \$17,788,428 for the periods ended December 31, 2001, 2002 and 2003 respectively.

As of December 31, 2003, the Company had net operating loss and research carryforwards for federal income tax purposes of approximately \$56,661,256 and \$1,370,930 which expire beginning in the year 2021. The Company also has state net operating loss and research credit carryforwards of approximately \$36,404,823 and \$1,527,518. The net operating losses begin expiring in 2007 and the research credits have no expiration date.

**Corgentech Inc.**  
**Notes to Financial Statements (Continued)**

**10. Income Taxes (Continued)**

Utilization of the Company's net operating loss may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss before utilization.

**11. Subsequent Events**

**Reverse Stock Split**

In January 2004, the Board of Directors and stockholders approved a one-for-four reverse stock split of the Company's outstanding shares of common stock and preferred stock and on January 23, 2004, the Company filed an amended and restated certificate of incorporation and increased the number of authorized shares of common stock and preferred stock to 100,000,000 and 18,367,260, respectively. All issued and outstanding common stock, preferred stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this stock split.

**Initial Public Offering**

In February 2004, the Company issued 6,900,000 shares of common stock at \$16.00 per share upon the closing of its initial public offering in which it raised approximately \$100.8 million, net of underwriting discounts and commissions and estimated expenses.

**12. Selected Quarterly Financial Data (Unaudited)**

	Three Months Ended December 31,		Three Months Ended September 30,		Three Months Ended June 30,		Three Months Ended March 31,	
	2003	2002	2003	2002	2003	2002	2003	2002
	(In thousands, except per share amounts)							
Contract revenue, related party . . . .	\$ 8,678	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Net loss attributable to common stockholders . . . .	\$(37,862)	\$(9,152)	\$(15,724)	\$(8,235)	\$(11,910)	\$(4,230)	\$(12,078)	\$(4,030)
Basic and diluted net loss per common share . . .	\$ (16.58)	\$ (4.91)	\$ (7.78)	\$ (4.57)	\$ (6.07)	\$ (2.42)	\$ (6.30)	\$ (2.35)

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 29, 2004.

CORGENTECH INC.

By:           /s/ JOHN P. MCLAUGHLIN          

**John P. McLaughlin**  
President and Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that the persons whose signatures appear below each severally constitutes and appoints John P. McLaughlin and Richard P. Powers, as true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for them in their name, place and stead, in any and all capacities, to sign any and all amendments to this Report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as they might or could do in person, hereby ratifying and confirming all which said attorneys-in-fact and agents, or any of them, or their substitute or substitutes, may lawfully do, or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ JOHN P. MCLAUGHLIN</u> John P. McLaughlin	President, Chief Executive Officer and Director ( <i>Principal Executive Officer</i> )	March 29, 2004
<u>/s/ RICHARD P. POWERS</u> Richard P. Powers	Vice President and Chief Financial Officer ( <i>Principal Financial and Accounting Officer</i> )	March 29, 2004
<u>/s/ RODNEY A. FERGUSON</u> Rodney A. Ferguson, Ph.D.	Chairman of the Board	March 29, 2004
<u>/s/ FRITZ R. BÜHLER</u> Fritz R. Bühler, M.D.	Director	March 29, 2004
<u>/s/ VICTOR J. DZAU</u> Victor J. Dzau, M.D.	Director	March 29, 2004
<u>/s/ DANIEL S. JANNEY</u> Daniel S. Janney	Director	March 29, 2004
<u>/s/ MICHAEL B. SWEENEY</u> Michael B. Sweeney	Director	March 29, 2004

## EXHIBIT INDEX

Exhibit Number	Description of Document
3.1(1)	Restated Certificate of Incorporation.
3.2(2)	Restated Bylaws.
4.1	Reference is made to Exhibits 3.1 through 3.2.
4.2(3)	Specimen stock certificate.
10.1(3)	2003 Equity Incentive Plan.
10.2(3)	2003 Non-Employee Directors' Stock Option Plan.
10.3(3)	2003 Employee Stock Purchase Plan.
10.4(3)	Lease Agreement, dated March 16, 2000, between Gateway Center, LLC and Corgentech Inc.
10.5(3)	Sublease, dated March 11, 2002, between Michael Gurfinkel and Corgentech Inc.
10.6(3)	Sublease, dated May 15, 2003, between Coulter Pharmaceuticals, Inc. and Corgentech Inc.
10.7(3)	Lease, dated November 7, 1997, between Coulter Pharmaceuticals, Inc. and HMS Gateway Office L.P., as amended by the First Amendment to Lease Agreement, dated November 10, 1998, and Second Amendment to Lease Agreement, dated May 19, 2000.
10.8(3)†	Restated and Amended Exclusive License Agreement, dated May 15, 2003, between The Board of Trustees of the Leland Stanford Junior University and Corgentech Inc.
10.9(3)†	Restated and Amended License Agreement, dated October 1, 2003, between The Brigham and Women's Hospital, Inc. and Corgentech Inc.
10.10(3)†	Collaboration Agreement, dated October 10, 2003, between Bristol-Myers Squibb Company and Corgentech Inc.
10.11(3)	Master Security Agreement, dated February 3, 2003, between GE Capital Corporation and Corgentech Inc., as amended.
10.12(3)	Amended and Restated Investor Rights Agreement, dated October 10, 2003.
10.13(3)	Form of Indemnity Agreement.
10.14(3)	Employment Letter, dated November 29, 1999, with John P. McLaughlin.
10.15(3)	Promissory Note, dated January 19, 2000, issued by John P. McLaughlin to Corgentech Inc.
10.16(3)	Stock Pledge Agreement, dated March 2, 2000, with John P. McLaughlin.
10.17(3)	Termination of Preemptive Rights and Registration Rights Agreement, dated May 17, 2002, between John P. McLaughlin and Corgentech Inc.
10.18(3)	Employment Letter, dated August 18, 2000, with Leslie M. McEvoy.
10.19(3)	Promissory Note, dated June 28, 2001, issued by Leslie M. McEvoy to Corgentech Inc.
10.20(3)	Promissory Note, dated August 24, 2001, issued by Leslie M. McEvoy to Corgentech Inc.
10.21(3)	Letter Agreement, dated June 30, 2001, with Leslie M. McEvoy.
10.22(3)	Letter Agreement, dated August 24, 2001, with Leslie M. McEvoy.

Exhibit Number	Description of Document
10.23(3)	Stock Pledge Agreement, dated August 28, 2001, with Leslie M. McEvoy.
10.24(3)	Employment Letter, dated October 18, 2001, with Richard P. Powers.
10.25(3)	Promissory Note, dated December 20, 2001, issued by Richard P. Powers to Corgentech Inc.
10.26(3)	Stock Pledge Agreement, dated December 20, 2001, with Richard P. Powers.
10.27(3)	Employment Letter, dated February 1, 2001, with Todd J. Lorenz.
10.28(3)	Employment Letter, dated July 2, 2002, with James Z. Huang.
10.29(3)	Letter Agreement, dated October 11, 2002, with James Z. Huang.
10.30(3)	Promissory Note, dated October 11, 2002, issued by James Z. Huang to Corgentech Inc.
10.31(3)	Stock Pledge Agreement, dated October 11, 2002, with James Z. Huang.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney (contained on signature page).
31.1	Certification required by Rule 13a-14(a).
31.2	Certification required by Rule 13a-4(a).
32.1*	Certification of President and Chief Executive Officer, as required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).
32.2*	Certification of Vice President and Chief Financial Officer, as required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

- (1) Filed as Exhibit 3.2 to our Registration Statement on Form S-1, as amended (File No. 333-110923), filed on December 4, 2003, and incorporated herein by reference.
- (2) Filed as Exhibit 3.4 to our Registration Statement on Form S-1, as amended (File No. 333-110923), filed on December 4, 2003, and incorporated herein by reference.
- (3) Filed as the like numbered Exhibit to our Registration Statement on Form S-1, as amended (File No. 333-110923), filed on December 4, 2003, and incorporated herein by reference.

† Confidential treatment has been granted for portions of this exhibit.

\* The certifications attached as Exhibit 32.1 and Exhibit 32.2 accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Corgentech Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

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**MANAGEMENT**

John P. McLaughlin  
*President and Chief Executive Officer,  
Director*

Nancy E. Donahue  
*Vice President of  
Cardiovascular Marketing*

Daniel J. Gennevois, M.D.  
*Vice President of Medical Affairs*

James Z. Huang  
*Vice President of  
Business Development and  
Commercial Operations*

Todd J. Lorenz, M.D.  
*Chief Medical Officer*

Leslie M. McEvoy, Ph.D.  
*Vice President of Research*

Patricia A. Oto, R.Ph.  
*Vice President of Regulatory Affairs  
and Quality Assurance*

Richard P. Powers  
*Vice President and  
Chief Financial Officer*

John X. Regan  
*Vice President of Manufacturing*

B. Lynn Seely, M.D.  
*Vice President of Clinical Research*

Thomas C. Yonker  
*Vice President of Project and  
Alliance Management*

**BOARD OF DIRECTORS**

Rodney A. Ferguson, J.D., Ph.D.  
*Chairman of the Board, Corgentech  
Managing Director, JP Morgan Partners*

Fritz R. Bühler, M.D.  
*Managing Partner  
Bear Stearns Health Innoventures*

Victor J. Dzau, M.D.  
*Director of Research and Chairman  
of the Department of Medicine  
Brigham and Women's Hospital, Inc./  
Harvard Medical School*

**BOARD OF DIRECTORS (CONT.)**

Daniel S. Janney  
*Director  
Alta Partners*

Michael B. Sweeney  
*General Partner  
InterWest Partners*

**CORPORATE COUNSEL**

Cooley Godward LLP  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306

**INDEPENDENT ACCOUNTANTS**

Ernst & Young LLP  
1001 Page Mill Road  
Building 1, Suite 200  
Palo Alto, CA 94304

**ANNUAL STOCKHOLDERS MEETING**

Annual report and proxy statement are mailed about April 15, 2004. Corgentech's annual meeting of stockholders will be held at 9:00 a.m. on Thursday, May 13, 2004 at:

The Westin San Francisco Airport Hotel  
1 Old Bayshore Highway  
Belmont Suite  
Millbrae, CA 94030

**COMMON STOCK INFORMATION**

Corgentech's stock is traded on the Nasdaq National Market System under the symbol: CGTK.

**COMPANY CONTACT**

Richard P. Powers  
*Vice President and  
Chief Financial Officer*  
650-624-9600  
investors@corgentech.com

**REGISTRAR AND TRANSFER AGENT**

Mellon Investor Services  
P.O. Box 3338  
South Hackensack, NJ 07606-1938  
800-240-0593  
www.melloninvestor.com

**QUARTERLY REPORTING AND OTHER INFORMATION**

Corgentech's Form 10-K and other SEC filings, news releases and other information regarding the company and its technology are available on the Internet:

www.corgentech.com

**FORM 10-K**

A copy of Corgentech's Form 10-K, which is filed with the SEC, is available upon request, free of charge. Write to:

Corgentech Inc.  
650 Gateway Boulevard  
South San Francisco, CA 94080

**FORWARD-LOOKING STATEMENT**

This annual report contains forward-looking statements, including without limitation all statements related to our clinical trials and product candidates. Words such as "believes," "anticipates," "plans," "expects," "intend," "will," "slated," "goal" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon our current expectations. Forward-looking statements involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the progress, timing and results of our clinical trials, intellectual property matters, difficulties or delays in obtaining regulatory approval, manufacturing our lead product candidate, competition from other pharmaceutical or biotechnology companies, our ability to obtain additional financing to support its operations and other risks detailed in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2003. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this annual report. All forward-looking statements are qualified in their entirety by this cautionary statement, and Corgentech undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.



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South San Francisco, CA 94080

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Fax: 650 624 7540

[www.corgentech.com](http://www.corgentech.com)