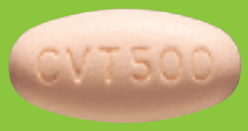
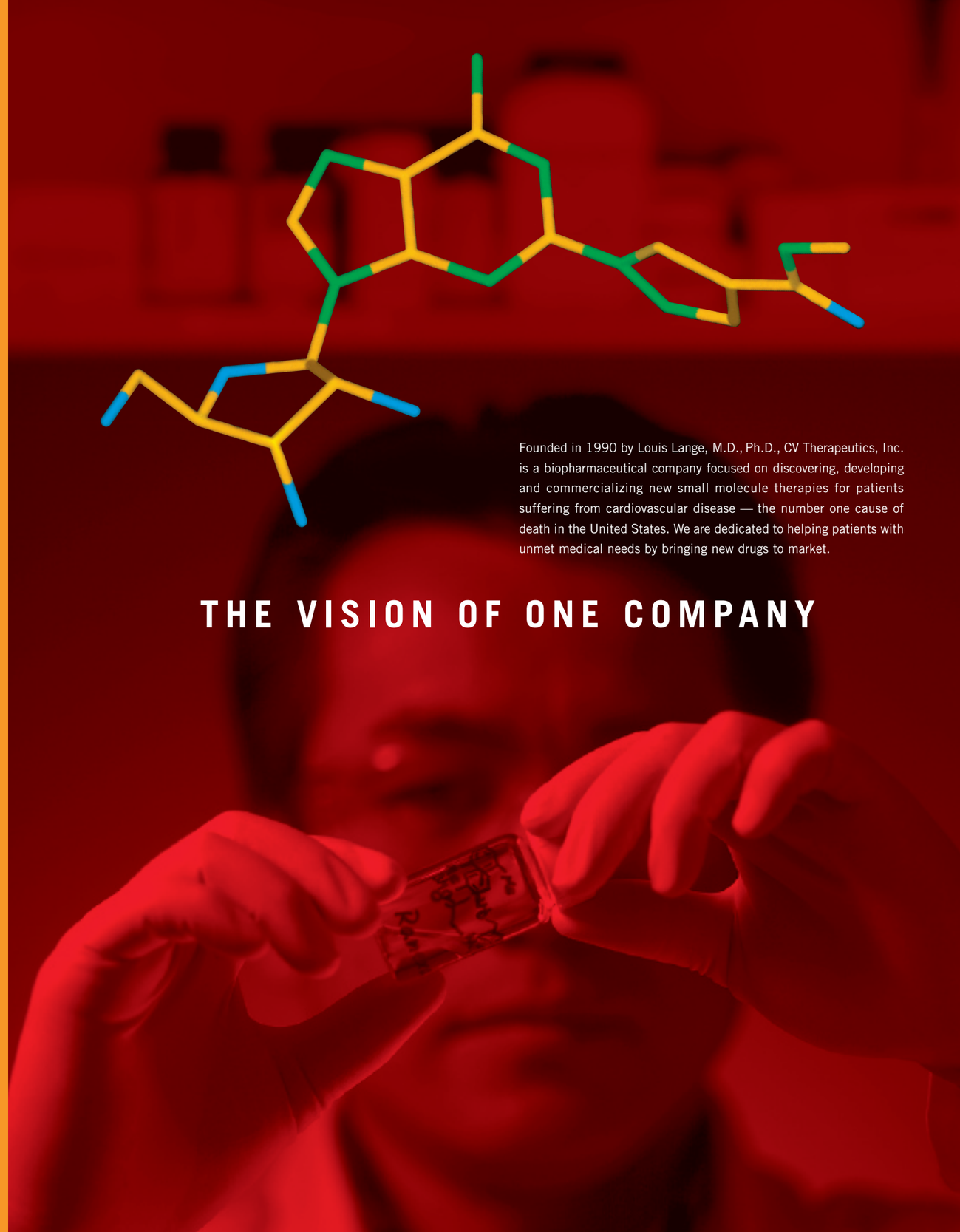

CVT 500

January 27, 2006

The FDA approval of Ranexa™ represents the first new pharmaceutical approach to treat chronic angina in more than 20 years in the United States



Founded in 1990 by Louis Lange, M.D., Ph.D., CV Therapeutics, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing new small molecule therapies for patients suffering from cardiovascular disease — the number one cause of death in the United States. We are dedicated to helping patients with unmet medical needs by bringing new drugs to market.

THE VISION OF ONE COMPANY

THE DEDICATION OF HUNDREDS

Bringing new drugs to market requires years of support and commitment from many people, including physicians and scientists who serve as investigators or advisors for our programs. Together, their dedication is vital to our goal of improving the quality of treatment for cardiovascular diseases. This pioneering spirit is the foundation for scientific progress, and their contributions are critical for developing potential new drugs that could make an important difference in patients' lives.

Despite the development of significant new therapies, cardiovascular disease ranks as the number one killer in the United States and today there are over 70 million people in the United States with cardiovascular disease, according to the American Heart Association. Our goal is to address unmet medical needs by developing innovative products, such as Ranexa, to treat patients.

THE HOPE OF MILLIONS

JAN 27, 2006

TWELVE MONTHS / TWO PRODUCTS

AUG 23, 2005

Ranexa The FDA approval of Ranexa™ (ranolazine extended-release tablets) in January 2006 represents the first new pharmaceutical approach to treat chronic angina in the United States in more than 20 years. Ranexa has antianginal and anti-ischemic effects that do not depend upon reductions in heart rate or blood pressure.

Ranexa is approved for the treatment of chronic angina in patients who have not achieved an adequate response with other antianginal drugs and should be used in combination with amlodipine, beta-blockers or nitrates. Complete safety and prescribing information can be found at www.Ranexa.com.

In order to potentially broaden the product labeling for Ranexa over time, we are conducting a study of 6,500 patients known as MERLIN (Metabolic Efficiency with Ranolazine for Less Ischemia in Non-ST Elevation Acute Coronary Syndromes) TIMI-36. Under a special protocol assessment agreement with the FDA, if treatment with Ranexa is not associated with an adverse trend in death or arrhythmia, the study could support potential approval of Ranexa as first-line chronic angina therapy. In addition, if the study demonstrates a significant improvement in the time to first occurrence of cardiovascular death, myocardial infarction or recurrent ischemia, Ranexa could gain potential approval for hospital-based and long-term prevention of acute coronary syndromes.

ACEON® In August 2005, the FDA expanded the approved indication of ACEON® (perindopril erbumine) Tablets to include reduction of the risk of cardiovascular mortality or nonfatal myocardial infarction in patients with stable coronary artery disease. ACEON®, an angiotensin converting enzyme (ACE) inhibitor, is also indicated for the treatment of essential hypertension.

The labeling expansion was based on the EUROPA (EUropean trial on Reduction Of cardiac events with Perindopril in patients with stable coronary Artery disease) study. In this study, perindopril significantly reduced the relative risk of cardiovascular death, nonfatal myocardial infarction or cardiac arrest by 20 percent. Complete safety and prescribing information, including the warning against product use during pregnancy, can be found at www.Aceon.com. CV Therapeutics co-promotes ACEON® with Solvay Pharmaceuticals, Inc.

FROM SCIENCE TO PATIENTS

Over the past 18 months, CV Therapeutics has evolved from an innovative research and development company with a pipeline based on cutting-edge science into a fully integrated biopharmaceutical company with two approved products and a skilled cardiovascular sales force.

We began this transformation by entering into an agreement to co-promote ACEON® in December 2004. Cardiologists are the primary prescribers of branded tissue-ACE inhibitors like ACEON®, and many of these ACEON® prescribers are also potential Ranexa prescribers. This overlap provided CV Therapeutics with the opportunity to build a commercial sales and marketing team in advance of the Ranexa launch and to begin developing relationships with many potential Ranexa customers. In 2005, we recruited and hired our 250-person cardiovascular sales force to complement our regional and district managers, account specialists for managed care, professional program managers and other essential commercial personnel. Following comprehensive sales training over the summer, we deployed our entire sales team in the fall, in time to capitalize on the expansion of the ACEON® labeling.

In March 2006, the American College of Cardiology Annual Scientific Sessions in Atlanta provided us with a premier platform to establish brand awareness of Ranexa among cardiologists and to begin promoting Ranexa. The product is now available in pharmacies and, for the first time in more than 20 years, physicians in the United States have a new pharmaceutical approach to offer their chronic angina patients.

While we are devoting significant attention and focus to establishing CV Therapeutics as a commercial organization, we remain dedicated to our cutting-edge science based on molecular cardiology. With the MERLIN TIMI-36 trial well underway, regadenoson in late Phase 3 development, and a number of other ongoing clinical and preclinical programs, our goal remains to bring products to market that help physicians address important unmet medical needs for appropriate patients.

Regadenoson

Regadenoson is a selective A_{2A}-adenosine receptor agonist in clinical development for potential use as a pharmacologic stress agent in myocardial perfusion imaging (MPI) studies. Regadenoson is administered via intravenous bolus and increases coronary blood flow as if the heart were responding to the demands of physical exercise. The selective action of regadenoson on the A_{2A}-adenosine receptor may potentially avoid some of the side effects caused by the less specific action of traditional agents when other adenosine receptor subtypes are also stimulated.

MPI studies are conducted to detect areas of insufficient blood perfusion to the heart muscle, which may be caused by blockages in coronary arteries. MPI studies are performed by comparing pictures of the heart at rest and during exercise. In 2002, approximately 7.8 million patients underwent MPI studies. Of those, approximately 3.4 million, or more than 40 percent, required a pharmacologic agent to generate maximum coronary blood flow because peripheral vascular disease, arthritis or other limiting medical conditions prevented them from exercising on the treadmill.

In 2005, the first of two Phase 3 trials of regadenoson met its primary endpoint by showing that MPI studies conducted with regadenoson were comparable to MPI studies conducted with ADENOSCAN® (adenosine injection). ADENOSCAN® is the market-leading pharmacologic stress agent in the United States for use with MPI and is marketed by our partner Astellas Pharma US, Inc. We expect data from a second Phase 3 trial of regadenoson in 2006. If successful, we would expect to submit a new drug application to the FDA.

Our Pipeline

Our research and development team is working to create new potential product opportunities through our expertise in molecular cardiology, and we have several ongoing clinical and preclinical programs.

One of our areas of expertise is the field of adenosine receptors. Adenosine is a small molecule that is naturally present in the body and has many actions in different organs. There are four types of adenosine receptors: A_1, A_{2A}, A_{2B} and A_3. Activation of these receptors initiates cascades of cellular biochemical events that result in specific changes in important cell functions.

The effects of adenosine serve as the basis for many of our research and development programs, including our regadenoson, tecadenoson and CVT-6883 clinical programs, as well as some of our preclinical programs.

In 2005, CVT-6883, a selective A_{2B}-adenosine receptor antagonist for the potential treatment of asthma, moved into the clinic. CVT-6883 acts by blocking the A_{2B}-adenosine receptor, which may limit or prevent mast cell activation of the inflammatory events that can lead to bronchoconstriction and airway hyperreactivity associated with asthma. CVT-6883 could potentially offer a novel therapeutic approach to asthma.

We have numerous preclinical and discovery programs, which focus on various areas such as late I_{NA} inhibition, reverse cholesterol transport, metabolic disorders, dyslipidemia and obesity.

	Compounds/Targets	Indication/ Area of Development	Discovery/ Preclinical	I	II	III	NDA	FDA Approval
Marketed	Ranexa® ranolazine extended-release tablets	Chronic Angina (reserved for 2nd line use)						
	ACEON® (perindopril erbumine) Tablets	Stable Coronary Artery Disease Hypertension						
Clinical	Ranexa™	Chronic Angina (1st line use) Acute Coronary Syndromes						
	Regadenoson	Myocardial Perfusion Imaging						
	Tecadenoson	PSVT Acute Atrial Fibrillation						
	Adentri™	Heart Failure						
	CVT-6883	Asthma						
Discovery/Preclinical	Adenosine Receptors	Atrial Arrhythmias Lipid Metabolism Diabetes Metabolic Syndrome Dyslipidemia Addiction						
	Late Sodium Current	Ischemic Conditions						
	Reverse Cholesterol Transport	Atherosclerosis						
	Other Programs	Metabolic Disorders Dyslipidemia Obesity						

Over the past 18 months, CV Therapeutics has achieved substantial clinical and regulatory success and capitalized on several strategic opportunities to transform itself from an R&D organization with no marketed products into an integrated commercial company with a 250-person cardiovascular specialty sales force promoting two complementary cardiovascular products.

This transformation was highlighted by the U.S. Food and Drug Administration approval of Ranexa™ (ranolazine extended-release tablets) in January 2006. This marked the first new pharmaceutical approach to chronic angina in the United States in more than 20 years and today, physicians are prescribing Ranexa for their appropriate chronic angina patients.

The approval of Ranexa capped an exceptional year for CV Therapeutics. In April 2005, we announced that the approval-enabling ERICA study of Ranexa had met its primary endpoint, with patients taking Ranexa achieving a statistically significant reduction in angina frequency. This was a particularly striking result because the reduction in angina frequency was observed in combination with the maximum labeled dose of the calcium channel blocker amlodipine. We submitted these data in an amendment to our new drug application and were pleased to receive approval of Ranexa for second-line use.

According to the American Heart Association, 6.5 million people in the United States suffer from chronic angina. Angina occurs both before and after interventional therapy and is a disease which is heavily treated using pharmacotherapy. There are more than 40 million beta-blocker, calcium channel blocker and long-acting nitrate prescriptions written for angina each year in the United States. According to the AHA/ACC angina guidelines, the goal of treatment should be "complete, or nearly complete, elimination of anginal chest pain." However, 61 percent of angina patients require multiple-drug therapy and 19 percent require triple therapy. A study published in the *New England Journal of Medicine* in 2001 noted that 81 percent of patients still had angina and/or took antianginal medication 12 months after revascularization with a stent.

We believe that the second-line indication for Ranexa will allow us to address an important market opportunity with a substantial unmet need. Ranexa has antianginal and anti-ischemic effects that do not depend on reductions in heart rate or blood pressure. The existing classes of antianginal therapy do depend on reductions in heart rate or blood pressure and, in my experience as a cardiologist who has prescribed these drugs many times, it is often the hemodynamic consequences that can limit the dosing and utility of existing antianginals in certain angina patients.

Since Ranexa is the first new pharmaceutical approach to treat chronic angina in more than 20 years in the United States, we face both a challenge and an opportunity to educate cardiologists on how Ranexa can be used appropriately to relieve chronic angina. While physicians will need to be educated on how to best use Ranexa, chronic angina is a highly symptomatic condition and we would expect that physicians and patients will quickly learn whether or not Ranexa is working for them.

An important factor in the commercial success of Ranexa will be managed care. Our National Account Management team has begun conducting meetings with the top managed care plans in order to make Ranexa available to their customers. Over the next six to 12 months, managed care plans will have an opportunity to review Ranexa and make their formulary decisions.

We believe we have significantly enhanced our potential Ranexa launch opportunities with cardiology specialists thanks to our decision to build our commercial team in advance around the labeling expansion for ACEON® (perindopril erbumine) Tablets. Last fall, our cardiovascular sales team began calling on many cardiology specialists who may be potential Ranexa prescribers. Having an experienced and established commercial sales and marketing organization in place that is already calling on important cardiology customers has allowed us to focus on key Ranexa success drivers.

We decided to accelerate the potential labeling expansion timeline for Ranexa by commencing MERLIN TIMI-36 in advance of receiving results from the ERICA study. Enrollment of the approximately 6,500-patient study continues to proceed well and could be completed in the second quarter of 2006. Based on our current projections, we expect topline data in the fourth quarter of 2006 or the first quarter of 2007.

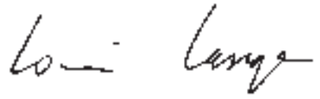
Looking beyond Ranexa, we also saw notable progress in 2005 with regadenoson and CVT-6883. We announced in August that the first of our two Phase 3 studies of regadenoson had met its primary endpoint by showing that myocardial perfusion imaging studies conducted with regadenoson were comparable to those conducted with ADENOSCAN®. We expect to announce results from our second, identically designed, Phase 3 study in 2006. If results from this study are also positive, we would expect a new drug application to follow in 2007.

Over the summer, we announced that we had initiated a clinical program for CVT-6883, a selective, potent and orally available A_{2B}-adenosine receptor antagonist intended to treat asthma. Blockade of the A_{2B}-adenosine receptor may limit or prevent mast cell degranulation, which in turn may lead to bronchoconstriction and the inflammatory process associated with asthma and cardiopulmonary disease. Therefore, CVT-6883 could potentially offer a new therapeutic approach to asthma.

We plan to continue applying our expertise in molecular cardiology to develop and commercialize innovative new therapies. Our balance sheet positions us well to capitalize on our commercial, clinical and preclinical programs, as we raised funds and redeemed outstanding debt in 2005 and ended the year with $460.2 million, compared to $404.5 million at December 31, 2004.

The approval of Ranexa is certainly a milestone for patients, physicians and CV Therapeutics. We have maintained our product rights to Ranexa and are currently launching the product to cardiology specialists nationwide. Ranexa has the potential to have a real impact on the treatment of chronic angina and we are looking forward to seeing patients benefit from this important product.

Thank you for your continued support of CV Therapeutics.



Louis G. Lange, M.D., Ph.D.
Chairman of the Board and Chief Executive Officer
March 31, 2006

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and Scientific Advisory Board

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

FORM 10-K

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

For the fiscal year ended December 31, 2005.

OR

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

For the transition period from to .

Commission file number: 0-21643

CV THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**43-1570294**
(State of Incorporation)	**(I.R.S. Employer Identification No.)**

3172 Porter Drive, Palo Alto, California 94304
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(650) 384-8500**

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**

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

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

Indicate by check whether the Registrant (1) has filed all reports to be filed by Section 13 or 15(d) of the Securities and 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 the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one).

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, was $805,597,957 as of June 30, 2005.

As of February 28, 2006, there were 45,035,370 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

CV THERAPEUTICS, INC.

FORM 10-K

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "hope," "may," "will," "plan," "intend," "estimate," "could," "should," "would," "continue," "seek," "pro forma" or "anticipate," or other similar words (including their use in the negative), or by discussions of future matters such as our future clinical or product development, regulatory review of our products or product candidates, commercialization of our products, our financial performance, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading "Item 1A. Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and that, if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Business

Business Overview and Strategy

CV Therapeutics, Inc., headquartered in Palo Alto, California, is a biopharmaceutical company focused on the discovery, development and commercialization of new small molecule drugs for the treatment of cardiovascular diseases. We apply advances in molecular biology and genetics to identify mechanisms of cardiovascular diseases and targets for drug discovery.

We currently have two approved cardiovascular products to promote with our national cardiovascular specialty sales force: Ranexa™ (ranolazine extended-release tablets) and ACEON® (perindopril erbumine) Tablets. Ranexa was approved in the United States in January 2006 for the treatment of chronic angina in patients who have not achieved an adequate response with other antianginal drugs. Ranexa represents the first new pharmaceutical approach to treat angina in the United States in more than 20 years. Ranexa should be used in combination with amlodipine, beta-blockers or nitrates. We plan to launch Ranexa in March 2006. ACEON®, an angiotensin converting enzyme inhibitor, or ACE inhibitor, is approved in the United States for use in patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction, or MI, and for the treatment of patients with essential hypertension. We co-promote ACEON® in the United States with our partner Solvay Pharmaceuticals, Inc. In addition to our marketed products, we are developing regadenoson, a selective A_{2A}-adenosine receptor agonist for potential use as a pharmacologic agent in myocardial perfusion imaging studies.

In January 2006, the U.S. Food and Drug Administration, or FDA, approved Ranexa for the treatment of chronic angina. Because Ranexa prolongs the QT interval, the approved product labeling indicates that it is

reserved for patients who have not achieved an adequate response with other antianginal drugs. Ranexa should be used in combination with amlodipine, beta-blockers or nitrates. Ranexa has antianginal and anti-ischemic effects that do not depend upon reductions in heart rate or blood pressure.

In order to potentially broaden the product labeling for Ranexa, we are conducting the Metabolic Efficiency with Ranolazine for Less Ischemia in Non-ST Elevation Acute Coronary Syndromes, or MERLIN TIMI-36, clinical study. This study is being conducted under a special protocol assessment, or SPA, agreement with the FDA. If treatment with Ranexa is not associated with an adverse trend in death or arrhythmia compared to placebo, the study could support potential approval of Ranexa as first-line chronic angina therapy, even if statistical significance on the primary endpoint is not achieved. In addition, if statistical significance on the primary endpoint is achieved, Ranexa could also gain potential approval for hospital-based and long-term prevention of acute coronary syndromes. The MERLIN TIMI-36 study began enrollment in October 2004 and is being conducted by the Harvard-based TIMI Study Group. We currently expect data from the MERLIN TIMI-36 study in the fourth quarter of 2006 or the first quarter of 2007.

In August 2005, the FDA approved a supplemental new drug application, or sNDA, for ACEON® for the treatment of patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction. The labeling expansion was based on the EUROPA (EUropean trial on Reduction Of cardiac events with Perindopril in patients with stable coronary Artery disease) study, which assessed the ability of perindopril to reduce cardiovascular death, nonfatal myocardial infarction and cardiac arrest in a broad population of patients who had stable coronary artery disease but not heart failure or substantial hypertension. In the EUROPA study, perindopril significantly reduced relative cardiovascular risk by 20% as assessed by the primary combined study endpoint of cardiovascular death, nonfatal myocardial infarction and cardiac arrest. ACEON® is also indicated for the treatment of hypertension.

One of our drug candidates which is in late-stage clinical development is regadenoson, a selective A_{2A}-adenosine receptor agonist for potential use as a pharmacologic agent in myocardial perfusion imaging studies. We completed a Phase 3 trial of regadenoson, which met its primary endpoint, in support of this proposed use in August 2005. Data from a second Phase 3 trial with the same design are expected in 2006.

In addition, we have several development, preclinical and research programs whose objectives are to bring additional drugs to market to help patients with unmet medical needs.

Business Strategy

Despite the development during the past 20 years of significant new therapies for patients with cardiovascular disease, heart disease remains one of the leading causes of death in the United States, claiming almost 1,000,000 lives in 2003. Cardiovascular diseases, including atherosclerosis (hardening of the arteries), hypertension (high blood pressure), and ischemia (lack of sufficient oxygen to the cells), may cause permanent damage to the heart and blood vessels, leading to angina, heart failure and myocardial infarction (heart attack). Molecular cardiology is providing new insight into the mechanisms underlying cardiovascular diseases and creating opportunities for improved therapies. The key elements of our business strategy are as follows:

Identify, develop and commercialize drugs primarily for cardiovascular disease

By focusing primarily on one therapeutic area, we believe that we can be relatively efficient in our drug discovery, development and commercialization efforts. Our concentrated focus on cardiovascular disease potentially enhances our efforts in the following areas:

- Sales and marketing efficiencies—marketing and promotion may focus primarily on the same cardiology specialists and other healthcare practitioners;

- Clinical investigators—investigators in one trial may be candidates for future trials;
- Consultants—thought leaders may be engaged for numerous internal programs;
- Clinical expertise—key employees have extensive experience and familiarity with the treatment of patients with cardiovascular disease,
- Regulatory—interactions are primarily with a single FDA division; and
- Research—primary focus is on the molecular mechanisms of the cardiovascular system.

Focus on small molecule drug candidates

Small molecule therapeutics can frequently be administered orally on an outpatient basis. By contrast, large molecule therapeutics, such as proteins or monoclonal antibodies, can very rarely be formulated to accommodate oral outpatient administration. In addition, our emphasis on small molecule therapeutics means that our drug candidates can be produced by conventional pharmaceutical manufacturing methods, using the established production capabilities of the contract pharmaceutical manufacturing industry.

In-licensing cardiovascular products with unique potential

We believe it is important to explore in-licensing opportunities to complement our expertise in cardiology. In December 2004, we entered into an agreement with Solvay Pharmaceuticals to co-promote ACEON® in the United States. We expect to continue to evaluate additional products for potential in-licensing or co-promotion as well as late stage clinical programs and research and discovery partnerships.

Commercialize products through concentrated sales and marketing efforts

A focused commercialization effort can provide sales and marketing efficiencies. Patients that have severe cardiovascular conditions often are treated by cardiologists and other specialists. We believe that a relatively small number of cardiology specialists is responsible for a significant portion of the patient visits associated with prescriptions written for important cardiovascular conditions. We believe these market dynamics may make it possible to market and sell our products with a focused commercialization effort using our own cardiovascular specialty sales force.

Product Portfolio

We have the following portfolio of products and product candidates, primarily in the area of cardiovascular disease:

Approved Products	Indication
Ranexa™ (ranolazine extended-release tablets)	Chronic angina (reserved for 2nd line use)
ACEON® (perindopril erbumine) Tablets	Stable coronary artery disease Hypertension

Products in Clinical Development	Area of Development	Status
Ranexa™	Chronic angina (1st line use)	
	Acute coronary syndromes	Phase 3
Regadenoson	Myocardial perfusion imaging	Phase 3
Tecadenoson	Paroxysmal supraventricular techycardias	Phase 3
	Acute atrial fibrillation	Phase 2
Adentri™	Heart failure	Phase 2
CVT-6883	Asthma	Phase 1

Preclinical Development Programs	Area of Development	Status
Adenosine receptors	Atrial arrhythmias, lipid metabolism, diabetes, metabolic syndrome, dyslipidemia, addiction	Preclinical
Late sodium current	Ischemic conditions	Preclinical
Reverse cholesterol transport	Atherosclerosis	Preclinical
Other programs	Programs related to cardiovascular disease and associated risk factors, such as metabolic disorders, dyslipidemia and obesity	Preclinical

In the table, under the heading "Status," generally "Phase 3" indicates evaluation of clinical efficacy and safety within an expanded patient population, at geographically dispersed clinical trial sites; "Phase 2" indicates clinical safety testing, dosage testing and initial efficacy testing in a limited patient population; "Phase 1" indicates initial clinical safety testing in healthy volunteers or a limited patient population, or studies directed toward understanding the mechanisms or metabolism of the drug; "Preclinical" indicates the program has not yet entered human clinical trials. For purposes of the table, "Development Status" indicates the most advanced stage of development that has been completed or is on-going.

Approved Products

Ranexa™ (ranolazine extended-release tablets)

Ranexa™ (ranolazine extended-release tablets) is a new small molecule drug which was approved in the United States by the FDA in January 2006. Ranexa has antianginal and anti-ischemic effects that do not depend upon reductions in heart rate or blood pressure. Ranexa represents the first new pharmaceutical approach to treat angina in the United States in more than 20 years. According to the approved product labeling, Ranexa is indicated for the treatment of chronic angina, and because Ranexa prolongs the QT interval, it should be reserved for patients who have not achieved an adequate response with other antianginal drugs. Ranexa should be used in combination with amlodipine, beta-blockers or nitrates. Based on the anti-ischemic properties we have observed in previous studies of Ranexa, we also are evaluating Ranexa for potential treatment and long-term prevention of acute coronary syndromes in the MERLIN TIMI-36 study.

We have exclusive license rights to Ranexa in the United States and specified foreign territories outside Asia for use in all cardiovascular indications, including chronic angina, from Roche Palo Alto LLC.

Chronic Angina

Cardiovascular disease results from the accumulation of disease to the heart and vessels that may take decades to develop. Beginning in the early years of life, the impact of cardiovascular risk factors such as smoking, lipid disorders, physical inactivity, obesity and others may eventually cause the heart to become unable to respond adequately to the energy demands placed on it. For some patients with heart disease, this continuum of progressive events may ultimately result in premature death. Chronic angina is an overt—and often the first physically evident—manifestation of the heart disease continuum. The atherosclerotic plaque of coronary artery disease narrows the vessels that carry blood throughout the heart. Myocardial ischemia ensues, making the heart unable to receive enough oxygen-rich blood to respond to increased energy demands caused by physical activity or emotional stress. The debilitating pain or discomfort that many patients with chronic angina can experience may negatively impact physical functioning and, in turn, lead to reduced activity and decreased quality of life.

Chronic angina is a growing health problem, affecting millions of people, generally over the age of 55. Annually, it costs the United States tens of billions of dollars in healthcare services and lost work. According to the American Heart Association, 6.5 million people in the United States live with chronic angina, with an additional 400,000 people newly diagnosed each year. The U.S. Census Bureau projects that the over 55 population, the group most at-risk for angina, will increase by approximately 70% over the next 25 years.

Pharmaceutical Approaches to Chronic Angina Treatment

Available drugs to treat chronic angina other than Ranexa include beta-blockers, calcium channel blockers and long-acting nitrates, all of which treat angina by decreasing the heart's demand for oxygen by lowering heart rate, blood pressure and/or the strength of the heart's contraction. These effects can limit or prevent the use of these other drugs in patients whose blood pressure or cardiac function is already decreased, and can have a negative impact on patients' quality of life, especially when these drugs are used in combination.

Up to now, despite the use of these other therapies, up to three-fourths of chronic angina patients in the United States still have angina symptoms, and some patients on multiple drugs continue to experience angina attacks. Adverse effects of drug therapy may include lower extremity edema associated with calcium channel blockers, impotence and depression associated with beta-blockers, and headaches associated with nitrates. Consequently, for some patients and physicians, these available medical treatments may not relieve angina without unacceptable effects.

Ranexa—A new pharmaceutical approach to angina treatment

We believe that an anti-anginal drug such as Ranexa, which provides efficacy in addition to that provided by other agents without further reducing blood pressure or heart rate, is a useful new tool to alleviate the burden of chronic angina in appropriate patients. Ranexa should be used in combination with amlodipine, beta blockers or nitrates.

The FDA approval of Ranexa was based on an amended new drug application, or NDA, submitted in July 2005. The approved product labeling highlights data from two Phase 3 studies: CARISA and ERICA. The Combination Assessment of Ranolazine in Stable Angina, or CARISA, trial and the Evaluation of Ranolazine In Chronic Angina, or ERICA, trial were randomized, double-blind, placebo controlled trials of Ranexa in patients with chronic angina. CARISA evaluated Ranexa when used in patients who were receiving either a beta-blocker or a calcium channel blocker. In CARISA, Ranexa significantly increased patients' symptom-limited exercise duration at trough drug concentrations compared to placebo, the primary endpoint of the study. ERICA, which was conducted under the FDA's special protocol assessment, or SPA, process, evaluated the effectiveness of

Ranexa in patients with chronic angina who remained symptomatic despite daily treatment with the maximum recommended dose of amlodipine, a calcium channel blocker. In ERICA, Ranexa met the primary endpoint of significantly reducing weekly angina frequency compared to placebo.

Ranexa is contraindicated in patients with pre-existing QT prolongation, with mild, moderate or severe hepatic impairment, on QT prolonging drugs, and on potent and moderately potent CPY3A inhibitors, including diltiazem. Ranolazine has been shown to prolong the QTc interval in a dose-related manner. While the clinical significance of the QTc prolongation in the case of ranolazine is unknown, other drugs with this potential have been associated with torsades de pointes-type arrhythmias and sudden death.

In clinical trials of angina patients, the most frequently reported adverse events (> 4%) occurring more often with Ranexa than placebo were dizziness (6.2%), headache (5.5%), constipation (4.5%), and nausea (4.4%). Fewer than 5% of patients discontinued treatment with Ranexa due to an adverse event in studies in angina patients. The most common adverse events that led to discontinuation more frequently on Ranexa than placebo were dizziness (0.7%) and nausea (0.6%). In ERICA and CARISA, syncope occurred in 0.7% of patients receiving Ranexa 1000 mg twice a day, and dizziness occurred in 6% of patients receiving that dose of Ranexa.

Preclinical research indicates that Ranexa is a selective late sodium current inhibitor, although this is not noted in the approved product labeling. Because of Ranexa's action to significantly reduce the late sodium current, we believe Ranexa prevents sodium overload and subsequent calcium overload in the heart, which occur during both ischemia and heart failure but not under other conditions or in the normal heart. We believe this in turn may preserve energy and mitochondrial function, improve contractility and diastolic function, and preserve proper ion balance during ischemia and/or heart failure.

Ranexa Development Status

In order to potentially broaden the product labeling for Ranexa beyond its current approved indication, we are conducting the Metabolic Efficiency with Ranolazine for Less Ischemia in Non-ST Elevation Acute Coronary Syndromes, or MERLIN TIMI-36, clinical study. This study is being conducted under a special protocol assessment, or SPA, agreement with the FDA. If treatment with Ranexa is not associated with an adverse trend in death or arrhythmia compared to placebo, the study could support potential approval of Ranexa as first-line chronic angina therapy, even if statistical significance on the primary endpoint is not achieved. As part of this SPA agreement, we must conduct a separate clinical evaluation of higher doses of Ranexa in order to obtain broader angina labeling (if any). In addition, if statistical significance on the primary endpoint for the MERLIN TIMI-36 study is achieved, Ranexa could also gain approval for hospital-based and long-term prevention of acute coronary syndromes.

MERLIN TIMI-36 is a multi-national, double-blind, randomized, placebo-controlled, parallel-group clinical trial designed to evaluate the efficacy and safety of Ranexa during acute and long-term treatment in approximately 6,500 patients with non-ST elevation acute coronary syndromes treated with standard therapy. The primary efficacy endpoint in MERLIN TIMI-36 is time to first occurrence of any element of the composite of cardiovascular death, myocardial infarction or recurrent ischemia in patients with non-ST elevation acute coronary syndromes receiving standard therapy. The safety of long-term treatment with Ranexa compared to placebo is also being evaluated in the study.

Within 48 hours of the onset of angina due to acute coronary syndromes, eligible hospitalized patients are enrolled in the study and randomized to receive intravenous Ranexa or placebo, followed by long-term outpatient treatment with oral Ranexa or placebo. All patients also receive standard therapy during both hospital-based and outpatient treatment. The oral doses of Ranexa used in MERLIN TIMI-36 have been studied in previous Phase 3 clinical trials.

In addition to performing periodic safety assessments, an independent data safety monitoring board, or DSMB, overseeing MERLIN TIMI-36 conducted an interim efficacy analysis when approximately half of the

anticipated major cardiovascular events occurred. A significant drug treatment effect on the rate of cardiovascular death with a p-value of less than 0.001 was pre-specified as being required for the DSMB to consider a recommendation to stop the study early. In February 2006, we were informed that the DSMB recommended that the study continue as planned.

The study's duration is event driven. It is expected to continue until at least 730 cases of cardiovascular death, myocardial infarction or severe recurrent ischemia have been observed, and at least 310 deaths from any cause have occurred. Currently there are approximately 500 study sites worldwide with study drug. The MERLIN TIMI-36 study was initiated in October 2004 and is being conducted by the Harvard-based TIMI Study Group. We expect data from MERLIN TIMI-36 in the fourth quarter of 2006 or the first quarter of 2007.

Ranexa Marketing Authorization Application in Europe

In March 2004, we submitted a marketing authorization application, or MAA, under a centralized procedure to European regulatory authorities seeking approval of ranolazine for the treatment of chronic angina in Europe. In October 2005, European regulatory authorities indicated that additional clinical pharmacokinetic data are needed prior to potential approval of ranolazine for the treatment of chronic angina in Europe. Therefore, we withdrew the MAA seeking approval of ranolazine in Europe.

ACEON® (perindopril erbumine) Tablets

ACEON® is an angiotensin converting enzyme inhibitor, or ACE inhibitor, that is approved in the United States for reduction of the risk of cardiovascular mortality or nonfatal myocardial infarction in patients with stable coronary artery disease and for the treatment of hypertension.

Stable Coronary Artery Disease

Coronary artery disease, or CAD, usually develops as a result of the deposition of fatty plaques along the walls of arteries that supply the heart with oxygen-rich blood. Over decades of life, these fatty plaques can begin to partially obstruct the flow of blood. The onset of CAD is typically silent, until the obstruction becomes so severe that the heart is prevented from receiving enough oxygen-rich blood to meet increased demands. As a result, often the first physically perceptible sign of CAD to patients is the onset of chronic angina pain or discomfort. For some patients, however, the initial signal may be myocardial infarction, or MI, also known as heart attack, that may occur without any prior warning signs. CAD is the largest killer of American men and women—causing one in every five deaths in 2003—and affects as many as 13 million people in the United States. The projected cost of CAD in the United States in 2006 is $142 billion.

Pharmaceutical Approaches to Stable Coronary Artery Disease Treatment

The treatment of CAD involves both interventional and preventive strategies. Interventional medical management for CAD includes drugs that help reduce the frequency and severity of angina pain or discomfort, such as beta-blockers, calcium channel blockers, and nitrates. In addition, revascularization procedures such as coronary artery bypass graft, or CABG, and angioplasty procedures with or without the use of stents, also known as percutaneous coronary intervention, or PCI, are used in patients with severe and/or multiple blockages in the heart.

Prevention is a multi-pronged effort. Patients are counseled to adhere to lifelong behavioral modifications to reduce their overall risk for CAD, including optimal and persistent management of high blood pressure, smoking cessation, a healthy diet, and regular, moderate exercise. Preventive pharmacotherapy includes cholesterol-lowering agents (such as statins) to help slow or halt the progression of CAD, and antiplatelet therapy to decrease the risk of clot formation in the heart.

Hypertension

In 2003, 65 million people in the United States were diagnosed with hypertension. Based on data collected in 1999-2000, approximately 70% of individuals with hypertension are aware of their condition, 60% are treated with drugs but only about 35% are controlled (meaning that their systolic blood pressure is less than 140 mmHg and their diastolic blood pressure is less than 90 mmHg). In the United States hypertension prevalence is expected to grow due to an aging population and increasingly sedentary lifestyles. Recent data from the Framingham Heart Study suggest that individuals who have normal blood pressure at age 55 have a 90% lifetime risk for developing hypertension.

Pharmaceutical Approaches to Hypertension Treatment

Clinical outcomes trial data show that lowering blood pressure using several classes of drugs, including ACE inhibitors, angiotensin receptor blockers, beta-blockers, calcium channel blockers and thiazide-type diuretics, in addition to lifestyle modifications, such as physical activity, weight loss, and a healthy diet, will reduce the complications of hypertension. Since more than 60% of patients cannot achieve adequate blood pressure control with one drug, physicians frequently prescribe multiple drugs from different classes.

ACE Inhibitors

In general, ACE inhibitors act by interfering with the conversion of angiotensin I in plasma to artery-constricting angiotensin II. Blocking the production of angiotensin II results in arterial vasodilation and an accompanying reduction in blood pressure. Additionally, angiotensin II is produced in the lining of tissue, including blood vessels and the heart, and is believed to have additional effects on the pathology of coronary artery disease. While all ACE inhibitors block the renin-angiotensin system, certain ACE inhibitors, including ACEON®, have been shown to also have an enhanced affinity for tissue ACE. Tissue ACE inhibitors like ACEON® have physical and chemical properties that allow them to penetrate the fatty environment of vascular tissue and atherosclerotic plaque more easily than ACE inhibitors which lack this quality.

ACEON®

FDA approved ACEON® in December 1993 for the treatment of patients with hypertension either as monotherapy or in combination with other classes of anti-hypertensives, especially thiazide diuretics. In August 2005, the FDA approved ACEON® for the treatment of patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction.

Perindopril has been launched in many countries. In Europe, perindopril is marketed under several brand names, including Coversyl®.

ACEON® is an ACE inhibitor indicated for use in patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal MI and for the treatment of patients with essential hypertension. For patients with stable CAD, ACEON® reduces the risk of cardiovascular mortality or nonfatal MI regardless of gender, age, hypertension, previous MI, diabetes or revascularization, including patients who are on concomitant therapies, such as antiplatelet therapies, beta-blockers, lipid-lowering agents and calcium channel blockers.

This approval for use in patients with stable CAD is based on the EUROPA trial. EUROPA was a multicenter, randomized, double-blind, placebo-controlled outcomes trial in 12,218 patients with stable coronary disease and without heart failure or substantial hypertension. The study was designed to assess the ability of perindopril to reduce cardiovascular death, myocardial infarction, and cardiac arrest.

EUROPA showed that in this broad population with stable coronary heart disease and no apparent heart failure, perindopril significantly reduced relative cardiovascular risk by 20% as assessed by the primary

combined study endpoint of cardiovascular death, nonfatal myocardial infarction and cardiac arrest. Treatment benefit was observed in patients taking lipid lowering therapy and beta-blockers.

For hypertensive patients, ACEON® offers continuous 24-hour blood pressure control with once-daily dosing. ACEON® may be used alone or with other classes of antihypertensives. In general, ACEON® is contraindicated in patients known to be hypersensitive to the product or to any other ACE inhibitors, and in patients with a history of angioedema related to previous treatment with an ACE inhibitor. ACEON® should not be used during pregnancy.

Product Candidates in Clinical Development

Regadenoson

Regadenoson is an A_{2A}-adenosine receptor agonist for potential use as a pharmacologic stress agent in myocardial perfusion imaging, or MPI, studies. As the diagnosis of coronary artery disease can present challenges to cardiologists and other practitioners, myocardial perfusion imaging studies offer an important alternative for the diagnosis of coronary artery disease. One of the most common methods for diagnosing coronary artery disease is the exercise treadmill test. Patients exercise on a treadmill to stress the heart in order to obtain an electrocardiogram. The observation of specific changes in the electrocardiogram, with or without the development of chronic angina pain or discomfort, signals the need for additional testing to confirm the presence of coronary artery disease. The ability of some patients to complete an exercise treadmill test may be limited because of long-term physical inactivity and/or concomitant illness such as arthritis, peripheral vascular disease, or heart failure. MPI studies using a pharmacologic stress agent offer an effective alternative for the diagnosis of coronary artery disease in these types of patients.

Myocardial Perfusion Imaging (MPI) Studies

MPI studies are usually performed in a nuclear medicine clinic. Medication is administered to the patient that temporarily increases coronary blood flow through the heart, mimicking the heart's physical response to the increased energy demand caused by exercise. Once the equivalent of maximal exercise is reached, a small amount of a radioactive substance is injected into the bloodstream, where it is absorbed into the area of the heart that is able to receive enough blood. An image of the area is then taken by a camera that specifically detects the distribution of radioactive substance in the heart during stress. Additional images are taken of the heart "at rest." If the images of the heart during stress and at rest show the same level of perfusion through the heart, then the test result is normal. However, if a perfusion defect is seen in the image of the stressed heart while the image of the heart at rest appears normal, then it is possible the defect is the result of a partial blockage caused by an atherosclerotic plaque associated with coronary artery disease, signaling the need for treatment and possibly additional testing to confirm the diagnosis. In 2002, approximately 7.8 million patients underwent MPI studies. Of those, approximately 3.4 million, or more than 40%, required a pharmacologic agent to generate maximum coronary blood flow because peripheral vascular disease, arthritis or other limiting medical conditions prevented them from exercising on the treadmill.

In addition to MPI studies, there are other approaches for diagnosing coronary artery disease, including electrocardiogram, electron beam computed tomography (for detecting and quantifying coronary calcification), CT angiography, echocardiography (echo), and contrast coronary angiography.

Current Approaches to Increasing Coronary Blood Flow During MPI Studies

MPI studies use pharmacological agents to increase coronary blood flow of the heart as if it were responding to the demands of physical exercise. Traditional agents used include dipyridamole and adenosine. Both agents are administered to patients by intravenous infusion with the aid of an infusion pump. Both of these agents act nonspecifically on the heart. While they are very effective at increasing coronary blood flow, their nonspecificity

may also produce undesirable and uncomfortable side effects. For example, dipyridamole is most commonly associated with chest pain, headache, and dizziness. In addition, the long half-life of dipyridamole may require lengthy patient monitoring following the procedure. Adenosine, while it has a short half-life, activates all adenosine receptor subtypes and, as a result, may cause flushing, dyspnea, and headache. The activation of other adenosine receptor subtypes may also cause sustained decreases in blood pressure (hypotension), reduced heart rate, and heart block. Adenosine is contraindicated in patients with asthma because of the risk of bronchoconstriction with the use of this agent.

Potential Treatment with Regadenoson

Regadenoson is a selective A_{2A}-adenosine receptor agonist administered by an intravenous bolus (without the use of an infusion pump) that stresses the heart by increasing coronary blood flow as if the heart were responding to the demands of physical exercise. The selective and specific action of regadenoson on the A_{2A}-adenosine receptor potentially may avoid some of the side effects caused by the less specific action of traditional agents. Bolus administration of regadenoson as well as its short half-life may also allow for more efficient administration during MPI studies.

Regadenoson Development Status

In October 2005, the results of the first Phase 3 trial evaluating the use of regadenoson as a pharmacologic stress agent in MPI studies were presented as a Late Breaking Clinical Trial at the American Society of Nuclear Cardiology Scientific Sessions 2005 in Seattle. The study met its primary endpoint by showing that MPI studies conducted with regadenoson were comparable to MPI studies conducted with Adenoscan®. In this study, regadenoson was generally well tolerated, and the most common adverse events reported in patients who received regadenoson were headache, chest pain, shortness of breath, flushing and gastrointestinal discomfort.

This multinational, randomized, double-blind pivotal Phase 3 study of 784 patients undergoing MPI studies was designed to evaluate the comparability of MPI studies conducted with regadenoson and Adenoscan®. All study participants received a clinically indicated baseline MPI study using Adenoscan®. Participants then were randomized in a double-blind fashion to receive either regadenoson or Adenoscan® in a second MPI study. Each patient's scans were classified as indicating normal, moderate or severe ischemia. Baseline and blinded scans were then evaluated to determine if the scans were comparable.

We expect data from a second Phase 3 trial of regadenoson using the same study design in 2006. If the second Phase 3 trial also is successful, we plan to file an NDA with the FDA seeking approval for regadenoson for use as a pharmacologic stress agent in MPI studies.

Regadenoson has not been determined by the FDA or any other regulatory authorities to be safe or effective in humans for any use.

Tecadenoson

Tecadenoson is a selective A_1-adenosine receptor agonist for the potential reduction of rapid heart rate during acute atrial arrhythmias. Atrial arrhythmias are characterized by abnormally rapid heart rates, and include the conditions of atrial fibrillation, atrial flutter and paroxysmal supraventricular tachycardias. Tecadenoson acts selectively on the conduction system of the heart to slow electrical impulses and may offer a new approach to rapid and sustained control of acute atrial arrhythmias by reducing heart rate without lowering blood pressure.

Tecadenoson Development Status

In 2002, we completed a Phase 3 trial of patients with paroxysmal supraventricular tachycardias, or PSVT, who were given tecadenoson. In this Phase 3 trial, all five dosing regimens of tecadenoson tested converted

patients with PSVT back into a normal heart rhythm ($p<0.0005$ versus placebo). The most frequent adverse symptom was paresthesia, a tingly sensation, following administration of tecadenoson. As expected based on the pharmacology of the study drug, dose dependent and transient atrial ventricular block was observed shortly after conversion across the highest three doses of tecadenoson.

In a Phase 2 trial of patients with atrial fibrillation or flutter, tecadenoson appeared to reduce heart rate from baseline without clinically meaningful changes in blood pressure. Hemodynamic parameters such as blood pressure and heart rate were not adversely affected by tecadenoson.

We are currently involved in only very limited development activity relating to tecadenoson and there are no clinical studies being conducted at this time. Tecadenoson has not been determined by the FDA or any other regulatory authorities to be safe or effective in humans for any use.

CVT-6883

CVT-6883 is a selective A_{2B}-adenosine receptor antagonist for potential treatment of asthma. Asthma is a chronic inflammatory disorder of the airways in which many cells of the immune system play a role, in particular mast cells, eosinophils, and T lymphocytes. Chronic inflammation caused by activation of these cells leads to an increase in airway hyperresponsiveness that is manifested in patients by wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning.

Currently available drug therapies for asthma include anti-inflammatory agents and/or bronchodilators. The two primary classes of therapy for asthma include controller medications for the prevention of symptoms and reduced frequency of attacks and reliever medications for acute reversal of asthma attacks. The three main classes of controller medications include inhaled and oral corticosteroids, long-acting inhaled beta-2 agonists, and leukotriene modifiers. The two main classes for reliever medications include rapid acting inhaled beta-2 agonists and anti-cholinergics. However, despite the availability of these drug classes, many asthma patients continue to have poorly controlled disease, which points to the need for new and innovative classes of asthma therapy.

CVT-6883 is being developed as a potential asthma controller medication. CVT-6883 acts selectively to block the A_{2B}-adenosine receptor, which may limit or prevent mast cell activation of the subsequent cascade of pro-inflammatory events that can lead to bronchoconstriction and airway hyperreactivity associated with asthma. Therefore, CVT-6883 could potentially offer a novel therapeutic approach to asthma.

CVT-6883 Development Status

In 2005, we completed a Phase 1 study for initial evaluation of the clinical safety, tolerability and absorption characteristics of orally administered CVT-6883. CVT-6883 has not been determined by the FDA or any other regulatory authorities to be safe or effective in humans for any use.

Preclinical Research and Development

Our research and development team is working to create new potential product opportunities through our expertise in molecular cardiology, and we have several ongoing preclinical research programs.

Adenosine Receptors

Adenosine is a small molecule that is naturally present in the body and has many actions in many different organs. Its effects on cells are the responses to activation by adenosine of cell-surface proteins called receptors. There are four types of adenosine receptors: A_1, A_{2A}, A_{2B} and A_3. Activation of these receptors initiates cascades of cellular biochemical events that result in specific changes of important cell functions, such as ion transport, electrical and contractile activity, and secretion of hormones and other small molecules.

The effects of adenosine serve as the basis for many of our research and development programs, including some preclinical programs and our regadenoson, tecadenoson and CVT-6883 clinical programs. Adenosine's effect to decrease the release of fatty acids from adipose tissue serves as the rationale for our preclinical program to investigate the use of an adenosine-like drug to decrease free fatty acids and blood triglyceride levels. The ability of adenosine to increase inflammatory responses in the asthmatic lung and to impact addictive behavior and withdrawal are the bases for our CVT-6883 program to design antagonists of these actions for treatment of inflammatory lung diseases and our preclinical program relating to addiction, respectively. The general goal of our adenosine programs is to further investigate additional therapeutic effects of both activation and blockade of adenosine receptors.

Late Sodium Current

We believe that inhibition of the late sodium current can reduce sodium overload and minimize calcium overload. This, in turn, can preserve energy and mitochondrial function, restore contractility and diastolic function, and preserve proper ion balance. We are building upon our scientific knowledge in this field to identify novel, orally bioavailable blockers of the late sodium current that may be effective in the treatment of chronic angina, acute coronary syndromes, and the acute and chronic treatment of heart failure. The goal of our late sodium current program is to further characterize the therapeutic potential and to discover new, proprietary potential products.

Reverse Cholesterol Transport

Our scientists and collaborators were one of several laboratories to discover that the ABCA1 protein is the rate limiting protein responsible for removal of cholesterol from the walls of blood vessels and atherosclerotic plaque, a process called reverse cholesterol transport. The activation of ABCA1 leads to an increase in high density lipoprotein, or HDL. The goal of our reverse cholesterol transport program is to discover a new potential proprietary product that will reduce the overall atherosclerotic burden in patients with cardiovascular disease.

Other Programs

We have several active discovery programs related to cardiovascular disease and associated risk factors, such as metabolic disorders, dyslipidemia and obesity.

Collaborations and Licenses

We have established, and intend to continue to establish, strategic partnerships to potentially expedite the development and commercialization of our products. In addition, we have licensed, and intend to continue to license, chemical compounds from academic collaborators and other companies. Our key collaborations and licenses currently in effect include:

Roche

In March 1996, we entered into a license agreement with Roche Palo Alto LLC (formerly Syntex (U.S.A.) Inc.) covering United States and foreign patent rights to ranolazine and related know how for the treatment of angina and other cardiovascular indications. The license agreement is exclusive and worldwide except for the following countries in which product rights are owned by Roche: Japan, Korea, China, Taiwan, Hong Kong, the Philippines, Indonesia, Singapore, Thailand, Malaysia, Vietnam, Myanmar, Laos, Cambodia and Brunei.

Under our license agreement, we paid an initial license fee and are obligated to make certain payments to Roche, upon receipt of the first and second product approvals for Ranexa in any of the following major market countries: France, Germany, Italy, the United States and the United Kingdom. In February 2006, we paid Roche an $11.0 million payment in connection with the FDA's approval of Ranexa in the United States in January 2006.

Unless the agreement is terminated, we are required to make a second payment of $9.0 million upon the second product approval, if any, in one of the major market countries specified above. In addition, we are required to make royalty payments based on net sales of approved products that utilize the licensed technology, including Ranexa. We are required to use commercially reasonable efforts to develop and commercialize the product for angina.

We or Roche may terminate the license agreement for material uncured breach, and we have the right to terminate the license agreement at any time on 120 days' notice if we decide not to continue to develop and commercialize ranolazine.

Astellas Pharma US

In July 2000, we entered into a collaboration with Astellas US LLC (formerly Fujisawa Healthcare, Inc.) to develop and market second generation pharmacologic myocardial perfusion imaging stress agents. Under this agreement, Astellas received exclusive North American rights to regadenoson, a short acting selective A_{2A}-adenosine receptor agonist, and to a backup compound. We received $10.0 million from Astellas consisting of a $6.0 million up-front payment, which is being recognized as revenue over the expected development term of the agreement, and $4.0 million for the sale of our common stock. To date, Astellas has paid us $5.0 million in milestone payments. We may receive up to an additional $19.0 million in cash milestone payments based on other development and regulatory milestones such as certain regulatory filings and approval. In addition, Astellas reimburses us for 75% of our development costs and we reimburse Astellas for 25% of their development costs. If the product is approved by the FDA, Astellas will be responsible for sales and marketing of regadenoson, and we will receive a royalty based on product sales of regadenoson and may receive a royalty on another product sold by Astellas.

Astellas may terminate the agreement for any reason on 90 days' written notice, and we may terminate the agreement if Astellas fails to launch a product within a specified period after marketing approval. In addition, we or Astellas may terminate the agreement in the event of material uncured breach, or bankruptcy or insolvency.

Solvay Pharmaceuticals

In December 2004, we entered into an agreement with Solvay Pharmaceuticals, Inc. to co-promote ACEON® (perindopril erbumine) Tablets, an angiotensin-converting enzyme inhibitor, or ACE inhibitor, in the United States. Under the agreement, we are responsible for brand marketing activities and for establishing a cardiovascular specialty sales force to promote the product. Under the agreement, Solvay Pharmaceuticals continues to handle the manufacturing and distribution of the product, and its primary care sales force continues to promote the product.

There were no upfront payments by either party associated with the co-promotion agreement. Solvay Pharmaceuticals records as revenue all sales of ACEON®. For all product sales above a specified baseline, there is a multi-tiered revenue-sharing structure and, on average, we receive a share of sales of approximately 50-60% of sales above the baseline. These economic terms are subject to adjustment if the FDA approves a generic to perindopril in the United States, or if we do not meet our minimum marketing and promotional commitments, or if we allow Solvay Pharmaceuticals to provide at least a specified number of details that turns out to be the majority of product details in any given year.

Under the co-promotion agreement, we are Solvay Pharmaceuticals' exclusive co-promotion partner in the United States, and we have agreed not to market any other ACE inhibitor or any angiotensin receptor blocker until our marketing and promotional commitments under the agreement have expired or terminated.

The period during which we must satisfy marketing and promotional commitments under the co-promotion agreement expires, unless earlier terminated, on the earlier of November 2008 or the date a generic to perindopril

is approved by the FDA, if any, although if patent protection for the product is extended beyond November 2009, we have the option to extend the term of our commitments provided that Solvay Pharmaceuticals obtains an extension of its United States license rights to the product. Immediately following the expiration of this period of our marketing and promotional commitments under the agreement, there is a residual term of three years. During the residual term, all of the agreement terms remain in effect except that we will no longer be required to meet any minimum marketing and promotional commitments, although to the extent we continue to market and promote the product we will be entitled to the same compensation as before the residual term. Assuming there is no extension of or successful challenge to the product's patent protection, no FDA approval of a generic to perindopril, and no earlier termination of the agreement, the co-promotion agreement expires in November 2011.

Either party may terminate the co-promotion agreement in the event of material uncured breach, and we may terminate the agreement for any reason on 180 days' advance written notice.

Marketing and Sales

Throughout 2005, we expanded our sales and marketing capabilities to develop and execute our commercialization strategies for the co-promotion of ACEON® and the launch of Ranexa in the United States. Our sales team includes regional and district managers, cardiology specialty sales personnel, account specialists for managed care, professional program managers, and marketing and sales operations infrastructure. The commercial team supports our sales and marketing activities for ACEON® and Ranexa. The members of the sales and marketing teams have extensive industry experience from a wide range of large and small companies and have substantial experience in the field of cardiology, as well as in launching and marketing pharmaceutical products.

In connection with our co-promotion agreement with Solvay Pharmaceuticals, we have hired and deployed a national cardiovascular specialty sales force that includes approximately 250 cardiovascular account specialists to promote ACEON® in the United States. Solvay Pharmaceuticals continues to handle the manufacturing and distribution of the product, and its primary care sales force also continues to promote the product.

We anticipate utilizing the sales team and systems we have developed to support the promotion of ACEON® and to support the launch and promotion of Ranexa. In addition, we may promote products in collaboration with marketing partners or rely on relationships with one or more companies with established distribution systems and direct sales forces. For example, Astellas Pharma US has agreed to market and sell regadenoson in North America, if approved by regulatory authorities.

Manufacturing

We do not currently operate, and have no current plans to develop, manufacturing facilities for clinical or commercial production of our products under development. We have no direct experience in manufacturing commercial quantities of any of our products, and we currently lack the resources or capability to manufacture any of our products on a clinical or commercial scale. As a result, we are dependent on corporate partners, licensees or other third parties for the manufacturing of clinical and commercial scale quantities of all of our products.

We have entered into several agreements with third party manufacturers relating to Ranexa, including for commercial-scale manufacturing of active pharmaceutical ingredient, bulk tablet manufacturing, packaging and supply of a raw material component for the product. We currently rely on a single supplier at each step in the production cycle of Ranexa. The commercial launch of Ranexa is dependent on these third party arrangements, and the marketing and sale of Ranexa could be affected by any delays or difficulties in performance of our third party manufacturers of Ranexa.

Pursuant to our co-promotion agreement, Solvay Pharmaceuticals is responsible for the manufacturing and distribution of ACEON®, and in turn is dependent on third parties for the manufacture of the product for sale and

sampling. If regadenoson is approved for marketing in the United States, Astellas Pharma US will be responsible for the manufacturing and distribution of regadenoson, and in turn will be dependent on third parties for the manufacture of the product for sale and sampling.

Patents and Proprietary Technology

Patents and other proprietary rights are important to our business. Our policy is to file patent applications in the United States and internationally in order to protect our technology, including inventions and improvements to inventions that are commercially important to the development and sales of our products. The evaluation of the patentability of United States and foreign patent applications can take several years to complete and can involve considerable expense.

We own multiple patents issued by and/or patent applications pending with the United States Patent and Trademark Office, or US PTO, and foreign patent authorities relating to our technology, including related to Ranexa and our clinical programs regadenoson and tecadenoson. We have received issued patents from the US PTO claiming methods of using various sustained release formulations of ranolazine (including the formulation tested in our three pivotal human clinical trials for Ranexa) for the treatment of chronic angina. These patents expire in 2019. We also have a license from Roche Palo Alto LLC in specified territories, which gives us exclusive rights to specified patents issued to Roche by the US PTO and foreign patent authorities related to Ranexa for use in developing and commercializing Ranexa for cardiovascular indications. The United States compound patent relating to Ranexa, which is licensed to us by Roche Palo Alto LLC, expired in 2003. However, now that Ranexa has been approved, we will reapply on a permanent basis for patent term extension and we expect to receive an extension under the Hatch-Waxman Act, which we anticipate will extend the patent protection to May 2008 for the approved product, which is the Ranexa extended-release tablet, for the approved use in chronic angina. In addition to patent term extension, because ranolazine is a new chemical entity, under applicable United States laws we will have exclusivity until January 2011 for the ranolazine compound.

The active ingredient in ACEON® is perindopril. Perindopril and its use in the treatment of stable coronary artery disease and hypertension are covered by an issued United States patent which provides compound coverage and expires in November 2009.

Regadenoson is the subject of two United States patents that expire in 2019.

Government Regulation

United States Regulation of Drug Compounds

The research, testing, manufacture and marketing of drug products are extensively regulated by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation by the FDA. The Federal Food, Drug and Cosmetic Act, and other federal and state statutes, regulations and guidelines, govern, among other things, the research, development, manufacture, testing, storage, recordkeeping, labeling, marketing, promotion and distribution of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject a company to a variety of administrative or judicially imposed sanctions.

The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include preclinical laboratory testing, formulation studies, the submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before clinical testing may commence in the United States, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the product candidate for each indication for which it is being tested.

Preclinical tests include laboratory evaluations of chemistry and formulations, as well as animal studies to assess the pharmacology and toxicology of the product candidate. The conduct of the preclinical tests and the

chemistry, manufacture and testing of our product candidates must comply with federal regulations and guidelines. Results of preclinical testing are submitted to the FDA as part of an IND.

Clinical studies involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators. Clinical studies must be conducted in compliance with federal regulations and guidelines, under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. For clinical studies conducted in the United States, a study protocol must be submitted to the FDA as part of the IND. The study protocol and informed consent information for patients participating in clinical studies must also be approved by an institutional review board for each institution where the studies will be conducted. In addition, the FDA may, at any time, impose a clinical hold on a clinical study. If the FDA imposes a clinical hold, clinical studies cannot be initiated or continued without FDA authorization and then only under terms the FDA authorizes.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the product candidate into healthy human volunteers or a limited number of patients, the product candidate is tested to assess safety, toxicity and metabolism. Phase 2 usually involves studies in a limited patient population to determine dose tolerance and the optimal dosage regimen, identify potential adverse effects and safety risks and provide preliminary support for the efficacy of the product candidate for the indication being studied.

If a product candidate appears to be effective and to have an acceptable safety profile in earlier testing, Phase 3 trials are undertaken to further evaluate clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. There can be no assurance that Phase 1, Phase 2 or Phase 3 testing of our product candidates will be completed successfully within any specified time period, if at all.

After completion of the required clinical testing, a marketing application called a new drug application, or NDA, is generally prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of virtually all preclinical and clinical testing and data relating to the product's chemistry, manufacture and testing.

The FDA has 60 days from its receipt of the NDA to determine whether the application will be accepted for filing based on the agency's threshold determination of whether the NDA is adequate to undertake review. Additional time may pass before the FDA formally notifies the sponsoring company whether the application will be reviewed. Once the submission is accepted for review, the FDA conducts an in-depth review of the NDA. As part of its review process, the FDA usually requests additional information and/or clarification regarding information already provided in the submission. Such requests can significantly extend the review period for the NDA, particularly if the FDA requests additional information and/or clarification that is not readily available, or requires additional studies or other time-consuming responses to requests. During the later stages of the review process, the FDA may refer the NDA to the appropriate outside advisory committee, typically a panel of clinicians and other experts, for evaluation as to whether the application should be approved or other recommendations. The FDA is not bound by the recommendations of any of its advisory committees.

Any FDA approval of a product is subject to a number of conditions that must be met in order to maintain approval of the NDA. For example, as a condition of NDA approval, the FDA may require extensive postmarketing testing and surveillance to monitor the product's safety, or impose other conditions. Once granted, product approvals may be withdrawn or restricted if compliance with regulatory standards is not maintained or safety concerns arise.

The FDA may decide not to approve an NDA for a new product candidate for a wide variety of reasons, including, without limitation, failure to demonstrate adequate product safety and/or efficacy. In such circumstances the FDA would typically require additional testing or information in order to satisfy the regulatory criteria for approval or may consider the product unapprovable.

Regulation by the FDA and other government authorities is also a significant factor in the marketing and promotion of drug products in the United States. Under the Food, Drug and Cosmetic Act, among other things the FDA approves all product labeling. The FDA also can review promotional materials and activities through its Division of Drug Marketing, Advertising, and Communications and may require corrective actions which are generally public, such as changes to the promotional materials. Under the Food, Drug and Cosmetic Act, the FDA has issued many detailed regulations and guidances applicable to the marketing and promotion of drug products. Failure to comply with FDA's many applicable requirements may subject a company to a variety of sanctions, including product seizure or recall.

In addition to FDA oversight, the marketing and promotion of drug products is also subject to a complex array of other federal and state laws, regulations and guidances, including federal and state antikickback and false claims statutes and regulations, and the federal Prescription Drug Marketing Act and related regulations. Anti-kickback laws make it illegal for a prescription drug manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify safe harbors or exemptions for arrangements that do not violate the anti-kickback statutes. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products, and those of our collaborative partners such as Solvay Pharmaceuticals and Astellas, will be subject to scrutiny under these laws and regulations. Applicable state laws and regulations also include state licensure requirements relating to facilities, drug distribution or drug sampling. Failure to comply with these many complex legal requirements can result in significant sanctions and penalties, both civil and criminal, as well as the possibility of exclusion of the approved product from coverage under governmental healthcare programs (including Medicare and Medicaid).

Our ability to sell drugs will also depend on the availability of reimbursement from government and private insurance companies.

Foreign Regulation of Drug Compounds

In countries outside the United States, approval of a product by foreign regulatory authorities is typically required prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. The approval procedure varies among countries and can involve additional testing. The time required may differ from that required for FDA approval. In general, countries outside the United States have their own procedures and requirements, many of which are just as complex, time-consuming and expensive as those in the United States. Thus, there can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

In Europe, marketing authorizations are generally submitted through a centralized or other procedure. The centralized procedure provides for marketing authorization throughout the European Union member states. In addition, a mutual recognition and decentralized procedure are also available which can result in approval of a product in selected European Union member states. Sponsoring companies must choose an appropriate regulatory filing strategy in Europe. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

Regulatory approval of prices is generally required in most foreign countries, including many countries in Europe.

Hazardous Materials

Our research and development processes and manufacturing activities involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal,

state and local laws and regulations governing the use, manufacture, storage, handling and disposing of hazardous materials and waste products.

Competition

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid and significant technological change. Ranexa competes with several well established classes of drugs for the treatment of chronic angina in the United States, including generic and/or branded beta-blockers, calcium channel blockers and long acting nitrates, and other treatments such as enhanced external counterpulsation therapy. In addition, other potential angina therapies may be under development. Surgical treatments such as coronary artery bypass grafting and percutaneous coronary intervention can be another option for angina patients. ACEON® is a member of the highly competitive class of drugs known as ACE inhibitors, many of which are generic. For the indication of coronary artery disease, there is at least one branded ACE inhibitor with substantial United States sales; for the treatment of hypertension there are other drug classes that are used to treat hypertension, including angiotensin receptor blockers, beta-blockers, calcium channel blockers and thiazide-type diuretics. In the United States, there are numerous marketed generic and/or branded pharmacologic stress agents, and at least two potential A_{2A}-adenosine receptor agonist compounds under development, that could compete with regadenoson. In addition, there are many therapeutic classes approved for the treatment of asthma in the United States, including steroids, beta-2 agonists, cromolyn, theophylline, and anti-IgE, all of which could represent competitive challenges to CVT-6883. We are also aware of companies that are developing products that may compete with our other drug candidates.

We believe that the principal competitive factors in the potential markets for Ranexa, ACEON®, regadenoson, tecadenoson and CVT-6883 will include:

- the length of time to regulatory approval;
- approved product labeling;
- risk management requirements;
- acceptance by the medical community;
- product performance;
- product price;
- product supply;
- formulary acceptance;
- marketing and sales resources and capabilities, including competitive promotional activities; and
- enforceability of patent and other proprietary rights.

We believe that we and our collaborative partners are or will be competitive with respect to these factors. Nonetheless, because our other products are still under development, our relative competitive position in the future is difficult to predict.

Employees

As of January 31, 2006, we employed 627 individuals full-time. Of our full-time work force, 169 employees are engaged in or directly support research and development activities and 458 are engaged in sales, marketing and general and administrative activities. Our employees are not represented by a collective bargaining agreement. We believe that our relations with our employees are good.

Research and Development

Since our inception, we have made substantial investments in research and development. In the years ended December 31, 2005, 2004 and 2003, we incurred research and development expenses of $128.4 million, $124.3 million and $80.8 million, respectively.

Available Information

We make available free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our director and officers' Section 16 reports, and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the EDGAR website directly to our reports. Our website address is *www.cvt.com*. Information on our website is not incorporated by reference and does not form a part of this report.

Item 1A. Risk Factors

Risk Factors Relating to Our Business

We expect to continue to operate at a loss, and we may never achieve profitability.

We have experienced significant operating losses since our inception in 1990, including net losses of $228.0 million in 2005, $155.1 million in 2004 and $111.0 million in 2003. As of December 31, 2005, we had an accumulated deficit of $812.6 million. The process of developing and commercializing our products requires significant research and development work, preclinical testing and clinical trials, as well as regulatory approvals, significant marketing and sales efforts, and manufacturing capabilities. These activities, together with our general and administrative expenses, require significant investments and are expected to continue to result in operating losses for the foreseeable future. We have not generated any product revenues to date, and even after we generate revenues relating to ACEON®, Ranexa™, and other approved products, if any, we may never achieve or sustain profitability.

Our operating results are subject to fluctuations that may cause our stock price to decline.

As we transition from a research and development-focused company to a company with commercial operations and revenues, we expect that our operating results will continue to fluctuate. Our product revenues will be unpredictable and may fluctuate due to many factors, many of which we cannot control. For example, factors affecting our revenues presently or in the future could include:

- timing and success of product launches by us and our collaborative partners, including the planned launch of Ranexa in the United States in March 2006;
- level of demand for our products, including physician prescribing habits;
- wholesaler buying patterns, product returns and contract terms;
- reimbursement rates or policies;
- the results of our clinical studies, including our MERLIN TIMI-36 clinical trial of Ranexa;
- regulatory constraints on, or delays in the review of, our product promotional materials and programs;
- government regulations;
- increased competition from new or existing products or therapies, including lower-priced generic products and alternatives to drug treatment such as interventional medicine;
- changes in our contract manufacturing activity, including the availability or lack of commercial supplies of products and samples for promotion and distribution;
- timing of non-recurring license fees and the achievement of milestones under new and existing license and collaborative agreements; and
- our product marketing, promotion, distribution and pricing strategies and programs, including, without limitation, post-approval studies and product lifecycle planning.

With respect to our co-promotion arrangement relating to ACEON®, in addition to the foregoing factors, we will not receive any revenues under the arrangement if specified sales levels are not achieved. There are also provisions in our agreement that could affect revenues. For example, the amount of revenues we receive under

the agreement will be modified if the FDA approves a generic to perindopril in the United States, if we do not meet our minimum marketing and promotional commitments under the agreement, or if we allow Solvay Pharmaceuticals to provide at least a specified number of details that turns out to be the majority of product details in any given year.

In addition, our expenses, including payments owed by us under licensing, collaborative or manufacturing arrangements, are unpredictable and may fluctuate from quarter to quarter. We believe that quarter-to-quarter comparisons of our operating results are not a good indicator of our future performance and should not be relied upon to predict our future performance. Also, our operating results in a particular quarter or quarters may not meet the expectations of securities analysts or investors, causing the market price of our common stock to decline.

If we are unable to secure additional financing, we may be unable to complete our research and development activities or successfully commercialize any of our products.

As of December 31, 2005, we had cash, cash equivalents and marketable securities of $460.2 million, which we expect will be sufficient to fund our current operations for at least the next 12 months. For the fiscal years ended December 31, 2005, 2004 and 2003, our net losses were $228.0 million, $155.1 million and $111.0 million, respectively. We currently estimate that our operating expenses for 2006 will be approximately $310.0 million to $330.0 million. Although we began to commercialize ACEON® during the second quarter of 2005, we have generated no revenue for 2005. We do not expect to generate sufficient revenues through our United States co-promotion of ACEON® or through our planned launch of Ranexa in March 2006 to achieve profitability without requiring additional funding in order to complete our future research, development and commercialization activities.

The amount of additional funding that we will require depends on many factors, including, without limitation:

- the amount of revenue, if any, that we are able to obtain from any approved products, and the time and costs required to achieve those revenues;
- the timing, scope and results of preclinical studies and clinical trials, including our MERLIN TIMI-36 clinical trial of Ranexa;
- the size and complexity of our programs;
- the time and costs involved in obtaining regulatory approvals;
- the costs of launching our products;
- the costs of commercializing our products, including marketing, promotional and sales costs;
- the costs of manufacturing or obtaining preclinical, clinical and commercial materials;
- our ability to establish and maintain strategic collaborative partnerships, such as our arrangement with Solvay Pharmaceuticals and our arrangement with Astellas US LLC (formerly Fujisawa Healthcare, Inc.);
- competing technological and market developments;
- the costs involved in filing, prosecuting, maintaining and enforcing patent claims; and
- progress in our research and development programs.

Additional financing may not be available on acceptable terms or at all. If we are unable to raise additional funds, we may, among other things:

- have to delay, scale back or eliminate some or all of our research and/or development programs;
- have to delay, scale back or eliminate some or all of our commercialization activities;
- lose rights under existing licenses;
- have to relinquish more of, or all of, our rights to product candidates on less favorable terms than we would otherwise seek; and
- be unable to operate as a going concern.

If additional funds are raised by issuing equity or convertible debt securities, our existing stockholders will experience dilution.

Our failure to manage our rapid growth could harm our business.

We have experienced rapid growth and expect to continue to expand our operations over time. In 2005, we more than doubled the size of our workforce, including by hiring, training and deploying a national cardiovascular specialty sales force of approximately 250 personnel. As we perform under the co-promotion arrangement relating to ACEON®, prepare for the launch of Ranexa in March 2006, continue to conduct a large clinical trial of Ranexa, continue to conduct clinical trials for our other product candidates and continue our drug discovery efforts, we have added personnel in many areas, including operations, sales, marketing, regulatory, clinical, finance, information systems and other general and administrative functions. We may not manage this growth effectively, which would harm our business and cause us to incur higher operating costs. If rapid growth continues, it may strain our operational, managerial and financial resources.

The commercialization of our products is substantially dependent on our ability to develop effective sales and marketing capabilities.

Our successful commercialization of Ranexa and ACEON® in the United States will depend on our ability to establish an effective sales and marketing organization in the United States. We have hired, trained and deployed additional marketing personnel and a national cardiovascular specialty sales force of approximately 250 personnel, which began to promote ACEON® in 2005 and is being trained to promote Ranexa in 2006. The size of our sales force may increase or decrease in the future, depending on many factors, including the effectiveness of the sales force, the level of market acceptance of Ranexa, and the results of our ongoing MERLIN TIMI-36 clinical trial of Ranexa. Recruiting, hiring, training, deploying and retaining a national sales force and additional personnel is very expensive, complex and time-consuming. We do not know if this sales force will be sufficient in size or scope to compete successfully in the marketplace. Among other factors, we may not be able to gain sufficient access to healthcare practitioners, which would have a negative effect on our ability to promote our products and gain market acceptance. Even if we gain access to healthcare practitioners, we may not be able to change prescribing patterns in favor of our approved products. We do not know whether the personnel we have recruited and trained will be effective or whether we will gain market acceptance for Ranexa or ACEON® in the United States.

Our approved products may not achieve market acceptance and revenues.

If Ranexa and ACEON® fail to achieve market acceptance, our product sales and our ability to become profitable in the future will be adversely affected. Many factors may affect the rate and level of market acceptance of Ranexa and ACEON® in the United States, including:

- our product marketing, promotion, distribution and pricing strategies and programs;

- our ability to provide acceptable evidence of the product's safety, efficacy, cost-effectiveness and convenience compared to that of competing products or therapies;
- product labeling claims;
- regulatory constraints on, or delays in the review of, our product promotional materials and programs;
- the perception of physicians and other members of the healthcare community of the product's safety, efficacy, cost-effectiveness and convenience compared to that of competing products or therapies;
- patient and physician satisfaction with the product;
- the effectiveness of our sales and marketing efforts and those of our strategic partners, including Solvay Pharmaceuticals and Astellas;
- the size of the market for the product;
- any publicity concerning the product or similar products;
- the introduction, availability and acceptance of competing treatments, including lower-priced generic products;
- the availability and level of third-party reimbursement for the product;
- the ability to gain formulary acceptance and favorable formulary positioning for our approved products on government and managed care formularies;
- the success of ongoing development work relating to the products, including our MERLIN TIMI-36 clinical trial of Ranexa;
- new data or adverse event information relating to the product or any similar products and any resulting regulatory scrutiny;
- our ability to satisfy post-marketing safety surveillance responsibilities and safety reporting requirements;
- whether or not regulatory authorities impose risk management programs on the product, which can vary widely in scope, complexity, and impact on market acceptance of a product, and can include education and outreach programs, controls on the prescribing, dispensing or use of the product, and/or restricted access systems;
- the continued availability of third parties to manufacture and distribute the product and product samples on acceptable terms, and the continued ability to manufacture commercial-scale quantities of the product successfully and on a timely basis;
- the outcome of patent or product liability litigation, if any, related to the product;
- regulatory developments relating to the development, manufacture, commercialization or use of the product; and
- changes in the regulatory environment.

For example, we believe that the approved product labeling for Ranexa and ACEON® will have a direct impact on our marketing, promotional and sales programs for these products, and could adversely affect market acceptance of our products.

Regulatory authorities approve product labeling with reference to the preclinical and clinical data that form the basis of the product approval, and as a result the scope of approved labeling is generally impacted by the available data. The approved product labeling for Ranexa states that because of the potential safety risk of QT prolongation caused by Ranexa, the product should be reserved for use in chronic angina patients who have not achieved an adequate response with other antianginal drugs, and should be used in combination with other common antianginal treatments, specifically amlodipine, beta-blockers or nitrates. As a result, Ranexa is approved for only a portion of the overall angina patient population in the United States. Any approval of Ranexa for broader use with angina patients will require, among other things, successful completion of our large ongoing MERLIN TIMI-36 clinical trial, from which preliminary results are expected at the end of 2006 or in the first quarter of 2007. We cannot assure you that the MERLIN TIMI-36 clinical trial will succeed or allow us to expand the approved labeling for Ranexa.

In addition to approving product labeling, the FDA typically reviews core promotional materials in connection with new product launches. We must obtain the FDA's review of our key promotional materials in connection with the planned launch of Ranexa in March 2006. We do not know when the FDA will review these materials, or whether the approved materials will allow us to effectively promote Ranexa with healthcare practitioners and managed care audiences. For example, the approved product labeling states that the mechanism of action of Ranexa is unknown. As a result, our promotional materials will not be able to discuss preclinical research that suggests that Ranexa is a selective late sodium current inhibitor, which may make it difficult for us to differentiate the product in the market.

The pharmaceutical and biopharmaceutical industries and the market for cardiovascular drugs in particular, are intensely competitive. Ranexa, ACEON® and any of our other products that receive regulatory approval will compete with well-established, proprietary and generic cardiovascular therapies that have generated substantial sales over a number of years and are widely used and accepted by health care practitioners. For example, ACEON® is a member of the highly competitive class of drugs known as ACE inhibitors, including at least one branded ACE inhibitor with substantial United States sales much larger than United States sales of ACEON®. Although the FDA approved ACEON® for the treatment of patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction in August 2005, to date there have been only minimal product sales and our marketing and promotional efforts have not materially increased overall market acceptance or resulted in any revenues to us under our co-promotion agreement with Solvay Pharmaceuticals.

We may also be hampered in our promotional efforts by a lack of familiarity with our products among healthcare practitioners in the United States. Relatively few United States physicians served as clinical investigators in the CARISA or ERICA clinical studies of Ranexa, and so only a limited number of United States healthcare practitioners are familiar with using Ranexa, even in a clinical trial setting. In addition, the EUROPA trial that led to the FDA's approval of ACEON® for a new indication in August 2005 was conducted entirely in Europe, and United States practitioners have relatively little experience using ACEON® for this indication.

In addition to direct competition, our products will also have to compete against the promotional efforts of other products in order to be noticed by physicians and patients. The level of promotional effort in the pharmaceutical and biopharmaceutical markets has increased substantially. Market acceptance of our products will be affected by the level of promotional effort that we are able to provide for our products. The level of our promotional efforts will depend in part on our ability to train, deploy and retain an effective sales and marketing organization, as well as our ability to secure additional financing. We cannot assure you that the level of promotional effort that we will be able to provide for our products or the levels of additional financing we are able to secure, if any, will be sufficient to obtain market acceptance of our products.

We expect to launch Ranexa in the United States in March 2006 and we continue to co-promote ACEON in the United States, which requires significant capital expenditures. If we are not successful in achieving market acceptance for these products, the significant amounts of capital we are spending in connection with their commercialization would be lost.

We are spending significant amounts of capital in connection with the planned launch of Ranexa in the United States in March 2006. The level of our operating expenses increased in the second half of 2005 in connection with our pre-commercialization efforts relating to Ranexa. We expect the level of our operating expenses to continue to increase substantially in connection with the planned launch of Ranexa in March 2006. Our Ranexa commercialization efforts include further building our sales and marketing infrastructure, building inventory of the product and product samples, making distribution arrangements with wholesalers including expensive launch-related arrangements to stock Ranexa at the retail pharmacy level, sales training, increased marketing research and communication efforts, deployment of our national cardiovascular specialty sales force of approximately 250 personnel in connection with initial promotional efforts, and additional hiring. Our previous and ongoing investments in the product would be lost if we cannot achieve market acceptance and revenues for the product.

We spent approximately $137.2 million on sales and marketing activities from January 1, 2002 through December 31, 2005, which primarily related to Ranexa and ACEON®. The loss of these investments would harm our business, increase our cash requirements and result in continued operating losses and a substantial decline in our stock price.

Even after a product has been approved for commercial sale, if we or others identify previously known or unknown side effects, approval could be withdrawn or sales of the product could be significantly reduced.

If we or others identify previously unknown side effects for Ranexa or ACEON® or any products perceived to be similar to Ranexa or ACEON®, or if any already known side effect becomes a more serious concern than was previously thought on the basis of new data or other developments, or if manufacturing problems occur, then in any of those circumstances:

- sales of the product may decrease significantly;
- regulatory approval for the product may be withdrawn;
- we may decide to, or be required to, withdraw the product from the market;
- we may decide to, or be required to, send product warning letters or field alerts to physicians and pharmacists;
- reformulation of the product, additional preclinical or clinical studies, changes in labeling of the product or changes to or re-approvals of manufacturing facilities may be required;
- our reputation in the marketplace may suffer; and
- investigations and lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of Ranexa or ACEON® and increase our commercialization costs and expenses, and could mean that our ability to commercialize the product is seriously impaired or stopped altogether.

Unlike other treatments for angina currently being used in the United States, the approved labeling for Ranexa warns of the risk that the product may cause a type of fatal arrhythmia known to healthcare practitioners as torsades de pointes. This fatal arrhythmia occurs in the general population of patients with cardiovascular

disease at a low rate of incidence that is not well understood, and can be triggered by a wide variety of factors including genetic predisposition and medical conditions such as low blood potassium levels or slow heart rate that are not uncommon among patients with cardiovascular disease. It is well known that some drugs cause this fatal arrhythmia, although to date Ranexa has not been shown to have caused torsades de pointes. Now that Ranexa is approved in the United States, we expect that the product will start to be used in a wider population than in previous controlled clinical studies of the product, including in patients with chronic angina who may be predisposed to the occurrence of torsades de pointes or other fatal arrhythmias and may be receiving other medications for a variety of conditions. In this potential patient population it is inevitable that some patients will die suddenly, and it is likely that in at least some of these cases there will not be sufficient information available to rule out Ranexa as a contributing factor or cause of mortality. As a result, regulatory authorities, healthcare practitioners and/or patients may perceive or conclude that the use of Ranexa is associated with torsades de pointes or sudden death, which could mean that our ability to commercialize Ranexa could be seriously impaired or stopped altogether, and we may become subject to product liability litigation and other claims against us. This could harm our business, increase our cash requirements and result in continued operating losses and a substantial decline in our stock price.

If we are unable to compete successfully in our market, it will harm our business.

There are many existing drug therapies approved for the treatment of the diseases targeted by our products, and we are also aware of companies that are developing new potential drug products that will compete in the same markets as our products. Ranexa competes with several well established classes of drugs for the treatment of chronic angina in the United States, including generic and/or branded beta-blockers, calcium channel blockers and long acting nitrates, and additional potential angina therapies may be under development. Surgical treatments such as coronary artery bypass grafting and percutaneous coronary intervention can be another option for angina patients. ACEON® is a member of the highly competitive class of drugs known as ACE inhibitors, many of which are generic. For the indication of coronary artery disease, there is at least one branded ACE inhibitor with substantial United States sales; for the treatment of hypertension there are other drug classes that are used to treat hypertension, including angiotensin receptor blockers, beta-blockers, calcium channel blockers and thiazide-type diuretics. In the United States, there are numerous marketed generic and/or branded pharmacologic stress agents, and at least two potential A_{2A}-adenosine receptor agonist compounds under development, that could compete with regadenoson, if approved. There are also numerous generic and/or branded drugs in the United States for the treatment of acute atrial arrhythmias, and at least one A_1-adenosine receptor agonist compound that could compete with tecadenoson may be under development. In addition, there are many therapeutic drug classes approved for the treatment of asthma, including steroids, beta-2 agonists, cromolyn, theophylline, and anti-IgE, all of which could compete with CVT-6883, if approved. We are also aware of companies that are developing products that may compete with our other product candidates and programs. There may also be potentially competitive products of which we are not aware. Many of these potential competitors have substantially greater product development capabilities and financial, scientific, marketing and sales resources. Other companies may succeed in developing products earlier or obtaining approvals from regulatory authorities more rapidly or broadly than either we or our strategic partners are able to achieve. Potential competitors may also develop products that are safer, more effective or have other potential advantages compared to those under development or proposed to be developed by us and our strategic partners. In addition, research, development and commercialization efforts by others could render our technology or our products obsolete or non-competitive.

Failure to obtain adequate reimbursement from government health administration authorities, private health insurers and other organizations could materially adversely affect our future business, market acceptance of our products, results of operations and financial condition.

Our ability and the ability of our collaborative partners to market and sell our products will depend significantly on the extent to which reimbursement for the cost of our products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Third party payers and governmental health administration authorities are increasingly attempting to limit and/or

regulate the price of medical products and services, especially branded prescription drugs. For example, under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare beneficiaries are now able to elect coverage for prescription drugs under Medicare Part D, and the various entities providing such coverage will attempt to negotiate price concessions from pharmaceutical manufacturers, which may increase pressure to lower prescription drug prices and may limit drug access. The full impact of this new law on our business as it relates to Ranexa and ACEON® in the United States is not yet clear to us, and the impact will depend in part on specific decisions regarding the level of coverage provided for the therapeutic categories in which our products are included, the terms on which such coverage is provided, and the extent to which preference is given to selected products in a category. These changes in Medicare reimbursement could have a negative effect on the revenue, if any, that we derive from sales of any of our products. In addition, the increased emphasis on managed healthcare in the United States will put additional pressure on the pricing and usage of any of our products, which may adversely affect product sales and revenues.

Even if our products are deemed to be safe and effective by regulatory authorities, third party payers and governmental health administration authorities may direct patients to generic products or other lower-priced therapeutic alternatives, and there are an increasing number of such alternatives available. Some third-party payers establish a preference for selected products in a category and provide higher levels of formulary acceptance and coverage for preferred products and higher co-payments for non-preferred products. The current level of reimbursement for ACEON® is low, and we may not be able to increase reimbursement levels or product revenues. We plan to launch Ranexa in the United States in March 2006, and significant uncertainty exists as to the reimbursement status of newly approved health care products. As a result, we cannot predict the availability or amount of reimbursement for Ranexa or how the product will be positioned relative to other antianginal products and therapies. In February 2006, we set the wholesale acquisition cost of Ranexa at $5.50 per day for the daily starting dose of 500 mg tablet twice daily. This represents a higher price than the cost of any other antianginal drug currently on the market in the United States. Our pricing for Ranexa may result in less favorable reimbursement and formulary positioning for the product under government programs or by third-party payers, and may result in more or higher barriers to patient access to the product such as higher copayments or prior authorization requirements. If we fail to obtain favorable reimbursement or formulary positioning for Ranexa or ACEON®, health care providers may limit how much or under what circumstances they will prescribe or administer these products. This would result in lower product sales and lower product revenues.

For sales of any of our products in Europe, if approved, we will be required to seek reimbursement approvals on a country-by-country basis. We cannot be certain that any products approved for marketing will be considered cost effective, that reimbursement will be available, or that allowed reimbursement will be adequate in these markets. In addition, payers' reimbursement policies could adversely affect our or any strategic partners' ability to sell our products on a profitable basis.

Our customer base will be highly concentrated.

We expect that our principal customers will be a small number of wholesale drug distributors. These customers comprise a significant part of the distribution network for pharmaceutical products in the United States. Three large wholesale distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, control a significant share of the market in the United States. Our ability to distribute our products, including Ranexa, to retail pharmacy chains and to recognize revenues on a timely basis will be substantially dependent on our ability to enter into commercially reasonable agreements with each of these wholesale distributors. The loss or bankruptcy of any of these customers could materially and adversely affect our future results of operations, financial condition and our ability to distribute our products.

Guidelines and recommendations published by various organizations may affect the use of our products.

Government agencies issue regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health/science foundations, and organizations involved in various diseases from time to time publish guidelines or recommendations to the health

care and patient communities. These various sorts of recommendations may relate to such matters as product usage, dosage, route of administration, and use of related or competing therapies. These organizations have in the past made recommendations about our products or products that compete with our products, such as the recommendations of the Joint National Congress relating to the treatment of hypertension and the treatment guidelines of the American Heart Association. These sorts of recommendations or guidelines could result in decreased use of our products. In addition, the perception by the investment community or stockholders that any such recommendations or guidelines will result in decreased use of our products could adversely affect the market price of our common stock.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual violation of healthcare statutes such as fraud and abuse laws, and our corporate compliance programs can never guarantee that we are in compliance with all relevant laws and regulations.

Our commercialization efforts in the United States are subject to various federal and state laws pertaining to pharmaceutical promotion and healthcare fraud and abuse, including the Food, Drug and Cosmetic Act, the Prescription Drug Marketing Act, and federal and state anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a drug. The federal government has published many regulations relating to the anti-kickback statutes, including numerous safe harbors or exemptions for certain arrangements. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products, and those of our strategic partners such as Solvay Pharmaceuticals and Astellas, will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities, or those of our strategic partners, comply with these complex legal requirements and regulations. Violations are punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the product from coverage under governmental healthcare programs (including Medicare and Medicaid). If the government were to investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, of violating any of these laws, this could have a material adverse effect on our business, including our stock price. Similarly, in the case of Solvay Pharmaceuticals under our co-promotion arrangement with respect to ACEON®, or in the case of Astellas under our license and collaboration arrangement with respect to regadenoson, if either of these strategic partners becomes subject to investigation, allegation or sanction, our ability to continue to commercialize the product and/or obtain revenues from its sale could be seriously impaired or stopped altogether.

Our activities and those of our strategic partners could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi-million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs as part of our efforts to commercialize Ranexa and ACEON®, we cannot assure you that we or our employees, directors or agents are or will be in compliance with all laws and regulations or that we will not come under investigation, allegation or sanction. If we fail to comply with any of these laws or regulations, various negative consequences could result, including criminal and/or civil prosecution, substantial criminal and/or civil penalties, exclusion of the approved product from coverage under governmental healthcare programs (including Medicare and Medicaid), and costly litigation. In addition, our efforts to comply with these laws will be time-consuming and expensive.

Under our co-promotion arrangement relating to ACEON®, Solvay Pharmaceuticals can terminate the agreement due to our uncured material breach, which could include our failure to comply with applicable laws and regulations relating to our commercialization efforts for ACEON®.

The successful commercialization of our products is substantially dependent on the successful and timely performance of our strategic collaborative partners and other vendors, over whom we have little control.

Our key collaborative partnerships, collaborations and licenses include the following:

- Roche Palo Alto LLC—a 1996 license agreement under which we received rights to develop and commercialize ranolazine for the treatment of angina and other cardiovascular indications;
- Biogen Idec Inc. (formerly Biogen Inc.)—a 1997 license agreement under which we licensed rights to Biogen to develop and commercialize products produced based on our A_1 adenosine receptor antagonist patents or technologies, which Biogen Idec has labeled its Adentri™ program;
- Astellas US LLC—a 2000 collaboration and license agreement to develop and commercialize second generation pharmacologic cardiac stress agents, including regadenoson; and
- Solvay Pharmaceuticals, Inc.—a 2004 co-promotion agreement under which we agreed to co-promote ACEON® in the United States with Solvay Pharmaceuticals.

The successful commercialization of our ACEON®, regadenoson and Adentri™ programs will depend significantly on the efforts of our collaborative partners for each of these programs. For instance, under our co-promotion agreement for ACEON® in the United States, Solvay Pharmaceuticals is responsible for the manufacture, distribution (including pricing and managed care contracting), development and maintenance of all regulatory approval of ACEON® in the United States. Solvay Pharmaceuticals is also responsible for promoting ACEON® to primary care physicians in the United States, and is responsible for supplying product samples to support all promotional efforts. Under our agreement with Astellas, Astellas is responsible for the commercial manufacture and distribution, marketing and sales of regadenoson in North America, if approved. Biogen Idec has sole responsibility for all worldwide development and commercialization of products from the Adentri™ program, if any.

We cannot control the amount and timing of resources that any of our strategic partners devote to these programs. Conflicting priorities may cause any of our strategic partners to deemphasize our programs or to pursue competing technologies or product candidates. In addition, these arrangements are each complex, and disputes may arise between the parties, which could lead to delays in the development or commercialization of the products involved. If Solvay Pharmaceuticals fails to perform its obligations under the co-promotion agreement with us relating to ACEON®, we would receive less or even no revenues under the arrangement. If Astellas fails to successfully manufacture, market and sell regadenoson in North America, if approved, we would receive less or even no revenues under the arrangement. If Biogen Idec fails to successfully develop and commercialize any product from the Adentri™ program, we would receive no revenues under the arrangement. To the extent that we enter into additional co-promotion or other commercialization arrangements in the future, our revenues will depend upon the efforts of third parties over which we will have little control.

Our successful commercialization of Ranexa and ACEON® will also depend on the performance of numerous third-party vendors over which we have little control. For example, we rely entirely on third-party vendors to manufacture and distribute Ranexa in the United States, to administer our physician sampling programs relating to Ranexa and ACEON®, and to perform some of our sales and marketing operations functions, such as our product call centers As a result, our level of success in commercializing Ranexa and ACEON® depends significantly on the efforts of these third parties, as well as our strategic partners. If these third parties fail to perform as expected, our ability to market and promote Ranexa and ACEON® would be significantly compromised.

We have no manufacturing facilities and will depend on third parties to manufacture our products.

We do not operate, and have no current plans to develop, any manufacturing facilities, and we currently lack the resources and capability to manufacture any of our products ourselves on a clinical or commercial scale. As a result, we are dependent on corporate partners, licensees, contract manufacturers and other third parties for the manufacturing of clinical and commercial scale quantities of all of our products, including Ranexa and ACEON®.

For example, under our co-promotion agreement with Solvay Pharmaceuticals, Solvay Pharmaceuticals is responsible for the manufacture and distribution of ACEON®, and the manufacture of product samples, and in turn is dependent on third parties for the manufacture of the active pharmaceutical ingredient and the drug product. We also have entered into several agreements with third party manufacturers relating to Ranexa, including for commercial-scale active pharmaceutical ingredient, bulk tablet manufacturing, packaging and supply of a raw material component of the product. We currently rely on a single supplier at each step in the supply chain for Ranexa. In addition, under our agreement with Astellas relating to regadenoson, Astellas is responsible for the commercial manufacture and supply of regadenoson, if approved, and in turn is dependent on third parties for the manufacture of the active pharmaceutical ingredient and the drug product. Our ability to commercialize Ranexa and our ability to co-promote ACEON® are each entirely dependent on these arrangements, and would be affected by any delays or difficulties in performance on the part of our contract manufacturers for Ranexa, or Solvay Pharmaceuticals or its third party manufacturers in the case of ACEON®. For example, in the case of our Ranexa supply chain, in which we are reliant on a single manufacturer at each step in the production cycle for the product, the failure of any manufacturers to supply product on a timely basis or at all, or to manufacture our product in compliance with product specifications or applicable quality or regulatory requirements, or to manufacture product or samples in volumes sufficient to meet market demand, would adversely affect our ability to commercialize Ranexa.

Furthermore, we and our third party manufacturers, laboratories and clinical testing sites may be required to pass pre-approval inspections of facilities by the FDA and corresponding foreign regulatory authorities before obtaining marketing approvals, including for any new drug application (if any) relating to one of our other product candidates, such as regadenoson. Even after product approval, our facilities and those of our contract manufacturers remain subject to periodic inspection by the FDA and other domestic and foreign regulatory authorities. We cannot guarantee that any such inspections will not result in compliance issues that could prevent or delay marketing approval or negatively impact our ability to maintain product approval, or require us to expend money or other resources to correct. In addition, we or our third party manufacturers are required to adhere to stringent federal regulations setting forth current good manufacturing practices for pharmaceuticals. These regulations require, among other things, that we manufacture our products and maintain our records in a carefully prescribed manner with respect to manufacturing, testing and quality control activities. In addition, drug product manufacturing facilities in California must be licensed by the State of California, and other states may have comparable requirements. We cannot assure you that we will be able to obtain such licenses when and where needed.

Any delay in the development of any of our drug product candidates will harm our business.

All of our product candidates in development require preclinical studies and/or clinical trials, and will require regulatory review and approval, prior to marketing and sale. Any delays in the development of our product candidates would delay our ability to seek and obtain regulatory approvals, increase our cash requirements, increase the volatility of our stock price and result in additional operating losses. One potential cause of a delay in product development is a delay in clinical trials. Many factors could delay completion of our MERLIN TIMI-36 clinical trial of Ranexa or our other clinical trials, including, without limitation:

- slower than anticipated patient enrollment;
- difficulty in obtaining sufficient supplies of clinical trial materials; and
- adverse events occurring during the clinical trials.

Our MERLIN TIMI-36 clinical trial is a large, ongoing clinical study of Ranexa, in which the completion and duration of the study is based on achieving specified numbers of events. We expect to enroll approximately 6,500 patients in this trial. Although we presently expect preliminary results from the trial at the end of 2006 or in the first quarter of 2007, the completion of our MERLIN TIMI-36 clinical trial may be delayed due to continued slower than anticipated event rates or enrollment. The MERLIN TIMI-36 clinical trial of Ranexa is a large and expensive clinical study, and any delay in its conduct or completion would adversely affect our statements of operations and increase the period of uncertainty about its results.

We may be unable to maintain our proposed schedules for investigational new drug applications, which are regulatory filings made by a drug sponsor to the FDA to allow human clinical testing in the United States, and equivalent foreign applications and clinical protocol submissions to the FDA and other regulatory agencies. In addition, we may be unable to maintain our proposed schedules for initiation and completion of clinical trials as a result of FDA or other regulatory action or other factors, such as lack of funding, the occurrence of adverse safety effects or other complications that may arise in any phase of a clinical trial program.

Furthermore, even if our clinical trials are completed on schedule, the data and results may differ from those obtained in preclinical studies and earlier clinical trials. Clinical trials may not demonstrate sufficient safety or efficacy to obtain the necessary marketing approvals. For example, although our previous phase 3 trials of Ranexa had positive results, our on-going MERLIN TIMI-36 study of Ranexa is in a different patient population for a different potential use with different entry criteria. These factors, other differences and the inherent variability of clinical trial results mean that there can be no assurance that we will obtain positive results from the MERLIN TIMI-36 study.

Another potential example of variability in clinical study results concerns our regadenoson program, for which we expect to obtain results from the second of two phase 3 studies that have an identical study design. The design of our identical phase 3 studies is different from the designs of our prior clinical studies of regadenoson. The two phase 3 studies are non-inferiority studies, using a complex comparison based on multiple readings of reperfusion imaging scans by various blinded human scan readers. The study design for phase 3 of the clinical program is unusual, and there is an inherently high degree of variability in the reading of reperfusion imaging scans (meaning that a single scan reviewed by two different readers, or even a single scan reviewed twice by the same reader, can produce different results). While we obtained positive results from the first completed phase 3 study in the clinical program, there can be no assurance that we will obtain positive results from the second phase 3 study of regadenoson when it is completed, or that the results of the first phase 3 study of regadenoson will be in any way predictive of the results of the second phase 3 study. Moreover, even if both phase 3 studies of regadenoson are positive, there can be no assurance that the data will sufficient to obtain marketing approval for regadenoson in the United States or abroad.

All of our products in development require regulatory review and approval prior to commercialization. Any delay in the regulatory review or approval of any of our products in development will harm our business.

All of our products in development require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our products in development would delay market launch, increase our cash requirements, increase the volatility of our stock price and result in additional operating losses.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We may not be able to maintain our proposed schedules for the submission of any new drug application in the United States or any marketing authorization application or other foreign applications for any of our products. We may not be able to maintain our proposed schedules for the submission of any supplemental new drug application (or equivalent foreign application) seeking changes to product labeling, manufacturing or other aspects of the NDA or foreign

marketing authorization for Ranexa or other approved products (if any). If we submit any new drug application or supplemental new drug application to the FDA, the FDA must decide whether to either accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that our marketing authorization applications to European or other foreign regulatory authorities will be validated for review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner without delaying potential regulatory action. We also cannot be certain that any of our products or proposed product changes (such as labeling changes proposed in any supplemental new drug application) will be approved by the FDA or foreign regulatory authorities.

Delays in approvals or rejections of regulatory approvals in the United States or foreign markets may be based upon many factors, including regulatory requests for additional analyses, reports, clinical inspections, clinical and/or preclinical data and/or studies, regulatory questions regarding data or results, unfavorable review by advisory committees, changes in regulatory policy during the period of product development and/or the emergence of new information regarding our products or other products. For example, in 2005 we withdrew our marketing authorization application for ranolazine filed with the European Medicines Agency, because these regulatory authorities requested additional clinical pharmacokinetic data regarding the product prior to approval.

Data obtained from preclinical and clinical studies are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our products. For example, some drugs that prolong the QT interval, which is a measurement of specific electrical activity in the heart as captured on an electrocardiogram, carry an increased risk of serious cardiac rhythm disturbances that can cause a type of fatal arrhythmia known as torsades de pointes, while other drugs that prolong the QT interval do not carry an increased risk of this fatal arrhythmia. Small but statistically significant mean increases in the QT interval were observed in clinical trials of Ranexa. QT interval measurements are not precise and there are different methods of calculating the corrected QTc interval, which is the QT interval as adjusted for heart rate. This uncertainty in the measurement and calculation of the QT and QTc intervals can contribute to different interpretations of these data. The clinical significance of the changes in QTc interval observed in clinical trials of Ranexa remains unclear, and other clinical and preclinical data do not suggest that Ranexa significantly pre-disposes patients to this fatal arrhythmia. Regulatory authorities may interpret the Ranexa data differently, which could delay, limit or prevent additional regulatory approvals of Ranexa. For example, when acting on the original new drug application for Ranexa in October 2003, the FDA did not approve the product and indicated that additional clinical information would be needed prior to approval, in part because of the FDA's safety concerns in light of the effect of Ranexa to prolong the QTc interval. We conducted an additional clinical study and submitted an amendment to the new drug application for Ranexa to the FDA in July 2005. In January 2006, the FDA approved Ranexa for use in chronic angina, with product labeling which indicates that because of the potential safety risk of QT prolongation caused by Ranexa, the product should be reserved for use in chronic angina patients who have not achieved an adequate response with other antianginal drugs, and should be used in combination with other common antianginal treatments, specifically amlodipine, beta-blockers or nitrates. Foreign regulatory authorities may have similar or other concerns which would delay or prevent the approval of Ranexa or any of our other product candidates outside the United States.

Similarly, as a routine part of the evaluation of any potential drug, clinical studies are generally conducted to assess the potential for drug-drug interactions that could impact potential product safety. While we believe that the interactions between Ranexa and other drugs have been well characterized as part of our clinical development programs, the data are subject to regulatory interpretation and an unfavorable interpretation by regulatory authorities could delay, limit or prevent additional regulatory approvals of Ranexa.

Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information (including on other products), changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes in the regulatory environment will be favorable or unfavorable to our business prospects.

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for marketing approval applications can fluctuate substantially, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

We intend to file applications for regulatory approval of our products in various foreign jurisdictions from time to time in the future. However, we have not received any regulatory approvals in any foreign jurisdiction for the commercial sale of any of our products. There are potentially important substantive differences in reviews of approval applications in the United States and foreign jurisdictions such as Europe. For example, preclinical and/or clinical trials and data that are accepted by the FDA in support of a new drug application may not be accepted by foreign regulatory authorities, and trials and data acceptable to foreign regulatory authorities in support of a product approval may not be accepted by the FDA. In addition, approval of a product in one jurisdiction is no guarantee that any other regulatory authorities will also approve it.

While we have negotiated a special protocol assessment agreement with the FDA relating to the MERLIN TIMI-36 clinical study of Ranexa, this agreement does not guarantee any particular outcome from regulatory review of the study or the product, including any approvals or expanded product labeling.

The FDA's special protocol assessment, or SPA, process creates a written agreement between the sponsoring company and the FDA regarding clinical trial design, clinical endpoints, study conduct, data analyses and other clinical trial issues. It is intended to provide assurance that if pre-specified trial results are achieved, they may serve as the primary basis for an efficacy claim in support of a new drug application. However, the SPA agreement is not a guarantee of an approval of a product or of any permissible claims about the product. In particular, it is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if the sponsor company fails to comply with the agreed upon trial protocols. Even after an SPA agreement is finalized, the SPA agreement may be changed by the sponsor company or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

In July 2004, we announced that we reached written agreement with the FDA on an SPA agreement for the MERLIN TIMI-36 clinical trial of Ranexa, which could support potential approval of Ranexa as first-line therapy for patients suffering from chronic angina if treatment with Ranexa is not associated with an adverse trend in death or arrhythmia compared to placebo, even if statistical significance on the primary study endpoint is not achieved, provided that we also successfully complete a clinical evaluation of higher doses of Ranexa. MERLIN TIMI-36 could also result in approval for Ranexa for the treatment and long-term prevention of acute coronary syndromes, if the study meets its primary endpoint. We cannot assure you that the MERLIN TIMI-36 clinical trial will succeed or allow us to expand the approved labeling for Ranexa. The MERLIN TIMI-36 study will enroll approximately 6,500 patients, although the study's duration and completion is based on achieving specified numbers of events. An independent data safety monitoring board overseeing the study may end the study early with no notice due to results observed by the board during one of its periodic safety assessments of the study. If the MERLIN TIMI-36 study shows that treatment of Ranexa is associated with an adverse trend in death or arrhythmia compared to placebo, our ability to commercialize Ranexa would be seriously impaired or stopped altogether, and we may become subject to product liability litigation and other claims against us. This would adversely affect our cash position, results of operations and our stock price.

In connection with our SPA agreement relating to the MERLIN TIMI-36 clinical study, we expect that the FDA will review our compliance with the protocol under our SPA agreement. We also expect that the FDA will conduct inspections of some of the approximately 500 MERLIN TIMI-36 clinical sites, most of which are located in 17 foreign countries. We do not know whether the clinical sites will pass such FDA inspections, and negative inspection results could significantly delay or prevent any potential expansion of the approved labeling

for Ranexa. In addition, the MERLIN TIMI-36 clinical trial involves the use of an intravenous formulation of ranolazine that the FDA has not approved. We do not know how the FDA will interpret the commitments under the SPA agreement relating to the MERLIN TIMI-36 clinical study, how it will interpret the data and results from the MERLIN TIMI-36 clinical study, or whether Ranexa will receive any additional approvals or any expanded product labeling as a result of this SPA agreement with the FDA or the MERLIN TIMI-36 clinical study. As a result, significant uncertainty remains regarding the MERLIN TIMI-36 clinical trial.

If we are unable to satisfy governmental regulations relating to the development and commercialization of our drug candidates, we may be subject to significant FDA sanctions.

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by numerous regulatory authorities in the United States, including the FDA, and in other countries. Failure to comply with FDA or other applicable regulatory requirements may subject a company to administrative or judicially imposed sanctions, including, without limitation:

- warning letters and other regulatory authority communications objecting to matters such as promotional materials and requiring corrective action such as corrective communications to healthcare practitioners;
- civil penalties;
- criminal penalties;
- injunctions;
- product seizure or detention;
- product recalls;
- total or partial suspension of manufacturing; and
- FDA refusal to review or approve pending new drug applications for unapproved products or supplemental new drug applications for previously approved products, and/or similar rejections of marketing applications or supplements by foreign regulatory authorities.

If we are unable to attract and retain collaborators, licensors and licensees, the development of our products could be delayed and our future capital requirements could increase substantially.

We may not be able to retain current or attract new corporate and academic collaborators, licensors, licensees and others. Our business strategy requires us to enter into various arrangements with these parties, and we are dependent upon the success of these parties in performing their obligations. If we fail to enter into and maintain these arrangements, the development and/or commercialization of our products would be delayed. We may be unable to proceed with the development, manufacture or sale of products or we might have to fund development of a particular product candidate internally. If we have to fund the development and commercialization of substantially all of our products internally, our future capital requirements will increase substantially.

The collaborative arrangements that we may enter into in the future may place responsibility on the strategic partner for preclinical testing and clinical trials, manufacturing and preparation and submission of applications for regulatory approval of potential pharmaceutical products. For example, under our agreement with Solvay Pharmaceuticals, Solvay Pharmaceuticals holds the new drug application for ACEON®, and is responsible for maintaining FDA approval of ACEON® in the United States including all product manufacturing. If Solvay Pharmaceuticals experiences manufacturing difficulties relating to the product or is not successful in maintaining FDA approval for ACEON®, this would increase our cash requirements, increase the volatility of our stock price and result in additional operating losses.

Under our arrangements, we or our strategic partners may also have to meet performance milestones. If we fail to meet our obligations under our arrangements, our partners could terminate their arrangements or we could suffer other consequences such as losing our rights to the compounds at issue. For example, under our agreement with Astellas relating to regadenoson, we are responsible for development activities and must meet development milestones in order to receive development milestone payments. Under our license agreement with Roche relating to Ranexa, we are required to use commercially reasonable efforts to develop and commercialize ranolazine for angina, and have related milestone payment obligations. Under our co-promotion agreement with Solvay Pharmaceuticals, we are required to satisfy specified minimum marketing and promotion commitments relating to ACEON®.

We cannot control the amount and timing of resources that our strategic partners devote to our programs. If a partner fails to successfully develop or commercialize any product, product launch would be delayed. In addition, our partners may pursue competing technologies or product candidates. In addition, arrangements in our industry are extremely complex, particularly with respect to intellectual property rights, financial provisions, and other provisions such as the parties' respective rights with respect to decision-making. Disputes may arise in the future with respect to these issues, such as the ownership of rights to any technology developed with or by third parties. These and other possible disagreements between us and our partners could lead to delays in the research, development or commercialization of product candidates, or in the amendment or termination of one or more of our license and collaboration agreements. These disputes could also result in litigation or arbitration, which is time consuming, expensive and uncertain.

If we are unable to effectively protect our intellectual property, we may be unable to complete development of any products and we may be put at a competitive disadvantage; and if we are involved in an intellectual property rights dispute, we may not prevail and may be subject to significant liabilities or required to license rights from a third party, or cease one or more product programs.

Our success will depend to a significant degree on, among other things, our ability to:

- obtain patents and licenses to patent rights;
- maintain trade secrets;
- obtain trademarks; and
- operate without infringing on the proprietary rights of others.

However, we cannot be certain that any patent will issue from any of our pending or future patent applications, that any issued patent will not be lost through an interference or opposition proceeding, reexamination request, litigation or otherwise, that any issued patent will be sufficient to protect our technology and investments or prevent the entry of generic or other competition into the marketplace, or that we will be able to obtain any extension of any patent beyond its initial term. The following table shows the expiration dates in the United States for the primary compound patents for our key products and product candidates:

Product/Product Candidate	United States Primary Compound Patent Expiration
Ranexa	2003*
ACEON®	2009†
Regadenoson	2019

* Because ranolazine is a new chemical entity, under applicable United States laws we expect exclusivity as a new chemical entity for five years from the date of the first FDA approval of Ranexa for the ranolazine compound, which was in January 2006. As a result, we expect this exclusivity for the ranolazine compound

to last until January 2011. In addition, the United States compound patent relating to Ranexa expired in 2003, but we have received several one-year interim patent term extensions under the Hatch-Waxman Act, and we reapplied on a permanent basis for patent term extension after the FDA approved Ranexa in January 2006. We expect to be able to receive an extension under the Hatch-Waxman Act, which we anticipate will extend the patent protection to May 2008 for the approved product, which is the Ranexa extended-release tablet, for the use in chronic angina approved by the FDA in January 2006. Also, we have received issued patents from the United States Patent and Trademark Office claiming various sustained release formulations of ranolazine and methods of using sustained release formulations of ranolazine, including the formulation tested in our Phase 3 trials for Ranexa, for the treatment of chronic angina. These patents expire in 2019. After January 2011, patent term extension and new chemical entity exclusivity under the laws of the United States will no longer be available, and unless we are able to obtain additional exclusivity relating to a successful supplemental new drug application and such additional exclusivity runs past January 2011, we will be entirely reliant on our then-issued patents claiming uses and formulations of Ranexa to continue to protect our investments in Ranexa's development and commercialization. It is possible that one or more competitors could develop competing products that do not infringe these patent claims, or could succeed in invalidating these issued patent claims, or that these patents could be lost through an interference or opposition proceeding, reexamination, litigation or otherwise. Generic challenges and related patent litigation are common in the biopharmaceutical industry.

† Perindopril is covered by an issued patent that covers the compound and expires in November 2009.

In addition to these issued patents, we seek to file patent applications pending relating to each of our potential products, and we seek trade name and trademark protection for our commercialized products such as Ranexa. Although patent applications filed in the United States are now published 18 months after their filing date, as provided by federal legislation enacted in 1999, this statutory change applies only to applications filed on or after November 2000. Applications filed in the United States prior to this date are maintained in secrecy until a patent issues. As a result, we can never be certain that others have not filed patent applications for technology covered by our pending applications or that we were the first to invent the technology. There may be third party patents, patent applications, trademarks and other intellectual property relevant to our compounds, products, services, development efforts and technology which are not known to us and that block or compete with our compounds, products, services, development efforts or technology. For example, competitors may have filed applications for, or may have received or in the future may receive, patents, trademarks and/or other proprietary rights relating to compounds, products, services, development efforts or technology that block or compete with ours.

In addition, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office. These proceedings determine the priority of invention and, thus, the right to a patent for the technology in the United States. We may also become involved in opposition proceedings in connection with foreign patent filings. In addition, litigation may be necessary to enforce any patents or trademarks issued to us, or to determine the scope and validity of the proprietary rights of us or third parties. Litigation, interference and opposition proceedings, even if they are successful, are expensive, time-consuming and risky to pursue, and we could use a substantial amount of our financial resources in any such case.

We also must not infringe patents or trademarks of others that might cover our compounds, products, services, development efforts or technology. If third parties own or have proprietary rights to technology or other intellectual property that we need in our product development and commercialization efforts, we will need to obtain licenses to those rights. We cannot assure you that we will be able to obtain such licenses on economically reasonable terms, if at all. If we fail to obtain any necessary licenses, we may be unable to complete product development and commercialization.

We also rely on proprietary technology and information, including trade secrets, to develop and maintain our competitive position. Although we seek to protect all of our proprietary technology and information, in part by confidentiality agreements with employees, consultants, collaborators, advisors and corporate partners, these

agreements may be breached. We cannot assure you that the parties to these agreements will not breach them or that these agreements will provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of our proprietary technology or information. In addition, we routinely grant publication rights to our scientific collaborators. Although we may retain the right to delay publication to allow for the preparation and filing of a patent application covering the subject matter of the proposed publication, we cannot assure you that our collaborators will honor these agreements. Publication prior to the filing of a patent application would mean that we would lose the ability to patent the technology outside the United States, and third parties or competitors could exploit the technology. We also may not have adequate remedies to protect our proprietary technology and information, including trade secrets. As a result, third parties may gain access to our trade secrets and other proprietary technology, or our trade secrets and other proprietary technology or information may become public. In addition, it is possible that our proprietary technology or information will otherwise become known or be discovered independently by our competitors.

In addition, we may also become subject to claims that we are using or misappropriating trade secrets of others without having the right to do so. Such claims can result in litigation, which can be expensive, time-consuming and risky to defend.

Litigation and disputes related to intellectual property matters are widespread in the biopharmaceutical industry. Although to date no third party has asserted a claim of infringement against us, we cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us with respect to our compounds, products, services, technology or other matters in the future. If they do, we may not prevail and, as a result, we may be subject to significant liabilities to third parties, we may be required to license the disputed rights from the third parties or we may be required to cease using the technology or developing or selling the compounds or products at issue. We may not be able to obtain any necessary licenses on economically reasonable terms, if at all. Any intellectual property-related claims against us, with or without merit, as well as claims initiated by us against third parties, may be time-consuming, expensive and risky to defend or prosecute. If we assert a patent against an alleged infringer and the alleged infringer is successful in invalidating the patent, the protection afforded by the patent is lost.

Our business depends on certain key personnel, the loss of whom could weaken our management team, and on attracting and retaining qualified personnel.

The growth of our business and our success depends in large part on our ability to attract and retain key management, research and development, sales and marketing and other operating and administrative personnel. Our key personnel include all of our executive officers and vice presidents, many of whom have very specialized scientific, medical or operational knowledge regarding one or more of our key products. We have entered into an employment agreement with our chairman and chief executive officer. We have entered into executive severance agreements with certain key personnel, and have a severance plan that covers our full-time employees. We do not maintain key-person life insurance on any of our employees. The loss of the services of one or more of our key personnel or the inability to attract and retain additional personnel and develop expertise as needed could limit our ability to develop and commercialize our existing and future product candidates. Such persons are in high demand and often receive competing employment offers.

Our ability to attract and retain key employees in a competitive recruiting environment is dependent on our ability to offer competitive compensation packages, which typically include equity compensation such as stock option grants. Changes in laws, regulations, corporate governance standards, listing requirements and accounting treatment regarding stock options and other equity awards that we grant to employees, as well as to other common compensation features such as loans, may limit or impair our ability to be competitive in attracting and retaining key personnel.

If there is an adverse outcome in our pending litigation, such as the securities class action litigation that has been filed against us, our business may be harmed.

We and certain of our officers and directors are named as defendants in a purported securities class action lawsuit filed in August 2003 in the U.S. District Court for the Northern District of California captioned *Crossen v. CV Therapeutics, Inc., et al*. The lawsuit is brought on behalf of a purported class of purchasers of our securities, and seeks unspecified damages. As is typical in this type of litigation, several other purported securities class action lawsuits containing substantially similar allegations were filed against the defendants. In November 2003, the court appointed a lead plaintiff, and in December 2003, the court consolidated all of the securities class actions filed to date into a single action captioned *In re CV Therapeutics, Inc. Securities Litigation*. In January 2004, the lead plaintiff filed a consolidated complaint. We and the other named defendants filed motions to dismiss the consolidated complaint in March 2004. In August 2004, these motions were granted in part and denied in part. The court granted the motions to dismiss by two individual defendants, dismissing both individuals from the action with prejudice, but denied the motions to dismiss by us and the two other individual defendants. After the motion to dismiss was decided, this action entered the discovery phase, and discovery in the action is ongoing.

In addition, certain of our officers and directors have been named as defendants in a derivative lawsuit filed in August 2003 in California Superior Court, Santa Clara County, captioned *Kangos v. Lange, et al.*, which names CV Therapeutics as a nominal defendant. The plaintiff in this action is one of our stockholders who seeks to bring derivative claims on behalf of CV Therapeutics against the defendants. The lawsuit alleges breaches of fiduciary duty and related claims based on purportedly misleading statements concerning our new drug application for Ranexa. At the appropriate time, we expect to file a motion to dismiss this lawsuit due to the plaintiff's unexcused failure to make a demand on us before filing the action.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation, and defending these lawsuits is likely to be costly, time-consuming and uncertain. Accordingly, no accrual has been established for these lawsuits. In the event of an adverse outcome, our business could be harmed.

Our operations involve hazardous materials, which could subject us to significant liability.

Our research and development and manufacturing activities involve the controlled use of hazardous materials, including hazardous chemicals, radioactive materials and pathogens, and the generation of waste products. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. We may have to incur significant costs to comply with additional environmental and health and safety regulations in the future. We currently do not carry insurance for hazardous materials claims. We do not know if we will be able to obtain insurance that covers hazardous materials claims on acceptable terms with adequate coverage against potential liabilities, if at all. Although we believe that our safety procedures for handling and disposing of hazardous materials comply in all material respects with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources and may materially adversely affect our business, financial condition and results of operations. Although we believe that we are in compliance in all material respects with applicable environmental laws and regulations, there can be no assurance that we will not be required to incur significant costs to comply with environmental laws and regulations in the future. There can also be no assurance that our operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

Changes in accounting rules for stock-based compensation will adversely affect our operating results, and may adversely affect our stock price and our competitiveness in the employee marketplace.

We are required to adopt SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R, on January 1, 2006. SFAS 123R requires all share-based payments to employees and directors, including grants of

stock options, restricted stock units and stock appreciation rights, to be recognized in the statement of operations based on their fair values. We expect that our adoption of SFAS 123R will cause our operating expenses and net loss to increase in 2006 compared to 2005, which may adversely affect our stock price. To the extent that we reduce our use of share-based payments to employees and directors in an effort to reduce our operating expenses and net loss, we may also reduce our ability to recruit, hire and retain employees.

We are exposed to risks related to foreign currency exchange rates.

A growing amount of our operating expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our ongoing clinical studies, such as our MERLIN TIMI-36 clinical trial of Ranexa, or the operations of our United Kingdom-based wholly owned subsidiary. We are primarily exposed to changes in exchange rates in Europe and Canada. When the United States dollar weakens against these currencies, the dollar value of the foreign-currency denominated expense increases, and when the dollar strengthens against these currencies, the dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations. We currently do not hedge against our foreign currency risks.

We may be subject to product liability claims if our products harm people, and we have only limited product liability insurance.

The manufacture and sale of human drugs and other therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. The approved labeling for Ranexa includes warnings regarding QT prolongation and the risk of arrhythmias and sudden death and tumor promotion. Despite these warnings, we may be subject to product liability claims in the future, including if patients on Ranexa die suddenly from arrhythmias or contract cancer. We currently have only limited product liability insurance for clinical trials testing and only limited commercial product liability insurance. We do not know if we will be able to maintain existing or obtain additional product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may not be available on acceptable terms or at all. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to develop or commercialize our potential products. A successful product liability claim brought against us in excess of our insurance coverage, if any, may require us to pay substantial amounts. This could adversely affect our cash position and results of operations and could increase the volatility of our stock price.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant, uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss. We currently maintain general liability, property, auto, workers' compensation, products liability, directors' and officers', and employment practices insurance policies. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. For example, the premiums for our directors' and officers' insurance policy have increased significantly, and this type of insurance may not be available on acceptable terms or at all. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Risk Factors Relating to Our Common Stock and Convertible Debt

Investor confidence and share value may be adversely impacted if our independent auditors are unable to provide us with the attestation of the adequacy of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission adopted rules requiring public companies to include in annual reports on Form 10-K an assessment by management of the effectiveness of internal controls over financial reporting. In addition, our independent auditors must attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. This requirement applies to each annual filing on Form 10-K. As we begin commercial operations, we are in the process of designing, implementing, documenting and testing new internal controls for these operations. In addition, we will become more dependent on the internal controls maintained by our collaborative partners. If we are not successful in implementing these new internal controls for commercial operations, or if our collaborative partners fail to maintain adequate internal controls on which we rely to prepare our financial statements, our management may determine that our internal controls over financial reporting are not effective. In addition, if our independent auditors are not satisfied with the effectiveness of our internal controls over financial reporting, including the level at which these controls are documented, designed, operated or reviewed, or if the independent auditors interpret the requirements, rules or regulations differently than we do, then they may be unable to attest to management's assessment or may be unable to issue an unqualified attestation report. Any of these events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares, increase the volatility of our stock price and adversely affect our ability to raise additional funding.

The market price of our stock has been and may continue to be highly volatile, and the value of an investment in our common stock may decline.

Within the last 12 months, our common stock has traded between $19.15 and $29.79 per share. The market price of the shares of our common stock has been and may continue to be highly volatile. Announcements and other events may have a significant impact on the market price of our common stock. We may have no control over information announced by third parties, such as our corporate partners or our competitors, which may impact our stock price.

Other announcements and events that can impact the market price of the shares of our common stock include, without limitation:

- results of our clinical trials and preclinical studies, or those of our corporate partners or our competitors;
- regulatory actions with respect to our products or our competitors' products;
- achievement of other research or development milestones, such as completion of enrollment of a clinical trial or making a regulatory filing;
- our operating results;
- our product sales and product revenues;
- adverse developments regarding the safety and efficacy of our products, our product candidates, or third-party products that are similar to our products or our product candidates;
- developments in our relationships with corporate partners;

- developments affecting our corporate partners;
- government regulations, reimbursement changes and governmental investigations or audits related to us or to our products;
- changes in regulatory policy or interpretation;
- developments related to our patents or other proprietary rights or those of our competitors;
- changes in the ratings of our securities by securities analysts;
- operating results or other developments that do not meet the expectations of public market analysts and investors;
- purchases or sales of our securities by investors who seek to exploit the volatility of our common stock price;
- market conditions for biopharmaceutical or biotechnology stocks in general; and
- general economic and market conditions.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be a significant impact on the market price of our common stock. In addition, as we approach the announcement of important news, such as the results of important clinical studies, and as we announce such news, we expect the price of our common stock to be particularly volatile, and negative news would have a substantial negative impact on the price of our common stock.

The stock market has from time to time experienced extreme price and volume fluctuations, which have particularly affected the market prices for emerging biotechnology and biopharmaceutical companies, and which have often been unrelated to their operating performance. These broad market fluctuations may adversely affect the market price of our common stock. In addition, sales of substantial amounts of our common stock in the public market could lower the market price of our common stock.

Our indebtedness and debt service obligations may adversely affect our cash flow, cash position and stock price.

As of December 31, 2005, we had approximately $399.5 million in long-term convertible debt and aggregate annual debt service obligations on this debt of approximately $11.0 million. If we issue other debt securities in the future, our debt service obligations and interest expense will increase.

We intend to fulfill our debt service obligations from our existing cash and investments. In the future, if we are unable to generate cash or raise additional cash through financings sufficient to meet these obligations and need to use existing cash or liquidate investments in order to fund these obligations, we may have to delay or curtail research, development and commercialization programs.

Our indebtedness could have significant additional negative consequences, including, without limitation:

- requiring the dedication of a portion of our cash to service our indebtedness and to pay off the principal at maturity, thereby reducing the amount of our expected cash available for other purposes, including funding our commercialization efforts, research and development programs and other capital expenditures;

- increasing our vulnerability to general adverse economic conditions;

- limiting our ability to obtain additional financing; and

- placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

If we sell shares of our common stock in future financings, existing common stockholders will experience immediate dilution and, as a result, our stock price may go down.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our existing common stockholders will experience immediate dilution upon the purchase of any shares of our common stock sold at such discount.

In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders will experience dilution.

Provisions of Delaware law and in our charter, by-laws and our rights plan may prevent or frustrate any attempt by our stockholders to replace or remove our current management and may make the acquisition of our company by another company more difficult.

Our board of directors has adopted a stockholder rights plan, authorized executive severance benefit agreements for our officers in the event of a change of control, and adopted a severance plan for all non-officer employees in the event of a change of control. We entered into such severance agreements with these executives. Subsequently, in November 2002 the board approved additional as well as amended executive severance agreements and a severance plan. Our rights plan and these severance arrangements may delay or prevent a change in our current management team and may render more difficult an unsolicited merger or tender offer.

The following provisions of our Amended and Restated Certificate of Incorporation, as amended, and our by-laws, may have the effects of delaying or preventing a change in our current management and making the acquisition of our company by a third party more difficult:

- our board of directors is divided into three classes with approximately one third of the directors to be elected each year, necessitating the successful completion of two proxy contests in order for a change in control of the board to be effected;

- any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of the stockholders and may not be effected by a consent in writing;

- advance written notice is required for a stockholder to nominate a person for election to the board of directors and for a stockholder to present a proposal at any stockholder meeting; and

- directors may be removed only for cause by a vote of a majority of the stockholders and vacancies on the board of directors may only be filled by a majority of the directors in office.

In addition, our board of directors has the authority to issue shares of preferred stock without stockholders' approval, which also could make it more difficult for stockholders to replace or remove our current management and for another company to acquire us. We are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law, which could delay a merger, tender offer or proxy contest or make a similar transaction more difficult. In general, this statute prohibits a publicly held Delaware corporation from

engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

If any or all of our existing notes and debentures are converted into shares of our common stock, existing common stockholders will experience immediate dilution and, as a result, our stock price may go down.

Our existing convertible debt is convertible, at the option of the holder, into shares of our common stock at varying conversion prices, subject to the satisfaction of certain conditions. We have reserved shares of our authorized common stock for issuance upon conversion of our existing convertible notes and convertible debentures. If any or all of our existing notes and debentures are converted into shares of our common stock, our existing stockholders will experience immediate dilution and our common stock price may be subject to downward pressure. If any or all of our notes and debentures are not converted into shares of our common stock before their respective maturity dates, we will have to pay the holders of such notes or debentures the full aggregate principal amount of the notes or debentures, as applicable, then outstanding. Any such payment would have a material adverse effect on our cash position. Alternatively, from time to time we might need to modify the terms of the notes and/or the debentures prior to their maturity in ways that could be dilutive to our stockholders, assuming we can negotiate such modified terms.

Available Information

We are subject to the information requirements of the Securities Exchange Act and we therefore file periodic reports, proxy statements and other information with the Securities and Exchange Commission relating to our business, financial statements and other matters. The reports, proxy statements and other information we file may be inspected and copied at prescribed rates at the Securities and Exchange Commission's Public Reference Room at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Securities and Exchange Commission's Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet site that contains reports, proxy statements and other information regarding issuers like us that file electronically with the Securities and Exchange Commission. The address of the Securities and Exchange Commission's Internet site is *www.sec.gov*. For more information about us, please visit our website at *www.cvt.com*. You may also obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports on the day the reports or amendments are filed with or furnished to the SEC by visiting our website at *www.cvt.com.*

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease three buildings used as laboratory and office space in Palo Alto, California. The first building has approximately 61,000 square feet of space. In December 2004, we amended this lease to add an adjacent building containing approximately 48,000 additional square feet of space. In January 2006, this lease was further amended to extend the lease term for both buildings to April 2016 with an option to renew for nine years. Our third building, leased in late 2000, has approximately 73,000 square feet of space and a lease term that runs through April 2012. This agreement is secured by an irrevocable letter of credit. Our European subsidiary leases approximately 4,000 square feet of office space in Stevenage, Hertfordshire in the United Kingdom. That lease expires in February 2008. We believe that these facilities will be adequate to meet our needs through 2006.

Item 3. Legal Proceedings

We and certain of our officers and directors are named as defendants in a purported securities class action lawsuit filed in August 2003 in the U.S. District Court for the Northern District of California captioned *Crossen v. CV Therapeutics, Inc., et al*. The lawsuit is brought on behalf of a purported class of purchasers of our securities, and seeks unspecified damages. As is typical in this type of litigation, several other purported securities class action lawsuits containing substantially similar allegations were filed against the defendants. In November 2003, the court appointed a lead plaintiff, and in December 2003, the court consolidated all of the securities class actions filed to date into a single action captioned *In re CV Therapeutics, Inc. Securities Litigation*. In January 2004, the lead plaintiff filed a consolidated complaint. We and the other named defendants filed motions to dismiss the consolidated complaint in March 2004. In August 2004, these motions were granted in part and denied in part. The court granted the motions to dismiss by two individual defendants, dismissing both individuals from the action with prejudice, but denied the motions to dismiss by us and the two other individual defendants. After the motion to dismiss was decided, this action entered the discovery phase, and discovery in the action is ongoing.

In addition, certain of our officers and directors have been named as defendants in a derivative lawsuit filed in August 2003 in California Superior Court, Santa Clara County, captioned *Kangos v. Lange, et al.*, which names CV Therapeutics as a nominal defendant. The plaintiff in this action is one of our stockholders who seeks to bring derivative claims on behalf of CV Therapeutics against the defendants. The lawsuit alleges breaches of fiduciary duty and related claims based on purportedly misleading statements concerning our new drug application for Ranexa. At the appropriate time, we expect to file a motion to dismiss this lawsuit due to the plaintiff's unexcused failure to make a demand on us before filing the action.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation, and defending these lawsuits is likely to be costly, time-consuming and uncertain. Accordingly, no accrual has been established for these lawsuits. In the event of an adverse outcome, our business could be harmed.

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

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades on the Nasdaq National Market under the symbol "CVTX".

The following table sets forth, for the periods indicated, the intraday high and low price per share of the common stock on the Nasdaq National Market.

	High	Low
Year Ended December 31, 2005		
First Quarter	$23.76	$19.15
Second Quarter	$23.73	$19.39
Third Quarter	$29.79	$22.15
Fourth Quarter	$28.42	$23.38
Year Ended December 31, 2004		
First Quarter	$17.48	$13.12
Second Quarter	$17.40	$12.20
Third Quarter	$16.73	$11.28
Fourth Quarter	$24.70	$12.08

On February 28, 2006, the closing price for our common stock was $26.91 per share. As of February 28, 2006, we had approximately 70 holders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder.

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.

Sales and Repurchases of Securities

We did not sell unregistered securities during our fiscal year ended December 31, 2005. We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2005.

Item 6. Selected Financial Data

The data set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this document and also with "Management's Discussion and Analysis of Financial Condition and Results of Operations." Certain reclassifications have been made to prior period balances in order to conform to the current presentation. We have combined line items in the consolidated statements of operations previously separately titled "sales and marketing" and "general and administrative" to a new category titled "selling, general and administrative."

	Year Ended December 31,				
	2005	2004	2003	2002	2001
	(in thousands, except per share amounts)				
Consolidated Statements of Operations Data					
Revenues:					
Collaborative research	$ 18,951	$ 20,428	$ 11,305	$ 5,287	$ 6,762
Operating expenses:					
Research and development	128,448	124,346	80,792	90,973	73,444
Selling, general and administrative	114,691	43,178	40,491	27,226	21,508
Total operating expenses	243,139	167,524	121,283	118,199	94,952
Loss from operations	(224,188)	(147,096)	(109,978)	(112,912)	(88,190)
Interest and other income, net	10,418	7,341	10,853	15,700	19,184
Interest expense	(13,043)	(13,579)	(11,659)	(10,410)	(10,464)
Other expense, net	(1,182)	(1,749)	(167)	(151)	(227)
Net loss	$(227,995)	$(155,083)	$(110,951)	$(107,773)	$ (79,697)
Basic and diluted net loss per share	$ (5.66)	$ (4.90)	$ (3.91)	$ (4.13)	$ (3.74)
Shares used in computing basic and diluted net loss per share	40,268	31,671	28,360	26,093	21,308

	December 31,				
	2005	2004	2003	2002	2001
			(in thousands)		
Consolidated Balance Sheet Data					
Cash, cash equivalents and marketable securities	$ 460,183	$ 404,503	$ 428,498	$ 410,913	$ 478,425
Working capital	425,479	381,465	420,948	398,958	470,412
Total assets	534,446	462,230	471,395	441,002	507,244
Long-term debt	399,500	329,680	296,250	196,643	197,036
Accumulated deficit	(812,554)	(584,559)	(429,476)	(318,525)	(210,752)
Total stockholders' equity	60,990	79,402	148,837	218,965	288,393

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations contain forward-looking statements that involve risks and uncertainties. These statements relate to future events or our future clinical or product development, financial performance or regulatory review of our potential products. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential" or "continue" or the negative of those terms and other comparable terminology. If one or more of these risks or uncertainties materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. Our actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in "Risk Factors" as well as such other risks and uncertainties detailed in our other Securities and Exchange Commission reports and filings. We undertake no obligation to publicly update any forward looking statements, whether as a result of new information, future events or otherwise.

Overview

CV Therapeutics, Inc., headquartered in Palo Alto, California, is a biopharmaceutical company focused on the discovery, development and commercialization of new small molecule drugs for the treatment of cardiovascular diseases. We apply advances in molecular biology and genetics to identify mechanisms of cardiovascular diseases and targets for drug discovery.

We currently have two approved cardiovascular products to promote with our national cardiovascular specialty sales force: Ranexa™ (ranolazine extended-release tablets) and ACEON® (perindopril erbumine) Tablets. Ranexa was approved in the United States in January 2006 for the treatment of chronic angina in patients who have not achieved an adequate response with other antianginal drugs. Ranexa represents the first new pharmaceutical approach to treat angina in the United States in more than 20 years. We plan to launch Ranexa in the United States in March 2006. ACEON®, an angiotensin converting enzyme inhibitor, or ACE inhibitor, is approved in the United States for use in patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction, or MI, and for the treatment of patients with essential hypertension. We co-promote ACEON® in the United States with our partner Solvay Pharmaceuticals, Inc. In addition to our marketed products, we are developing regadenoson, a selective A_{2A}-adenosine receptor agonist for potential use as a pharmacologic agent in myocardial perfusion imaging studies.

In January 2006, the U.S. Food and Drug Administration, or FDA, approved Ranexa for the treatment of chronic angina. Because Ranexa prolongs the QT interval, the approved product labeling indicates that it is reserved for patients who have not achieved an adequate response with other antianginal drugs. Ranexa should be used in combination with amlodipine, beta-blockers or nitrates. Ranexa has antianginal and anti-ischemic effects that do not depend upon reductions in heart rate or blood pressure.

In order to potentially broaden the product labeling for Ranexa, we are conducting the Metabolic Efficiency with Ranolazine for Less Ischemia in Non-ST Elevation Acute Coronary Syndromes, or MERLIN TIMI-36, clinical study. This study is being conducted under a special protocol assessment, or SPA, agreement with the FDA. If treatment with Ranexa is not associated with an adverse trend in death or arrhythmia compared to placebo, the study could support potential approval of Ranexa as first-line chronic angina therapy, even if statistical significance on the primary endpoint is not achieved. In addition, if statistical significance on the primary endpoint is achieved, Ranexa could also gain potential approval for hospital-based and long-term prevention of acute coronary syndromes. The MERLIN TIMI-36 study began enrollment in October 2004 and is being conducted by the Harvard-based TIMI Study Group. We currently expect data from the MERLIN TIMI-36 study in the fourth quarter of 2006 or the first quarter of 2007.

In August 2005, the FDA approved a supplemental new drug application, or sNDA, for ACEON® for the treatment of patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction. The labeling expansion was based on the EUROPA (EUropean trial on Reduction Of cardiac events with Perindopril in patients with stable coronary Artery disease) study, which assessed the ability of perindopril to reduce cardiovascular death, nonfatal myocardial infarction and cardiac arrest in a broad population of patients who had stable coronary artery disease but not heart failure or substantial hypertension. In the EUROPA study, perindopril significantly reduced relative cardiovascular risk by 20% as assessed by the primary combined study endpoint of cardiovascular death, nonfatal myocardial infarction and cardiac arrest. ACEON® is also indicated for the treatment of hypertension.

One of our drug candidates which is in late-stage clinical development is regadenoson, a selective A_{2A}-adenosine receptor agonist for potential use as a pharmacologic agent in myocardial perfusion imaging studies. We completed a Phase 3 trial of regadenoson which met its primary endpoint, for this proposed use in August 2005. Data from a second Phase 3 trial with the same design are expected in 2006.

In addition, we have several development, preclinical and research programs whose objectives are to bring additional drugs to market to help patients with unmet medical needs.

Critical Accounting Policies and the Use of Estimates

Within the framework of generally accepted accounting principles, management judgments and estimates must be made and applied in connection with the preparation of our consolidated financial statements in any accounting period. If management made different judgments or utilized different estimates, material differences could result in the amount and timing of transactions recorded in any period. We believe the following critical accounting policies presently involve our more significant judgments, assumptions and estimates used in the preparation of our consolidated financial statements:

Valuation of Marketable Securities

We invest in short-term and long-term marketable debt securities for use in current operations. We classify our investments as available-for-sale and report the securities at fair value, with unrealized gains and losses reported in stockholders' equity as a component of other comprehensive income (loss). For securities with unrealized losses as of the period end, we evaluate whether the impairment is other-than-temporary. Our assessment includes a consideration of our intent and ability to hold the impaired security for a period of time sufficient to recover its cost basis. If we conclude that an other-than-temporary impairment exists, we recognize an impairment charge to reduce the investment to fair value and record the related charge as a reduction of interest and other income, net. As a result of increases in market interest rates during 2005, we had unrealized losses of $3.2 million in our investment portfolio as of December 31, 2005. After consideration of the scheduled maturities in our investment portfolio, our policies with respect to the concentration of investments with issuers or within industries, and our forecasted needs to support our operations, we concluded that we did not have the ability to hold impaired securities for a period of time sufficient to recover their cost basis. As a result, for the year ended December 31, 2005, we recorded an impairment charge of $3.2 million related to these securities. If market interest rates continue to increase in future periods, we may record additional impairment charges related to our investments.

Revenue Recognition

Revenue under our collaborative research arrangement is recognized based on the performance requirements of the contract. Amounts received under such arrangements consist of up-front license payments, periodic milestone payments and reimbursements for research activities. Up-front or milestone payments which are still subject to future performance requirements are recorded as deferred revenue and are amortized over the performance period. The performance period is estimated at the inception of the arrangement and is reevaluated

at each reporting period. The reevaluation of the performance period may shorten or lengthen the period during which the deferred revenue is recognized. We reevaluated the performance period for certain collaborative research arrangements in 2005, which resulted in an immaterial change in revenues as compared to our original estimate. We will continue to reevaluate the performance period for our collaborative arrangements in future periods. We evaluate the appropriate performance period based on research progress attained and certain events, such as changes in the regulatory and competitive environment. Revenues related to substantive, at-risk milestones are recognized upon achievement of the scientific or regulatory event specified in the underlying agreement. Revenues for research activities are recognized as the related research efforts are performed.

Revenue under our ACEON® co-promotion agreement is recognized based on net product sales recorded by Solvay Pharmaceuticals, our co-promotion partner, for each reporting period. We have not recognized any co-promotion revenue to date.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility related expenses, outside contract services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting and vendor activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our expense accruals for clinical trials are based on estimates of the services received pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Expense accruals for the contracts depend on estimates we make on factors such as the achievement of certain events, the successful accrual of patients, and the degree of completion of the event or events specified in the specific clinical study or trial contract. We determine our estimates through discussions with internal clinical personnel and outside service providers as to the progress made or stage of completion of trials or services and the agreed upon fee to be paid for such services. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. The objective of our accrual policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. If we underestimate or overestimate activity levels associated with various studies at a given point in time, adjustments to research and development expenses would be necessary in future periods. To date, such adjustments have not been material.

Inventory Valuation

Prior to regulatory approval of our drug candidates, we incur expenses for the manufacture of drug product that could potentially be available to support the commercial launch of these drug candidates. Until the necessary initial regulatory approval has been received or is otherwise considered assured, we charge all such amounts to research and development expenses. As of December 31, 2005, all Ranexa inventory costs have been expensed. As a result, our initial sales of Ranexa will result in higher gross margins than if the inventory costs had not previously been expensed. After receiving regulatory approval for Ranexa in January 2006, we will begin to capitalize the commercial inventory costs associated with manufacturing Ranexa.

Stock Compensation Valuation

The preparation of the financial statement footnotes requires us to estimate the fair value of stock-based payments granted to employees and consultants. While fair value may be readily determinable for awards of

stock or restricted stock units, market quotes are not available for long-term, non-transferable stock options or stock appreciation rights because these instruments are not traded. We currently use the Black-Scholes and other option pricing models to estimate the fair value of employee stock options, stock appreciation rights, restricted stock units and the employee stock purchase plan. Our estimate of compensation expense will require a number of complex and subjective assumptions including our stock price volatility and employee exercise patterns. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, lengthier option terms provide more opportunity to exploit market highs. However, empirical data shows that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. Accordingly, companies are required to estimate the expected term of the option for input to an option-pricing model. When establishing an estimate of the expected term, we consider the vesting period for the award, our historical experience of employee stock option exercises, the expected volatility, and a comparison to relevant peer group data. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, we are likely to change our valuation assumptions used to value stock based awards granted in future periods. Changes to the subjective input assumptions could materially affect the estimated fair value of our stock-based payments.

Results of Operations—Comparison of Years Ended December 31, 2005, 2004 and 2003

Revenues

Total revenues and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year ended December 31,		
	2005	**2004**	**2003**
Collaborative research revenues	$19.0	$20.4	$11.3
Dollar change from prior year	$ (1.4)	$ 9.1	
Percentage change from prior year	(7)%	81%	

The decrease in collaborative research revenues in 2005 from 2004 was primarily due to decreased reimbursable development costs incurred in connection with our two Phase 3 clinical trials undertaken in our collaboration with Astellas US LLC for the development of regadenoson. In August 2005, we announced data for one of the two Phase 3 clinical trials for regadenoson which has now been completed, while the other Phase 3 trial is ongoing.

The increase in collaborative research revenues in 2004 from 2003 was primarily due to increased reimbursable development costs associated with two Phase 3 clinical trials undertaken in our collaboration with Astellas US LLC for the development of regadenoson.

We have not recognized any ACEON® co-promotion revenue to date. We expect that any future ACEON® co-promotion revenues will depend upon the achievement of sales above a specified baseline by us and our collaborative partner, Solvay Pharmaceuticals.

Research and Development Expenses

Total research and development expenses and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year ended December 31,		
	2005	**2004**	**2003**
Total research and development expenses	$128.4	$124.3	$80.8
Dollar change from prior year	$ 4.1	$ 43.5	
Percentage change from prior year	3%	54%	

The increase in research and development expenses in 2005 from 2004 was primarily due to increased outside contract service expenses for our Phase 3 Ranexa studies, and to a lesser extent, higher personnel related expenses resulting from increased headcount in our research and development organization. These increases were partially offset by the accrual in 2004 of $10.1 million for a milestone due under our license agreement with Roche Palo Alto LLC for Ranexa and decreased outside contract service expenses for our Phase 3 regadenoson studies.

The increase in research and development expenses in 2004 from 2003 was primarily due to increased outside contract service expenses for our Phase 3 Ranexa and regadenoson studies as well as an expense associated with an accrual of $10.1 million for a milestone due under our license agreement with Roche Palo Alto LLC for Ranexa.

We categorize our research and development expenses by project. The table below shows research and development expenses for our two primary clinical development programs, Ranexa and regadenoson, as well as expenses associated with all other projects in our research and development pipeline. Other projects consist primarily of numerous pre-clinical research projects, none of which individually constitutes more than 10% of our total research and development expenses for the periods presented.

	Year ended December 31,		
	2005	**2004**	**2003**
		(in thousands)	
Ranexa	$ 67,954	$ 69,590	$46,478
Regadenoson	27,873	29,631	11,860
Other projects	32,621	25,125	22,454
Total research and development expenses	$128,448	$124,346	$80,792

We expect total research and development expenses to increase in 2006 as we continue the Phase 3 MERLIN TIMI-36 study and other clinical and preclinical studies for Ranexa, regadenoson and expand our other research and development projects.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year ended December 31,		
	2005	**2004**	**2003**
Total selling, general and administrative expenses	$114.7	$43.2	$40.5
Dollar change from prior year	$ 71.5	$ 2.7	
Percentage change from prior year	166%	7%	

The increase in selling, general and administrative expenses in 2005 from 2004 was primarily due to additional personnel and related expenses incurred in conjunction with establishing and maintaining a national cardiovascular specialty sales force that includes approximately 250 cardiovascular account specialists as well as other ACEON® co-promotion related activities and, to a significantly lesser extent, to higher personnel-related general and administrative expenses due to increased headcount to support our increased commercialization and other business activities.

The increase in selling, general and administrative expenses in 2004 from 2003 was primarily due to additional general and administrative personnel and related expenses to support our pre-commercialization and research and development efforts, partially offset by decreased marketing planning and communications activities for Ranexa in 2004 and a non-cash expense recorded in 2003 of approximately $3.7 million related to a warrant issued to Quintiles Transnational Corp. upon modification of our commercialization agreement.

We expect selling, general and administrative expenses to increase in 2006 as we launch Ranexa and continue to co-promote ACEON® in the United States. We established our national cardiovascular specialty sales force in the second quarter of 2005. In 2006 and future years, we will incur a full year of expenses related to our national cardiovascular specialty sales force.

Interest and Other Income, Net

Total interest and other income, net and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year ended December 31,		
	2005	**2004**	**2003**
Total interest and other income, net	$10.4	$ 7.3	$10.9
Dollar change from prior year	$ 3.1	$(3.6)	
Percentage change from prior year	42%	(33)%	

The increase in interest and other income, net in 2005 from 2004 was primarily due to higher interest rates earned on our investment portfolio, partially offset by a non-cash investment impairment charge of $3.2 million related to losses on our investment portfolio that were deemed to be other-than-temporary.

The decrease in interest and other income, net in 2004 from 2003 was primarily due to losses recognized on sales of marketable securities in the year ended December 31, 2004, compared to gains recognized on sales of marketable securities in the year ended December 31, 2003.

We expect interest and other income, net to fluctuate in the future with changes in average investment balances and market interest rates.

Interest Expense

Total interest expense and dollar and percentage changes as compared to the prior year are as follows (dollar amounts are presented in millions):

	Year ended December 31,		
	2005	**2004**	**2003**
Total interest expense	$13.0	$13.6	$11.7
Dollar change from prior year	$ (0.6)	$ 1.9	
Percentage change from prior year	(4)%	16%	

The decrease in interest expense in 2005 from 2004 was primarily due to the write-off in 2005 of $0.6 million of previously unamortized debt issuance costs associated with the August 2005 redemption of the

remaining outstanding $79.6 million principal amount of our 4.75% subordinated convertible notes due 2007, compared to the write-off in 2004 of $1.6 million of previously unamortized debt issuance costs associated with the May and June 2004 repurchases of $116.6 million principal amount of our 4.75% subordinated convertible notes due 2007. These factors were partially offset by higher interest expense in 2005 related to higher average convertible debt balances.

The increase in interest expense in 2004 from 2003 was primarily due to the write-off in 2004 of $1.6 million of debt issuance costs from the repurchase of approximately $116.6 million of our previously issued 4.75% subordinated convertible notes due 2007 and the amortization of debt issuance costs and interest associated with the June 2003 issuance of our 2.0% senior subordinated convertible debentures.

Our 4.75% convertible subordinated notes due 2007 accounted for $3.1 million, $8.1 million and $10.3 million of interest expense in the years ended December 31, 2005, 2004 and 2003, respectively. Our 2.0% senior subordinated convertible debentures due 2023 accounted for $2.5 million, $2.5 million and $1.3 million of interest expense in the years ended December 31, 2005, 2004 and 2003, respectively. Our 2.75% senior subordinated convertible notes due 2012 accounted for $4.7 million and $2.9 million of interest expense in the years ended December 31, 2005 and 2004, respectively. Our 3.25% senior subordinated convertible notes due 2013 accounted for $2.7 million of interest expense in the year ended December 31, 2005. We expect interest expense to fluctuate in the future with average convertible debt balances.

Other Expense, Net

Total other expense, net and dollar and percentage changes as compared to the prior years are as follows (dollar amounts are presented in millions):

	Year ended December 31,		
	2005	**2004**	**2003**
Total other expense, net	$ 1.2	$ 1.7	$0.2
Dollar change from prior year	$(0.5)	$ 1.5	
Percentage change from prior year	(29)%	750%	

The decrease in other expense, net in 2005 from 2004 was primarily due to the premium paid above the principal value of approximately $1.1 million for the August 2005 redemption of $79.6 million principal amount of our 4.75% subordinated convertible notes due 2007 compared to the premium paid above the principal value of approximately $1.7 million for the May and June 2004 repurchases of $116.6 million principal amount of our 4.75% subordinated convertible notes due 2007.

The increase in other expense, net in 2004 from 2003 was due to $1.7 million in premium payments above the principal value incurred from the repurchase of approximately $116.6 million of our previously issued 4.75% convertible subordinated notes due 2007.

Taxes

We have not generated taxable income to date. As of December 31, 2005, the net operating losses potentially available to offset future taxable income for federal and California income tax purposes were approximately $791.5 million and $506.8 million, respectively. Utilization of the net operating loss carryforwards will likely be subject to substantial annual limitations due to the ownership change limitations provided by the Internal Revenue Code and similar California provisions. The federal carryforwards expire at various dates beginning in 2006, if not utilized. The California carryforwards expire at various dates beginning in 2007, if not utilized. The federal research tax credits will expire at various dates beginning in the year 2008, if not utilized. The California research tax credit carry forwards can be carried forward indefinitely. As a result of annual limitations, a portion of these carryforwards and research tax credits may expire before becoming available to reduce our federal and California income tax liabilities.

Recent Accounting Pronouncements

We are required to adopt Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard No. 123R, "*Share-Based Payment*," (Statement 123R) on January 1, 2006. Generally, the approach in Statement 123R is similar to the approach described in Statement 123. However, Statement 123R requires all stock-based payments to employees, including grants of employee stock options, stock appreciation rights, restricted stock units and our employee stock purchase plan, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. We intend to recognize stock-based compensation expense on all awards on a straight-line basis over the requisite service period using the modified prospective method for all options issued after January 1, 2006 and we will intend to use the Black-Scholes option pricing model to value stock-based payments under Statement 123R.

As permitted by Statement 123, we currently account for stock-based payments to employees using Accounting Principles Board Opinion No. 25's intrinsic value method. As a result, we generally recognize no compensation cost for employee stock options. However, we do include expense amounts associated with grants of restricted stock units and stock appreciation rights in our results of operations. The adoption of Statement 123R's fair value method will have a significant impact on our consolidated results of operations, although it will have no impact on our overall financial position. The impact of adopting Statement 123R will depend in part on levels of share-based payments granted in the future and other unknown variables, such as estimated forfeiture rates, volatility, interest rates and option term length.

In accordance with Statement 123R, deferred compensation and related common stock on our balance sheet as of December 31, 2005 (which totals approximately $18.2 million as of December 31, 2005) will be reversed and future charges for deferred compensation from our restricted stock units will be recorded to common stock directly as the related services are performed. We are assessing the cumulative benefit of a change in accounting principle, which may result from the net cumulative impact of estimating future forfeitures for unvested restricted stock units outstanding as of January 1, 2006, in the determination of period expense, rather than recording forfeitures when they occur as previously permitted.

In November 2005, the FASB issued FASB Staff Position (FSP) No. FAS 115-1, "*The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments*." FSP No. FAS 115-1 provides additional guidance on the determination as to when an investment is considered impaired, whether that impairment is other-than-temporary, and the measurement of the loss. Although FSP No. FAS 115-1 is effective for fiscal years beginning after December 15, 2005, we believe the FSP's clarification to the guidance regarding when an other-than-temporary impairment should be recognized is consistent with other existing literature, such as Staff Accounting Bulletin No. 59, "*Accounting for Noncurrent Marketable Equity Securities.*" We have adopted FSP No. FAS 115-1 as of December 31, 2005. Accordingly, we recorded a non-cash impairment charge of approximately $3.2 million as an offset to interest and other income, net for the year ended December 31, 2005 to write down the carrying value of our marketable securities to fair value.

Liquidity and Capital Resources

(in millions)	As of December 31,		
	2005	2004	2003
Cash, cash equivalents and marketable securities	$ 460.2	$ 404.5	$428.5

	Year ended December 31,		
	2005	2004	2003
Cash flows:			
Net cash used in operating activities	$(196.6)	$(124.1)	$ (99.4)
Net cash (used in) provided by investing activities	$ (67.9)	$ 13.3	$ (36.4)
Net cash provided by financing activities	$ 267.4	$ 115.7	$133.0

We have financed our operations since inception primarily through private placements and public offerings of debt and equity securities, equipment and leasehold improvement financing, other debt financing and payments under corporate collaborations. For at least the next 12 months, we expect to be able to fund our operations from our cash, cash equivalents and marketable securities available as of December 31, 2005. We currently estimate that our operating expenses for 2006 will be approximately $310.0 million to $330.0 million.

Net cash used in operating activities for the years ended December 31, 2005 and 2004 resulted primarily from operating losses adjusted for changes in accrued and other liabilities, non-cash expenses and changes in restricted cash.

Net cash used in investing activities for the year ended December 31, 2005 consisted primarily of purchases of marketable securities of $354.0 million and capital expenditures of $9.0 million, largely offset by sales and maturities of marketable securities of $295.1 million. Net cash provided by investing activities in the year ended December 31, 2004 consisted primarily of proceeds from sales and maturities of marketable securities of $402.6 million, largely offset by purchases of marketable securities of $385.2 million and capital expenditures and other investing activities of $4.1 million. In the future, net cash provided by or used in investing activities may fluctuate from period to period due to timing of payments for capital expenditures and maturities/sales and purchases of marketable securities.

Net cash provided by financing activities in the year ended December 31, 2005 was primarily due to the completion of concurrent public equity and debt financings in July 2005 with net proceeds totaling approximately $315.0 million. We sold 8,350,000 shares of common stock at a price of $21.60 per share and issued $149.5 million aggregate principal amount of 3.25% senior subordinated convertible notes due 2013. Additionally, we realized net proceeds of approximately $25.0 million from the sale of 1,275,711 shares of common stock under our financing arrangement with Acqua Wellington North American Equities Fund, Ltd. in February 2005, and proceeds of approximately $7.2 million from the issuance of 560,138 shares of common stock through stock options exercised and the employee stock purchase plan. In August 2005, we redeemed the remaining outstanding $79.6 million principal amount of our 4.75% convertible subordinated notes due 2007 at a premium to the principal amount of the notes. Net cash provided by financing activities in the year ended December 31, 2004 was primarily due to net proceeds of $145.1 million from the issuance of 2.75% senior subordinated convertible notes, net proceeds of approximately $59.9 million from the sale of 3,579,472 shares of common stock under our financing agreement with Acqua Wellington, net proceeds of approximately $24.5 million from the sale of 1,609,186 shares of common stock under our common stock purchase agreement with Mainfield Enterprises, Inc., and proceeds of approximately $3.1 million from the issuance of 297,960 share of common stock through stock options exercised and the employee stock purchase plan, partially offset by the repurchase of approximately $116.6 million principal amount of our 4.75% senior subordinated convertible notes.

We may from time to time seek to retire our outstanding debt through cash purchases and/or conversions or exchanges for equity securities in open market purchases, privately negotiated transactions or otherwise. Such purchases, conversions or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved may be material. Alternatively, we may from time to time seek to restructure our outstanding debt through exchanges for new debt securities in open market transactions, privately negotiated transactions, or otherwise. The amounts involved may be material.

Contractual Obligations and Significant Commercial Commitments

The following summarizes our contractual obligations and the periods in which payments are due as of December 31, 2005:

	2006	2007	2008	2009	2010	Thereafter	Total
				(in thousands)			
Convertible notes(1)	$11,591	$10,984	$10,984	$10,984	$10,984	$445,263	$500,790
Manufacturing obligations(2)	8,496	2,501	2,501	1,251	–	–	14,749
Operating leases(3)	12,508	13,570	14,610	14,403	15,613	29,471	100,175
	$32,595	$27,055	$28,095	$26,638	$26,597	$474,734	$615,714

(1) "Convertible notes" consist of principal and interest payments on our 2.0% senior subordinated convertible debentures due 2023, our 2.75% senior subordinated convertible notes due 2012 and our 3.25% senior subordinated convertible notes due 2013. The holders of our 2.0% senior subordinated convertible debentures due 2023 may require us to purchase all or a portion of their debentures on May 16, 2010, May 16, 2013 and May 16, 2018, in each case at a price equal to the principal amount of the debentures to be purchased, plus accrued and unpaid interest, if any, to the purchase date.

(2) "Manufacturing obligations" include significant non-cancelable orders and minimum commitments under our agreements related to the manufacturing of Ranexa.

(3) "Operating leases" consists of minimum lease payments related to real estate leases for our facilities covering 186,000 square feet. As of December 31, 2005, these leases expire between February 2008 and April 2014. One of the leases is secured by a $6.0 million irrevocable letter of credit. In January 2006, we amended another lease which extended the lease term to April 2016 with an option to renew for nine years. Minimum payments related to the amended lease have not been included in the above table. The amended lease provides for net rent reductions of $3.7 million over five years in return for the issuance of warrants to the landlord and the ground lessor.

The table above excludes any commitments that are contingent upon future events. In January 2006, we received FDA approval for Ranexa, resulting in the following commitments:

We have a commitment related to our license agreement with Roche Palo Alto LLC for Ranexa. Under our license agreement, we paid an initial license fee, and are obligated to make certain payments to Roche, upon receipt of the first and second product approvals for Ranexa in any of the following major market countries: France, Germany, Italy, the United States and the United Kingdom. As of December 31, 2005, we have accrued $10.1 million of the $11.0 million payment, and expensed this amount as research and development expenses in the year ended December 31, 2004. In February 2006, we paid $11.0 million to Roche in accordance with this agreement. Unless the agreement is terminated, within thirty days of the approval of Ranexa in a second major market country, if any, we will owe a second payment of $9.0 million to Roche.

We have a commitment related to an agreement with a vendor whereby amounts are due to them upon the approval of Ranexa by the FDA for the manufacture of certain materials related to the production of Ranexa. Upon FDA approval of Ranexa, we are required to pay a $5.0 million milestone and fees based upon the amount of Ranexa manufactured until total amounts paid reach $12.0 million. In January 2006, we paid $5.0 million to this vendor in accordance with the agreement.

We have a commitment related to an agreement with Quintiles Transnational Corp. whereby we are required to engage Quintiles to provide $10.0 million or more of commercialization services by or before six months following the approval of Ranexa by the FDA. Otherwise, we are obligated to pay Quintiles ten percent of the difference between $10.0 million and the actual amounts of commercialization services we have engaged with them during the end of the six month period following the approval of Ranexa.

Risks and Uncertainties Related to Our Future Capital Requirements

According to industry statistics, it generally takes 10 to 15 years to research, develop and bring to market a new prescription medicine in the United States. Drug development in the United States and other countries is a process that includes multiple steps defined by the FDA under applicable statutes, regulations and guidance documents. After the preclinical research process of identifying, selecting and testing in animals a potential pharmaceutical compound, the clinical development process begins with the filing of an investigational new drug application, or IND, or equivalent foreign filing, to allow clinical study of the product candidate. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are usually for Phase 3 trials, which tend to be the longest and largest studies conducted during the drug development process. After the completion of a successful preclinical and clinical development program, a new drug application, or foreign equivalent, must be filed with regulatory authorities, which includes among other things very large amounts of preclinical and clinical data and results and manufacturing-related information necessary to support requested approval of the product candidate. The review and approval process with regulatory authorities is often uncertain, time-consuming and costly. In light of the steps and complexities involved, the successful development of our product candidates is highly uncertain. Actual product timelines and costs are subject to enormous variability and are very difficult to predict, as our clinical development programs are updated and changed to reflect the most recent clinical and preclinical data and other relevant information. In addition, various statutes and regulations also govern or influence the testing, manufacturing, safety reporting, labeling, storage, recordkeeping and marketing of each product. The lengthy process of seeking these regulatory reviews and approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for our potential products could materially adversely affect our business. We will continue to incur substantial expenditures for, and devote a significant amount of time to, preclinical testing and clinical trials. The amounts of the expenditures that will be necessary to execute our business plan are subject to numerous uncertainties that may adversely affect our liquidity and capital resources to a significant extent.

Our future capital requirements will depend on many factors, including revenues, if any, generated from ACEON® and Ranexa, market acceptance of our approved products, progress in our research, development and commercialization programs, the size and complexity of these programs, the timing, scope and results of preclinical studies and clinical trials, our ability to establish and maintain collaborative partnerships, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the cost of manufacturing preclinical and clinical material and other factors not within our control. We cannot guarantee that the additional financing to meet our capital requirements will be available on acceptable terms or at all. Insufficient funds may require us to delay, scale back or eliminate some or all of our research, development or commercialization programs, to lose rights under existing licenses or to relinquish greater or all rights to product candidates on less favorable terms than we would otherwise choose, or may adversely affect our ability to operate as a going concern. If we issue equity or convertible debt securities to raise additional funds, substantial dilution to existing stockholders may result.

The significant amounts of capital that we are spending to provide and/or enhance infrastructure, headcount and inventory to co-promote ACEON® in the United States and to launch and commercialize Ranexa in the United States will be lost if we cannot significantly increase the level of United States sales of ACEON® or achieve market acceptance for Ranexa. Our ACEON® and Ranexa commercialization efforts include building our sales and marketing infrastructure, increasing our marketing communications efforts, hiring and deploying a national specialty cardiovascular sales force that includes approximately 250 cardiovascular account specialists and launching Ranexa in March 2006. If we cannot substantially increase the level of United States sales of ACEON® or if we do not achieve market acceptance for Ranexa, the future benefits of these expenditures and any future commitments of capital will be lost. The loss of future benefits from this investment may harm our business, increase our cash requirements, increase the volatility of our stock price and result in additional operating losses. Our sales and marketing expenses have increased substantially as we have begun to co-promote ACEON® and launch Ranexa in the United States. We expect that our operating expenses will increase substantially in connection with the market launch of Ranexa.

We may require substantial additional funding in order to complete our research and development activities and commercialize our products and product candidates. As of December 31, 2005, our cash, cash equivalents and marketable securities totaled $460.2 million. We estimate that our cash, cash equivalents and marketable securities as of December 31, 2005 should be sufficient to fund our operations for at least the next 12 months. However, we cannot assure you that we will not require or seek additional funding prior to then or that additional financing will be available on acceptable terms or at all.

We have experienced significant operating losses since our inception in 1990, including net losses of $228.0 million in 2005, $155.1 million in 2004 and $111.0 million in 2003. As of December 31, 2005, we had an accumulated deficit of $812.6 million. The process of developing and commercializing our product candidates requires significant research and development work, preclinical testing and clinical trials, as well as regulatory approvals, significant marketing and sales efforts, and manufacturing capability. These activities, together with our general and administrative expenses, require significant investments and are expected to continue to result in operating losses for the foreseeable future. We have not generated any product revenues to date, and even after we generate revenues relating to ACEON®, Ranexa and other approved products, if any, we may never achieve or sustain profitability.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We do not use derivative financial instruments in our investment portfolio. We place our investments with high quality issuers and, by policy, limit the exposure to any one issuer except for United States government securities or by one of its agencies. We are averse to principal loss and strive to ensure the safety and preservation of our invested funds by limiting default, market and reinvestment risk. We classify our cash equivalents and marketable securities as "fixed-rate" if the rate of return on such instruments remains fixed over their term. These "fixed-rate" investments include U.S. government securities, commercial paper, asset backed securities and corporate bonds. Fixed-rate securities may have their fair market value adversely affected due to a rise in interest rates and we may suffer losses in principal if forced to sell securities that have declined in market value due to a change in interest rates. We classify our cash equivalents and marketable securities as "variable-rate" if the rate of return on such investments varies based on the change in a predetermined index or set of indices during their term. As of December 31, 2005, there have been no material changes in these market risks since December 31, 2004.

Our long-term debt at December 31, 2005 includes $100.0 million of our 2.0% senior subordinated convertible debentures due 2023, $150.0 million of our 2.75% senior subordinated convertible notes due 2012, and $149.5 million of our 3.25% senior subordinated convertible notes due 2013, which was issued in July 2005. Interest on the 2.0% senior subordinated convertible debentures is fixed and payable semi-annually on May 16 and November 16 each year. Interest on the 2.75% senior subordinated convertible notes is fixed and payable semi-annually on May 16 and November 16 each year. Interest on the 3.25% senior subordinated convertible notes due 2013 is fixed and payable semi-annually on February 16 and August 16 each year, beginning February 16, 2006. All the notes and debentures are convertible into shares of our common stock at any time prior to maturity, unless previously redeemed or repurchased, subject to adjustment in certain events. The market value of our long-term-debt will fluctuate with movements of interest rates and with movements in the value of our common stock.

The table below presents the amounts and related average interest rates of our investment portfolio and our long-term debt as of December 31, 2005:

	Average Interest Rate	Estimated Market Value
		($ in thousands)
Cash equivalents:		
Variable rate	4.08%	$ 15,879
Fixed rate	4.04%	$ 6,830
Marketable securities portfolio:		
Fixed rate (mature in 2006)	3.26%	$197,393
Fixed rate (mature in 2007)	4.14%	$155,106
Variable rate (mature in 2007)	4.39%	$ 8,769
Fixed rate (mature in 2008)	4.16%	$ 73,226
Variable rate (mature in 2008)	4.41%	$ 2,000
Long-term debt:		
2.0% senior subordinated convertible debentures due 2023	2.00%	$ 89,680
2.75% senior subordinated convertible notes due 2012	2.75%	$225,000
3.25% senior subordinated convertible notes due 2013	3.25%	$166,274

Foreign Currency Risk

We are exposed to foreign currency exchange rate fluctuations related to the operation of our European subsidiary in the United Kingdom. At the end of each reporting period, expenses of the subsidiary are remeasured into U.S. dollars using the average currency rate in effect for the period and assets and liabilities are remeasured into U.S. dollars using either historical rates or the exchange rate in effect at the end of the period. Additionally, we are exposed to foreign currency exchange rate fluctuations relating to payments we make to vendors and suppliers using foreign currencies. In particular, we have foreign expenses associated with our ongoing clinical studies, such as the MERLIN-TIMI 36 clinical trial of Ranexa. We currently do not hedge against this foreign currency risk. Although fluctuations in exchange rates impact our financial condition and results of operations as reported in U.S. dollars, foreign currency gains and losses for 2005, 2004 and 2003 have not been significant.

Item 8. Financial Statements and Supplementary Data

Our financial statements and notes thereto appear beginning on page 88 of this report.

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

Not Applicable.

Item 9A. Controls and Procedures

(a) *Evaluation of Disclosure Controls and Procedures:*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of December 31, 2005, the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Management's Annual Report on Internal Control Over Financial Reporting:*

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005 based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2005.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Ernst & Young LLP, an independent registered public accounting firm.

(c) *Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting*

The Board of Directors and Stockholders of CV Therapeutics, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting that CV Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). CV Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, management's assessment that CV Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, CV Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of CV Therapeutics, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005 and our report dated February 24, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
February 24, 2006

(d) *Changes in Internal Control Over Financial Reporting:*

There has been no change in the company's internal controls over financial reporting during the company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the company's internal controls over financial reporting.

Inherent Limitations of Internal Controls

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Item 9B. Other Information

On March 6, 2006, we amended the co-promotion agreement with Solvay Pharmaceuticals to adjust the baseline above which we receive a share of product sales, and to modify related economic terms of the agreement. We have elected to disclose this amendment in this report instead of under Item 1.01 of Form 8-K.

PART III

Item 10. Directors and Executive Officers of the Registrant

Directors

The names of the members of our board of directors and their ages as of January 31, 2006 are as follows:

Name of Director	Age	Principal Occupation
Louis G. Lange, M.D., Ph.D.	57	Chairman of the Board, Chief Executive Officer and Chief Science Officer
Santo J. Costa(2)	60	Retired Vice Chairman, Quintiles Transnational Corp.
Joseph M. Davie, M.D., Ph.D.	66	Retired Senior Vice President Department of Research, Biogen, Inc. (now Biogen Idec)
Thomas L. Gutshall(1)	67	Chairman of the Board of Directors, Cepheid Corporation
Peter Barton Hutt	71	Senior Counsel in the law firm of Covington & Burling
Kenneth B. Lee, Jr.(1)(2)	58	General Partner, Hatteras BioCapital
Barbara J. McNeil, M.D., Ph.D.(1)(3)	64	Ridley Watts Professor of Health Care Policy, Chairman of the Department of Health Care Policy, Harvard Medical School
Thomas E. Shenk, Ph.D.(3)	58	Elkins Professor of Molecular Biology, Princeton University

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Governance Committee

Louis G. Lange, M.D., Ph.D., was a founder of CV Therapeutics and has served as our Chairman of the Board and Chief Executive Officer since August 1992. Dr. Lange has served as a trustee on the University of Rochester Board of Trustees since May 1997, a member of the governing body of the Emerging Company Section of the Biotechnology Industry Organization since February 1999, and is on the boards of directors of Maxygen, Inc. and several private companies. From 1980 to 1992, Dr. Lange served on the faculty of Washington University School of Medicine, including as Chief of Cardiology at Jewish Hospital in St. Louis, Missouri from 1985 to 1992, and as a full Professor of Medicine from 1990 until 1992. Dr. Lange holds an M.D. from Harvard Medical School and a Ph.D. in biological chemistry from Harvard University.

Santo J. Costa has served as a director of CV Therapeutics since May 2001. Mr. Costa retired as Vice Chairman of Quintiles Transnational Corp. in May 2001. While at Quintiles, Mr. Costa also served as President and Chief Operating Officer from 1994 until 1999. Previously, Mr. Costa served as Senior Vice President, Administration and General Counsel of Glaxo Inc., where he sat on the company's board of directors. Previously, Mr. Costa was U.S. Area Counsel for Merrell Dow Pharmaceuticals. Mr. Costa started his career as food and drug counsel for Norwich/Eaton Pharmaceuticals. Mr. Costa currently serves on the boards of directors of Labopharm Inc., NeuroMedix Inc., NPS Pharmaceuticals, Inc. and several private companies. Mr. Costa is also of counsel to the law firm of Maupin Taylor P.A. Mr. Costa received a B.S. degree in pharmacy and a J.D. from St. John's University.

Joseph M. Davie, M.D., Ph.D., has served as a director of CV Therapeutics since January 2006. Dr. Davie was senior vice president of research at Biogen, Inc. (now Biogen Idec), a biopharmaceutical company, from 1993 to 2000, and held several positions at G.D. Searle & Co., including president of research and development and senior vice president of science and technology, from 1987 to 1993. Dr. Davie was professor and head of the Department of Microbiology and Immunology at Washington University School of Medicine from 1975 to 1987. He currently serves as a director of Targeted Genetics, Curis, Inc., Inflazyme Pharmaceuticals, Ltd. and several privately held companies. Dr. Davie received his A.B., M.A. and Ph.D. in bacteriology from Indiana University and his M.D. from Washington University School of Medicine.

Thomas L. Gutshall has served as a director of CV Therapeutics since December 1994. Mr. Gutshall has served as Chairman of the board of directors of Cepheid, a diagnostics company, since 1996 and from August 1996 to April 2002, Mr. Gutshall also served as Chief Executive Officer of Cepheid. From September 1996 to December 2002, Mr. Gutshall served as a consultant to CV Therapeutics, and from January 1995 to September 1996, he served as our President and Chief Operating Officer. From June 1989 until December 1994, Mr. Gutshall served as Executive Vice President at Syntex Corporation, a pharmaceutical and healthcare company. Mr. Gutshall serves on the boards of directors of several private companies. Mr. Gutshall earned a B.S. degree in chemical engineering from the University of Delaware and completed the Executive Marketing Management Program at Harvard Business School.

Peter Barton Hutt, Esq. has served as a director of CV Therapeutics since August 2000. Mr. Hutt is senior counsel in the Washington, D.C. law firm of Covington & Burling, specializing in food and drug law and trade association law. From 1971 to 1975, he was Chief Counsel for the United States Food and Drug Administration. He is the coauthor of a casebook used to teach food and drug law and teaches a full course on this subject each year during winter term at Harvard Law School. He is a member of the Institute of Medicine of the National Academy of Sciences, and has served on the IOM Executive Committee. Mr. Hutt also serves on the boards of directors of Favrille, Inc., Introgen Therapeutics, Inc., Ista Pharmaceuticals, Momenta Pharmaceuticals, Inc. and Xoma Ltd. Mr. Hutt also serves on a wide variety of academic and scientific advisory boards and on the boards of directors of several private companies. Mr. Hutt has served on the IOM Roundtable for the Development of Drugs and Vaccines Against AIDS, the Advisory Committee to the Director of the National Institutes of Health, the National Academy of Sciences Committee on Research Training in the Biomedical and Behavioral Sciences, the NIH Advisory Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS established by the President's Cancer Panel of the National Cancer Institute at the request of former President Bush, and five Office of Technology Assessment advisory panels. Mr. Hutt has twice been a councilor of the Society for Risk Analysis and is presently Legal Counsel to the Society as well as the American College of Toxicology. Mr. Hutt earned a B.A. degree from Yale University, an LL.B. from Harvard University and an L.L.M. from New York University.

Kenneth B. Lee, Jr., has served as a director of CV Therapeutics since January 2002. Mr. Lee is a general partner of Hatteras BioCapital. Mr. Lee served as President of A.M. Pappas & Associates, an international life sciences venture development company, from January 2002 to June 2002. From September 1972 to December 2001, Mr. Lee was a partner and employee at Ernst & Young LLP and Ernst & Young Capital Advisors, LLC. While at Ernst & Young, Mr. Lee served as head of their Health Sciences Investment Banking group from 2000 to 2001, as a Transaction Advisor of their Center for Strategic Transactions from 1997 to 2000, and as Co-Chairman of their International Life Sciences Practice from 1995 to 1997. Mr. Lee formerly served on the Emerging Companies Section of the Board of the Biotechnology Industry Organization and on the Board of the California Healthcare Institute. Mr. Lee currently serves on the boards of directors of Abgenix, Inc., Inspire Pharmaceuticals, Inc., Pozen Inc. and a private company. Mr. Lee also serves on the Board of Visitors of Lenoir-Rhyne College, the Board of the North Carolina Biotechnology Industry Organization and the Board of Visitors of the Lineberger Cancer Center of the University of North Carolina at Chapel Hill. Mr. Lee received a B.A. degree from Lenoir-Rhyne College and an M.B.A. degree from the University of North Carolina at Chapel Hill, and is a certified public accountant.

Barbara J. McNeil, M.D., Ph.D., has served as a director of CV Therapeutics since December 1994. Since 1990, Dr. McNeil has served as the Ridley Watts Professor of Health Care Policy at Harvard Medical School. In addition, since 1988, she has served as the Chair of the Department of Health Care Policy at Harvard Medical School. Since 1983, Dr. McNeil has been a Professor of Radiology at both Harvard Medical School and Brigham and Women's Hospital in Boston, Massachusetts. Dr. McNeil serves on the board of directors of Edwards Lifesciences Corporation. Dr. McNeil holds an M.D. from Harvard Medical School and a Ph.D. in biological chemistry from Harvard University.

Thomas E. Shenk, Ph.D., has served as a director of CV Therapeutics since December 2004. Dr. Shenk has been Elkins Professor of Molecular Biology at Princeton University since 1984 and is a world-renowned expert

in virology and gene therapy with over 20 years of experience in the biopharmaceutical field. Dr. Shenk is a member of the National Academy of Sciences, the Institute of Medicine, the American Academy of Arts and Sciences and the American Academy of Microbiology. He is a past president of the American Society for Virology and past president of the American Society for Microbiology, and has published more than 225 scientific papers in various journals. Dr. Shenk is also a member of the boards of directors of Merck & Co., Inc. and Cell Genesys, Inc. Dr. Shenk, who trained as a postdoctoral fellow in molecular biology at Stanford Medical Center, received his B.S. in biology from the University of Detroit and his Ph.D. in microbiology from Rutgers University.

Executive Officers

The names of our chief executive officer and each of our other executive officers as of the end of the last fiscal year, and their ages as of January 31, 2006 are as follows:

Name	Age	Position
Louis G. Lange, M.D., Ph.D.	57	Chairman of the Board, Chief Executive Officer and Chief Science Officer
Daniel K. Spiegelman	47	Senior Vice President and Chief Financial Officer
Brent K. Blackburn, Ph.D.	45	Senior Vice President, Drug Discovery and Development
David McCaleb	52	Senior Vice President, Commercial Operations
Tricia Borga Suvari, Esq.	45	Vice President, General Counsel and Assistant Secretary

Daniel K. Spiegelman has served as our Senior Vice President and Chief Financial Officer since September 1999. From January 1998 to September 1999, Mr. Spiegelman served as our Vice President and Chief Financial Officer. From 1991 until 1998, Mr. Spiegelman was employed by Genentech, Inc., a biotechnology company, holding various positions in the Treasury department, including the position of Treasurer from 1996 to 1998. Mr. Spiegelman is a member of the board of directors of Xcyte Therapies, Inc. Mr. Spiegelman holds a B.A. in Economics from Stanford University and an M.B.A. from Stanford Graduate School of Business.

Brent K. Blackburn, Ph.D., has served as our Senior Vice President, Drug Discovery and Development since January 2004. From January 2002 until January 2004, Dr. Blackburn served as our Senior Vice President, Drug Discovery and Pre-Clinical Development. From June 2000 until January 2002, Dr. Blackburn served as our Vice President, Drug Discovery and Pre-Clinical Development. From September 1997 until June 2000, Dr. Blackburn served as our Vice President, Developmental Research. From 1989 until 1997, Dr. Blackburn served in the Research Department at Genentech, Inc., a biotechnology company. From 1993 to 1997, Dr. Blackburn also served as the project team leader for the oral GPII(b)III(a) antagonist project, a cardiovascular product, in the Development Department at Genentech. Dr. Blackburn holds a B.S. in Chemistry from Texas Christian University and a Ph.D. in Chemistry from the University of Texas at Austin.

David C. McCaleb has served as our Senior Vice President, Commercial Operations since 2005. From October 1999 to 2005, he served as our Vice President, Marketing. From 1997 to October 1999, he served as our senior marketing advisor. In 1994, Mr. McCaleb founded McCaleb Associates, a private biotechnology consulting firm, and has served as its President since that time. In this capacity, in addition to consulting for CV Therapeutics, he served as senior marketing advisor to a number of other leading biotechnology companies, including Gilead Sciences, Inc. and Cephalon, Inc. From 1988 until 1994, Mr. McCaleb held several marketing positions at Amgen, Inc., a biotechnology company. From 1986 until 1988, Mr. McCaleb was marketing manager for respiratory pharmaceuticals at Forest Laboratories. Mr. McCaleb held various sales and marketing positions in the cardiology field at Merck & Co. from 1981 until 1986. Mr. McCaleb holds a B.S. and an M.B.A. from Arizona State University and an M.S. in biology from Marquette University.

Tricia Borga Suvari, Esq., has served as our Vice President, General Counsel and Assistant Secretary since May 2000. From 1991 until 2000, Ms. Suvari was employed by Genentech, Inc., a biotechnology company,

holding various positions in the legal department. From 1988 until 1991, Ms. Suvari was employed by the law firm Irell & Manella LLP in Los Angeles. Ms. Suvari holds a B.S. in Geology and Geophysics from Yale College and a J.D. from Harvard Law School.

See "Directors" above for a brief description of the educational background and business experience of Dr. Lange.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the Securities and Exchange Commission ("SEC") initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than 10% stockholders are required by the SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended December 31, 2005, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with, except that Dr. Costa G. Sevastopoulos, a director of CV Therapeutics until May 2005, did not timely file a Form 4 for a transaction occurring in April, 2005, but such Form 4 was subsequently filed.

Board Independence and Committees

Our board of directors has determined that all of the members of the board of directors, other than Dr. Lange, are "independent" as that term is defined in the Nasdaq Marketplace Rules. Dr. Lange is not considered independent because he is an executive officer of CV Therapeutics. In addition, our board of directors has determined that each member of the Audit Committee also satisfies the independence requirements of Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The board of directors has an Audit Committee, a Compensation Committee and a Nominating and Governance Committee. The board of directors has adopted a charter for each of the three standing committees and copies of the charters for the Audit Committee and the Nominating and Governance Committee are available in the Investor Relations section of our website at www.cvt.com.

Audit Committee

The primary purpose of the Audit Committee is to oversee our accounting and financial reporting processes and the audits of our financial statements. The Audit Committee acts pursuant to a written charter that has been adopted by our board of directors. During the fiscal year ended December 31, 2005, the Audit Committee was composed of three (3) non-employee directors, Messrs. Gutshall and Lee and Dr. McNeil. Mr. Lee served as Chair. The board of directors has determined that all members of the Audit Committee are "independent" as that term is defined in Rule 4200(a)(15) of the National Association of Securities Dealers' listing standards. The board of directors has further determined that Mr. Lee is an "audit committee financial expert" as defined by Item 401(h) of Regulation S-K of the Securities Act of 1933, as amended (the "Securities Act").

Compensation Committee

The Compensation Committee determines salaries and incentive compensation, grants stock awards to executive officers and employees under our equity plans, and otherwise determines compensation levels and performs such other functions regarding compensation as the board of directors may delegate. From January 1, 2005 through April 1, 2005, the Compensation Committee was composed of three (3) non-employee directors, Messrs. Groom and Costa and Dr. Sevastopoulos. Dr. Sevastopoulos served as Chair. Following the resignation of Dr. Sevastopoulos from our board of directors, Mr. Costa served as Chair. From April 1, 2005 through

November 30, 2005, the Compensation Committee was composed of three (3) non-employee directors, Messrs. Groom, Costa and Lee. Mr. Costa served as Chair. Following the resignation of Mr. Groom from our board of directors, from December 1, 2005 through December 31, 2005, the Compensation Committee was composed of two (2) non-employee directors, Messrs. Costa and Lee. Mr. Costa served as Chair. The board of directors has determined that all of the members of the Compensation Committee are "independent" as defined in the Nasdaq Marketplace Rules.

Nominating and Governance Committee

The Nominating and Governance Committee establishes qualification standards for board of directors membership, identifies qualified individuals for board of directors membership, considers and recommends director nominees for approval by the board of directors and the stockholders and oversees the administration of bylaw provisions relating to stockholder recommendations for director nominees. The Nominating and Governance Committee considers suggestions from many sources, including stockholders, regarding possible candidates for director. The Nominating and Governance Committee also monitors the independence of members of the board of directors under Nasdaq and SEC standards, oversees the board of directors' annual self-evaluation and oversees and approves the membership of the boards of directors of our subsidiaries. From January 1, 2005 through May 26, 2005, the Nominating and Governance Committee was composed of two (2) non-employee directors, Mr. Costa and Dr. McNeil, with Mr. Costa serving as Chair from January 1, 2005 through May 26, 2005, and Dr. McNeil serving as Chair from May 26, 2005 through December 31, 2005. From November 30, 2005 through December 31, 2005, the Nominating and Governance Committee was composed of two (2) non-employee directors, Drs. Shenk and McNeil. The board of directors has determined that each member of the Nominating and Governance Committee is "independent" as defined in the Nasdaq Marketplace Rules.

Code of Ethics

We have adopted a written code of ethics that applies to all of our employees and to our Board of Directors. A copy of our code of ethics is available in the Investor Relations section of our website at *www.cvt.com*.

Item 11. Executive Compensation

Director Compensation

During the fiscal year ended December 31, 2005, our non-employee directors received an annual retainer of $10,000 and a payment of $5,000 per meeting for each of the regularly scheduled meetings of the board attended (or $500 if attendance was by telephone). Members of the Audit, Compensation and Nominating and Governance Committees receive an additional annual retainer of $5,000 for each committee on which the member serves, except that the chair of each of the Audit, Compensation and Nominating and Governance Committees receives an additional annual retainer of $10,000. Directors are also reimbursed for reasonable expenses in connection with attendance at board and committee meetings. For each board member, the aggregate total annual retainer owed to such board member is paid in quarterly installments each year. Dr. Lange is not separately compensated for his services as a director.

Historically, each of our non-employee directors received stock option grants to purchase shares of common stock under our Non-Employee Directors' Stock Option Plan (the "Directors' Plan"). No options were granted under this plan during the fiscal year ended December 31, 2005.

In April 2005, we terminated our Directors' Plan and approved our Non-Employee Director Equity Compensation Policy (the "Director Equity Policy"), under which non-employee directors automatically receive grants of stock awards under our 2000 Equity Incentive Plan. However, options outstanding at the time of such termination remain outstanding under our Directors' Plan.

Under our Director Equity Policy, all non-employee directors are to receive option grants on the same terms and conditions as those previously set forth in our Directors' Plan. Specifically, commencing after our 2005 Annual Meeting held on May 26, 2005, and with respect to each annual meeting of stockholders at which directors are elected thereafter, each non-employee director initially elected to be a non-employee director by our board of directors or stockholders shall, upon such initial election, automatically be awarded an option to purchase 25,000 shares of the common stock with an exercise price equal to one hundred percent (100%) of the fair market value on the date of grant (the "Initial Option"). Additionally, commencing with our 2005 Annual Meeting held on May 26, 2005, and with respect to each annual meeting of stockholders at which directors are elected thereafter, each existing non-employee director shall automatically be awarded an option to purchase 7,500 shares of common stock (the "Annual Replenishment Option") with an exercise price equal to one hundred percent (100%) of the fair market value on the date of grant.

Each Initial Option and Annual Replenishment Option shall be a nonstatutory stock option subject to the terms and conditions of the 2000 Equity Incentive Plan. Each Initial Option shall vest at the rate of 1/36th per month over thirty six (36) months from the date of grant of the Initial Option, and each Annual Replenishment Option shall vest at the rate of 1/12th per month over twelve (12) months from the date of grant. Furthermore, Initial Options and Annual Replenishment Options shall vest only during the optionholder's Continuous Service (as defined in the Incentive Plan); provided, however, that our Compensation Committee has the power to accelerate the time during which an option may vest or be exercised.

Initial Options and Annual Replenishment Options will terminate upon the earlier of (i) ten (10) years after the date of grant or (ii) six (6) months after the date of termination of the optionholder's Continuous Service (or such longer or shorter period as the Compensation Committee may specify), or, if the termination of Continuous Service is due to the optionholder's death, eighteen (18) months after the date of the optionholder's death by the person or persons to whom the rights to such option pass by will or by the laws of descent and distribution (or such longer or shorter period as the Compensation Committee may specify).

Under our 2000 Equity Incentive Plan, during the fiscal year ended December 31, 2005, Annual Replenishment options to acquire 7,500 shares of common stock at an exercise price of $19.91 per share were granted to each non-employee member of the board. Dr. Sevastopoulos did not receive an Annual Replenishment Option, as he resigned from our board of directors in May 2005 prior to our 2005 annual meeting of stockholders. In April 2005, Dr. Sevastopoulos was appointed as a director of CV Therapeutics Europe Limited, our wholly owned subsidiary. In connection with his appointment as a director of CV Therapeutics Europe Limited, Dr. Sevastopoulos received a grant of 5,000 shares of common stock with an exercise price equal to one hundred percent (100%) of the fair market value on the date of grant. Mr. Groom resigned from our board of directors in December 2005. Prior to his resignation, Mr. Groom was appointed as a director of CV Therapeutics Europe Limited. In connection with his appointment as a director of CV Therapeutics Europe Limited, Mr. Groom received a grant of 5,000 shares of common stock with an exercise price equal to one hundred percent (100%) of the fair market value on the date of grant.

In April 2005, in connection with Dr. Sevastopoulos' service on the board of directors of CV Therapeutics Europe Limited, our board of directors amended the following three stock options that had been granted to Dr. Sevastopoulos under the Directors' Plan: an option grant dated May 16, 2000 for 7,500 shares of our common stock with an exercise price of $37.125 per share; an option grant dated May 29, 2001 for 7,500 shares of our common stock with an exercise price of $49.00 per share; and an option grant dated May 22, 2003 for 7,500 shares of our common stock with an exercise price of $23.94 per share. In November 2005, in connection with Mr. Groom's service on the board of directors of CV Therapeutics Europe Limited, our board of directors amended an option grant dated May 29, 2001 for 25,000 shares of our common stock with an exercise price of $49.00 per share that had been granted to Mr. Groom under the Directors' Plan. The three amended options for Dr. Sevastopoulos and the one amended option for Mr. Groom were amended to provide for continued exercisability of the options for so long as the optionee continues to provide continuous and uninterrupted service as an employee, consultant or director of CV Therapeutics or an affiliate (as such term is defined in the

Directors' Plan) of CV Therapeutics, even if his service as a non-employee director on our board of directors has ended. The amendment of Dr. Sevastopoulos' options further provided that each of the options shall terminate on the earlier of (i) the expiration date of such option or (ii) the date that is six (6) months following the date of termination of his continuous service as an employee, consultant or director of CV Therapeutics or an affiliate of CV Therapeutics. The amendment of Mr. Groom's option further provided that the option shall terminate on the earliest of (i) the expiration date of such option, (ii) the date that is six (6) months following the date of termination of his continuous service as an employee, consultant or director of CV Therapeutics or an affiliate of CV Therapeutics or (iii) December 31, 2006. All other terms of the amended options remained unchanged.

Compensation of Executive Officers

The following table sets forth, for the fiscal years ended December 31, 2003, 2004 and 2005, certain compensation awarded or paid to, or earned by, our chief executive officer and each of our other four most highly compensated executive officers as of the end of the last fiscal year, including salary, bonuses, stock options, restricted stock units ("RSUs") and certain other compensation. We refer to these individuals elsewhere as the "named executive officers."

Summary Compensation Table

		Annual Compensation			Long-Term Compensation	
Name and Principal Position	**Year**	**Salary (1)($)**	**Bonus ($)(2)**	**Other Annual Compensation (3)($)**	**Securities Underlying Options/RSUs (#)(4)**	**All Other Compensation ($)**
Louis G. Lange, M.D., Ph.D.	2005	$600,000	$525,000	$ –	325,000	$14,000(6)
Chairman of the Board, Chief	2004	475,000	525,000	–	–	13,000(7)
Executive Officer and Chief	2003	440,000	250,000	43,750(5)	175,000	10,000(8)
Science Officer						
Daniel K. Spiegelman	2005	300,000	165,000	–	60,000	14,000(6)
Senior Vice President and Chief	2004	267,500	160,000	–	–	13,000(7)
Financial Officer	2003	260,000	75,000	20,000(5)	75,000	10,000(8)
Brent K. Blackburn, Ph.D.	2005	300,000	165,000	–	60,000	14,000(6)
Senior Vice President, Drug	2004	272,500	160,000	–	–	13,000(7)
Discovery and Development	2003	247,500	80,000	16,000(5)	75,000	10,000(8)
David McCaleb	2005	253,000	125,000	20,000(5)	60,000	14,000(6)
Senior Vice President, Commercial	2004	240,000	120,000	20,000(5)	–	13,000(7)
Operations	2003	221,500	60,000	20,000(5)	60,000	10,000(8)
Tricia Borga Suvari, Esq.	2005	274,000	120,000	–	60,000	14,000(6)
Vice President, General Counsel	2004	234,487	120,000	–	–	13,000(7)
and Assistant Secretary	2003	225,000	60,000	–	50,000	10,000(8)

(1) Includes amounts earned but deferred at the election of the executive, such as salary deferrals under our 401(k) Plan.

(2) These bonus amounts do not include any amounts attributable to our Long-Term Incentive Plan, whose participants include named executive officers. Our Long-Term Incentive Plan does not presently permit individual participants to elect to defer any of their compensation; however, the company may make contributions to the Long-Term Incentive Plan with the approval of our board of directors. To date, the only contribution to the Long-Term Incentive Plan was a company contribution in 2003. With respect to any company contribution under the Long-Term Incentive Plan, each participant's individual contribution amount is subject to vesting based on continued service to the company, in accordance with the following schedule: 10% vests on the one-year anniversary of the date the company contribution is credited; 20% vests

on the two-year anniversary of the date the company contribution is credited; and 70% vests on the three-year anniversary of the date the company contribution is credited. All company contributions are distributable only upon certain specified future events pursuant to the terms of the Long-Term Incentive Plan. In the case of the 2003 company contribution, 10% vested in January 2004, 20% vested in January 2005 and 70% vested in January 2006, subject to continued service with the company. With respect to each of the following named executive officers, such officer's account vested in the following respective amounts under our Long-Term Incentive Plan in January 2005: $54,000 for Dr. Lange, $27,000 for Mr. Spiegelman, $25,000 for Dr. Blackburn, $21,000 for Mr. McCaleb, and $21,000 for Ms. Suvari.

(3) As permitted under rules promulgated by the SEC, no amounts are shown for any named executive officer with respect to certain "perquisites" (such as imputed interest on loans at or below market value rates), where such amounts do not exceed the lesser of (i) ten percent (10%) of the sum of the amounts of Salary and Bonus for the named executive officer or (ii) $50,000.

(4) In addition to the options and RSU awards listed in the Summary Compensation Table, each named executive officer also received a grant of a stock appreciation right ("SAR") in January 2005. These SAR grants are described in detail below under "Option Grants in Last Fiscal Year", and in note 10 to our consolidated financial statements for the fiscal year ended December 31, 2005. These SAR grants are not included in this table because payments under the SAR awards may be settled in cash, common stock or other property, and because the number of shares of our common stock underlying the SAR awards cannot be calculated.

(5) Consists of loan amounts forgiven pursuant to the terms of a loan in effect as of July 30, 2002, the effective date of the Sarbanes-Oxley Act of 2002.

(6) Consists of our matching contribution under the 401(k) Plan for 2005. For 2005, we made a discretionary matching contribution to all eligible participants in our 401(k) Plan in the form of cash and shares of common stock. All eligible participants in the 401(k) Plan were allocated this matching contribution on January 9, 2006, with the number of shares being allocated to participants' accounts based on the closing price of the common stock on that date ($25.11 per share). Each of Dr. Lange, Mr. Spiegelman, Dr. Blackburn, Mr. McCaleb and Ms. Suvari received a matching contribution of 336 shares of common stock (with a value on the allocation date of $6,981 based on the price per share on such date) and $7,019 in cash.

(7) Consists of our matching contribution under the 401(k) Plan for 2004. For 2004, we made a discretionary matching contribution to all eligible participants in our 401(k) Plan in the form of cash and shares of common stock. All eligible participants in the 401(k) Plan were allocated this matching contribution on January 24, 2005, with the number of shares being allocated to participants' accounts based on the closing price of the common stock on that date ($19.31 per share). Each of Dr. Lange, Mr. Spiegelman, Dr. Blackburn, Mr. McCaleb and Ms. Suvari received a matching contribution of 336 shares of common stock (with a value on the allocation date of $6,488 based on the price per share on such date) and $6,512 in cash.

(8) Consists of our matching contribution under the 401(k) Plan for 2003. For 2003, we made a discretionary matching contribution to all eligible participants in our 401(k) Plan in the form of shares of common stock. All eligible participants in the 401(k) Plan were allocated this matching contribution on January 13, 2004, with the number of shares being allocated to participants' accounts based on the closing price of the common stock on that date ($14.67 per share). Each of Dr. Lange, Mr. Spiegelman, Dr. Blackburn, Mr. McCaleb and Ms. Suvari received a matching contribution of 681 shares of common stock (with a value on the allocation date of $10,000 based on the price per share on such date).

Option Grants in Last Fiscal Year

We presently grant options to our executive officers under our 2000 Equity Incentive Plan (the "Incentive Plan"), although in the past, we have granted options to our executive officers and other officers and employees under the 1992 Stock Option Plan (the "1992 Plan"), the 1994 Equity Incentive Plan (the "1994 Plan") and the 2000 Nonstatutory Incentive Plan. The 1992 Plan and the 1994 Plan terminated in May 2000 and the 2000 Nonstatutory Incentive Plan terminated in May 2004; however, options outstanding at the time of the termination if each plan remain outstanding. As of January 31, 2006, options to purchase an aggregate of 7,224,749 shares were outstanding under the Incentive Plan, the 2000 Nonstatutory Incentive Plan, the 1994 Plan and the 1992 Plan, and options to purchase 1,730,564 shares remained available for grant under the Incentive Plan. During the fiscal year ended December 31, 2005, grants of stock options, stock appreciation rights ("SARs") and RSUs were made to the named executive officers under our 2000 Equity Incentive Plan.

The following table provides information pertaining to grants of stock options, SARs and RSUs made to each of our named executive officers in 2005.

	Individual Grants							
	Securities Underlying Stock Options/RSUs/SARs Granted (#)			% of Total Options/RSUs Granted to Employees in Fiscal 2005 (%)(3)	Exercise Price Per Share ($)		Potential Realizable value at Assumed Annual Rates of Stock Price Appreciation for Option Term ($)(4)	
Name	Options (1)	RSUs	SARs (2)			Expiration Date	5%	10%
Louis G. Lange, M.D. Ph.D. . .	36,000	–	–	1.3%	$24.94(5)	December 5, 2015	$1,462,487	$2,328,766
	–	–	175,000	N/A	N/A(6)	January 3, 2009	N/A	N/A
	–	60,000(7)	–	2.2%	–(8)	January 3, 2009	677,399	2,020,458
	–	48,000(9)	–	1.7%	–(8)	December 5, 2009	455,107	1,752,703
	–	181,000(10)	–	6.5%	–(8)	December 22, 2009	541,967	6,675,403
Daniel K. Spiegelman	15,000	–	–	0.5%	24.94(5)	December 5, 2015	609,369	970,319
	–	–	75,000	N/A	N/A(6)	January 3, 2009	N/A	N/A
	–	25,000(7)	–	0.9%	–(8)	January 3, 2009	698,916	841,858
	–	20,000(9)	–	0.7%	–(8)	December 5, 2009	606,295	730,293
Brent K. Blackburn	15,000	–	–	0.5%	24.94(5)	December 5, 2015	609,369	970,319
	–	–	75,000	N/A	N/A(6)	January 3, 2009	N/A	N/A
	–	25,000(7)	–	0.9%	–(8)	January 3, 2009	698,916	841,858
	–	20,000(9)	–	0.7%	–(8)	December 5, 2009	606,295	730,293
David C. McCaleb	15,000	–	–	0.5%	24.94(5)	December 5, 2015	609,369	970,319
	–	–	75,000	N/A	N/A(6)	January 3, 2009	N/A	N/A
	–	25,000(7)	–	0.9%	–(8)	January 3, 2009	698,916	841,858
	–	20,000(9)	–	0.7%	–(8)	December 5, 2009	606,295	730,293
Tricia Borga Suvari, Esq. . . .	15,000	–	–	0.5%	24.94(5)	December 5, 2015	609,369	970,319
	–	–	75,000	N/A	N/A(6)	January 3, 2009	N/A	N/A
	–	25,000(7)	–	0.9%	–(8)	January 3, 2009	698,916	841,858
	–	20,000(9)	–	0.7%	–(8)	December 5, 2009	606,295	730,293

(1) Consists of options to purchase shares of our common stock granted on December 5, 2005. Each of the options vests in forty-eight (48) equal monthly installments beginning on the date of grant.

(2) The numbers presented in this column represent the number of SARs awarded, not the number of shares of common stock underlying the SAR awards. Twenty five percent (25%) of each SAR grant will be automatically exercised on the one (1)-year, two (2)-year, three (3)-year and four (4)-year anniversaries of the January 2005 grant date. For purposes of the SAR payout on the first anniversary of the grant date, the payment amount on the January 2006 settlement date equaled the excess of our stock price on the settlement date over the $26.45 base exercise price, with the potential payment amount capped at $30 per share. The Company's stock price is calculated based on the volume-weighted average price over the preceding one (1)-year measurement period prior to the automatic exercise date. The SARs may be settled, at our option, in cash, common stock or other property. In January 2006, the board of directors modified the SAR terms relating to the calculation of compensation under the SARs for purposes of settlement on the second, third and fourth anniversaries of the January 2005 grant date, although the other terms of the SAR remain unchanged.

(3) Based on an aggregate of approximately 2,789,000 options and RSUs granted during 2005 to our employees, non-employee directors and consultants, including options and RSUs granted to our named executive officers. As the SAR awards may be settled, at our option, in cash, common stock or other property, there are no shares reserved against future settlement of the SARs. As a result, we have entered "N/A" for each SAR award in this column.

(4) The 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by rules of the SEC. There can be no assurance provided to any executive office or any other holder of our securities that the actual stock price appreciation over the 10-year

option term will be at the assumed 5% and 10% levels or at any other defined level. Unless the market price of the common stock appreciates over the option term, no value will be realized from the option grants made to the executive officers. RSUs are valued using a 4-year term.

(5) Options are granted at an exercise price equal to the closing market price per share on the day before the date of grant.

(6) SAR recipients are not required to pay an exercise price upon exercise of the SAR. Instead, when the SAR vests, the SAR recipient will receive compensation, if any, calculated with reference to the SAR's base value, which is a predetermined price of $26.45, representing a 15% premium to the market price on the grant date.

(7) Vests in forty-eight (48) equal monthly installments beginning on the date of grant, except that vesting will accelerate if CV Therapeutics satisfies a performance milestone relating to the achievement of product revenues. Distribution of vested shares of common stock will occur on the two (2)-year, three (3)-year and four (4)-year anniversaries of the January 2005 grant date.

(8) There is no exercise price for these RSU grants. Upon payout, the named executive officer is entitled to receive one (1) share of common stock for each one (1) RSU.

(9) Vests in forty-eight (48) equal monthly installments beginning on the date of grant. Distribution of vested shares of common stock will occur on the one (1)-year, two (2)-year, three (3)-year and four (4)-year anniversaries of the December 2005 grant date.

(10) 20,169 shares of this grant vested effective December 22, 2005; the remaining RSUs vest quarterly over four years starting on the date of grant. Distribution of vested shares of common stock will occur on the twelve (12) month anniversary of each vesting date.

As more fully described below under "Item 13—Certain Relationships and Related Transactions – Employment Agreement," on January 1, 2006, we granted Dr. Lange an RSU grant for 20,694 shares of our common stock.

Aggregate Option Exercises in Fiscal 2005 and December 31, 2005 Option Values

The following table sets forth information for any options exercised by each of the named executive officers during fiscal year 2005, and the number and value of securities underlying unexercised options held by each of the named executive officers at December 31, 2005:

Name	Shares Acquired on Exercise (#)	Value Realized ($)(1)	Number of Securities Underlying Unexercised Options at December 31, 2005 (2)		Value of Unexercised In-the-Money Options at December 31, 2005 (3)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Louis G. Lange, M.D., Ph.D. . .	–	–	652,000	183,500	$2,974,635	$1,165,375
Daniel K. Spiegelman	26,500	$423,160	237,500	77,500	633,475	502,775
Brent K. Blackburn, Ph.D. . . .	8,000	133,823	292,500	77,500	1,650,713	502,775
David McCaleb	–	–	277,100	61,000	1,807,473	396,140
Tricia Borga Suvari, Esq.	–	–	194,000	56,000	439,810	338,290

(1) Value realized is based on the fair market value of our common stock on the date of exercise minus the exercise price (or the actual sales price if the shares were sold by the optionee simultaneously with the exercise) without taking into account any taxes that may be payable in connection with the transaction.

(2) Reflects shares vested and unvested at December 31, 2005. Certain options granted under the Incentive Plan are immediately exercisable, but are subject to our right to repurchase unvested shares on termination of employment.

(3) Based on the fair market value of our common stock at December 31, 2005 ($24.73 per share) minus the exercise price of the options.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2005, the following individuals served on our Compensation Committee: Santo J. Costa, John Groom, Kenneth B. Lee, Jr. and Costa G. Sevastopoulos, Ph.D. There are and were no interlocking relationships between our board of directors or the Compensation Committee and the board of directors or compensation committee of any other company, nor has any such interlocking relationship existed in the past.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of January 31, 2006 by: (i) each stockholder who is known by us based on publicly available records to own beneficially more than five percent (5%) of our common stock; (ii) the named executive officers; (iii) each director; and (iv) all of our directors and executive officers, as a group. The address for each director and executive officer listed in the table below is c/o CV Therapeutics, Inc., 3172 Porter Drive, Palo Alto, California 94304.

Beneficial Owner	Shares Beneficially Owned(1)	
	Number	Percent of Total
FMR Corp.(2) 82 Devonshire Street Boston, Massachusetts 02109	5,005,000	11.14%
Wellington Management Company, LLP 75 State Street Boston, Massachusetts 02109	3,575,983	7.96%
Legg Mason Capital Management, Inc. 100 Light Street Baltimore, MD 21202	2,991,725	6.66%
Goldman, Sachs & Co. 85 Broad Street New York, NY 10004	2,507,621	5.58%
Mazama Capital Management, Inc. One S.W. Columbia, Suite 1500 Portland, Oregon 97258	2,396,308	5.34%
Delaware Management Holdings(3) 2005 Market Street Philadelphia, PA 19103	2,207,066	4.91%
Louis G. Lange, M.D., Ph.D.(4)	803,309	1.79%
Brent K. Blackburn, Ph.D.(5)	319,730	*
Santo J. Costa(6)	53,570	*
Joseph M. Davie, M.D., Ph.D.(7)	1,385	*
Thomas L. Gutshall(8)	91,461	*
Peter Barton Hutt, Esq.(9)	64,250	*
Kenneth B. Lee, Jr.(10)	54,325	*
David McCaleb(11)	295,417	*
Barbara J. McNeil, M.D., Ph.D.(12)	66,050	*
Thomas E. Shenk, Ph.D.(13)	17,666	*
Daniel K. Spiegelman(14)	253,965	*
Tricia Borga Suvari, Esq.(15)	212,710	*
All directors and executive officers as a group (12 persons)(16)	2,233,838	4.95%

* Represents beneficial ownership of less than one percent (1%).

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Beneficial ownership also includes shares of stock subject to options and warrants currently exercisable or convertible, or exercisable or convertible within sixty (60) days of January 31, 2006 (or April 1, 2006). Except as indicated by footnote, and subject to community property laws where applicable, to our knowledge, all persons named in the table above have sole voting and investment power with respect to all shares of common stock shown as beneficially owned

by them. The percentages of beneficial ownership are based on 44,918,898 shares of common stock outstanding as of January 31, 2006, adjusted as required by rules promulgated by the SEC. For purposes of computing the percentage of outstanding shares held by each person or group of persons named above on a given date, any shares which such person or persons has the right to acquire within sixty (60) days after such date are deemed to be outstanding, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person.

(2) Fidelity Management & Research Company, a wholly-owned subsidiary of FMR Corp. and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940, is the beneficial owner of 5,005,000 shares, or 11.14% of our outstanding common stock as a result of acting as investment adviser to various investment companies registered under Section 8 of the Investment Company Act of 1940. The ownership of one investment company, Fidelity Growth Company Fund, amounted to 4,472,000 shares, or 10.00% of the common stock outstanding. Fidelity Growth Company Fund has its principal business office at 82 Devonshire Street, Boston, Massachusetts 02109. Edward C. Johnson III, FMR Corp., through its control of Fidelity, and the funds each have sole power to dispose of the 5,005,000 shares owned by the funds. Neither FMR Corp. nor Edward C. Johnson III, Chairman of FMR Corp., has the sole power to vote or direct the voting of the shares owned directly by the funds, which power resides with the funds' Boards of Trustees. Fidelity carries out the voting of the shares under written guidelines established by the funds' Boards of Trustees. Members of the Edward C. Johnson III family are the predominant owners of Class B shares of common stock of FMR Corp., representing approximately 49% of the voting power of FMR Corp. The Johnson family group and all other Class B shareholders have entered into a shareholders' voting agreement under which all Class B shares will be voted in accordance with the majority vote of Class B shares. Accordingly, through their ownership of voting common stock and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR Corp.

(3) Lincoln National Corp. is the ultimate parent of Delaware Management Holdings.

(4) Includes 682,687 shares issuable upon the exercise of options as of April 1, 2006. Also includes 7,500 shares held in The Louis Lange Family Trust and 2,500 shares held by minors in Dr. Lange's household. Dr. Lange disclaims beneficial ownership of the shares held in The Louis Lange Family Trust, except to the extent of his pecuniary interests therein.

(5) Includes 305,624 shares issuable upon the exercise of options as of April 1, 2006.

(6) Represents 53,750 shares issuable upon the exercise of options as of April 1, 2006.

(7) Represents 1,388 shares issuable upon the exercise of options as of April 1, 2006.

(8) Includes 76,750 shares issuable upon the exercise of options as of April 1, 2006. Also includes 3,997 shares held in the Gutshall Family Trust DTD 3-7-90.

(9) Includes 61,250 shares issuable upon the exercise of options as of April 1, 2006.

(10) Includes 53,750 shares issuable upon the exercise of options as of April 1, 2006.

(11) Includes 286,787 shares issuable upon the exercise of options as of April 1, 2006.

(12) Includes 55,550 shares issuable upon the exercise of options as of April 1, 2006.

(13) Includes 16,666 shares issuable upon the exercise of options as of April 1, 2006.

(14) Includes 250,624 shares issuable upon the exercise of options as of April 1, 2006.

(15) Includes 203,062 shares issuable upon the exercise of options as of April 1, 2006.

(16) Includes 2,055,888 shares issuable upon the exercise of options held by all directors and executive officers as of April 1, 2006. See footnotes (4)–(15).

Equity Compensation Plan Information

We have two equity compensation plans that have been approved by our stockholders: the 2000 Equity Incentive Plan and the Employee Stock Purchase Plan. We have had two equity compensation plans that have not been approved by our stockholders: the 2000 Nonstatutory Incentive Plan and the 2004 Employment Commencement Incentive Plan. The 2000 Nonstatutory Incentive Plan was adopted before the current rules requiring stockholder approval of all equity plans went into effect, and was terminated in May 2004 as to any further grants thereunder. The 2004 Employment Commencement Incentive Plan was approved by our board of directors in December 2004 to provide for the grant of stock awards which are intended to be stand-alone inducement awards as permitted pursuant to NASDAQ Marketplace Rule 4350(i)(1)(A)(iv). Only newly hired employees who have not previously been an employee or director of the company or an affiliate, or following a bona fide period of non-employment by the company or an affiliate, are eligible to participate in the 2004 Employment Commencement Incentive Plan. The following table sets forth the number and weighted-average exercise price of securities to be issued upon exercise of outstanding options and RSUs and the number of securities remaining available for future issuance under all of our equity compensation plans, at December 31, 2005:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights ($)(1)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Security Holders(2)	4,519,415	$28.05	2,114,155
Equity Compensation Plans Not Approved by Security Holders	4,055,016	$25.54	43,900
Total	8,574,431		2,158,055

(1) Represents weighted average exercise price for options only. There is no exercise price for our RSU grants.

(2) Information for our Employee Stock Purchase Plan is included in the "Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans" column only.

For a brief description of the material features of all of our equity compensation plans, please see note 10 to our consolidated financial statements for the fiscal year ended December 31, 2005.

Item 13. Certain Relationships and Related Transactions

Loans

The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") prohibits all loans to executive officers and directors of a public company and also prohibits any material modifications to loans outstanding at the time of enactment of the Sarbanes-Oxley Act on July 30, 2002. At the time of the enactment of the Sarbanes-Oxley Act, we had loans outstanding to Drs. Lange and Blackburn, and to Messrs. Spiegelman and McCaleb, under arrangements put in place before the enactment of such legislation. All loan arrangements between us and Drs. Lange and Blackburn and Mr. Spiegelman have been concluded, and as disclosed below the loan arrangement between us and Mr. McCaleb was concluded in January 2005. As a result there are no outstanding loan arrangements between us and any of our executive officers. In accordance with such legislation, we will not provide any new loans to directors or executive officers.

In February 2000, the Company made a loan to Mr. McCaleb in the principal amount of $100,000 at an annual interest rate of six and twenty-one one-hundredths (6.21%) pursuant to a promissory note secured by deed of trust on Mr. McCaleb's residence. In January 2005, the remaining outstanding principal balance of $20,000 was forgiven in accordance with the loan terms. As a result, there are no outstanding loan arrangements between the Company and Mr. McCaleb.

Executive Severance Benefits Agreements

We entered into executive severance agreements approved by our board of directors with each of Drs. Lange, Blackburn and Mr. Spiegelman in February 1999, with Mr. McCaleb in October 1999 and with Ms. Suvari in August 2000. Subsequently, in November 2002 our board of directors approved amended executive severance benefits agreements with each of the named executive officers, and also approved new executive severance benefits agreements with additional non-executive officers as well as a severance plan covering all of our full-time employees. In addition, in September 2005 our board of directors approved amended and restated executive severance benefits agreements with Mr. McCaleb and Ms. Suvari, and also approved new executive severance benefit agreements with additional non-executive officers. Dr. Lange's executive severance agreement was terminated in connection with the employment agreement he entered into in December 2005, as described more fully below.

Under the amended agreements with Dr. Blackburn and Mr. Spiegelman and under the amended and restated agreements with Mr. McCaleb and Ms. Suvari, in connection with a change of control of the company, all of the executive's then-outstanding options will become immediately and fully vested and exercisable, subject to the terms of the agreement. In addition, if the executive's employment with us is terminated without cause or the executive is constructively terminated within thirteen (13) months following a change of control of the company, the executive is entitled to receive the following additional severance benefits subject to the terms of the agreement: a payment equal to eighteen (18) months of such executive's base salary at the time of termination; a payment equal to one hundred and fifty percent (150%) percent of such executive's annual bonus (if any) in the year prior to the change in control; continued health benefits for eighteen (18) months following termination; and in the event that any benefits would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, as amended, an additional gross-up payment sufficient to cover all excise taxes (including any interest or penalties) on such benefits as well as all federal, state and local taxes and excise taxes (including any interest or penalties) on the gross-up payment itself.

Employment Agreement

In December 2005, we entered into an employment agreement with Dr. Lange. The employment agreement supersedes Dr. Lange's previous severance agreement and any other agreement Dr. Lange entered into with us relating to severance benefits. The employment agreement provides that Dr. Lange will serve as our Chairman of the Board, Chief Executive Officer and Chief Science Officer.

Dr. Lange's minimum base salary pursuant to the employment agreement is $624,000 per year effective January 1, 2006, and, based on periodic review by our Compensation Committee of Dr. Lange's base salary in relation to comparator and peer groups and in relation to his performance, may be increased by the Compensation Committee from time to time. The Compensation Committee shall review and set Dr. Lange's annual bonus compensation in relation to comparator and peer groups and in relation to CV Therapeutics' and his performance, with the target annual bonus established by our board of directors to be no less favorable than the target annual bonus for Dr. Lange as of the December 2005 effective date of the employment agreement. In connection with the execution of the employment agreement, on December 22, 2005, we granted Dr. Lange an RSU grant for 181,000 shares of our common stock, and on January 1, 2006, we granted Dr. Lange an RSU grant for 20,694 shares of our common stock. 20,169 shares of common stock underlying the December 22, 2005 RSU grant vested on the grant date. The remaining 160,831 shares of common stock underlying the December 22, 2005 RSU grant will vest with respect to 5.54% of the shares of common stock underlying such grant, and all of the shares of common stock underlying the January 1, 2006 RSU grant will vest with respect to 5.625% of the shares of common stock underlying such grant, in either case, at the end of each three-month period commencing on the respective grant date, so as to be 100% vested on the fourth anniversary of the respective grant date provided that Dr. Lange remains in continuous employment with us through each vesting date.

The employment agreement has an eight-year term, provided that either we or Dr. Lange may terminate Dr. Lange's employment at any time and for any reason. In the event of such a termination by us without "cause"

or by Dr. Lange for "good reason" (including a termination by reason of Dr. Lange's death or disability), we are required to make a severance payment to Dr. Lange in the amount of 200% of his base salary, 200% of his average annual bonus (with such average annual bonus to be calculated based on the annual bonuses received by Dr. Lange in the three full calendar years prior to the year in which such termination occurs), and a pro rata amount of his target annual bonus for the year in which such termination occurs. We will also continue to pay health benefit premiums for Dr. Lange and his family for 18 months (or, if such termination occurs within 18 months following a change of control, 24 months) following such termination. In addition, in connection with any such termination, all of Dr. Lange's outstanding options to purchase common stock will vest in full, his RSU grants will continue to vest for an additional twelve months and the time during which Dr. Lange may exercise certain of his options will be extended. We are obligated to make a gross-up payment to Dr. Lange in the event that the severance payment is subject to excise taxes.

Under Dr. Lange's employment agreement, effective December 2005, Dr. Lange is entitled to receive from the Company reimbursement for all expenses reasonably incurred by him in connection with the performance of his duties; a monthly allowance of $1,000 for the use of an automobile; reimbursement for financial, legal and IT support and assistance expenses of up to $25,000 annually; supplemental long-term disability insurance providing no less than $10,000 per month in additional coverage; and reimbursement for reasonable attorney's fees incurred by him in connection with the negotiation of the employment agreement, not to exceed $30,000.

Following Dr. Lange's employment with the Company and until he reaches the age of 70, our board of directors will look favorably upon nominating Dr. Lange for continued service as a member of our board of directors and will give serious consideration to having Dr. Lange remain as the Chairman of the Board.

Ernst & Young LLP

Kenneth B. Lee, Jr., who was appointed to the board of directors and the Audit Committee of the board of directors in January 2002, was a partner at Ernst & Young LLP until December 31, 2001. Ernst & Young LLP has audited our consolidated financial statements since our inception and has been selected by the board of directors as our independent auditor for the fiscal year ended December 31, 2005. While at Ernst & Young LLP, Mr. Lee was the partner in charge of auditing our financial statements prior to 1995. Prior to appointing Mr. Lee to the board of directors and to the Audit Committee, the board of directors determined that Mr. Lee's prior relationship with Ernst & Young LLP would not hinder their respective independence or ability to act in the best interests of the company and its stockholders, Mr. Lee's ability to serve on the board of directors and the Audit Committee, or Ernst & Young LLP's ability to serve as our independent auditor. In addition, the board has determined that Mr. Lee satisfies the independence requirements for board members under Rule 4200(a)(15) of the National Association of Securities Dealers' listing standards, and also satisfies the independence requirements for members of the Audit Committee under Rule 10A-3(b)(1) of the Securities and Exchange Act of 1934, as amended.

Item 14. Principal Accounting Fees and Services

The following table sets forth the aggregate fees billed or to be billed by Ernst & Young LLP for the following services during fiscal 2004 and 2005:

Description of Services	2004 Fees	2005 Fees
Audit fees(1)	$645,682	$803,232
Audit-related fees(2)	$ 21,597	$ 22,500
Tax fees(3)	$ 60,764	$ 72,594
All other fees(4)	$ 2,224	$ 3,460
Total	$730,226	$899,685

In accordance with the Audit Committee charter, the Audit Committee's policy is to pre-approve all audit and non-audit services provided by the independent auditor, including the estimated fees and other terms of any such engagement. These services may include audit services, audit-related services, tax services and other services. Any pre-approval is detailed as to the particular service or category of services and is subject to a specific budget. The Audit Committee may elect to delegate pre-approval authority to one or more designated committee members in accordance with its charter. The Audit Committee considers whether such audit or non-audit services are consistent with the SEC's rules on auditor independence.

(1) **Audit Fees:** represent the aggregate fees billed or to be billed for professional services rendered for the audits of our annual consolidated financial statements and for internal control over financial reporting and for the review of the financial statements included in our quarterly reports during such period, or for services that are normally provided by the independent auditor in connection with statutory and regulatory filings or engagements, for example, in 2004 and 2005 fees for review of registration statements on Form S-8, convertible debt offering services, review of registration statements on Form S-3 and amendments to such registration statements. 100% of these services for 2005 and 2004 were pre-approved by the Audit Committee.

(2) **Audit-Related Fees:** represent the aggregate fees billed or to be billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements but that are not included as Audit Fees, for example, fees for the audit of our 401(k) plan in 2004 and 2005. 100% of these services for 2005 and 2004 were pre-approved by the Audit Committee.

(3) **Tax Fees:** represent the aggregate fees billed or to be billed for professional services rendered for tax compliance (e.g., 2004 Ohio return, 2005 UK tax return), tax advice and tax planning. 100% of these services for 2005 and 2004 were pre-approved by the Audit Committee.

(4) **All Other Fees:** represent the aggregate fees billed for products and services other than audit, audit-related and tax fees. 100% of these services for 2005 and 2004 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Index to Financial Statements and Reports of Independent Registered Public Accounting Firm

The Consolidated Financial Statements required by this item are submitted in a separate section beginning on page 88 of this report.

(a)(2) Index to Financial Statements Schedules

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

(a)(3) Exhibits

Exhibit Number	
3.1	Amended and Restated Certificate of Incorporation of the Company (Filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, and incorporated herein by reference).
3.2	Amendment No. 1 to the Amended and Restated Certificate of Incorporation (Filed as Exhibit 4.2 to the Company's Registration Statement on Form S-3, File No. 333-53206, and incorporated herein by reference).
3.3	Restated Bylaws of the Company (Filed as Exhibit 3.5 to the Company's Registration Statement on Form S-1, File No. 333-12675, and incorporated herein by reference).
3.4	Certificate of Designation of Series A Junior Participating Preferred Stock dated February 2, 1999 (Filed as Exhibit 10.78 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2000, and incorporated herein by reference).
3.5	Certificate of Designation of Series A Junior Participating Preferred Stock dated February 23, 2004 (Filed as Exhibit 3.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003, and incorporated herein by reference).
4.1	Indenture between the Company and Norwest Bank Minnesota Company dated March 7, 2000 (Filed as Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the First Quarter 2000, and incorporated herein by reference).
4.2	Convertible subordinated note dated March 7, 2000 (Filed as Exhibit 10.73 to the Company's Quarterly Report on Form 10-Q for the First Quarter 2000, and incorporated herein by reference).
4.3	Indenture between the Company and Wells Fargo Bank, N.A. dated as of June 18, 2003 (Filed as Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2003, and incorporated herein by reference).
4.4	Form of 2.0% Senior Convertible Subordinated Debenture (Filed as Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2003, and incorporated herein by reference).

Exhibit Number	
4.5	Indenture between the Company and Wells Fargo Bank Minnesota, N.A. dated May 18, 2004 (Filed as Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2004, and incorporated herein by reference).
4.6	Form of 2.75% Senior Convertible Subordinated Note dated May 18, 2004 (Filed as Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2004, and incorporated herein by reference).
4.7	Warrant to Purchase Shares of Common Stock dated April 1, 2003 issued to The Wheatley Family Limited Partnership dba Matadero Creek, successor in interest to Jack R. Wheatley dba Matadero Creek (Filed as Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the First Quarter 2003, and incorporated herein by reference).
4.8	Amendment to Warrant to Purchase Shares of Common Stock entered into as of April 1, 2003 issued to The Wheatley Family Limited Partnership dba Matadero Creek, successor in interest to Jack R. Wheatley dba Matadero Creek and the Company (Filed as Exhibit 4.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003, and incorporated herein by reference).
4.9	Warrant to Purchase Shares of Common Stock dated July 9, 2003 issued to Qfinance, Inc. (Filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed by the Company on July 11, 2003, and incorporated herein by reference).
4.10	Warrant to Purchase Shares of Common Stock dated January 19, 2006 issued by the Company to The Wheatley Family Limited Partnership.
4.11	Warrant to Purchase Shares of Common Stock dated January 19, 2006 issued by the Company to The Board of Trustees of the Leland Stanford Junior University.
4.12	First Amended and Restated Rights Agreement dated July 19, 2000 between the Company and Wells Fargo Bank Minnesota, N.A. (Filed as Exhibit 10.77 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2000, and incorporated herein by reference).
4.13	Form of Right Certificate dated July 19, 2000 (Filed as Exhibit 10.79 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2000, and incorporated herein by reference).
4.14	Summary of Rights to Purchase Preferred Shares dated July 19, 2000 (Filed as Exhibit 10.80 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2000, and incorporated herein by reference).
4.15	Indenture, dated July 1, 2005 between the Company and Wells Fargo Bank, National Association, as Trustee (Filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed by the Company on July 6, 2005, and incorporated herein by reference).
4.16	Form of 3.75% Senior Subordinated Convertible Note dated July 1, 2005 (Filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed by the Company on July 6, 2005, and incorporated herein by reference).
10.1*	1992 Stock Option Plan, as amended (Filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1, File No 333-12675, and incorporated herein by reference).
10.2*	1994 Equity Incentive Plan, as amended (Filed as Exhibit 10.46 to the Company's Registration Statement on Form S-8, File No 333-44717, and incorporated herein by reference).
10.3	Amended and Restated Non-Employee Directors' Stock Option Plan (Filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the First Quarter 2005, and incorporated herein by reference).

Exhibit Number	
10.4*	Form of Restricted Stock Unit Agreement under the 2000 Equity Incentive Plan, as amended (Filed as Exhibit 4.9 to the Company's Registration Statement on Form S-8, File No 333-121328, and incorporated herein by reference).
10.5*	Form of Stock Appreciation Right Agreement under the 2000 Equity Incentive Plan.
10.6*	Form of Notice of Grant of Stock Option and Stock Option Terms and Conditions under the 2000 Equity Incentive Plan, as amended (Filed as Exhibit 4.11 to the Company's Registration Statement on Form S-8, File No 333-121328, and incorporated herein by reference).
10.7*	Employee Stock Purchase Plan, as amended (Filed as Exhibit 4.6 to the Company's Registration Statement on Form S-8, File No 333-109333, and incorporated herein by reference).
10.8*	Amended and Restated 2000 Equity Incentive Plan (Filed as Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004, and incorporated herein by reference).
10.9*	2000 Nonstatutory Incentive Plan, as amended (Filed as Exhibit 10.49 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).
10.10*	CV Therapeutics, Inc. Long-Term Incentive Plan (Filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2003, and incorporated herein by reference).
10.11*	2004 Employee Commencement Incentive Plan (Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed by the Company on December 16, 2004, and incorporated herein by reference).
10.12*	Amended and Restated Executive Severance Benefits Agreement between the Company and Louis G. Lange, dated December 31, 2002 (Filed as Exhibit 10.55 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).
10.13*	Employment Agreement dated as of December 22, 2005 between the Company and Louis G. Lange, M.D., Ph.D.
10.14*	Amended and Restated Executive Severance Benefits Agreement between the Company and Brent K. Blackburn, dated December 31, 2002 (Filed as Exhibit 10.56 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).
10.15*	Amended and Restated Executive Severance Benefits Agreement between the Company and Richard M. Lawn, dated December 31, 2002 (Filed as Exhibit 10.57 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).
10.16*	Amended and Restated Executive Severance Benefits Agreement between the Company and Daniel K. Spiegelman, dated December 31, 2002 (Filed as Exhibit 10.58 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).
10.17*	Amended and Restated Executive Severance Benefits Agreement between the Company and Tricia Borga Suvari, dated September 20, 2005 (Filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the Third Quarter 2005, and incorporated herein by reference).
10.18*	Amended and Restated Executive Severance Benefits Agreement between the Company and David C. McCaleb, dated September 20, 2005 (Filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the Third Quarter 2005, and incorporated herein by reference).
10.19*	CV Therapeutics, Inc. Change in Control Plan with Respect to Options and Severance (and Summary Plan Description) (Filed as Exhibit 10.61 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, and incorporated herein by reference).

Exhibit Number	
10.20*	Form of Indemnification Agreement between Company and its directors and officers (Filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1, File No. 333-12675, and incorporated herein by reference).
10.21	Lease Agreement between the Company and Matadero Creek, dated August 6, 1993 and addendum thereto; Letter Amendment to Lease Agreement, dated June 30, 1994 and Second Amendment to Lease Agreement, dated June 30, 1994 (Filed as Exhibit 10.25 to the Company's Registration Statement on Form S-1, File No. 333-12675, and incorporated herein by reference).
10.22	Third Amendment to Lease, dated February 16, 2001, between the Company and Jack R. Wheatley dba Matadero Creek (Filed as Exhibit 10.72 to the Company's Quarterly Report on Form 10-Q for the First Quarter 2001, and incorporated herein by reference).
10.23	Fourth Amendment to Lease, dated as of April 1, 2003, between the Company and The Wheatley Family Limited Partnership dba Matadero Creek, successor in interest to Jack R. Wheatley dba Matadero Creek (Filed as Exhibit 10.62 to the Company's Quarterly Report on Form 10-Q for the First Quarter 2003, and incorporated herein by reference).
10.24	Fifth Amendment to Lease, dated as of April 1, 2003, by and between the Company and the Wheatley Family Partnership, a California Limited Partnership dba Matadero Creek, successor in interest to Jack R. Wheatley dba Matadero Creek (Filed as Exhibit 10.63 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003, and incorporated herein by reference).
10.25	Sixth Amendment to Lease, dated as of December 22, 2004, by and between the Company and the Wheatley Family Partnership, a California Limited Partnership dba Matadero Creek, successor in interest to Jack R. Wheatley dba Matadero Creek (Filed as Exhibit 10.28 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004, and incorporated herein by reference).
10.26	Seventh Amendment to Lease, dated as of January 19, 2006, by and between the Company and the Wheatley Family Partnership, a California Limited Partnership dba Matadero Creek, successor in interest to Jack R. Wheatley dba Matadero Creek.
10.27	Lease between the Company and Kaiser Marquardt, Inc. dated as of December 1, 2000 (Filed as Exhibit 10.69 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, and incorporated herein by reference).
10.28**	License Agreement between Company and University of Florida Research Foundation, Inc., dated June 7, 1994 (Filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1, File No. 333-12675, and incorporated herein by reference).
10.29**	Research Agreement between Company and University of Florida, dated June 27, 1994 (Filed as Exhibit 10.72 to the Company's Registration Statement on Form S-1, File No. 333-12675, and incorporated herein by reference).
10.30**	Letter Agreement, dated March 7, 1997, between the Company and the University of Florida Research Foundation, Inc. (Filed as Exhibit 10.43 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 1997, and incorporated herein by reference).
10.31**	License Agreement between Company and Syntex (U.S.A.) Inc., dated March 27, 1996 (Filed as Exhibit 10.25 to the Company's Amendment No. 2 to Registration Statement on Form S-3, File No. 333-59318, and incorporated herein by reference).
10.32**	First amendment to License Agreement, effective as of July 3, 1997 (Filed as Exhibit 10.32 to the Company's Amendment No. 2 to Registration Statement on Form S-3, File No. 333-59318, and incorporated herein by reference).

Exhibit Number	
10.33	Amendment No. 2 to License Agreement, effective as of November 30, 1999, between the Company and Syntex (U.S.A.), Inc. (Filed as Exhibit 10.73 to the Company's Amendment No. 2 to Registration Statement on Form S-3, File No. 333-59318, and incorporated herein by reference).
10.34	Amendment No. 3 to License Agreement dated as of March 25, 2005, by and between the Company and Roche Palo Alto LLC. (Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed by Company on March 30, 2005, and incorporated herein by reference).
10.35**	Research Collaboration and License Agreement (U.S.) between the Company and Biogen, Inc., dated March 7, 1997 (Filed as Exhibit 10.39 to the Company's Quarterly Report on Form 10-Q for the First Quarter 1997, and incorporated herein by reference).
10.36**	Research Collaboration and License Agreement (Europe) between the Company and Biogen Manufacturing Ltd., dated March 7, 1997 (Filed as Exhibit 10.40 to the Company's Quarterly Report on Form 10-Q for the First Quarter 1997, and incorporated herein by reference).
10.37	Amendment to Research Collaboration and License Agreement (U.S.), dated June 12, 1998, between the Company and Biogen, Inc. (Filed as Exhibit 10.54 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 1998, and incorporated herein by reference).
10.38**	Letter agreement regarding termination of research program of the Research Collaboration and License Agreement, dated June 12, 1998, between the Company and Biogen, Inc. (Filed as Exhibit 10.56 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 1998, and incorporated herein by reference).
10.39**	Collaboration and License Agreement between the Company and Fujisawa Healthcare, Inc. dated as of July 10, 2000 (Filed as Exhibit 10.83 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2000, and incorporated herein by reference).
10.40**	Amendment to Collaboration and License Agreement dated as of August 30, 2005, between the Company and Astellas US LLC (successor-in-interest to Fujisawa Healthcare, Inc.). (Filed as Exhibit 10.1 to the Company's current Report on Form 8-K filed by Company on September 6, 2005, and incorporated herein by reference).
10.41***	Co-Promotion Agreement between the Company and Solvay Pharmaceuticals, Inc., dated as of December 6, 2004 (Filed as Exhibit 10.42 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004, and incorporated herein by reference).
10.42***	Amendment dated March 6, 2006, to the Co-Promotion Agreement between the Company and Solvay Pharmaceuticals, Inc.
10.43	Purchase Agreement, dated as of June 13, 2003, by and among the Company and Citigroup Global Markets, Inc., CIBC World Markets Corp., Deutsche Bank Securities Inc., First Albany Corporation, Needham & Company, Inc. and SG Cowen Securities Corporation, as representatives of the Initial Purchasers named in Schedule I thereto (Filed as Exhibit 10.66 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2003, and incorporated herein by reference).
10.44	Purchase Agreement, dated May 12, 2004, by and among the Company and Merrill Lynch & Co., Citigroup Global Markets Inc., Deutsche Bank Securities Inc., First Albany Capital Inc., J.P. Morgan Securities Inc., Needham & Company, Inc., Piper Jaffray & Co. and SG Cowen & Co., LLC, as representatives of the Initial Purchasers named in Schedule A thereto (Filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2004, and incorporated herein by reference).

Exhibit Number	
10.45	Registration Rights Agreement, dated May 18, 2004, by and among the Company, Merrill Lynch & Co., Citigroup Global Markets Inc., Deutsche Bank Securities Inc., First Albany Capital Inc., J.P. Morgan Securities Inc., Needham & Company, Inc., Piper Jaffray & Co. and SG Cowen & Co., LLC (Filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2004, and incorporated herein by reference).
10.46	Pledge and Escrow Agreement dated as of June 18, 2003, by and among the Company, Wells Fargo Bank Minnesota, N.A., as Trustee and Wells Fargo Bank Minnesota, N.A. as Escrow Agent (Filed as Exhibit 10.68 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2003, and incorporated herein by reference).
10.47	Pledge and Escrow Agreement dated as of May 18, 2004, by and among the Company, Wells Fargo Bank, N.A., as Trustee and Wells Fargo Bank, N.A. as Escrow Agent (Filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the Second Quarter 2004, and incorporated herein by reference).
10.48	Amended and Restated Sales and Marketing Services Agreement dated as of July 9, 2003, by and between the Company, Innovex (North America), Inc., as successor to Innovex Inc., Innovex LP, and Quintiles Transnational Corp. (Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed by Company on July 11, 2003, and incorporated herein by reference).
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certificate of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certificate of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.
** Confidential treatment has previously been granted for portions of this exhibit.
*** Confidential treatment has been requested for portions of this exhibit.

(c) Exhibits

See Exhibits listed under Item 15(a)(3) above.

(d) Financial Statements and Schedules

The financial statement schedules required by this Item are listed under 15(a)(1) and (2) above.

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 on Form 10-K to be signed on its behalf, by the undersigned, thereunto duly authorized, in the City of Palo Alto, County of Santa Clara, State of California, on March 10, 2006.

CV THERAPEUTICS, INC.

By: /s/ LOUIS G. LANGE
Louis G. Lange, M.D., Ph.D.
Chairman of the Board of CV Therapeutics
Chief Executive Officer

POWER OF ATTORNEY KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Louis G. Lange and Daniel K. Spiegelman, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this report on Form 10-K, 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 connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his 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 on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ LOUIS G. LANGE **Louis G. Lange, M.D., Ph.D.**	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 10, 2006
/s/ DANIEL K. SPIEGELMAN **Daniel K. Spiegelman**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2006
/s/ SANTO J. COSTA **Santo J. Costa**	Director	March 10, 2006
/s/ JOSEPH M. DAVIE **Joseph M. Davie, M.D., Ph.D.**	Director	March 10, 2006
/s/ THOMAS L. GUTSHALL **Thomas L. Gutshall**	Director	March 10, 2006
/s/ PETER BARTON HUTT **Peter Barton Hutt**	Director	March 10, 2006
/s/ KENNETH B. LEE, JR. **Kenneth B. Lee, Jr.**	Director	March 10, 2006
/s/ BARBARA J. MCNEIL **Barbara J. McNeil, M.D., Ph.D.**	Director	March 10, 2006
/s/ THOMAS E. SHENK **Thomas E. Shenk, Ph.D.**	Director	March 10, 2006

Report of Independent Registered Public Accounting Firm on Consolidated Financial Statements

The Board of Directors and Stockholders of
CV Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of CV Therapeutics, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of CV Therapeutics, Inc. at December 31, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of CV Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
February 24, 2006

CV THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,688	$ 20,759
Marketable securities	436,495	383,744
Restricted cash	10,587	6,125
Prepaid and other current assets	18,236	17,275
Total current assets	489,006	427,903
Notes receivable from related parties	75	435
Property and equipment, net	20,491	15,284
Restricted cash	10,990	6,797
Other assets	13,884	11,811
Total assets	$ 534,446	$ 462,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,690	$ 6,745
Accrued liabilities	58,172	38,568
Current portion of capital lease obligations	–	96
Current portion of deferred revenue	665	1,029
Total current liabilities	63,527	46,438
Capital lease obligations	–	35
Convertible subordinated notes	399,500	329,645
Deferred revenue	–	543
Other liabilities	10,429	6,167
Total liabilities	473,456	382,828
Commitments and contingencies (Notes 6 and 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding	–	–
Common stock, $0.001 par value, 85,000,000 shares authorized, 44,858,060 and 34,634,727 shares issued and outstanding at December 31, 2005 and 2004, respectively	891,724	666,119
Accumulated deficit	(812,554)	(584,559)
Deferred stock-based compensation	(18,218)	–
Cumulative other comprehensive income (loss)	38	(2,158)
Total stockholders' equity	60,990	79,402
Total liabilities and stockholders' equity	$ 534,446	$ 462,230

See accompanying notes

CV THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year ended December 31,		
	2005	2004	2003
Revenues:			
Collaborative research	$ 18,951	$ 20,428	$ 11,305
Operating expenses:			
Research and development	128,448	124,346	80,792
Selling, general and administrative	114,691	43,178	40,491
Total operating expenses	243,139	167,524	121,283
Loss from operations	(224,188)	(147,096)	(109,978)
Interest and other income, net	10,418	7,341	10,853
Interest expense	(13,043)	(13,579)	(11,659)
Other expense, net	(1,182)	(1,749)	(167)
Net loss	$(227,995)	$(155,083)	$(110,951)
Basic and diluted net loss per share	$ (5.66)	$ (4.90)	$ (3.91)
Shares used in computing basic and diluted net loss per share	40,268	31,671	28,360

See accompanying notes

CV THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Deferred Stock-Based Compensation	Accumulated Deficit	Cumulative Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2002	27,116,805	$533,522	$ –	$(318,525)	$ 3,968	$ 218,965
Issuance of common stock, net of repurchases	1,970,913	37,315	–	–	–	37,315
Compensation related to grants of certain stock options	–	651	–	–	–	651
Common Stock Warrant	–	6,296	–	–	–	6,296
Comprehensive loss:						
Net loss	–	–	–	(110,951)	–	(110,951)
Net unrealized losses on investments	–	–	–	–	(3,439)	(3,439)
Total comprehensive loss						(114,390)
Balances at December 31, 2003	29,087,718	577,784	–	(429,476)	529	148,837
Issuance of common stock, net of repurchases	5,547,009	88,327	–	–	–	88,327
Compensation related to grants of certain stock options	–	8	–	–	–	8
Comprehensive loss:						
Net loss	–	–	–	(155,083)	–	(155,083)
Net unrealized losses on investments	–	–	–	–	(2,687)	(2,687)
Total comprehensive loss						(157,770)
Balances at December 31, 2004	34,634,727	666,119	–	(584,559)	(2,158)	79,402
Issuance of common stock, net of repurchases	10,223,333	202,994	–	–	–	202,994
Compensation related to grants of certain stock options	–	956	–	–	–	956
Deferred stock-based compensation related to issuance of restricted stock units	–	21,655	(21,655)	–	–	–
Amortization of stock-based compensation	–	–	3,437	–	–	3,437
Comprehensive loss:						
Net loss	–	–	–	(227,995)	–	(227,995)
Net unrealized losses on investments	–	–	–	–	2,196	2,196
Total comprehensive loss						(225,799)
Balances at December 31, 2005	44,858,060	$891,724	$(18,218)	$(812,554)	$ 38	$ 60,990

See accompanying notes

CV THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2005	**2004**	**2003**
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$(227,995)	$(155,083)	$(110,951)
Adjustments to reconcile net loss to net cash used in operating activities:			
(Gain) loss on the sale of investments	656	621	(1,755)
Impairment recognized for unrealized loss on marketable securities	3,180	–	–
Write-off of unamortized issuance costs on convertible subordinated notes repurchased	621	1,615	–
Forgiveness of related party notes receivable	64	73	100
Non cash expense associated with issuance of stock options, stock appreciation rights, restricted stock units, stock and warrants	5,317	1,185	5,425
Depreciation and amortization	10,751	14,343	14,204
Change in assets and liabilities:			
Prepaid and other current assets	(466)	(6,261)	(2,057)
Restricted cash	(8,655)	(8,036)	(4,886)
Other assets	25	391	(322)
Accounts payable	(2,055)	2,729	(1,526)
Accrued and other liabilities	22,851	25,335	3,360
Deferred revenue	(907)	(1,029)	(1,029)
Net cash used in operating activities	(196,613)	(124,117)	(99,437)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of investments	(354,006)	(385,156)	(462,864)
Maturities of investments	83,041	23,255	35,190
Sales of investments	212,058	379,326	396,645
Capital expenditures	(8,963)	(3,604)	(4,580)
Notes receivable from related parties	–	500	165
Equity investment in collaboration partner	–	(1,000)	(1,000)
Net cash (used in) provided by investing activities	(67,870)	13,321	(36,444)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments on capital lease obligations	–	(440)	(393)
Borrowings on capital lease obligations	–	178	–
Repayments of convertible subordinated notes	(79,645)	(116,605)	–
Borrowings under senior subordinated convertible notes, net of issuance costs	144,727	145,141	–
Borrowings under senior subordinated convertible debentures, net of issuance costs	–	–	96,730
Net proceeds from issuance of common stock	202,330	87,441	36,617
Net cash provided by financing activities	267,412	115,715	132,954
Net increase (decrease) in cash and cash equivalents	2,929	4,919	(2,927)
Cash and cash equivalents at beginning of year	20,759	15,840	18,767
Cash and cash equivalents at end of year	$ 23,688	$ 20,759	$ 15,840
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid for interest	$ 9,550	$ 11,751	$ 10,202
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES			
Accrued cost for acquisition of property and equipment	$ 866	$ –	$ –

See accompanying notes

CV THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIALS STATEMENTS

1. Summary of Significant Accounting Policies

The Company

CV Therapeutics, Inc., headquartered in Palo Alto, California, is a biopharmaceutical company focused on the discovery, development and commercialization of new small molecule drugs for the treatment of cardiovascular diseases. We apply advances in molecular biology and genetics to identify mechanisms of cardiovascular diseases and targets for drug discovery.

We currently have two approved cardiovascular products to promote with our national cardiovascular specialty sales force: Ranexa™ (ranolazine extended-release tablets) and ACEON® (perindopril erbumine) Tablets. Ranexa was approved in the United States in January 2006 for the treatment of chronic angina in patients who have not achieved an adequate response with other antianginal drugs. ACEON®, an angiotensin converting enzyme inhibitor, or ACE inhibitor, is approved in the United States for use in patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction, or MI, and for the treatment of patients with essential hypertension. We co-promote ACEON® in the United States with our partner Solvay Pharmaceuticals, Inc. In addition to our marketed products, we are developing regadenoson, a selective A_{2A}-adenosine receptor agonist, for potential use as a pharmacologic agent in myocardial perfusion imaging studies.

Reclassifications

Certain reclassifications have been made to prior period balances in order to conform to the current presentation. We have combined line items in the consolidated statements of operations previously separately titled “sales and marketing” and “general and administrative” to a new category titled “selling, general and administrative.”

Principles of Consolidation

The financial statements include the accounts of our company and our wholly owned subsidiary. The functional currency of our wholly-owned European subsidiary in the United Kingdom is the U.S. dollar, and all intercompany transactions and balances have been eliminated. All foreign currency remeasurement gains and losses are recorded in the consolidated statements of operations in accordance with Statement of Financial Accounting Standards No. 52, “*Foreign Currency Translation*,” and have not been significant.

Use of Estimates

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

Cash Equivalents and Marketable Securities

We consider all highly liquid debt investments with a maturity from date of purchase of three months or less to be cash equivalents. Cash equivalents consist of money market funds, commercial paper and cash on deposit at banks. All other liquid investments are classified as marketable securities.

We invest in marketable debt securities that we consider to be available for use in current operations. Accordingly, we have classified all investments as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date. We classify our investment in debt securities as

1. Summary of Significant Accounting Policies (Continued)

available-for-sale. Available-for-sale securities are carried at fair value, based upon quoted market prices for these or similar instruments, with unrealized gains and losses reported in stockholders' equity as a component of other comprehensive income (loss). The amortized cost of these securities is adjusted for amortization of premiums and accretions of discounts to maturity. Such amortization, as well as realized gains and losses are included in interest and other income, net. The cost of securities sold is based on the specific identification method. If we conclude that an other than temporary impairment exists, we recognize an impairment charge to reduce the investment to fair value and record the related charge as a reduction of interest and other income, net. In determining whether to recognize an impairment charge, we consider factors such as the length of time and extent to which the fair market value has been below the cost basis, the current financial condition of the investee, the financial condition, future cash flow needs and business outlook for our company and our intent and ability to hold the investment for a sufficient period of time to allow for any anticipated recovery in market value.

Restricted Cash

Restricted cash includes the current and non current portions in the funding of escrow accounts to secure interest payments for our $100.0 million aggregate principal amount of senior subordinated convertible debentures due 2023, $150.0 million aggregate principal amount of senior subordinated convertible notes due 2012 and $149.5 million of our 3.25% senior subordinated convertible notes due 2013 (see Note 7). These escrow accounts consist of held-to-maturity U.S. Treasury securities that are carried at amortized cost, which approximates fair market value.

Inventory

Prior to regulatory approval of our drug candidates, we incur expenses for the manufacture of drug product that could potentially be available to support the commercial launch of these drug candidates. Until the necessary initial regulatory approval has been received or is otherwise considered assured, we charge all such amounts to research and development expenses. As of December 31, 2005, all Ranexa inventory costs have been expensed.

Valuation of Long-Lived Assets

Long-lived assets to be held and used are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When an asset's expected future undiscounted cash flows are less than its carrying value, an impairment loss is recognized and the asset is written down to its estimated value. Long-lived assets to be disposed of are reported at the lower of the carrying amount of fair value less cost to dispose.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives, generally three to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the remaining term of the lease. Repairs and maintenance costs are charged to expense as incurred.

Comprehensive Loss

Statement of Financial Accounting Standards No. 130, "*Reporting Comprehensive Income*" (SFAS No. 130), established standards for the reporting and display of comprehensive income (loss) and its components.

1. Summary of Significant Accounting Policies (Continued)

Comprehensive loss consists of net loss plus the changes in unrealized gains and losses on available-for-sale investment securities. At each balance sheet date presented, our cumulative other comprehensive income consists solely of unrealized gains and losses on available-for-sale investment securities. Comprehensive income (loss) for the years ended December 31, 2005, 2004 and 2003 are as follows (in thousands):

	Year Ended December 31,		
	2005	2004	2003
Net loss	$(227,995)	$(155,083)	$(110,951)
Increase in unrealized losses on available-for-sale securities	(1,640)	(3,308)	(1,684)
Reclassification adjustment for (gains) losses on available-for-sale securities recognized in earnings	3,836	621	(1,755)
Comprehensive loss	$(225,799)	$(157,770)	$(114,390)

Concentrations of Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. We strive to limit concentration of risk by diversifying investments among a variety of issuers in accordance with our investment guidelines. No one issuer or group of issuers from the same holding company is to exceed 5% of market value of our portfolio except for securities issued by the U.S. Treasury or by one of its agencies. We also strive to limit risk by specifying a minimum credit quality of A1/P1 for commercial paper and A-/A3 for all other investments.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility related expenses, outside contract services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

1. Summary of Significant Accounting Policies (Continued)

Advertising Costs

All costs associated with advertising are expensed in the year incurred. Advertising expense for the year ended December 31, 2005 was $0.2 million. There was no advertising expense for the years ended December 31, 2004 and 2003.

Revenue Recognition

Revenue under our collaborative research arrangements is recognized based on the performance requirements of each contract. Amounts received under such arrangements consist of up-front license payments, periodic milestone payments and reimbursement for research activities. We evaluate whether the delivered elements under these arrangements have value to our collaboration partner on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered item exists. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. Up-front or milestone payments, which are subject to future performance requirements, are recorded as deferred revenue and are recognized over the performance period. The performance period is estimated at the inception of the arrangement and is reevaluated each reporting period. The reevaluation of the performance period may shorten or lengthen the period during which the deferred revenue is recognized. We evaluate the appropriate performance period based on research progress attained and certain events, such as changes in the regulatory and competitive environment. Revenues related to substantive, at-risk milestones are recognized upon achievement of the scientific or regulatory event specified in the underlying agreement. Revenues for research activities are recognized as the related research efforts are performed. Revenue under our ACEON® co-promotion agreement is recognized based on net product sales recorded by Solvay Pharmaceuticals, Inc., our co-promotion partner, for each reporting period. We have not recognized any co-promotion revenue to date.

Stock-Based Compensation

We have elected to continue to account for stock-based awards granted to employees using the intrinsic-value method as prescribed by Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*" (APB No. 25). We recognize no compensation expense for stock options granted to our employees with exercise prices equal to the fair market value of our common stock on the date of grant.

During 2005, we issued restricted stock units (RSUs) to our employees, including executives, and to certain consultants. In accordance with APB No. 25, we valued the RSUs at the market price of our common stock on the date of the award and we are recognizing the associated stock compensation expense, using the straight-line method, over the period the services are performed, which is generally 48 months. Some of the RSUs provide for immediate acceleration of vesting in the event that we achieve a certain annualized product revenue threshold over four consecutive quarters. Deferred stock-based compensation on our consolidated balance sheet represents the value of RSUs granted to employees as of the grant date remaining to be amortized as the services are performed.

We also issued stock appreciation rights (SARs) to certain executives in the first quarter of 2005. The SARs are valued in accordance with APB No. 25 and Financial Accounting Standards Board Interpretation No. 28, "*Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinions No. 15 and 25*." Compensation is measured at the end of each period as the amount by which the volume weighted average market price of the shares covered by the SAR exceeds the SAR base value (the predetermined strike price of the instrument of $26.45, which represented a 15% premium to the market price on

1. Summary of Significant Accounting Policies (Continued)

the grant date), and compensation expense, if any, is accrued using the accelerated attribution method over the period the related services are performed. Changes in the SAR value are reflected as an adjustment of compensation expense in the periods in which the changes occur. We currently expect to settle all amounts due under the SARs, if any, using shares of our common stock.

We recognize compensation for stock-based payments granted to consultants in accordance with Emerging Issues Task Force Consensus No. 96-18 (EITF 96-18), "*Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*." The estimated fair value of options granted to consultants is determined using the Black-Scholes option pricing model.

For purposes of disclosures pursuant to Statement of Financial Accounting Standards No. 123, "*Accounting for Stock-Based Compensation*" (SFAS 123), as amended by Statement of Financial Accounting Standards No. 148, "*Accounting for Stock-Based Compensation—Transition and Disclosure*" (SFAS No. 148), the estimated fair value of stock options, RSUs and SARs is amortized to expense over the vesting periods. The following table illustrates the effect on reported net loss and net loss per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in thousands, except per share amounts):

	2005	2004	2003
Net loss:			
As reported	$(227,995)	$(155,083)	$(110,951)
Add: Stock-based employee compensation included in reported net loss	3,485	–	–
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards	(21,286)	(15,338)	(21,845)
Pro forma net loss	$(245,796)	$(170,421)	$(132,796)
Net loss per share basic and diluted:			
As reported	$ (5.66)	$ (4.90)	$ (3.91)
Pro forma	$ (6.10)	$ (5.38)	$ (4.68)

The fair value of our options granted to employees was estimated assuming no expected dividends and the following weighted-average assumptions:

	2005	2004	2003
Stock options:			
Expected life (years)	5.4	5.0	5.1
Expected volatility	61%	65%	65%
Risk-free interest rate	4.1%	3.5%	2.7%

Net Loss Per Share

In accordance with Statement of Financial Accounting Standards No. 128 "*Earnings Per Share*" (SFAS No. 128), basic and diluted net loss per share have been computed using the weighted average number of shares of common stock outstanding during each period. Our calculation of diluted net loss per share excludes potentially dilutive shares, as these shares were antidilutive for all periods presented. Our calculation of diluted net income (loss) per share may be affected in future periods by dilutive impact of our outstanding stock options,

1. Summary of Significant Accounting Policies (Continued)

restricted stock units, stock appreciation rights, and warrants as disclosed in Note 10. In addition, our calculation of diluted net income (loss) per share may be affected in future periods by our convertible notes and debentures as disclosed in Note 7.

Fair Value of Financial Instruments

Our financial instruments consist principally of cash and cash equivalents, marketable securities, restricted cash, other current assets and certain other assets, accrued liabilities, convertible subordinated notes and long-term obligations. Cash, cash equivalents, marketable securities and restricted cash are reported at their respective fair values on the consolidated balance sheets (see Note 3). The fair value of the convertible subordinated notes at December 31, 2005 was determined by obtaining quotes from a market maker for the notes (see Note 7).

Segments

We operate in one segment, drug discovery, development and commercialization, using one measurement of profitability to manage our business, in accordance with Statement of Financial Accounting Standard No. 131 "Disclosures about Segments of an Enterprise and Related Information." For the years ended December 31, 2005, 2004 and 2003, all revenue recognized was primarily from one collaboration partner within the United States.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard No. 123R, "*Share-Based Payment*," (Statement 123R) which is a revision of SFAS No. 123. Statement 123R supersedes APB No. 25 and amends SFAS No. 95, "*Statement of Cash Flows*." Generally, the approach in Statement 123R is similar to the approach described in SFAS 123. However, Statement 123R requires all stock-based payments to employees, including grants of employee stock options, stock appreciation rights, restricted stock units and our employee stock purchase plan, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. We intend to recognize stock-based compensation expense on all awards on a straight-line basis over the requisite service period using the modified prospective method for all options issued after January 1, 2006 and intend to use the Black-Scholes option pricing model to value stock-based payments under Statement 123R. In January 2005, the Security and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 107, which provides supplemental implementation guidance for Statement 123R. Statement 123R will be effective for us beginning in the first quarter of 2006.

As permitted by SFAS 123, we currently account for stock-based payments to employees using APB No. 25's intrinsic value method. As a result, we generally recognize no compensation cost for employee stock options. We have, however, begun including expense amounts associated with grants of restricted stock units and stock appreciation rights in our results of operations beginning January 1, 2005. The adoption of Statement 123R's fair value method will have a significant impact on our consolidated results of operations, although it will have no impact on our overall financial position. The impact of adopting Statement 123R will depend in part on levels of share-based payments granted in the future and other unknown variables, such as estimated forfeiture rates, volatility, interest rates and option term length.

In accordance with Statement 123R, deferred compensation and related common stock on our balance sheet as of December 31, 2005 (which totals approximately $18.2 million as of December 31, 2005) will be reversed

1. Summary of Significant Accounting Policies (Continued)

and future charges for deferred compensation from our restricted stock units will be recorded to common stock directly as the related services are performed. We are assessing the cumulative benefit of a change in accounting principle, which may result from the net cumulative impact of estimating future forfeitures for unvested restricted stock units outstanding as of January 1, 2006, in the determination of period expense, rather than recording forfeitures when they occur as previously permitted.

In November 2005, the FASB issued FASB Staff Position (FSP) No. FAS 115-1, "*The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments*." FSP No. FAS 115-1 amends SFAS No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*," as well as APB Opinion No. 18, "*The Equity Method of Accounting for Investments in Common Stock*" and this guidance nullifies certain requirements of Emerging Issues Task Force (EITF) 03-1, "*The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments*." FSP No. FAS 115-1 addresses the determination as to when an investment is considered impaired, whether that impairment is other-than-temporary, and the measurement of the loss. FSP No. FAS 115-1 also include accounting considerations subsequent to the recognition of other-than-temporary impairments, as well as require other-than-temporary impaired debt securities be written down to its impaired value, which becomes the new cost basis. Although FSP No. FAS 115-1 is effective for fiscal years beginning after December 15, 2005, we believe the FSP's clarification to the guidance regarding when an other-than-temporary impairment should be recognized is consistent with other existing literature, such as Staff Accounting Bulletin No. 59, "*Accounting for Noncurrent Marketable Equity Securities*." We have adopted FSP No. FAS 115-1 as of December 31, 2005. Accordingly, we recorded a non-cash impairment charge of approximately $3.2 million as an offset to interest and other income, net for the year ended December 31, 2005 to write down the carrying value of our marketable securities to fair value.

2. License and Collaboration Agreements

Roche Palo Alto LLC

In March 1996, we entered into a license agreement with Roche Palo Alto LLC (formerly Syntex (U.S.A.) Inc.) covering United States and foreign patent rights to ranolazine and related know how for the treatment of angina and other cardiovascular indications. The license agreement is exclusive and worldwide except for the following countries in which product rights are owned by Roche: Japan, Korea, China, Taiwan, Hong Kong, the Philippines, Indonesia, Singapore, Thailand, Malaysia, Vietnam, Myanmar, Laos, Cambodia and Brunei.

Under our license agreement, we paid an initial license fee and are obligated to make certain payments to Roche, upon receipt of the first and second product approvals for Ranexa in any of the following major market countries: France, Germany, Italy, the United States and the United Kingdom. In February 2006, we paid Roche an $11.0 million payment in connection with the FDA's approval of Ranexa in the United States in January 2006. As of December 31, 2005, we have accrued $10.1 million of the $11.0 million payment. Unless the agreement is terminated, we are required to make a second payment of $9.0 million upon the second product approval, if any, in one of the major market countries specified above. In addition, we are required to make royalty payments based on net sales of approved products that utilize the licensed technology, including Ranexa. We are required to use commercially reasonable efforts to develop and commercialize the product for angina.

We or Roche may terminate the license agreement for material uncured breach, and we have the right to terminate the license agreement at any time on 120 days' notice if we decide not to continue to develop and commercialize ranolazine.

2. License and Collaboration Agreements (Continued)

Astellas Pharma US

In July 2000, we entered into a collaboration agreement with Astellas US LLC (formerly Fujisawa Healthcare, Inc.) to develop and market second generation pharmacologic myocardial perfusion imaging stress agents. Under this agreement, Astellas received exclusive North American rights to regadenoson, a short acting selective A_{2A}-adenosine receptor agonist, and to a backup compound. We received $10.0 million from Astellas consisting of a $6.0 million up-front payment, which is being recognized as revenue over the expected development term of the agreement, and $4.0 million for the sale of our common stock. To date, Astellas has paid us $5.0 million in milestone payments. We may receive up to an additional $19.0 million in cash milestone payments based on other development and regulatory milestones such as certain regulatory filings and approval. In addition, Astellas reimburses us for 75% of our development costs and we reimburse Astellas for 25% of their development costs. If the product is approved by the FDA, Astellas will be responsible for sales and marketing of regadenoson, and we will receive a royalty based on product sales of regadenoson and may receive a royalty on another product sold by Astellas. Collaborative research revenues for the reimbursement of development costs were $17.9 million, $19.4 million and $7.3 million for 2005, 2004 and 2003, respectively. As of December 31, 2005, $3.1 million was due from Astellas for reimbursement of our development costs.

Astellas may terminate the agreement for any reason on 90 days' written notice, and we may terminate the agreement if Astellas fails to launch a product within a specified period after marketing approval. In addition, we or Astellas may terminate the agreement in the event of material uncured breach, or bankruptcy or insolvency.

Solvay Pharmaceuticals

In December 2004, we entered into an agreement with Solvay Pharmaceuticals, Inc. to co-promote ACEON® (perindopril erbumine) Tablets, an angiotensin-converting enzyme inhibitor, or ACE inhibitor, in the United States. Under the agreement, we are responsible for brand marketing activities and for establishing a cardiovascular specialty sales force to promote the product. Under the agreement, Solvay Pharmaceuticals continues to handle the manufacturing and distribution of the product, and its primary care sales force continues to promote the product.

There were no upfront payments by either party associated with the co-promotion agreement. Solvay Pharmaceuticals records as revenue all sales of ACEON®. For all product sales above a specified baseline, there is a multi-tiered revenue-sharing structure and, on average, we receive a share of sales of approximately 50-60% of sales above the baseline. These economic terms are subject to adjustment if the FDA approves a generic to perindopril in the United States, or if we do not meet our minimum marketing and promotional commitments, or if we allow Solvay Pharmaceuticals to provide at least a specified number of details that turns out to be the majority of product details in any given year.

Under the co-promotion agreement, we are Solvay Pharmaceuticals' exclusive co-promotion partner in the United States, and we have agreed not to market any other ACE inhibitor or any angiotensin receptor blocker until our marketing and promotional commitments under the agreement have expired or terminated.

The period during which we must satisfy marketing and promotional commitments under the co-promotion agreement expires, unless earlier terminated, on the earlier of November 2008 or the date a generic to perindopril is approved by the FDA, if any, although if patent protection for the product is extended beyond November 2009, we have the option to extend the term of our commitments provided that Solvay Pharmaceuticals obtains an extension of its United States license rights to the product. Immediately following the expiration of this period of

2. License and Collaboration Agreements (Continued)

our marketing and promotional commitments under the agreement, there is a residual term of three years. During the residual term, all of the agreement terms remain in effect except that we will no longer be required to meet any minimum marketing and promotional commitments, although to the extent we continue to market and promote the product we will be entitled to the same compensation as before the residual term. Assuming there is no extension of or successful challenge to the product's patent protection, no FDA approval of a generic to perindopril, and no earlier termination of the agreement, the co-promotion agreement expires in November 2011.

Either party may terminate the co-promotion agreement in the event of material uncured breach, and we may terminate the agreement for any reason on 180 days' advance written notice.

For the year ended December 31, 2005, we have not recognized any revenues related to this agreement.

3. Marketable Securities

The following is a summary of available-for-sale securities at December 31, 2005 and 2004:

December 31, 2005	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Cash equivalents:				
Money market funds	$ 6,830	$ –	$ –	$ 6,830
Commercial paper	15,875	3	–	15,878
	$ 22,705	$ 3	$ –	$ 22,708
Marketable securities:				
US government securities	$152,062	$ 1	$ –	$152,063
Asset backed securities	44,166	22	–	44,188
Corporate bonds	240,232	12	–	240,244
	$436,460	$ 35	$ –	$436,495

December 31, 2004	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Cash equivalents:				
Money market funds	$ 7,020	$ –	$ –	$ 7,020
US government securities	13,247	2	–	13,249
	$ 20,267	$ 2	$ –	$ 20,269
Marketable securities:				
US government securities	$128,408	$ 7	$ (865)	$127,550
Asset backed securities	49,587	–	(242)	49,345
Corporate bonds	207,909	14	(1,074)	206,849
	$385,904	$ 21	$(2,181)	$383,744

As of December 31, 2005, we had marketable securities with maturities of one year or less of $197.4 million and greater than one year of $239.1 million. The average contractual maturity as of December 31, 2005 was approximately thirteen months, with no single investment's maturity exceeding thirty-six months.

3. Marketable Securities (Continued)

Realized gains on available-for-sale securities included in the consolidated statements of operations were $0.1 million, $0.3 million and $2.2 million for 2005, 2004 and 2003, respectively, while realized losses for those years were $0.8 million, $0.9 million and $0.5 million, respectively.

We review and analyze our marketable securities portfolio to determine whether declines in the fair value of individual marketable securities that were below amortized cost are other-than-temporary. In order to determine whether a decline in fair value is other-than temporary, we evaluated, among other factors, the duration and extent to which the fair value has been less than the amortized cost; the financial condition of and business outlook for our company, including future cash flow needs; and our intent and ability to hold the investment for a period of time sufficient to allow for a recovery of fair value to its amortized cost. As a result of increases in market interest rates during 2005, we had unrealized losses of $3.2 million in our investment portfolio as of December 31, 2005. After consideration of the scheduled maturities in our investment portfolio, our policies with respect to the concentration of investments with issuers or within industries, and our forecasted needs to support our operations, we concluded that we did not have the ability to hold impaired securities for a period of time sufficient to recover their cost basis. As of December 31, 2005, management has not determined which individual securities we would sell in order to meet our future cash requirements. As a result, we determined that all individual marketable securities in our portfolio with fair values below amortized cost were other-than-temporarily impaired. Accordingly, we recorded a non-cash impairment charge of approximately $3.2 million as an offset to interest and other income, net for the year ended December 31, 2005 to write down the carrying value of these securities to fair value.

4. Property and Equipment

Property and equipment are recorded at cost and consist of the following:

	December 31, 2005	December 31, 2004
	(in thousands)	
Machinery and equipment	$ 24,646	$ 18,202
Furniture and fixtures	2,429	2,308
Construction in progress	3,292	553
Leasehold improvements	11,687	11,162
	42,054	32,225
Less accumulated depreciation and amortization	(21,563)	(16,941)
	$ 20,491	$ 15,284

As of December 31, 2005, we had no property and equipment under capital leases. Property and equipment included $1.2 million recorded under capital leases at December 31, 2004. Accumulated depreciation related to leased assets totaled $0.9 million at December 31, 2004.

Depreciation expense, including depreciation of assets under capital leases, was $3.5 million, $3.6 million and $3.2 million for 2005, 2004 and 2003, respectively. Amortization expense for leasehold improvements was $1.1 million, $1.0 million and $1.0 million for 2005, 2004 and 2003, respectively.

5. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2005	December 31, 2004
	(in thousands)	
Accrued interest	$ 3,195	$ 1,936
Accrued marketing and promotional costs	5,447	–
Accrued compensation	12,680	7,748
Accrued clinical trial costs	17,510	14,693
Roche Palo Alto LLC milestone accrual	10,080	10,080
Other	9,260	4,111
	$58,172	$38,568

6. Commitments

Operating Leases

We have operating leases related to our facilities. As of December 31, 2005, these leases expire between February 2008 and April 2014. One of the leases is secured by a $6.0 million irrevocable letter of credit. As security for this letter of credit, we are obligated to maintain $6.0 million in compensating balances in deposit with the counterparty. Because the compensating balance is not restricted as to withdrawal, it is not classified as restricted cash in our consolidated balance sheet. In January 2006, we amended another lease which extended the lease term to April 2016 with an option to renew for nine years. Minimum payments related to the amended lease have not been included in the table below. The amended lease provides for net rent reductions of $3.7 million over five years in return for the issuance of warrants to the landlord and the ground lessor. Gross rent expense for the years ended December 31, 2005, 2004, and 2003 was $13.5 million, $12.9 million and $12.6 million, respectively. Separately, we also had sublease rental income for the year ended December 31, 2003 of $1.0 million. As of December 31, 2005, minimum payments under operating lease arrangements were as follows (in thousands):

2006	$ 12,508
2007	13,570
2008	14,610
2009	14,403
2010	15,613
Thereafter	29,471
	$100,175

Manufacturing Obligations

We have entered into manufacturing supply arrangements, under which we have non-cancelable orders and minimum commitments related to the manufacturing of Ranexa. Our minimum payments as of December 31, 2005 under these supply agreements were as follows (in thousands):

2006	$ 8,496
2007	2,501
2008	2,501
2009	1,251
	$14,749

7. Convertible Subordinated Notes

Convertible subordinated notes consist of the following:

	December 31,	
	2005	2004
	(in thousands)	
4.75% Convertible Subordinated Notes Due 2007	$ –	$ 79,645
2.0% Senior Subordinated Convertible Debentures Due 2023	100,000	100,000
2.75% Senior Subordinated Convertible Notes Due 2012	150,000	150,000
3.25% Senior Subordinated Convertible Notes Due 2013	149,500	–
	$399,500	$329,645

4.75% Convertible Subordinated Notes Due 2007

In March 2000, we completed a private placement of $196.2 million aggregate principal amount of 4.75% convertible subordinated notes due 2007. The notes were unsecured and subordinated in right of payment to all existing and future senior debt as defined in the indenture governing the notes. We paid interest semi-annually on March 7th and September 7th of each year. The conversion rate was 15.66 shares of common stock per $1,000 principal amount of notes, which is equivalent to a conversion price of $63.84 per share. In May and June 2004, we repurchased approximately $116.6 million of these outstanding notes. In connection with the repurchases, we recorded a loss of approximately $3.3 million for the early extinguishment of debt, which included $1.6 million in unamortized offering costs recorded in interest expense and $1.7 million in premium payments above the principal value of the notes recorded in other expense, net, in the accompanying consolidated statement of operations. In August 2005, we redeemed the remaining approximately $79.6 million principal amount of our outstanding 4.75% convertible subordinated notes due 2007. In connection with the redemption, we recorded a loss of approximately $1.7 million for the redemption of debt, which included $0.6 million in unamortized offering costs, recorded in interest expense, and $1.1 million in premium payments above the principal value of the notes, recorded in other expense.

2.0% Senior Subordinated Convertible Debentures Due 2023

In June 2003, we completed a private placement of $100.0 million aggregate principal amount of 2.0% senior subordinated convertible debentures due May 16, 2023. The holders of the debentures may require us to purchase all or a portion of their debentures on May 16, 2010, May 16, 2013 and May 16, 2018, in each case at a price equal to the principal amount of the debentures to be purchased, plus accrued and unpaid interest, if any, to the purchase date. The debentures are unsecured and subordinated in right of payment to all existing and future senior debt, as defined in the indenture governing the debentures, equal in right of payment to our future senior subordinated debt and senior in right of payment to our existing and future subordinated debt. We are required to pay interest semi-annually on May 16 and November 16 of each year. The initial conversion rate of the debentures, which is subject to adjustment in certain circumstances, is 21.0172 shares of common stock per $1,000 principal amount of debentures, which is equivalent to an initial conversion price of $47.58 per share. We may, at our option, redeem all or a portion of the debentures in cash at any time on or after May 16, 2006 at pre-determined prices from 101.143% to 100.000% of the face value of the debentures per $1,000 of principal amount, plus accrued and unpaid interest to the date of redemption. We can elect to settle these debentures with shares of common stock or cash at our option.

At December 31, 2005, we have reserved 2,101,720 shares of common stock for issuance upon conversion of the debentures. We incurred issuance costs related to this private placement of approximately $3.4 million,

7. Convertible Subordinated Notes (Continued)

which have been recorded as other assets and are being amortized to interest expense ratably over the life of the debentures. Additionally, in connection with the private placement, as of December 31, 2005, we have restricted cash of approximately $1.0 million classified as current restricted cash in the accompanying consolidated balance sheets. The restricted cash secures the next interest payment due on the debentures.

Holders may convert their debentures into shares of our common stock only under any of the following circumstances: (i) during any calendar quarter after the quarter ended September 30, 2003, if the sale price of our common stock, for at least 20 trading days during the period of 30 consecutive trading days ending on the last trading day of the previous calendar quarter, is greater than or equal to 120% of the conversion price per share of our common stock, (ii) during the five business-day period after any five consecutive trading-day period in which the trading price per debenture for each day of that period was less than 97% of the product of the sale price of our common stock and the conversion rate on each such day, (iii) if the debentures have been called for redemption by us, or (iv) upon the occurrence of specified corporate transactions.

The fair value of our senior subordinated convertible debentures, based on the estimated market price of a market maker for the debentures at December 31, 2005, was approximately $89.7 million.

2.75% Senior Subordinated Convertible Notes Due 2012

In May and June 2004, we sold $150.0 million aggregate principal amount of 2.75% senior subordinated convertible notes due 2012 through a private placement to qualified institutional buyers in reliance on Rule 144A. The net proceeds to us were approximately $145.2 million, which was net of the initial purchasers' discount of $4.5 million and approximately $0.3 million in legal, accounting and printing expenses. Costs relating to the issuances of these notes were capitalized and are being amortized ratably over the term of the debt. The notes are unsecured and subordinated to all of our existing and future senior debt, equal in right of payment with our existing and future senior subordinated debt, and senior in right of payment to our existing and future subordinated debt. We are required to pay interest semi-annually on May 16 and November 16 of each year. The notes are convertible, at the option of the holder, at any time on or prior to maturity, into shares of our common stock. The notes are convertible at a conversion rate of 56.5475 shares of common stock per $1,000 principal amount of notes, which is equal to an initial conversion price of approximately $17.68 per share. At December 31, 2005, we have reserved 8,482,125 shares of common stock for issuance upon conversion of the notes. We may redeem some or all of the notes for cash at any time on or after May 20, 2009 at specified redemption prices, together with accrued and unpaid interest. A portion of the net proceeds from the offering were used to repurchase approximately $116.6 million principal amount of our 4.75% convertible subordinated notes and to fund the interest escrow account. As of December 31, 2005, we had approximately $6.0 million of restricted cash, of which approximately $4.1 million is classified as current restricted cash and approximately $1.9 million is classified as long term restricted cash in the accompanying consolidated balance sheets. The restricted cash secures the next three interest payments due on the notes. We can elect to settle these notes with shares of common stock or cash at our option.

In November 2004, a shelf registration statement on Form S-3 for the resale of the notes and the common stock issuable upon conversion of the notes was declared effective by the Securities and Exchange Commission. We have agreed to keep the shelf registration statement effective until June 8, 2006.

The fair value of our senior subordinated convertible notes, based on the market price for the notes at December 31, 2005, was approximately $225.0 million.

7. Convertible Subordinated Notes (Continued)

3.25% Senior Subordinated Convertible Notes Due 2013

In July 2005, we sold $149.5 million aggregate principal amount of 3.25% senior subordinated convertible notes due 2013. The net proceeds to us were approximately $144.7 million, which was net of the initial purchasers' discount of $4.5 million and approximately $0.3 million in legal, accounting and printing expenses. Costs relating to the issuances of these notes were capitalized and are being amortized ratably over the term of the debt. The notes are unsecured and subordinated to all of our existing and future senior debt, equal in right of payment with our existing and future senior subordinated debt, and senior in right of payment to our existing and future subordinated debt. We are required to pay interest semi-annually on February 16 and August 16 of each year, beginning February 16, 2006. We used approximately $14.2 million of the net proceeds from the convertible note offering to fund an escrow account to provide security for the first six scheduled interest payments on the notes. As of December 31, 2005, approximately $5.5 million is classified as current restricted cash and approximately $9.0 million is classified as long-term restricted cash in the accompanying consolidated balance sheets. The notes are convertible, at the option of the holder, at any time prior to maturity, at a conversion rate of 37.037 shares per $1,000 principal amount of notes, which is equal to a conversion price of approximately $27.00 per share, subject to adjustment. At December 31, 2005, we have reserved 5,537,032 shares of common stock for issuance upon conversion of the notes. We may redeem some or all of the notes for cash at any time on or after August 20, 2010 at specified redemption prices, together with accrued and unpaid interest.

The fair value of our senior subordinated convertible notes, based on the market price for the notes at December 31, 2005, was approximately $166.3 million.

8. Related Party Transactions

From 1992 through 2002, we issued loans to certain of our executive officers and other employees related to relocation and other business purposes. However, in July 2002 the Sarbanes-Oxley Act of 2002 prohibited any extension of credit (for example, a loan) to any director or executive officer, and we have complied with this legal prohibition. Loans to non-executive officers and employees aggregating $0.1 million and $0.4 million were outstanding at December 31, 2005 and 2004, respectively. These loans bear interest at 3.65% to 5.07% per annum. The amounts are repayable on various dates through October 30, 2008. Loans outstanding at December 31, 2005 are secured by secondary deeds of trust on real estate.

9. Contingencies

We and certain of our officers and directors are named as defendants in a purported securities class action lawsuit filed in August 2003 in the U.S. District Court for the Northern District of California captioned *Crossen v. CV Therapeutics, Inc., et al*. The lawsuit is brought on behalf of a purported class of purchasers of our securities, and seeks unspecified damages. As is typical in this type of litigation, several other purported securities class action lawsuits containing substantially similar allegations were filed against the defendants. In November 2003, the court appointed a lead plaintiff, and in December 2003, the court consolidated all of the securities class actions filed to date into a single action captioned *In re CV Therapeutics, Inc. Securities Litigation*. In January 2004, the lead plaintiff filed a consolidated complaint. We and the other named defendants filed motions to dismiss the consolidated complaint in March 2004. In August 2004, these motions were granted in part and denied in part. The court granted the motions to dismiss by two individual defendants, dismissing both individuals from the action with prejudice, but denied the motions to dismiss by us and the two other individual defendants. After the motions to dismiss were decided, this action entered the discovery phase, and discovery in the action is ongoing.

9. Contingencies (Continued)

In addition, certain of our officers and directors have been named as defendants in a derivative lawsuit filed in August 2003 in California Superior Court, Santa Clara County, captioned *Kangos v. Lange, et al*., which names CV Therapeutics as a nominal defendant. The plaintiff in this action is one of our stockholders who seeks to bring derivative claims on behalf of CV Therapeutics against the defendants. The lawsuit alleges breaches of fiduciary duty and related claims based on purportedly misleading statements concerning our new drug application for Ranexa. At the appropriate time, we expect to file a motion to dismiss this lawsuit due to the plaintiff's unexcused failure to make a demand on us before filing the action.

As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation, and defending these lawsuits is likely to be costly, time-consuming and uncertain. Accordingly, no expense accrual has been established for these lawsuits. In the event of an adverse outcome, our business could be harmed.

10. Stockholders' Equity

Preferred Stock

Of the 5,000,000 shares of preferred stock that we are authorized to issue, 850,000 shares are designated Series A junior participating preferred stock and are reserved for issuance pursuant to our Stockholders Rights Plan. Our board of directors may increase the number of shares designated as Series A junior participating preferred stock without further stockholder action. Under our Restated Certificate of Incorporation, our board of directors is authorized without further stockholder action to provide for the issuance of up to 5,000,000 shares of our preferred stock, in one or more series, with such voting powers, full or limited, and with such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated in the resolution or resolutions providing for the issue of a series of such stock adopted, at any time or from time to time, by our board of directors. The rights of the holders of each series of the preferred stock will be subordinate to those of our general creditors.

Equity Line of Credit and Significant Equity Transactions

In August 2000, we entered into a financing arrangement with Acqua Wellington to purchase our common stock. Under the purchase agreement, we had the ability to sell up to $149.0 million of our common stock to Acqua Wellington through December 2003. Applicable Nasdaq National Market rules limited the number of shares of common stock that we could issue under our purchase agreement with Acqua Wellington to approximately 3,703,000 shares. Since we effectively reached the Nasdaq limit, effective April 4, 2003, the purchase agreement terminated in accordance with its terms. We issued an aggregate of 3,687,366 shares of common stock in exchange for aggregate net cash proceeds of $113.7 million under this arrangement.

In July 2003, we entered into a new financing arrangement with Acqua Wellington to purchase our common stock. Under this purchase agreement, we had the ability to sell up to $100.0 million of our common stock, or 5,686,324 shares of our common stock, whichever occurred first, to Acqua Wellington through November 2005. In February 2005, the purchase agreement with Acqua Wellington automatically terminated when we reached the $100.0 million limit of this financing arrangement. We issued an aggregate of 5,442,932 shares of common stock to Acqua Wellington for aggregate gross proceeds of $100.0 million under this arrangement.

Warrants

In April 2003, we amended the lease on our 3172 Porter Drive facility in Palo Alto, California to, among other things, extend the term of the lease until April 2014 and provide for rent reductions, facility improvements

10. Stockholders' Equity (Continued)

and the issuance to the landlord of a warrant to purchase 200,000 shares of our common stock at an exercise price of $17.29 per share. The warrant is exercisable, in whole or in part, until the later of (i) the tenth anniversary of April 1, 2003 if (but only if) at any time prior to the fifth anniversary of April 1, 2003, the closing price of our common stock on the Nasdaq National Market has not been more than $34.58 for each trading day during any period of twenty consecutive trading days or (ii) the fifth anniversary of April 1, 2003. In accordance with EITF 96-18, the warrant was valued using the Black-Scholes model, assuming a term of ten years, a risk-free interest rate of 3.9% and volatility of 65%. We are accounting for the warrant as non-cash rent expense over the life of the lease.

In July 2003, we and Quintiles Transnational Corp. (Quintiles) modified our commercialization agreement for Ranexa. The modified agreement provides us with complete commercialization rights for Ranexa, including the opportunity to hire and train a dedicated cardiovascular sales force. Quintiles and its commercial sales and marketing subsidiary, Innovex Inc., continue to have a commercialization services relationship with us relating to Ranexa and also became a preferred provider of their full range of pharmaceutical services to us. In addition, pursuant to the modified agreement, Quintiles received a fully vested, non-forfeitable warrant, with a five-year term, to purchase 200,000 shares of our common stock at an exercise price of $32.93 per share. In accordance with EITF 96-18, the warrant was valued using the Black-Scholes model, assuming a term of five years, a risk-free interest rate of 2.5% and volatility of 65%, resulting in a charge to sales and marketing expense of approximately $3.7 million in the year ended December 31, 2003.

Employee Stock Purchase Plan

In September 1996, our board of directors adopted the Employee Stock Purchase Plan (Purchase Plan) covering an aggregate of 150,000 shares of our common stock. In May 2000, our stockholders approved an additional 75,000 shares for this Purchase Plan with annual automatic increases through 2005 in an amount equal to the least of (i) one-half of one percent of the number of outstanding shares of our common stock, (ii) 100,000 shares, or (iii) a smaller number of shares determined by the board of directors. In May 2003, our stockholders approved an amendment to provide that, on the day following each annual meeting beginning in 2003 and continuing through the annual meeting in 2007, the number of shares of common stock reserved for issuance under the Purchase Plan shall automatically be increased by the lesser of (i) 250,000 shares of common stock or (ii) a lesser number of shares of common stock as determined by the Board of Directors. This Purchase Plan is designed to allow eligible employees of ours or an affiliate of ours to purchase shares of our common stock at quarterly intervals through their periodic payroll deductions, which may not exceed 15 percent of any employee's compensation and may not exceed a value of $25,000 in any calendar year, at a price not less than the lesser of an amount equal to 85 percent of the fair market value of our common stock at the beginning of the offering period or an amount equal to 85 percent of the fair market value of our common stock on each purchase date. Employees may end their participation in the offering at any time during the offering period, and participation ends automatically on termination of employment with us. We have reserved 673,889 shares for issuance under this purchase plan. For the years ending December 31, 2005, 2004, and 2003, 274,732, 177,311 and 116,178 shares, respectively, were issued under the plan.

Stock Option Plans

We reserved 345,000 shares of common stock for issuance under our amended and restated 1992 Stock Option Plan, which provided for common stock options to be granted to employees, consultants, officers, and directors. No additional grants will be made under this plan.

10. Stockholders' Equity (Continued)

We reserved 1,800,000 shares of common stock for issuance under our amended and restated 1994 Equity Incentive Plan which provided for common stock options to be granted to employees of and consultants to us and our affiliates. No additional grants will be made under this plan.

Non-Employee Directors' Stock Option Plan

We have reserved an aggregate of 365,300 shares of our common stock for issuance under our Non-Employee Directors' Stock Option Plan (Directors' Plan) to our directors who are not otherwise an employee of, or consultant of ours or any affiliate of ours. Options granted under our Directors' Plan expire no later than 10 years from the date of grant. The exercise price of each option is the fair market value of the stock subject to such option on the date such option is granted. Following an August 2000 amendment to the Directors' Plan approved by our board of directors, generally (i) options covered by initial grants to new members of our board of directors vest in increments over a period of three years from the date of grant for new directors and (ii) options covered by replenishment grants to existing members of our board of directors vest in increments over a period of one year from the date of grant for existing directors. In the event of a "change of control" of the Company, each outstanding option under the Directors' Plan shall, automatically and without further action by us, become fully vested and exercisable with respect to all of the shares of common stock subject thereto no later than five (5) business days before the closing of such change of control event. Our Directors' Plan was terminated by our stockholders in May 2005, and no additional grants will be made under the Directors' Plan. Following approval by our board of directors and stockholders in April and May 2005, respectively, up to 20,335 shares of common stock previously reserved and available for issuance under the Directors' Plan as of March 31, 2005 and all shares of common stock that would have again become available for issuance under the Directors' Plan in the future in connection with the expiration or termination of options granted before March 31, 2005 under the Directors' Plan will be available for issuance under our 2000 Equity Incentive Plan.

2000 Equity Incentive Plan

As amended and restated by our stockholders effective May 26, 2005, our 2000 Equity Incentive Plan authorizes the issuance of a number of shares of common stock equal to the sum of (i) 4,450,000 shares of common stock, (ii) that number of shares of common stock available for issuance as of March 29, 2004 under our 2000 Nonstatutory Incentive Plan (Nonstatutory Plan), which was terminated in 2004 (not to exceed 404,685 shares of common stock), and all shares of common stock that would have again become available for issuance under the Nonstatutory Plan in the future in connection with the expiration or termination of options granted before March 29, 2004 under the Nonstatutory Plan, and (iii) that number of shares of common stock available for issuance as of March 31, 2005 under the Directors' Plan, which was terminated by our stockholders in May 2005 (not to exceed 20,335 shares of common stock), and all shares of common stock that would have again become available for issuance under the Directors' Plan in the future in connection with the expiration or termination of options granted before March 31, 2005 under the Directors' Plan.

The 2000 Equity Incentive Plan provides for the grant of stock awards consisting of incentive stock options, nonstatutory stock options, restricted stock and/or restricted stock units, and stock appreciation rights. Options granted under the 2000 Equity Incentive Plan expire no later than 10 years from the date of grant. The exercise price of an option shall be not less than 100% of the fair market value of the stock subject to the option on the date the option is granted, unless granted to a person who owns 10% or more of the fair market value of the stock of the company and its affiliates, in which case the exercise price shall be not less than 110% of the fair market value of the stock subject to the option on the date of grant. The vesting provisions of individual options may vary but in each case will provide for vesting of at least 20% of the total number of shares subject to the option

10. Stockholders' Equity (Continued)

per year. Restricted stock and/or restricted stock units granted under the 2000 Equity Incentive Plan shall have such terms and conditions as are approved by the board of directors. Grants of restricted stock and/or restricted stock units may have a purchase price or no purchase price, as determined by the board of directors, and shall be subject to a vesting schedule or forfeiture or share repurchase option as determined by the board of directors. Stock appreciation rights granted under the 2000 Equity Incentive Plan shall have such terms and conditions as are approved by the board of directors. Grants of stock appreciation rights shall have a term and exercise price as set by the board of directors, and a participant exercising a stock appreciation right shall receive consideration as determined by the board of directors. In the event of a "change of control" of the Company, each outstanding stock award under the 2000 Equity Incentive Plan shall, automatically and without further action by us, become fully vested and exercisable with respect to all of the shares of common stock subject thereto no later than five (5) business days before the closing of such change of control event.

2000 Nonstatutory Incentive Plan

We have reserved an aggregate of 2,665,216 shares of our common stock for issuance under our 2000 Nonstatutory Incentive Plan to our employees and consultants and those of our affiliates. The Nonstatutory Plan allowed for the grant of nonstatutory stock options. Options granted under our Nonstatutory Plan expire no later than 10 years from the date of grant. The exercise price of each nonstatutory option is not less than 100% of the fair market value of the stock subject to the option on the date the option is granted. The vesting provisions of individual options may vary but in each case provided for vesting of at least 20% of the total number of shares subject to the option per year. In the event of a "change of control" of the Company, each outstanding option under the Incentive Plan shall, automatically and without further action by us, become fully vested and exercisable with respect to all of the shares of common stock subject thereto no later than five (5) business days before the closing of such change of control event. Our Nonstatutory Plan was terminated by our stockholders in May 2004, and no additional grants will be made under the Nonstatutory Plan. Following approval by our board of directors and stockholders in April and May 2004, respectively, up to 404,685 shares of common stock previously reserved and available for issuance under the Nonstatutory Plan as of March 29, 2004 and all shares of common stock that would have again become available for issuance under the Nonstatutory Plan in the future in connection with the expiration or termination of options granted before March 29, 2004 under the Nonstatutory Plan will be available for issuance under our 2000 Equity Incentive Plan.

2004 Employee Commencement Incentive Plan

In December 2004, the board of directors approved the 2004 Employee Commencement Incentive Plan (Commencement Plan). The Commencement Plan became effective immediately thereafter. The Commencement Plan provides for the grant of nonstatutory stock options, restricted stock awards and restricted stock units, referred to collectively as awards. The awards granted pursuant to the Commencement Plan are intended to be stand-alone inducement awards pursuant to NASDAQ Marketplace Rule 4350(i)(1)(A)(iv). The Commencement Plan is not subject to the approval of the company's stockholders. Any employee who has not previously been an employee or director of the company or an affiliate, or following a bona fide period of non-employment by the company or an affiliate, is eligible to participate in the Commencement Plan only if he or she is granted an award in connection with his or her commencement of employment with the company or an affiliate and such grant is an inducement material to his or her entering into employment with the company or an affiliate. The board of directors administers the Commencement Plan. Subject to the provisions of the Commencement Plan, the board of directors has the power to construe and interpret the Commencement Plan and to determine the persons to whom and the dates on which awards will be granted, the number of shares of common stock to be subject to each award, the time or times during the term of each award within which all or a portion of such award may be

10. Stockholders' Equity (Continued)

exercised, the exercise price, the type of consideration and other terms of the award. Awards may be granted under the Commencement Plan upon the approval of a majority of the board's independent directors or upon the approval of the compensation committee of the board of directors. Prior to or concurrently with the grant of any awards under the Commencement Plan, our board of directors reserves for issuance pursuant to the Commencement Plan the number of shares of common stock as may be necessary in order to accommodate such awards. Each award granted under the Commencement Plan shall be in such form and shall contain such terms and conditions as the board of directors shall deem appropriate. The provisions of separate awards need not be identical.

The following table summarizes option and restricted stock unit activity under all our equity plans (in thousands, except per share amounts):

		Outstanding Options		
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Outstanding Restricted Stock Units
Balance at December 31, 2002	2,262	5,282	$31.47	–
Shares authorized	–			
Options granted	(1,803)	1,803	$17.62	–
Options forfeited	174	(174)	$39.08	–
Options expired	(17)	–	$ –	–
Options exercised	–	(155)	$ 7.71	–
Balance at December 31, 2003	616	6,756	$28.12	–
Shares authorized	–			
Options granted	(384)	384	$14.86	–
Options forfeited	766	(766)	$33.20	–
Options expired	(4)	–	$ –	–
Options exercised	–	(120)	$ 8.39	–
Balance at December 31, 2004	994	6,254	$27.04	–
Shares authorized	3,434	–		
Options granted	(1,868)	1,868	$23.39	–
Options forfeited	172	(172)	$24.88	–
Options expired	(1)	–	$ 2.50	–
Options exercised	–	(286)	$12.86	–
Restricted Stock Units (RSUs) granted	(921)	–	$ –	921
RSUs forfeited	8	–	$ –	(8)
RSUs exercised	–	–	$ –	(3)
Balance at December 31, 2005	1,818	7,664	$26.73	910

10. Stockholders' Equity (Continued)

The following table summarizes information about stock options outstanding at December 31, 2005:

	Outstanding Options			Exercisable Options	
Range of Exercise Prices	Shares Outstanding (in thousands)	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number of Shares (in thousands)	Weighted Average Exercise Price
$ 2.00 - $13.38	1,588	6.25	$11.48	1,008	$10.53
$13.39 - $22.03	1,604	7.69	$18.71	702	$17.61
$22.20 - $26.05	1,605	8.37	$23.73	478	$23.51
$26.27 - $40.61	1,637	6.39	$34.44	1,165	$36.80
$41.40 - $86.56	1,230	5.37	$50.52	1,228	$50.53
	7,664	6.89	$26.73	4,581	$30.37

As of December 31, 2005, 2004, and 2003, the total number of options exercisable was 4,581,000, 3,777,000 and 2,915,000 shares, respectively.

Restricted Stock Units

During 2005, we issued 921,000 restricted stock units (RSUs) to our employees, including executives, and to certain consultants. In accordance with APB No. 25, we valued the RSUs at the market price of our common stock on the date of the award and we are recognizing the associated stock compensation expense, using the straight-line method, over the period the services are performed, which is generally 48 months. RSUs generally vest monthly over a period of 48 months and are settled and issued on specific distribution dates. Some of the RSUs provide for immediate acceleration of vesting in the event that we achieve a certain annualized product revenue threshold over four consecutive quarters. As of December 31, 2005, we have a balance of $18.2 million of deferred stock-based compensation on our consolidated balance sheet, which represents the value of RSUs granted to employees as of the grant date remaining to be amortized as the services are performed. For the year ended December 31, 2005, we recorded $3.4 million of compensation expense related to these restricted stock units. As of December 31, 2005, 141,725 RSUs were vested.

Stock Appreciation Rights

During 2005, we granted 950,000 stock appreciation rights (SARs) to certain executives. The SARs vest annually over four years and are automatically exercised upon each vesting date. When an award vests, employees will receive compensation equal to the amount, if any, by which the volume weighted average market price of the shares covered by the SAR exceeds the SAR base value for each SAR vested. The SAR base value is a predetermined strike price of $26.45, which represented a 15% premium to the market price on the grant date. We currently expect to settle all amounts due under the SARs, if any, using shares of our common stock. As of December 31, 2005, a total of 237,500 SARS were vested and we recorded $38,000 of compensation expense related to the vested SARS for the year ended December 31, 2005, in accordance with APB No. 25 and Financial Accounting Standards Board Interpretation No. 28, "*Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinions No. 15 and 25*." We have reserved 1,483 shares as of December 31, 2005 to be issued in January 2006 related to these vested SARs for the year ended December 31, 2005.

10. Stockholders' Equity (Continued)

Stockholders Rights Plan

In February 1999, we announced that the board of directors approved the adoption of a Stockholders Rights Plan under which all stockholders of record as of February 23, 1999 received and all stockholders receiving newly issued shares after that date have or will receive rights to purchase shares of a new series of preferred stock.

This plan is designed to enable all company stockholders to realize the full value of their investment and to provide for fair and equal treatment for all stockholders in the event that an unsolicited attempt is made to acquire the company. The adoption of this plan is intended as a means to guard against abusive takeover tactics and was not in response to any particular proposal.

The rights were distributed as a non-taxable dividend and will expire on February 1, 2009, unless such date is extended or the rights are earlier exchanged or redeemed as provided in the plan. The rights will be exercisable only if a person or group acquires 20% or more of the company's common stock or announces a tender offer of the company's common stock. If a person acquires 20% or more of the company's stock, all rightsholders except the buyer will be entitled to acquire the company's common stock at discount. The effect will be to discourage acquisitions of more than 20% of the company's common stock without negotiations with the board of directors.

In July 2000, the board of directors approved certain amendments to this plan, including lowering the trigger percentage from 20% to 15%, and raising the exercise price for each right from $35.00 to $500.00.

11. Income Taxes

Our net loss includes the following components (in thousands):

	Year ended December 31,		
	2005	2004	2003
Domestic	$(228,373)	$(155,173)	$(110,951)
Foreign	378	90	–
Total	$(227,995)	$(155,083)	$(110,951)

A reconciliation of income taxes computed at the statutory federal income tax rate to our reported amounts is as follows (in thousands):

	Year ended December 31,		
	2005	2004	2003
U.S. federal taxes (benefit) at statutory rate	$(77,518)	$(52,759)	$(37,723)
Unutilized (utilized) net operating losses	77,480	53,089	38,513
Stock-based compensation	(167)	(441)	(1,024)
Other	205	111	234
Total	$ –	$ –	$ –

11. Income Taxes (Continued)

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 amount used for income tax purposes. Significant components of our deferred tax assets as of December 31, 2005 and 2004 are as follows (in thousands):

	2005	2004
Deferred tax assets:		
Net operating loss carryforwards	$ 299,501	$ 204,796
Research tax credit carryforwards	10,246	12,459
Non deductible accrued expenses	18,392	11,825
Capitalized research and development expenses	10,411	19,262
Other	–	863
Total deferred tax assets	338,550	249,205
Less valuation allowance	(338,565)	(249,205)
Subtotal	(15)	–
Deferred tax liabilities:		
Unrealized gains on investments	15	–
Net deferred tax assets	$ –	$ –

Realization of deferred tax assets is dependent upon taxable income, 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 $89.4 million, $65.5 million and $49.1 million during 2005, 2004 and 2003, respectively. Approximately $18.2 million of the valuation allowance at December 31, 2005 relates to the benefit of the stock option deductions, which, if and when recognized, will be credited to stockholders' equity.

As of December 31, 2005, we had federal and California net operating loss carryforwards of approximately $791.5 million and $506.8 million, respectively. We also had federal and California research and development tax credit carryforwards of approximately $6.5 million and $5.2 million, respectively. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in the year 2006, if not utilized. The California net operating loss carryforwards will expire at various dates beginning in the year 2007, if not utilized. The federal research tax credit carryforwards will expire at various dates beginning in the year 2008, if not utilized. The California research tax credit carryforwards can be carried forward indefinitely.

Utilization of the our net operating loss and tax credit carryforwards will likely be subject to substantial annual limitations due to ownership change limitations provided by the Internal Revenue Code and similar California provisions. As a result of annual limitations, a portion of these carryforwards may expire before becoming available to reduce our federal and California income tax liabilities.

12. 401(k) Plan

Our 401(k) plan covers all of our eligible employees. Under the plan, employees may contribute specified percentages or amounts of their eligible compensation, subject to certain Internal Revenue Service restrictions. For 2005 and 2004, the board of directors approved a discretionary matching contribution under the 401(k) plan for eligible employees having an aggregate value equal to up to seven percent of each such employee's eligible compensation. Fifty percent of the matching contribution was paid in cash, and fifty percent of the matching contribution was in the form of fully vested shares of our common stock. For the 2005 match, which was paid out January 2006, we expensed a total of $1.3 million in cash and issued a total of 51,922 shares of our common

12. 401(k) Plan (Continued)

stock, which stock had an aggregate value of $1.3 million. For the 2004 match, which was paid out in 2005, we paid a total of $0.7 million in cash and issued a total of 35,716 shares of our common stock, which stock had an aggregate value of $0.7 million. For 2003, the board of directors approved a discretionary matching contribution for eligible employees having an aggregate value to up to five percent of such employee's eligible compensation, and one hundred percent of the match was in the form of fully vested shares of our common stock. In January 2004, we issued 60,391 shares of our common stock for the 2003 match with a value of $0.9 million.

13. Quarterly Financial Data (Unaudited)

The following tables summarize the unaudited quarterly financial data for the last two fiscal years (in thousands, except per share data):

	Fiscal 2005 Quarter Ended			
	Mar. 31	Jun. 30	Sep. 30	Dec. 31
	(in thousands, except per share amounts)			
Revenues	$ 5,630	$ 5,747	$ 4,142	$ 3,432
Loss from operations	(45,854)	(50,979)	(55,272)	(72,083)
Net loss	(46,422)	(51,601)	(55,920)	(74,052)
Basic and diluted net loss per share	$ (1.31)	$ (1.43)	$ (1.26)	$ (1.65)

	Fiscal 2004 Quarter Ended			
	Mar. 31	Jun. 30	Sep. 30	Dec. 31
	(in thousands, except per share amounts)			
Revenues	$ 2,939	$ 4,264	$ 5,645	$ 7,580
Loss from operations	(29,788)	(32,652)	(31,782)	(52,874)
Net loss	(31,324)	(37,227)	(32,770)	(53,762)
Basic and diluted net loss per share	$ (1.04)	$ (1.18)	$ (1.03)	$ (1.62)

14. Subsequent Events

FDA Approval of Ranexa

The FDA approved Ranexa in January 2006. As a result, we are now obligated to pay the following commitments that were contingent upon Ranexa's approval:

In February 2006, we paid $11.0 million to Roche in accordance with our agreement with Roche Palo Alto LLC, as disclosed in Note 2. Unless the agreement is terminated, within thirty days of the second product approval of Ranexa, if any, in one of the major market countries, we will owe a second payment of $9.0 million to Roche.

We have a commitment related to an agreement with a vendor whereby amounts are due to them upon the approval of Ranexa by the FDA and the manufacture of certain materials related to the production of Ranexa. Upon FDA approval of Ranexa, we are required to pay a $5.0 million milestone and certain fees based upon the amount of Ranexa manufactured until total amounts paid reach $12.0 million. In January 2006, we paid $5.0 million to this vendor in accordance with the agreement.

We have a commitment related to an agreement with Quintiles Transnational Corp. whereby we are required to engage Quintiles to provide $10.0 million or more of commercialization services by or before six months

14. Subsequent Events (Continued)

following the approval of Ranexa by the FDA. Otherwise, we are obligated to pay the Quintiles ten percent of the difference between $10.0 million and the actual amounts of commercialization services we have engaged with them during the end of the six month period following the approval of Ranexa.

Lease Amendment

In January 2006, we extended our lease to our Porter Drive buildings in Palo Alto, CA. The lease term was extended to April 2016 with an option to renew for nine years, and the lease provided for net rent reductions of $3.7 million over five years in return for the issuance of warrants to the landlord and the ground lessor to purchase an aggregate total of 200,000 shares of our common stock at a price of $24.04. Each warrant is exercisable, in whole or in part, until the later of (i) the tenth anniversary of January 19, 2006 if (but only if) at any time prior to the fifth anniversary of January 19, 2006 the closing price of our common stock on the Nasdaq National Market has not been more than $48.08 for each trading day during any period of twenty consecutive trading days or (ii) the fifth anniversary of January 19, 2006.

Stock Appreciation Rights Amendment

In January 2006, the board of directors amended the terms of the SAR agreements issued to certain executives in 2005. In addition to receiving compensation equal to the amount, if any, by which the volume weighted average market price of the shares covered by the SAR exceeds the SAR base value for each SAR vested for the current year, for that current year the employee will also receive compensation, if any, equal to the amount(s), if any, settled and received in prior years. We expect to settle all amounts due under the SARs, if any, using shares of our common stock.

Employment Commencement Incentive Plan

In February 2006, we announced that in accordance with Nasdaq marketplace rule 4350, we granted 18 new non-executive employees inducement stock options covering an aggregate 54,700 shares of common stock under our 2004 Employment Commencement Incentive Plan. These inducement stock options are classified as non-qualified stock options with an exercise price equal to the fair market value on the grant date. The options have a ten-year term and vest over four years as follows: 20% of these options will vest on the date one year from the optionee's hire date, 20% of the options will vest in monthly increments during each of the second and third years, and 40% of the options will vest in monthly increments during the fourth year (in all cases subject to the terms and conditions of CV Therapeutics 2004 Employment Commencement Incentive Plan).

Amendment to Co-Promotion Agreement

In March 2006, we amended the co-promotion agreement with Solvay Pharmaceuticals to adjust the baseline above which we receive a share of product sales, and to modify related economic terms of the agreement.

Annual Meeting

The annual meeting of stockholders will be held at 8:00 am local time on June 6, 2006 at CV Therapeutics, Inc., 3172 Porter Drive, Palo Alto, California.

Investor and Financial Information

Recent press releases and other CV Therapeutics information, including our report on Form 10-K as filed with the Securities and Exchange Commission, are available without charge on CV Therapeutics' website at http://www.cvt.com or upon written request to:

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Independent Auditors

Ernst & Young LLP
Palo Alto, California

Corporate Secretary

Alan C. Mendelson, Esq.
Latham & Watkins LLP
Menlo Park, California

Market Information

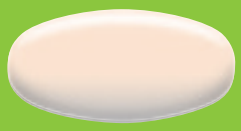
CV Therapeutics' Common Stock trades on The Nasdaq National Market under the symbol CVTX. The table below sets forth the high and low sale prices for the Common Stock during the last four fiscal years, as reported by The Nasdaq National Market.

Stock Price	2005		2004		2003		2002	
	High	Low	High	Low	High	Low	High	Low
First Quarter	23.76	19.15	17.48	13.12	21.37	15.73	52.91	35.34
Second Quarter	23.73	19.39	17.40	12.20	41.50	16.66	36.20	15.82
Third Quarter	29.79	22.15	16.73	11.28	36.65	20.75	28.99	14.66
Fourth Quarter	28.42	23.38	24.70	12.08	24.75	12.20	27.94	17.65

Stock Profile

As of March 8, 2006, there were approximately 70 stockholders of record of the Company's Common Stock, one of which is Cede & Co., a nominee for Depository Trust Corporation (DTC). All of the shares of the Company's Common Stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one stockholder. As of March 8, 2006, there were 45,036,161 shares outstanding. No dividends have been paid on the Common Stock since the Company's inception.

Design: Hane Chow, Inc., Oakland, California Photography: Jim Karageorge



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