Rtlos THERAPEUTICS, INC.

TO OUR SHAREHOLDERS, CLINICAL COLLABORATORS, PARTNERS, EMPLOYEES AND FRIENDS

Fiscal year 2002 was a year of achieving significant milestones and laying the foundation for structuring a premier biopharmaceutical company that is focused on building shareholder value. We entered 2002 as a single-product company and emerged with a stronger oncology portfolio that will further contribute to the long-term success of the business. We remain committed to our mission of developing, acquiring and commercializing innovative therapeutic agents that provide increased treatment alternatives for patients and make current cancer therapies more effective.

Pivotal Clinical Trial Completed | A highlight of the past year was the completion of our pivotal Phase 3 clinical trial of our lead drug candidate, RSR13 (efaproxiral) in patients with brain metastases. Brain metastasis is cancer that has spread to the brain from the site of the primary tumor within the body. This study was one of the largest international randomized Phase 3 studies ever conducted in patients with brain metastases. We enrolled the maximum number of patients that the protocol would allow—a total of 538 patients at 83 leading cancer centers in 11 countries—and completed enrollment earlier than expected. The rapid enrollment in this study confirmed to us that the treatment of patients with brain metastases is a clear unmet medical need. We are grateful to each of the patients who participated in this study, as well as the investigators, study coordinators, and nursing staff who advised and supported the patients throughout the process.

On April 23, 2003, we reported the preliminary results of the Phase 3 trial. The primary endpoint of the study was an increase in overall survival, the most stringent of all endpoints in pharmaceutical development. While the difference in overall survival in patients who received RSR13 plus whole brain radiation therapy and patients who received only whole brain radiation therapy was not statistically significant, we did see strong clinical evidence of patient benefit of RSR13. The benefits observed in patients with metastatic breast cancer were particularly encouraging, providing a median of an additional four months of survival in this group. In addition, several patients with metastatic breast cancer who received RSR13 were approaching two years of survival post therapy. A more complete analysis of the Phase 3 trial will be presented to the scientific community at a medical meeting later this year.

Looking Ahead in 2003 | We have several reasons to be encouraged about the outcome of our Phase 3 study. This is the first time a radiation sensitizer has shown a survival benefit in any class of patients with brain metastases in a large randomized Phase 3 trial. The study results not only provide confirmation that RSR13 is safe and well tolerated by patients, but also support our original hypothesis that local control in the brain allows for prolonged systemic therapy, resulting in an increase in survival. Because brain metastasis is a very heterogeneous disease with poor prognosis, we believe that any survival benefit is significant to these patients and their caregivers. Accordingly, we believe the results of this trial support the further development of RSR13 as a radiation sensitizer.

While RSR13 has been our primary focus, PDX, a small molecule, anti-folate dihydrofolate reductase inhibitor, is another compound that holds great promise for the future. The successful in-license of this novel compound represents a validation of our internal capabilities and confirmation of our partners' confidence in our ability to provide value-added drug development expertise. PDX has completed a Phase 2 study for the second-line treatment of non-small cell lung cancer and is also being studied in mesothelioma and non-Hodgkin's lymphoma. Our development objective for the coming year is to complete the manufacturing scale-up process that enables us to produce sufficient drug quantities to support future clinical trials.

We expect the next several months to be challenging until the development pathway for RSR13 becomes clearer. Our scheduled meeting with the FDA to discuss the results of our Phase 3 study is the first step in this process. Any delay in the original timeline for the approval of RSR13 will require adjustments to our current business plan, including development plans for both RSR13 and other products. In preparation for

this possible outcome, we are carefully evaluating our corporate structure and clinical development priorities in light of our current cash position and the restrictive financing environment. We also intend to actively explore partnering and financing opportunities that contribute to the long-term success of the company.

In Closing | I would like to extend a heartfelt thank you from the entire Allos Therapeutics' management team for the interest and support of our shareholders, clinical collaborators, partners, employees and friends. It is our belief that combination therapy will remain the foundation of cancer treatment, with the goal of improving survival without compromising quality of life. We remain committed to developing novel compounds like RSR13 and PDX that can make a difference in someone's life. I look forward to continuing the dialogue on our progress in the coming months.

Sincerely,

Michael E. Hart
President and Chief Executive Officer

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, 2002.

☐ 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
000-29815

Allos Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	54-1655029
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11080 CirclePoint Road, Suite 200
Westminster, Colorado 80020
(303) 426-6262
(Address, including zip code, and telephone number, including area code, of principal executive offices)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock $.001 Par Value
(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

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

Indicate by check mark whether the Registrant is an accelerated filer (as defined by Exchange Act Rule 12b-2).

Yes ☒ No ☐

As of March 20, 2003, there were 25,884,554 shares of the Registrant's common stock outstanding and the aggregate market value of such shares held by nonaffiliates of the Registrant (based upon the closing sale price of such shares on the Nasdaq National Market on June 28, 2002) was approximately $81,603,682. Shares of the Registrant's common stock held by each current executive officer and director and by each person who is known by the Registrant to own 10% or more of the outstanding common stock have been excluded from this computation in that such persons may be deemed to be affiliates of the Registrant. Share ownership information of certain persons known by the Registrant to own greater than 10% of the outstanding common stock for purposes of the preceding calculation is based solely on information on Schedule 13G filed with the Commission and is as of December 31, 2002. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the 2003 Annual Meeting of Stockholders are incorporated by reference into Part III of this report on Form 10-K to the extent stated therein.

Certain exhibits filed with the Registrant's Registration Statement on Form S-1 (File No. 333-95439), Annual Report on Form 10-K (File No. 000-29815), for fiscal year ended December 31, 2000, Annual Report on Form 10-K (File No. 000-29815), for fiscal year ended December 31, 2001 and Registration Statements on Forms S-8 (Nos. 333-38696, 333-60430 and 333-76804) are incorporated by reference into Part IV of this report on Form 10-K.

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PART I

Unless the context requires otherwise, references in this report to "Allos," the "Company," "we," "us," and "our" refer to Allos Therapeutics, Inc.

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements concerning our plans to continue development of our current product candidates; conduct clinical trials with respect to our product candidates; seek regulatory approvals; address certain markets; initiate marketing activities related to commercialization of our products; increase the scale of third-party clinical manufacturing activities; raise additional capital; hire sales and marketing personnel; develop relationships with pharmaceutical companies; obtain and protect rights to technology; establish new collaborative and licensing agreements; and evaluate additional product candidates for in-license and subsequent clinical and commercial development. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of such terms and other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among other things, those discussed under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All forward-looking statements included in this report are based on information available to us as of the date hereof and we undertake no obligation to revise any forward-looking statements in order to reflect any subsequent events or circumstances. Forward-looking statements not specifically described above also may be found in these and other sections of this report.

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative small molecule drugs for improving cancer treatments. Small molecule drugs, in general, are non-protein products produced by chemical synthesis rather than biologic methods. Our lead compound, RSR13 (efaproxiral), is a synthetic small molecule that enhances the diffusion of oxygen to hypoxic (oxygen-deprived) tumor tissues from hemoglobin, the oxygen-carrying protein contained within red blood cells. The presence of oxygen in tumors is an essential element for the effectiveness of radiation therapy and some chemotherapy agents in the treatment of cancer. By increasing tumor oxygenation, RSR13 has the potential to enhance the efficacy of standard radiation therapy and certain chemotherapeutic drugs. Unlike chemotherapeutics or other radiation sensitizers, RSR13 does not have to cross the blood brain barrier and enter the tumor to be effective. We believe RSR13 can be used to improve existing cancer treatments and treat many diseases and clinical conditions attributed to or aggravated by oxygen deprivation.

We have demonstrated in Phase 2 clinical trials that RSR13 significantly improves the efficacy of radiation therapy for treating brain metastases, or tumors that have spread to the brain, glioblastoma multiforme, or GBM, a highly aggressive form of primary brain cancer, and non-small cell lung cancer, or NSCLC. We have completed a pivotal Phase 3 trial of RSR13 for the treatment of patients with brain metastases and expect to have complete preliminary results in the second quarter of 2003. We believe that this trial, if positive, will serve as the basis for seeking marketing approval for RSR13 from the Food and Drug Administration (FDA) for this indication. In November 2002, we announced updated median survival results from a Phase 2 clinical trial evaluating the use of RSR13 in patients with locally advanced, inoperable NSCLC receiving radiation therapy following induction chemotherapy. We have received FDA concurrence and are in the planning stages prior to initiating a Phase 3 clinical trial of RSR13 in patients with NSCLC. We believe RSR13 could have application in many other tumor types and clinical situations requiring radiation therapy, such as cervical, pancreatic, esophageal and head and neck cancers.

In addition to RSR13, we have expanded our oncology development pipeline through the in-license of BGP-15, a small molecule compound that has shown potential chemoprotectant properties in preclinical studies, and PDX, a novel, proprietary anti-folate dihydrofolate reductase (DHFR) inhibitor, which has shown significant single-agent activity in a Phase 2 trial of 39 previously treated patients with NSCLC.

Our Business Strategies for Growth

The key elements of our business strategy include:

- *Focusing on developing and commercializing RSR13 to address the large markets for the treatment of cancer.* We are currently focusing our efforts on completing clinical development and preparing for commercialization of RSR13 for the treatment of several tumor types.
- *Expanding our oncology pipeline through the in-license or acquisition of complementary products.* We will continue to evaluate additional compounds that enhance our oncology portfolio with the intent to build a pipeline of compounds for development and commercialization.
- *Extending the RSR13 product line to other indications outside oncology through collaborations.* We believe RSR13 can be used to treat many other diseases and clinical conditions. We are evaluating non-oncology indications that we may pursue alone or in conjunction with a corporate partner to jointly develop RSR13 for treating the hypoxic effects of acute blood loss and decreased blood flow encountered in surgical procedures and also for improving the effectiveness of treatments for cardiovascular disease and stroke.

Available Information

We were incorporated under the laws of the Commonwealth of Virginia in September 1992 as Hemotech Sciences, Inc. We reincorporated in Delaware as Allos Therapeutics, Inc. in October 1996. We are located in Westminster, Colorado, a suburb of Denver. Our current mailing address is 11080 CirclePoint Road, Westminster, Colorado 80020.

Our website address is *www.allos.com*. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as any amendments to those reports, are available free of charge through our website as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Once at *www.allos.com*, go to Investors/Media/Fundamentals/SEC Filings.

In 2003, we intend to adopt a code of ethics that applies to our principal executive officer and principal financial officer, and intend to post the text of our code of ethics on our website at www.allos.com in connection with "Investor" materials. In addition, we intend to promptly disclose (1) the nature of any amendment to our code of ethics that applies to our principal executive officer and principal financial officer, functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Synthetic Allosteric Modifiers

Scientific Background

Oxygen is indispensable to all human tissues. It is transported through the body by hemoglobin, a protein contained within red blood cells, and is consumed in the production of energy for sustaining life. Each hemoglobin protein can bind up to four molecules of oxygen. After picking up oxygen in the lungs and circulating to various tissues in the body, each hemoglobin protein, on average, releases one of its four oxygen molecules and retains the other three in reserve. Thus, approximately 75% of the oxygen carried by hemoglobin represents an untapped reservoir of oxygen potentially available to the body. When hemoglobin returns to the lungs, it replenishes its store of oxygen for its next round trip through the body.

Although oxygen is ordinarily vital for life, in some instances, energized forms of oxygen, called oxygen radicals, can be toxic to cells. For example, during radiation therapy for a cancerous tumor, radiation-induced oxygen radicals contribute to the death of cells in the tumor. Therapies that increase oxygen levels in tumors at the time of radiation can therefore enhance the cytotoxicity of radiation therapy.

Malignant tumors often have a poorly regulated blood supply caused by the disorganized growth of new blood vessels into the tumor. This, in addition to the rapid cell growth of malignant tumors, leads to the formation of hypoxic regions within the tumor, a phenomenon known as tumor hypoxia. Research shows that hypoxic regions within malignant tumors are substantially more resistant to cell damage from radiation than oxygenated regions. Even small hypoxic regions in a tumor may affect the overall response to radiation therapy and increase the number of surviving tumor cells. Tumor cells that survive radiation therapy can become resistant to therapy, and

can cause the tumor to recur in the same location and metastasize to distant sites, causing continued illness and death.

Tissue hypoxia is also a factor in many other diseases and clinical conditions. For example, during cardiac and other types of surgery, tissue hypoxia can occur from decreased oxygen carrying capacity caused by acute blood loss or decreased blood flow to major organs, such as the brain, heart, liver and kidneys. In addition, hypoxia caused by the acute blockage of a major blood vessel can lead to conditions that cause significant morbidity and mortality, such as acute angina, or chest pain caused by decreased blood flow to the heart, myocardial infarction, or heart attack, and stroke.

The body has developed certain natural responses to mitigate or reverse the damage of some forms of hypoxia. For example, when the body is suddenly subjected to acute hypoxia, such as during acute blood loss, several highly predictable responses occur. Initially, the body increases the rate of breathing to more fully oxygenate the blood as it passes through the lungs. The body also attempts to improve blood flow by increasing the rate and force of cardiac contractions. Subsequently, the red blood cells produce increased amounts of 2,3-diphosphoglycerate, or 2,3-DPG, a naturally occurring small molecule that chemically decreases the oxygen binding affinity of hemoglobin. 2,3-DPG essentially taps into hemoglobin's oxygen reservoir, and increases the average unloading of oxygen from hemoglobin from 25% to approximately 35%. Finally, over the next several weeks to months, the body produces a natural hormone known as erythropoetin to stimulate production of new red blood cells.

Although production of 2,3-DPG is effective as a natural response mechanism, it is not a viable candidate for therapeutic applications. 2,3-DPG is produced inside the red blood cells and cannot by itself penetrate the red blood cell membrane if medically administered to a patient. As a result, therapeutic administration of 2,3-DPG cannot be used to oxygenate cancerous tumors to enhance the effectiveness of radiation therapy. In addition, the natural increase of 2,3-DPG levels during acute hypoxic episodes takes several hours to days to reach a peak effect. 2,3-DPG, therefore, is not effective in treating or preventing acute hypoxic conditions associated with surgical blood loss or cardiovascular disease, conditions that require an immediate response.

RSR13 (efaproxiral)

In traditional approaches to drug development, a small molecule drug is used to bind to the active site of a protein to modify the protein's function. In some cases, the drug activates, and in others it inhibits, the protein's function.

In contrast to traditional approaches, our core technology is based on using small molecules to modify a protein's function by altering the protein's three-dimensional structure. This is called allosteric modification. In allosteric modification, a small molecule drug alters a protein's three-dimensional structure by binding to the protein at a site different from the protein's active site. This change in conformational structure affects the binding affinity of the protein for the molecules that normally bind to its active site. The ability of a drug to increase or decrease this affinity can have important clinical implications. For example, an allosteric modifier that decreases the oxygen-binding affinity of hemoglobin, and thereby stimulates the release of oxygen into tissues, can be used to mitigate the adverse effects of many forms of tissue hypoxia.

Our lead product candidate, RSR13, is designed to mitigate the effects of tissue hypoxia. RSR13 has been studied for the prevention or treatment of conditions associated with tissue hypoxia in 17 trials under 3 separate Investigational New Drug applications, or INDs, filed with the FDA. RSR13 has been administered safely to over 550 adult patients in 9 oncology studies, most of whom were cancer patients receiving concurrent radiation therapy. We have shown that RSR13 is generally well tolerated and has an acceptable safety profile for use in cancer patients.

RSR13 has a well-defined mechanism of action and is the first synthetic drug to emulate and amplify the action of 2,3-DPG, the naturally occurring allosteric modifier of hemoglobin. Like 2,3-DPG, RSR13 binds to hemoglobin away from the hemoglobin's oxygen-binding site and enhances the diffusion of oxygen from hemoglobin to hypoxic tissues. RSR13 has several distinguishing characteristics from 2,3-DPG that make it particularly well suited for therapeutic applications:

- RSR13 is able to cross the red blood cell membrane when medically administered to a patient;
- RSR13 has an immediate onset of action;

- on average, RSR13 increases the normal 25% unloading of oxygen from hemoglobin to an estimated 50% by increasing oxygen release from the large reservoir of unused hemoglobin-bound oxygen in the blood; and
- RSR13 remains in the bloodstream while oxygen naturally diffuses into the surrounding tissue.

By emulating and amplifying the body's natural response to acute hypoxia, RSR13 has the potential for treating a wide variety of diseases and clinical conditions caused by tissue hypoxia. We believe that increasing oxygen levels in hypoxic tumors can enhance the effects of radiation therapy. In addition, we believe RSR13 could also be used to prevent complications associated with tissue hypoxia that frequently occur during or after surgery. In the cardiovascular area, we believe RSR13 can be used to help treat acute angina, myocardial infarction and stroke, among other conditions.

Products Under Development

We currently retain exclusive, worldwide commercial rights for RSR13 for all target indications. The table below summarizes our current product candidates, their target indications and clinical program status.

Product Candidate	Target Indication	Clinical Program Status
RSR13		
Radiation Sensitizer	Brain metastases	Phase 3 complete
	Non-small cell lung cancer	Phase 3
	Glioblastoma multiforme	Phase 2 complete
	Cervical cancer	Phase 1/2
	Other cancer types	Phase 1's and 2's planned
Chemotherapy Enhancer	Recurrent glioblastoma multiforme	Phase 1b/2
Surgical Hypoxia	Cardiopulmonary bypass surgery	Phase 2
Cardiovascular Disease	Angina	Phase 1 complete
	Myocardial infarction	Preclinical
	Stroke	Preclinical
PDX	Non-small cell lung cancer	Phase 2
	Mesothelioma	Phase 2
	Non-Hodgkin's lymphoma	Phase 1
BGP-15	Chemoprotectant	Preclinical
Pyruvate Kinase Inhibitors	Chronic hypoxia	Research

RSR13 for Treating Cancer

According to an independent healthcare research company, the worldwide oncology drug market was estimated at $23.1 billion in 2001. Despite the enormous effort undertaken by the pharmaceutical industry to develop oncology products, cancer remains the second-leading cause of death in the United States and remains a largely unmet medical need. Over 1.2 million new cases of cancer are diagnosed each year in the United States, and approximately 565,000 patients die each year of cancer.

The appropriate cancer therapy for each patient depends on the cancer type and careful assessment of the size, location and extent to which the tumor has spread. Therapy typically includes some combination of surgery, radiation therapy or chemotherapy. Radiation therapy is used to cure certain cancers, to control local tumor invasion and thus prolong life, and to treat symptomatic problems in patients who are expected to die of their cancer. Chemotherapy and surgery are used to cure certain cancers or prolong life in some patients with malignant tumors.

RSR13 as a Radiation Sensitizer

Radiation therapy is the principal non-surgical means of treating malignant tumors in patients with cancer. Each year in the United States, approximately 50% of all newly diagnosed cancer patients, or 600,000 patients, receive radiation therapy as part of their primary treatment, in addition to approximately 150,000 patients who

receive radiation therapy for persistent or recurrent cancer. The estimated 750,000 cancer patients who receive radiation therapy annually are approximately twice the number of cancer patients who are treated with chemotherapy. A course of radiation therapy can cost between $5,000 and $25,000 depending on the complexity and duration of treatment. Although radiation therapy can be effective in treating certain types of cancer, an unmet medical need exists for products that can increase the effectiveness of radiation therapy.

RSR13 is administered by a 30-minute intravenous infusion through a peripherally inserted central catheter (PICC line), or less common central venous catheter, commencing approximately one hour before scheduled radiation therapy. Patients are also given supplemental oxygen, like that commonly administered to individuals with chronic lung disease, to fully saturate hemoglobin and increase the therapeutic potential of RSR13. RSR13 has an immediate onset of action after administration and has a short duration of action of four-to-six hours.

Unlike existing drugs and other attempts to enhance the effects of radiation therapy, the radiation enhancing effect of RSR13 is not dependent on its direct diffusion into the cancerous tumor. Instead, the beneficial effects of RSR13 are the result of causing increased amounts of oxygen release from blood flowing through the tumor. It is the oxygen, and not the drug, which diffuses across the cancer cell membranes to oxygenate the tumors. This is particularly important in the case of primary or metastatic brain tumors, where the blood brain barrier acts to exclude or impede the entry of most chemical agents into the brain tissue. The fact that RSR13 does not have to actually enter the cancer cell to increase radiosensitivity is an important difference between RSR13 and other pharmacologic attempts to improve the efficacy of radiation therapy.

We have completed nine clinical trials of RSR13 in patients receiving radiation therapy and have shown that RSR13 is generally well tolerated and has an acceptable safety profile for use in cancer patients. The most common side effects of RSR13 in cancer patients are dose and frequency related. These side effects include low hemoglobin oxygen saturation (which is readily treated with supplemental oxygen like that used in patients with chronic lung disease), reversible kidney dysfunction (typically in patients who are also taking blood pressure medications or common anti-inflammatory drugs), allergic rash and other symptoms often seen in cancer patients receiving radiation therapy, such as headache, nausea and vomiting.

RSR13 in the Treatment of Brain Metastases

We intend to seek FDA approval of RSR13 first for the treatment of patients who are receiving radiation therapy for brain metastases. This condition occurs in approximately one out of five cancer patients, most often in patients with lung or breast cancer. Radiation therapy for treatment of brain metastases is administered to approximately 170,000 patients per year in the United States and is intended to prevent or reduce complications and increase survival. The median survival of patients with brain metastases who receive radiation therapy is about four-to-six months and can vary depending on various clinical factors such as age, general health, whether the primary cancer is controlled, and the extent of cancer metastases to other regions in the body. Approximately 40% to 50% of patients with brain metastases will die from disease progression in the brain, and the remainder will die from disease progression in other regions in the body.

We previously completed a 20-patient Phase 1b safety study in patients receiving RSR13 in combination with radiation therapy that suggested a potential role for RSR13 in treating patients with brain metastases. Based on this study, we completed a 69-patient, multi-center, open-label, Phase 2 clinical trial to evaluate the efficacy and safety of RSR13 in cancer patients receiving standard radiation therapy for treatment of brain metastases. The primary efficacy endpoint of this study was survival compared to historical data using the Brain Metastases Database, or BMD, maintained by the Radiation Therapy Oncology Group, or RTOG, of the American College of Radiology. The study results of 57 RPA Class II patients showed an overall median survival time for the RSR13-treated group of 6.4 months compared to 4.1 months for the BMD control group, representing a statistically significant improvement in median survival of 56%. In addition, the RSR13-treated group had one-year survival rates of 23%, compared to the one-year survival rate of 15% for the BMD control group. In patients where the cause of death was determined, death due to tumor progression in the brain was seen in only 12% of the RSR13-treated patients compared to 37% of the BMD control group. When case-match analysis was performed using patients in the BMD that most closely paralleled the RSR13-treated patients, the median survival time of RSR13-treated patients was increased by 115% (7.3 months for the RSR13 group versus 3.4 months for the BMD control group) and one-year survival rates were increased to 24%, compared to 8% for the BMD control group.

Based on this positive Phase 2 data, we received concurrence from the FDA to proceed with a Phase 3 trial of RSR13 in patients with brain metastases. In February 2000, we commenced an international, pivotal, Phase 3,

randomized study called R.E.A.C.H. (Radiation Enhancing Allosteric Compound for Hypoxic brain metastases) evaluating the safety and efficacy of RSR13 used in combination with whole brain radiation therapy in treating patients with metastatic brain cancer. Patients were randomly assigned to treatment with either standard whole brain radiation therapy or treatment with standard whole brain radiation therapy plus RSR13. The primary efficacy endpoint was survival. The secondary endpoints were time to tumor progression in the brain, response rate in the brain, cause of death and quality of life. In May 2001, we amended the protocol to increase the number of patients enrolled in this pivotal study in order to conduct an appropriately powered subgroup analysis of patients with primary breast and non-small cell lung tumors. Patient enrollment was concluded in August 2002, and we expect to complete preliminary analysis of the primary and secondary endpoints in the second quarter of 2003.

If the Phase 3 trial is positive, we intend to file a new drug application, or NDA, with the FDA to obtain marketing approval for RSR13 for the treatment of patients who are receiving radiation therapy for brain metastases. In November 2000, we announced that the FDA designated RSR13 a Fast Track Product for the treatment of brain metastases. Designation as a Fast Track Product, under the FDA Modernization Act of 1997, means that the FDA will facilitate the development and expedite the review of a drug if it is intended for the treatment of a serious or life-threatening condition, and it demonstrates the potential to address unmet medical needs for such a condition.

RSR13 in the Treatment of Non-Small Cell Lung Cancer (NSCLC)

NSCLC is the most common type of lung cancer and occurs in approximately 170,000 patients per year in the United States. NSCLC accounts for almost 80% of lung cancer cases. We are currently evaluating RSR13 as a radiation sensitizer for the treatment of patients with locally advanced, unresectable NSCLC, also known as Stage III NSCLC. Radiation therapy for treatment of Stage III NSCLC is administered to approximately 40,000 patients per year in the United States and is intended to prevent or reduce complications and control local tumor growth in the chest. The median survival time of patients with Stage III NSCLC is approximately nine to twelve months.

At the May 2002 Annual Meeting of the American Society of Clinical Oncology (ASCO), we presented updated positive results from a 52-patient, open-label, multi-center, Phase 2 clinical trial of induction chemotherapy followed by chest radiation therapy in combination with RSR13 for stage IIIA/IIIB NSCLC. The median follow up of 22.9 months showed median survival results of 20.6 months, 1-year survival rate of 67% and an estimated 2-year survival rate of 35%. Analyzing the response data from 44 evaluable patients receiving RSR13 plus radiation therapy demonstrated an overall response rate of 89%, with 80% partial responses and 9% complete responses. The objectives of this study were to evaluate overall survival, progression-free interval in the chest, complete and partial response rates in the chest (radiation portal) and time-to-disease progression outside of the radiation portal. The patients received two courses of induction paclitaxel and carboplatin chemotherapy followed by daily RSR13 combined with chest radiation therapy for 32 doses. In September 2002, we presented updated positive response rate and survival results for this trial at the European Society for Therapeutics Radiology and Oncology (ESTRO). The updated 2-year follow up results showed that the median survival rate of 20.6 months was maintained, 1-year survival rate of 67% and a 2-year survival rate of 37%. Overall, partial and complete response rates were maintained at 89%, 80% and 9% respectively. We have received FDA concurrence and are in the planning stages prior to initiating a Phase 3 clinical study of RSR13 in patients with Stage III NSCLC. The trial, known as ELITE (Enhanced Lung cancer treatment with Induction chemotherapy and Thoracic radiation and Efaproxiral), is a comparative study of induction chemotherapy followed by standard thoracic radiation therapy with supplemental oxygen, with or without RSR13, in patients with locally advanced, unresectable (Stage IIIA/IIIB) NSCLC. We plan to enroll approximately 600 patients in this trial over an estimated 3-year period.

RSR13 in the Treatment of Glioblastoma Multiforme (GBM)

GBM is a deadly form of primary brain cancer. This condition occurs in approximately 11,000 patients per year in the United States. The median survival time of patients with GBM is approximately nine to ten months. Radiation therapy is administered to most patients with GBM and is intended to prevent or reduce complications and improve survival time.

We have collaborated with the National Cancer Institute, or NCI, sponsored New Approaches to Brain Tumor Therapy, or NABTT, Consortium to complete Phase 1b and Phase 2 clinical trials of RSR13 in patients with GBM. Based on a 19-patient Phase 1b study, which showed RSR13 was safe and well tolerated, the NABTT

Consortium conducted a 50-patient, multi-center, Phase 2 efficacy and safety study of RSR13 combined with a standard six-week course of cranial radiation therapy in newly diagnosed GBM patients. The primary efficacy endpoint of the study was survival time. The Phase 2 study showed that RSR13-treated patients demonstrated overall survival time of 12.3 months compared to 9.7 months for the NABTT historical control group. The survival rate of RSR13-treated patients at 6 months, 12 months and 18 months were 86%, 54% and 22.2% versus 72.3%, 34.7% and 6.2% for the NABTT control group. With a median follow-up time of 17.6 months, there was a very significant 258% improvement in 18-month survival. Based on these positive survival results, the NABTT Consortium has recommended that a Phase 3 trial be conducted with RSR13 in patients with newly diagnosed GBM.

We have also completed a 67-patient, multi-center, Phase 2 companion trial of RSR13 and cranial radiation therapy in newly diagnosed GBM patients. The trial was comparable in design and methods to the NABTT Phase 2 trial. Per protocol, the survival results were compared to historical data using the RTOG GBM database instead of the NABTT database. The RTOG GBM database consists primarily of older RTOG studies of patients who, for 75% of them, had received treatment with aggressive BCNU (carmustine) chemotherapy in addition to cranial radiation therapy, early in the course of treatment. Treatment with BCNU is considered efficacious and is a FDA approved therapy for the treatment of malignant glioma (high-grade brain cancer, including GBM). BCNU therapy is an independent prognostic factor for survival in the RTOG GBM database. When compared to the RTOG GBM database, including BCNU treated patients, the RSR13-treated patients demonstrated comparable overall survival. When compared to a subset of patients from the RTOG GBM database that had not received aggressive BCNU therapy, the RSR13-treated patients demonstrated a 29% improvement in median survival. However, this result was not statistically significant. The magnitude of survival improvement was quite comparable to that observed in the statistically significant 50-patient NABTT sponsored study. Additional follow-up is ongoing prior to final analysis.

We have concurrence from the FDA to proceed with a Phase 3 trial of RSR13 in patients receiving radiation therapy for the treatment of GBM and may consider further development of this indication in the future.

RSR13 in the Treatment of Cervical Cancer

Cervical cancer is the third most common form of cancer in women and is the second leading cause of cancer related deaths in women worldwide. Each year, more than 190,000 women die of cervical cancer. Surgery and radiation therapy are the primary modes of therapy for patients with advanced cervical cancer.

In August 2002, we initiated a Phase 1/2 clinical trial of RSR13 for patients with locally advanced cancer of the cervix receiving chemoradiation. This clinical trial is an open-label, multi-center study of RSR13 administered to patients receiving a course of weekly cisplatin with a combination of external beam and intracavitary radiation therapy for locally advanced carcinoma of the cervix. The goal of the Phase 1 part of the study is to assess the safety and tolerance of escalating doses of RSR13 in this combination and to determine the maximum tolerated dose (MTD) of RSR13 in patients with cervical cancer. The objective of the Phase 2 part is to further evaluate the safety profile and to assess the efficacy of RSR13 at the MTD in combination with cisplatin and radiation therapy determined by the progression rate at two years. The trial is expected to take approximately two years to complete enrollment.

RSR13 in the Treatment of Other Cancers

We believe that RSR13 eventually could be used in many other tumor types and clinical situations requiring radiation therapy, such as esophageal, head and neck, pancreatic, prostate, rectal and breast cancers. We anticipate conducting several additional Phase 2 trials in the future.

RSR13 as a Chemotherapy Enhancer

Chemotherapy is administered to more than 350,000 cancer patients each year in the United States. Depending on the complexity, chemotherapy agent and duration of treatment, a course of chemotherapy can cost between $6,000 and $12,000. As with radiation therapy, certain types of chemotherapy drugs require the presence of oxygen for optimal cytotoxic effects on cancer cells. Thus, stimulating oxygen release from hemoglobin to hypoxic tumor tissue, by the administration of RSR13, may also enhance the beneficial effects of certain types of chemotherapy.

We have conducted preclinical studies with RSR13 as a chemotherapy enhancer for use in conjunction with certain chemotherapy agents. Our preclinical studies suggest that RSR13 increases the activity of certain chemotherapy agents in animal tumor models and enhances tumor response. We believe this effect may be related to increasing the oxygen level in the tumors and enhancing the effect of specific chemotherapy agents.

In December 2000, we initiated a Phase 1/2 study evaluating the safety and efficacy of RSR13 administered with BCNU (carmustine) chemotherapy for the treatment of recurrent malignant glioma, a type of primary brain cancer. This study is an ongoing, nonrandomized, open-label, multi-center study of escalating doses of RSR13 given with a fixed dose of BCNU to patients with recurring glioma. The study is being conducted by the NCI-sponsored NABTT Consortium. This group previously completed two positive clinical studies of RSR13 combined with whole brain radiation therapy for the treatment of newly diagnosed GBM.

RSR13 for Treating Surgical Hypoxia

Each year in the United States, approximately 762,000 people undergo cardiopulmonary bypass surgery, or CPB, and approximately seven million patients who have significant cardiovascular risk factors undergo non-cardiac surgery. Over one million of these patients experience cardiovascular complications that frequently result in death or permanent disability. In patients undergoing non-cardiac surgery who have chronic medical conditions, such as coronary artery disease, diabetes and hypertension, complications resulting from tissue hypoxia can be as high as 20%. By inducing hemoglobin to release a greater amount of oxygen during surgery, we believe RSR13 can help mitigate tissue hypoxia resulting from decreased oxygen carrying capacity, decreased blood flow, and, in the case of CPB, decreased body temperature.

Based on preclinical studies of RSR13 in CPB and a successful Phase 1b study in elective surgery patients, we conducted a randomized 30-patient Phase 2 clinical trial of RSR13 in patients undergoing CPB for first time coronary artery bypass grafting. This study demonstrated that RSR13 can be safely given during CPB and provided preliminary evidence of a protective effect on heart function. Although the patients undergoing this surgery were generally healthy beyond having coronary artery disease, myocardial protective effects from RSR13 were still observed. There was also a trend toward a lower blood transfusion requirement in the RSR13-treated group.

Based on the results of the Phase 1b general surgery study and the Phase 2 CPB study, an additional randomized 164-patient Phase 2 study was initiated. The purpose of this trial was to assess the ability of RSR13 treatment to decrease the morbidity and mortality associated with heart and brain hypoxia in patients with moderate to high risk factors undergoing CPB. This study was terminated when it was determined in an interim safety analysis of 62 patients, 32 of whom received RSR13 and 30 of whom received placebo, that there was a significant imbalance of patients with high risk factors in the RSR13-treated group compared to the placebo group. Based on these findings, we are considering conducting a new Phase 2 trial designed to better account for stratification of risk factors in the treatment groups and may perform this study in conjunction with a corporate partner.

RSR13 for Treating Cardiovascular Disease and Stroke

There are approximately 1.7 million hospitalizations per year in the United States for acute coronary syndrome, which includes unstable angina and myocardial infarction. We believe that RSR13 could play a major role in the treatment of patients with acute coronary syndrome. We currently anticipate clinical development for this indication would be in cooperation with a corporate partner.

We have demonstrated that increasing oxygen release from hemoglobin with RSR13 results in a significant decrease in myocardial hypoxia experienced in animals during reduced coronary artery blood flow. We have also shown that treatment with RSR13 results in a decrease in the release of a biochemical marker associated with heart damage in animal models of myocardial infarction. Based on these findings, an initial Phase 1b safety study was performed on 24 patients with chronic angina taking multiple medications for treatment of their heart disease. This study demonstrated that RSR13 was safe and well tolerated in this patient population. In addition, a 10-patient Phase 2 clinical trial has been completed to determine if RSR13 can improve the exercise tolerance of patients with coronary artery disease. We are currently evaluating the results of this trial.

Additionally, our preclinical studies have demonstrated that RSR13 may play a beneficial role in the treatment of stroke.

Other Synthetic Allosteric Modifiers

Through our research collaborations, we have expanded our drug discovery efforts on the development of synthetic allosteric modifiers for targets of therapeutic interest other than hemoglobin. One such target is red blood cell pyruvate kinase, an enzyme central to the control of red blood cell 2,3-DPG metabolism. Red blood cell pyruvate kinase is an allosteric protein that is structurally very similar to hemoglobin. Increasing red blood cell 2,3-DPG levels by inhibiting red blood cell pyruvate kinase may lead to the development of orally administered products for chronic hypoxic indications, such as peripheral vascular disease, chronic angina and congestive heart failure.

PDX

In December 2002, we obtained an exclusive worldwide license from Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute to intellectual property covering a novel, small molecule cytotoxic injectable anti-folate identified as PDX. PDX has an expected superior potency and side effect profile relative to methotrexate and related anti-folates. PDX is currently under development as a single agent and in combination with docetaxel for the treatment of NSCLC and in a Phase 2 study for mesothelioma. PDX is also being studied as a single agent in non-Hodgkin's lymphoma (NHL). We have the right to develop and market any product derived from any formulation of PDX in connection with all diagnostic and therapeutic uses, including human and veterinary diseases. We will make certain cash payments to the licensor upon the earlier of achievement of certain development milestones or the passage of certain time periods, and will pay the licensor a royalty based on a percentage of net revenues arising from sales of the product or sublicense revenues arising from sublicensing the product, if and when such sales or sublicenses occur.

A Phase 2 trial of PDX as a single agent for the second-line treatment of NSCLC was completed in 2001. This trial enrolled 39 patients. The overall response rate was 11%, with a median survival of 13.5 months. Fifty-eight percent of the patients were alive at one year, and 28% have achieved two-year survival. We are currently scaling up the manufacturing process to obtain adequate clinical Good Manufacturing Practices (GMP) material for use in our clinical development programs.

BGP-15

In March 2002, we obtained an exclusive United States license from N-Gene Research Laboratories to intellectual property covering BGP-15, a novel, orally bioavailable small molecule that reduces cellular stress induced by chemotherapy. While chemotherapy and radiation therapy kill tumors cells, they also destroy normal cells, leading to side effects. Many side effects are serious in nature, expensive to manage, may impact treatment outcome and dramatically decrease the patient's quality of life. BGP-15 is an orally bioavailable preclinical compound being developed to potentially reduce the incidence of some side effects, reduce management cost, improve patients' quality of life and positively impact treatment outcome. We have the right to develop and market in the United States any product derived from any formulation of BGP-15 covered under the licensed intellectual property in the field of oncology and certain cardiovascular conditions. We will make certain cash payments to the licensor upon the issuance of certain product related patents. In addition, we will pay the licensor a royalty based on a percentage of net revenues arising from sales of the product in the United States, if and when such sales occur. We are currently performing preclinical studies of BGP-15 and intend to file an IND in 2003.

We expensed approximately $10.7 million, $12.7 million and $13.9 million related to research and development activities in the years ended December 31, 2000, 2001 and 2002, respectively.

Manufacturing

RSR13

We have entered into arrangements with two third-party manufacturers for the supply of RSR13 bulk drug substance, efaproxiral sodium, and a third for the formulated drug product. This enables us to minimize fixed costs and capital expenditures, and gain access to advanced manufacturing process capabilities and expertise.

Hovione FarmaCiencia SA, is our primary supplier of efaproxiral sodium. Hovione operates under current GMP and is an established contract manufacturer with experience in manufacturing bulk drug substances for use in injectable formulations. Hovione successfully validated the process for efaproxiral sodium in 2001. Under the terms of our contract, Hovione is committed to manufacture sufficient quantities to support commercial scale manufacturing for both pre-commercialization and post-commercialization phases of production. In addition, we have successfully transferred the process to a second manufacturer Raylo Chemicals Inc. (a division of Degussa located in Edmonton, Alberta), and demonstrated the ruggedness and reliability of the process. Both of these suppliers are in good standing with the FDA, having passed recent inspections.

After manufacture, efaproxiral sodium is formulated under contract for us into the drug product, efaproxiral injection. Akorn, Inc. (formerly known as Taylor Pharmaceuticals, Inc.) in Decatur, IL, manufactured the clinical units during the development phase. Akorn specializes in parenteral products and Akorn manufactured the first NDA stability batches. Because efaproxiral injection is a large volume parenteral with relatively high projected annual units, a manufacturer with greater capacity has been identified. In July 2002, Allos and Baxter Healthcare signed a term sheet for commercial manufacture of efaproxiral injection and development of a presentation in a flexible container. Baxter Healthcare has significant experience in manufacturing large volume injectables at large scale. We anticipate a final supply agreement will be signed in the second quarter of 2003.

BGP-15

The initial process development for the bulk drug synthesis has been completed by a third party manufacturer and the first clinical scale batch of BGP-15 bulk drug substance has been produced. The formulation development work required for filing an IND is currently underway.

PDX

In 2003, we have initiated the process development work with a third party manufacturer to obtain adequate clinical GMP material for our clinical development programs.

Sales and Marketing

If and when we obtain FDA approval, we intend to market RSR13 directly to the approximately 9,400 radiation and medical oncologists in the United States through an experienced oncology sales force. We hired a vice president of sales and marketing in 2002 and expect to begin hiring sales and marketing staff around the time the FDA accepts our New Drug Application (NDA) for review.

In order to maximize the commercial opportunity for RSR13 outside the United States, we intend to partner with one or more pharmaceutical companies that are experienced in the sales, marketing and distribution of oncology therapeutics. We will consider for review any potential partnering opportunity that may also include a co-marketing or co-promotional relationship for the U.S. market. We expect that the combination of proprietary marketing and sales capabilities, combined with potential partnering relationships, will allow us to maximize the global commercial opportunity for RSR13.

Government Regulation

FDA Regulation and Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our product candidates.

The process required by the FDA before our product candidates may be marketed in the United States generally involves the following:

- preclinical laboratory and animal tests;
- submission to the FDA of an Investigational New Drug, or IND application, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use; and
- submission to the FDA of a New Drug Application, or NDA, that must be approved.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess its potential safety and efficacy. We then submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND application, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after the FDA acknowledges that the filing is complete, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Further, an independent Institutional Review Board at each medical center proposing to conduct the clinical trials must review and approve any clinical study.

Human clinical trials are typically conducted in three sequential phases, which may overlap:

- PHASE 1: The drug is initially administered into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- PHASE 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- PHASE 3: When Phase 2 evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase 3 trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites.

In the case of product candidates for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers. Since these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 trials and thus these trials are frequently referred to as Phase 1b trials.

We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or the Institutional Review Boards or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, preclinical studies and clinical studies are submitted to the FDA as part of a NDA for approval of the marketing and commercial shipment of the product candidate. The FDA may deny a NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products, which have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

In November 1997, the Food and Drug Administration Modernization Act was signed into law. That act codified the FDA's policy of granting "Fast Track" approval for cancer therapies and other therapies intended to treat severe or life-threatening diseases. Previously, the FDA approved cancer therapies primarily based on patient survival rates and/or data on improved quality of life. This new policy is intended to facilitate the study of cancer therapies and shorten the total time for marketing approvals; however, the effect, if any, that these new provisions

may actually have on product approvals is uncertain. In November 2000, we announced that the FDA had designated RSR13 a Fast Track Product for the treatment of brain metastases.

Satisfaction of the above FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product candidate. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our product candidates on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our product candidates abroad will require similar regulatory approvals and is subject to similar risks. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current Good Manufacturing Practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the current Good Manufacturing Practices and other FDA regulatory requirements.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses. Under the Modernization Act of 1997, the FDA will permit the promotion of a drug for an unapproved use in certain circumstances, but subject to very stringent requirements.

We and our product candidates are also subject to a variety of state laws and regulations in those states or localities where such product candidates may be marketed. Any applicable state or local regulations may hinder our ability to market our product candidates in those states or localities.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations, which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation, which might arise from future legislative or administrative action, either in the United States or abroad.

Foreign Regulation and Product Approval

Outside the United States, our ability to market a product candidate is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product in more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance discussed above.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or

potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Intellectual Property

We believe that patent protection and trade secret protection are important to our business and that our future success will depend, in part, on our ability to maintain our technology licenses, maintain trade secret protection, obtain and maintain patents and operate without infringing the proprietary rights of others both in the United States and abroad. We believe that obtaining patents in countries other than the United States may, in some cases, be more difficult than obtaining United States patents because of differences in patent laws. In addition, the protection provided by non-United States patents may be weaker than that provided by United States patents.

Under a 1994 agreement with the Center for Innovative Technology, or CIT, we have obtained exclusive worldwide rights to 16 United States patents, a European patent which has been validated in the United Kingdom, France, Italy, and Germany, two pending patent applications which have been approved in Canada, two pending patent applications which have been approved in Japan, and one pending patent application in Europe. Pursuant to this agreement, we have agreed to sponsor research at Virginia Commonwealth University, or VCU, relating to allosteric hemoglobin modifier compounds, and are entitled to an exclusive worldwide license of any technology developed in connection with such research. We will be required to pay a quarterly royalty based on percentages, as defined in the agreement, of either net revenues arising from sales of products produced in Virginia or net revenues from sales of products produced outside Virginia. This agreement was assigned by CIT to the Virginia Commonwealth University Intellectual Property Foundation, or VCUIPF, in 1997. Under the agreement, we have the right to grant sublicenses, for which we must also pay royalties to VCUIPF for products produced by the sublicensees. VCUIPF has the primary responsibility to file, prosecute, and maintain intellectual property protection, but we have agreed to reimburse costs incurred by VCUIPF after July 1, 1993 related to obtaining and maintaining intellectual property protection. Also, pursuant to the agreement, we will pay VCUIPF a running royalty of 1.25% of our worldwide net revenue arising from the sale, lease or other commercialization of the allosteric hemoglobin modifier compounds. This agreement terminates on the date the last United States patent licensed to us under the agreement expires, which is October 2016.

The licensed patents, which expire at various times between February 2010 and October 2016, contain claims covering methods of allosterically modifying hemoglobin with RSR13 and other compounds, the site within hemoglobin where RSR13 binds, and certain clinical applications of RSR13 and other allosteric hemoglobin modifier compounds, including, among others:

- treating cancerous tumors;
- treating ischemia or oxygen deprivation;
- treating stroke or cerebral ischemia;
- treating surgical blood loss;
- performing cardiopulmonary bypass surgery; and
- treating hypoxia.

Under a separate agreement with VCUIPF, we have rights to acquire an exclusive worldwide license to any technology that is developed using research funding provided by us to VCU under a Sponsored Research Agreement. This agreement allows us to access VCU's drug discovery capabilities without having to develop comparable in-house research and development capabilities. We have the option to acquire a license for six months from the date any developed technology is disclosed to us. To exercise our option, we must provide notification to VCUIPF and assume responsibility for all legal expenses for securing intellectual property protection for technology developed under the Sponsored Research Agreement. We have the exclusive right to sublicense any technology to third parties and affiliates. We are required to pay VCUIPF a running royalty on our worldwide net revenue arising from commercialization of the technology developed. We have exercised our option on one technology under this agreement, which pertains to allosteric inhibitors and activators of red blood cell kinase. We may terminate this agreement without cause by giving VCUIPF ninety days written notice. VCUIPF may terminate this agreement upon certain payment and reporting breaches by us. Either party may terminate this agreement for certain uncured breaches.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of confidential information. The agreements also oblige our employees, consultants, advisors and collaborators to assign to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products competitive with those being developed by us. Therefore, our product candidates may give rise to claims that they infringe the patents or proprietary rights of other parties now and in the future. Furthermore, to the extent that we, or our consultants or research collaborators, use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in related or resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that we are prevented from the development, manufacture or sale of products requiring such licenses. In addition, we could incur substantial costs in defending ourselves in legal proceedings instituted before the United States Patent and Trademark Office or in a suit brought against us by a private party based on such patents or proprietary rights, or in a suit by us asserting our patent or proprietary rights against another party, even if the outcome is not adverse to us.

Competition

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including a number of large pharmaceutical companies as well as several specialized biotechnology companies, are developing cancer drugs similar to ours. There are products on the market that will compete directly with the products that we are developing. In addition, colleges, universities, governmental agencies and other public and private research institutions will continue to conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect license fees, milestone payments and royalties in exchange for license rights to technologies that they have developed, some of which may directly compete with our technologies. These companies and institutions also compete with us in recruiting qualified scientific personnel. Many of our competitors have substantially greater financial, research and development, human and other resources than do we. Furthermore, large pharmaceutical companies have significantly more experience than we do in preclinical testing, human clinical trials and regulatory approval procedures.

Our competitors may:

- develop safer and more effective products;
- obtain patent protection or intellectual property rights that limit our ability to commercialize products; and/or
- commercialize products earlier than us.

We expect technology developments in our industry to continue to occur at a rapid pace. Commercial developments by our competitors may render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business and financial condition.

Human Resources

As of December 31, 2002, we had a total of 85 full-time employees and 7 part-time employees. Of those, 64 are engaged in clinical development, regulatory affairs, biometrics, manufacturing and pre-clinical development. The remaining 28 are involved in marketing, corporate development, finance, administration and operations. We believe that we have good relationships with our employees. We have never had a work stoppage, and none of our employees is represented under a collective bargaining agreement.

RISK FACTORS

Our business faces significant risks. These risks include those described below and may include additional risks of which we are not currently aware or which we currently do not believe are material. If any of the events or circumstances described in the following risk factors actually occurs, our business, financial condition and results of operations could be materially adversely affected. These risks should be read in conjunction with the other information set forth in this report.

We have a history of operating losses and an accumulated deficit, and we may not achieve or maintain revenue or profitability in the future.

We have experienced operating losses since we began operations in 1994. As of December 31, 2002, we had an accumulated deficit of approximately $112.6 million. We expect to incur additional operating losses over the next several years and expect cumulative losses to increase substantially as our research and development, preclinical, clinical, manufacturing and commercialization efforts expand. We have had no revenue to date. Our ability to achieve revenue and profitability is dependent on our ability, alone or with partners, to successfully complete the development of our product candidates, conduct clinical trials, obtain the necessary regulatory approvals, and manufacture and market our product candidates. If the results of our Phase 3 clinical trial of RSR13 are satisfactory, we expect to submit an NDA filing with the FDA, and to incur large cash expenditures associated with preparations to commercialize RSR13. Expenditures associated with developing a commercial organization and pre-launch marketing activities will require additional capital that we may not be able to raise. We cannot assure you that we will achieve revenue or profitability.

Our product candidates are in various stages of development and may never be fully developed in a manner suitable for commercialization. If we do not develop commercially successful products, our ability to generate revenue will be limited.

If we are unable to successfully commercialize our product candidates, we will be unable to generate any meaningful amounts of revenue and will incur continued losses. We may not be able to continue as a going concern if we are unable to generate meaningful amounts of revenue to support our operations or cannot otherwise raise the necessary funds to support our operations. We have no products that have received regulatory approval for commercial sale. All of our product candidates are in various stages of development, and significant research and development, financial resources and personnel will be required to develop commercially viable products and obtain regulatory approvals. Most of our efforts and expenditures will be devoted to RSR13 over the next few years. Accordingly, our future prospects are substantially dependent on favorable results from clinical trials utilizing RSR13. Even if our Phase 3 trial of RSR13 is successful, RSR13 is not expected to be commercially available until at least 2004, while our other current product candidates are not expected to be commercially available until at least 2007.

We cannot predict when or if we will obtain regulatory approval to commercialize our product candidates.

A pharmaceutical product cannot be marketed in the United States or most other countries until it has completed a rigorous and extensive regulatory approval process. If we fail to obtain regulatory approval to market our product candidates, we will be unable to sell our products and generate revenue, which would jeopardize our ability to continue operating our business. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Of particular significance are the requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. We may not obtain regulatory approval for any product candidates we develop, including RSR13, or we may not obtain regulatory review of such product candidates in a timely manner. See "Business—Government Regulation" for a detailed discussion of the regulatory approval process.

We will not be able to obtain regulatory approval to commercialize our product candidates if we fail to adequately demonstrate their safety and efficacy.

Product candidates developed by us, alone or with others, may not prove to be safe and efficacious in clinical trials and may not meet all of the applicable regulatory requirements needed to receive regulatory approval. To demonstrate safety and efficacy, we must conduct significant additional research, animal testing, referred to as preclinical testing, and human testing, referred to as clinical trials, for our product candidates. Preclinical testing

and clinical trials are long, expensive and uncertain processes. It may take us several years to complete our testing, and failure can occur at any stage.

Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory clearances, and the FDA can request that we conduct additional trials. For example, we are currently planning to perform only one Phase 3 clinical trial prior to seeking FDA approval for our first product candidate. We believe that if the results of this Phase 3 clinical trial are consistent with our prior Phase 2 clinical results, this Phase 3 clinical trial can serve as the basis for obtaining FDA approval. However, if the results are inconclusive, a second Phase 3 trial may be necessary. If we have to conduct further clinical trials, whether for RSR13 or other product candidates we develop in the future, these trials would significantly increase our expenses and delay marketing of our product candidates. See "Business—Government Regulation" for a detailed discussion of the regulatory approval process.

We may experience delays in our clinical trials that could adversely affect our financial position and our commercial prospects.

We do not know whether planned clinical trials will begin on time or whether any of our clinical trials will be completed on schedule or at all. Our product development costs will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. If the delays are significant, our ability to generate revenue from product sales will be correspondingly delayed, and we may have insufficient capital resources to support our operations. Even if we do have sufficient capital resources, our ability to become profitable will be delayed. We typically rely on third-party clinical investigators at medical institutions to conduct our clinical trials and we occasionally rely on other third-party organizations to perform data collection and analysis. As a result, we may face additional delaying factors outside our control.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practices and are subject to oversight by the FDA and institutional review boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under the FDA's Good Manufacturing Requirements and may require large numbers of test subjects. Clinical trials may be suspended by us or the FDA at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results and acceptable results in early trials may not be repeated in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated or terminated. In addition, failure to construct clinical trial protocols to screen patients for risk profile factors relevant to the trial for purposes of segregating patients into the patient populations treated with the drug being tested and the control group could result in either group experiencing a disproportionate number of adverse events and could cause a clinical trial to be repeated or terminated.

Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will limit our ability to generate revenue and become profitable.

Even if approved for marketing, our products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory approval for the uses that we are studying;
- the establishment and demonstration in the medical community of the safety and efficacy of our products and their potential advantages over existing and newly developed therapeutic products;
- ease of use of our products;
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations and other plan administrators; and
- the effectiveness of our sales and marketing efforts.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products or to pay or reimburse for their use.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop our product candidates.

We expect that significant additional financing will be required to continue our research and development efforts and to commercialize our product candidates. If the results of our Phase 3 clinical trial of RSR13 are satisfactory, we expect to submit an NDA filing with the FDA, and to incur large cash expenditures associated with preparations to commercialize RSR13. Expenditures associated with developing a commercial organization and pre-launch marketing activities will require additional capital that we may not be able to raise. If adequate funds are not available to us, we will be required to delay, reduce the scope of or eliminate one or more of our development programs and our business and future prospects for revenue and profitability may be harmed. We do not know whether additional financing will be available when needed or we will obtain financing on terms favorable to our stockholders or us. We have consumed substantial amounts of cash to date and expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure and preclinical and clinical trial activities. We may seek to raise additional financing through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements.

We believe that our existing cash and investment securities will be sufficient to support our current operating plan through at least the end of 2003. We have based this estimate on assumptions that may prove to be wrong. Because we have not derived any commercial revenues from product sales and a significant amount of our capital resources are held in the form of short-term and long-term financial instruments, we are subject to risks associated with decreasing yields on instruments such as United States government securities, high-grade commercial paper and corporate notes and money market funds, as well as risks associated with market price changes and economic downturns. Our future capital requirements depend on many factors that affect our research, development, collaboration and sales and marketing activities. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

If we are unable to effectively protect our intellectual property, we would be unable to prevent third parties from using our technology, which would impair our competitiveness and ability to commercialize our product candidates. In addition, enforcing our proprietary rights may be expensive and result in increased losses.

Our success will depend in part on our ability to obtain and maintain meaningful patent protection for our products, both in the United States and in other countries. We rely on patents to protect a large part of our intellectual property and our competitive position. We currently own or exclusively license 54 patents and patent applications (including pending applications, abandoned applications, and U.S. provisional applications), both in the United States and in other countries. Any patents issued to or licensed by us could be challenged, invalidated, infringed, circumvented or held unenforceable. In addition, it is possible that no patents will issue on any of our licensed patent applications. It is possible that the claims in patents that have been issued or licensed to us or that may be issued or licensed to us in the future will not be sufficiently broad to protect our intellectual property or that the patents will not provide protection against competitive products or otherwise be commercially valuable. Failure to obtain and maintain adequate patent protection for our intellectual property would impair our ability to be commercially competitive.

Our commercial success will also depend in part on our ability to commercialize our product candidates without infringing patents or other proprietary rights of others or breaching the licenses granted to us. We may not be able to obtain a license to third-party technology that we may require to conduct our business or, if obtainable, we may not be able to license such technology at a reasonable cost. If we fail to obtain a license to any technology that we may require to commercialize our technologies or product candidates, or fail to obtain a license at a reasonable cost, we will be unable to commercialize the affected product or to commercialize it at a price that will allow us to become profitable.

In addition to patent protection, we also rely upon trade secrets, proprietary know-how and technological advances which we seek to protect through confidentiality agreements with our collaborators, employees and

consultants. Our employees and consultants are required to enter into confidentiality agreements with us. We also have entered into non-disclosure agreements, which are intended to protect our confidential information delivered to third parties for research and other purposes. However, these agreements could be breached and we may not have adequate remedies for any breach, or our trade secrets and proprietary know-how could otherwise become known or be independently discovered by others.

Furthermore, as with any pharmaceutical company, our patent and other proprietary rights are subject to uncertainties. Our patent rights related to our product candidates might conflict with current or future patents and other proprietary rights of others. For the same reasons, the products of others could infringe our patents or other proprietary rights. Litigation or patent interference proceedings, either of which could result in substantial costs to us, may be necessary to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of other parties' proprietary rights. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease selling our future products. We are not currently a party to any infringement claims.

If our competitors develop and market products that are more effective than ours, our commercial opportunity will be reduced or eliminated.

Even if we obtain the necessary governmental approvals to market RSR13 or other product candidates, our commercial opportunity will be reduced or eliminated if our competitors develop and market products that are more effective, have fewer side effects or are less expensive than our product candidates. Our potential competitors include large fully integrated pharmaceutical companies and more established biotechnology companies, both of which have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Academic institutions, government agencies, and other public and private research organizations conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing. It is possible that competitors will succeed in developing technologies that are more effective than those being developed by us or that would render our technology obsolete or noncompetitive. We are not aware of any products in research or development by any potential competitors, which address allosteric regulation of proteins in the way being targeted by us. There are, however, other companies addressing the same indications as we are.

We rely on third-party collaborators to conduct our clinical trial activities and manufacture our product candidates. If our collaborative partners do not perform as expected, we may be unable to develop and commercialize our product candidates, which would limit our ability to generate revenue and become profitable and our ability to develop and commercialize our product candidates could be severely limited.

We do not have our own research or manufacturing facilities and currently do not plan to establish such facilities. Instead, we depend upon academic, research and non-profit institutions and commercial service and manufacturing organizations for chemical synthesis and analysis, product formulation, assays, preclinical and clinical testing, container development, fill finish, and manufacture of our product candidates. If our collaborative partners do not perform these functions satisfactorily, our ability to develop and commercialize our product candidates could be severely limited which would limit our ability to sell our products or to sell them in quantities sufficient to generate enough revenue to allow us to become profitable.

Currently, we are supporting research with respect to allosteric modification of proteins at Virginia Commonwealth University in the laboratories of Dr. Donald Abraham, a founder, stockholder and director. In addition, our manufacturing is currently performed by a limited number of third-party manufacturers with whom we have contracts. Any failure by our third-party manufacturers to supply our requirements for clinical trial materials, including RSR13 bulk drug substance or formulated drug product, would jeopardize the completion of such trials and our ability to commercialize RSR13. Prior to regulatory approval of RSR13, we may seek to establish supply agreements with additional sources of supply for bulk drug substance and formulated drug product. However, only a limited number of contract manufacturers are both capable of manufacturing our product candidates and complying with current federal and state Good Manufacturing Practice regulations. Accordingly, we may not be able to enter into supply agreements on commercially acceptable terms and, even if we do, any manufacturers with which we contract may not be able to deliver supplies in appropriate quantity.

If conflicts arise between us and our academic collaborators, scientific advisors, manufacturers or other suppliers, including Dr. Abraham, the other party may act in its self-interest and not in the interest of our stockholders. We generally do not have control over the resources or degree of effort that any of our existing collaborative partners may devote to our collaborations. If our collaborators breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in accordance with agreed upon schedules, our ability to develop, commercialize and sell products would be limited. In addition, our collaborative partners could cease operations or offer, design, manufacture or promote competing products. Any of these occurrences could materially limit our potential revenue and profitability.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

The testing and marketing of pharmaceutical products entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, health care providers or by pharmaceutical companies or others selling our future products. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to limit the commercialization of our product candidates. We have obtained limited product liability insurance coverage for our human clinical trials. However, insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim in excess of our insurance coverage could have a material adverse effect on our business, financial condition and results of operations. We may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

Our operating results may fluctuate, and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in our stock price, causing investor losses.

Our results of operations have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our stock price to decline. Some of the factors that could cause our results of operations to fluctuate include:

- the status of development of our various product candidates;
- the time at which we enter into research and license agreements with corporate partners, if any, that provide for payments to us, and the timing and accounting treatment of payments to us under those agreements;
- whether or not we achieve specified research or commercialization milestones;
- timely payment by our corporate partners, if any, of amounts payable to us;
- the addition or termination of research programs or funding support; and
- variations in the level of expenses related to our proprietary product candidates during any given period.

We believe that period-to-period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as an indication of future performance. It is possible that in some future quarter or quarters, our operating results will be below the expectations of securities analysts or investors. In that case, our stock price could fluctuate significantly or decline.

Failure to attract, retain and motivate skilled personnel and cultivate key academic collaborations will delay our product development programs and our research and development efforts.

We are a small company with approximately 85 full-time and 7 part-time employees, and our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions and scientists. Competition for personnel and academic collaborations is intense. In particular, our product development programs depend on our ability to attract and retain highly skilled clinical development personnel. In addition, we will need to hire additional personnel and develop additional academic collaborations as we continue to expand our research and development activities. We do not know if we will be able to attract, retain or motivate personnel or maintain relationships. If we fail to negotiate additional acceptable collaborations with academic

institutions and scientists, or if our existing academic collaborations were to be unsuccessful, our product development programs may be delayed.

ITEM 2. PROPERTIES

Our corporate headquarters facility consists of approximately 43,377 square feet in Westminster, Colorado. We lease our corporate headquarters facility pursuant to a lease agreement that expires in November 2008. We believe that our leased facilities are adequate to meet our needs for the next 3 years. We also lease approximately 1,800 square feet of office and laboratory space in Richmond, Virginia. We lease this space under a renewable operating lease, which expires in October 2004.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any legal proceedings.

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

No matters were submitted to a vote of security holders, through solicitation of proxies or otherwise, during the fourth quarter of 2002.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information and Holders

Our common stock is traded on the Nasdaq National Market® under the symbol "ALTH." Trading of our common stock commenced on March 28, 2000, following completion of our initial public offering. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported by the Nasdaq National Market:

Year Ended December 31, 2001	HIGH	LOW
First Quarter	$8.88	$4.28
Second Quarter	$7.63	$4.41
Third Quarter	$5.66	$4.25
Fourth Quarter	$7.60	$4.40

Year Ended December 31, 2002	HIGH	LOW
First Quarter	$7.50	$5.66
Second Quarter	$9.08	$6.15
Third Quarter	$9.25	$7.26
Fourth Quarter	$9.89	$6.18

On March 20, 2003, we had approximately 75 registered holders of record of our common stock.

Dividends

We have never paid any cash dividends on our capital stock and do not intend to pay any such dividends in the foreseeable future.

Recent Sales of Unregistered Securities

On April 24, 2002, we entered into a securities purchase agreement with a single purchaser, Perseus-Soros BioPharmaceutical Fund, L.P., pursuant to which we issued 2,500,000 shares of common stock at a purchase price of $6.00 per share to such purchaser in exchange for $15.0 million in cash. The shares were issued to the purchaser in a private placement pursuant to an exemption from registration in reliance upon Section 4(2) and Rule 506 of Regulation D of the Securities Act of 1933, as amended.

In September 2002, we issued an aggregate of 9,685 shares of common stock to Comdisco, Inc. pursuant to their net exercise of two warrants previously issued to them.

Use of Proceeds from Sales of Registered Securities

The effective date of our first registration statement, filed on Form S-1 under the Securities Act of 1933, as amended (No. 333-95439), relating to our initial public offering of our Common Stock, was March 27, 2000. Aggregate gross proceeds from the offering were $90,000,000.

We incurred the following expenses in connection with the offering: underwriters' discounts and commissions of $6.3 million and approximately $900,000 in other expenses, for total expenses of approximately $7.2 million. After deducting expenses of the offering, we received net offering proceeds of approximately $82.8 million. No payments constituted direct or indirect payments to any of our directors, officers or general partners or their associates, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

From the time of receipt through December 31, 2002, we have used an estimated $44.1 million of the net proceeds from the offering for research and development activities, capital expenditures, repayment of indebtedness, net purchases of investments, acquisition of property and equipment, working capital and other general corporate purposes. None of the net proceeds of the initial public offering were paid directly or indirectly to any of our directors, officers or general partners or their associates, to persons owning 10% or more of any class of our equity securities or to any of our affiliates. The remainder of the net proceeds is invested in short-term and long-term financial instruments.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K regarding securities authorized for issuance under equity compensation plans is incorporated by reference to our definitive Proxy Statement to be filed in connection with the Annual Meeting of Stockholders to be held on May 21, 2003.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below should be read in conjunction with our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in this report. The statement of operations data for the years ended December 31, 2000, 2001, 2002, and cumulative period from September 1, 1992 through December 31, 2002, and the balance sheet data as of December 31, 2001 and 2002, are derived from, and qualified by reference to, our audited financial statements included elsewhere in this report. The statement of operations data for the years ended December 31, 1998 and 1999, and the balance sheet data as of December 31, 1998, 1999 and 2000 are derived from our audited financial statements that do not appear in this report. The historical results are not necessarily indicative of the operating results to be expected in the future.

	Years Ended December 31,					Cumulative period from September 1, 1992 (from inception) through December 31, 2002
	1998	1999	2000	2001	2002	
	(in thousands, except share and per share data)					
Statement of Operations Data:						
Operating expenses:						
Research and development	$ 5,941	$ 7,836	$ 10,737	$ 12,660	$ 13,860	$ 60,202
Clinical manufacturing	1,768	1,382	3,200	3,143	3,776	15,284
General and administrative	1,486	2,379	13,775	9,277	10,444	40,667
Total operating expenses	9,195	11,597	27,712	25,080	28,080	116,153
Loss from operations	(9,195)	(11,597)	(27,712)	(25,080)	(28,080)	(116,153)
Interest and other income, net	621	309	4,351	4,936	2,311	13,143
Net loss	(8,574)	(11,288)	(23,361)	(20,144)	(25,769)	(103,010)
Dividend related to beneficial conversion feature of preferred stock	—	(9,613)	—	—	—	(9,613)
Net loss attributable to common stockholders	$ (8,574)	$ (20,901)	$ (23,261)	$ (20,144)	$ (25,769)	$(112,623)
Weighted-average basic and diluted net loss per share	$ (4.38)	$ (10.48)	$ (1.30)	$ (0.88)	$ (1.03)	
Weighted-average shares used in computing basic and diluted net loss per share	1,959,071	1,994,764	18,058,802	22,970,974	24,942,496	

	As of December 31,				
	1998	1999	2000	2001	2002
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 9,582	$ 9,475	$ 61,777	$ 59,769	$ 54,983
Long-term marketable securities	—	—	23,906	9,843	5,816
Working capital	8,146	8,784	59,170	55,650	48,679
Total assets	10,480	10,206	86,259	72,174	64,401
Long-term obligations, less current portion	147	69	8	—	—
Convertible preferred stock	30,751	49,899	—	—	—
Common stock	207	7,022	156,625	156,948	171,046
Accumulated deficit	(22,447)	(43,348)	(66,710)	(86,854)	(112,623)
Total stockholders' equity	8,371	8,991	83,411	67,151	57,322

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

Overview

We have incurred significant operating losses since our inception in 1992 and, as of December 31, 2002, had an accumulated deficit of approximately $112.6 million. We have devoted substantially all of our resources to date to the clinical development of RSR13. We completed enrollment in our pivotal Phase 3 clinical trial of RSR13 in patients with brain metastases during the third quarter of 2002, and we expect to perform a preliminary analysis of the results during the second quarter 2003. If the Phase 3 trial is positive, we intend to file an NDA with the FDA to seek marketing approval for RSR13 for the treatment of patients who are receiving radiation therapy for brain metastases. If the Phase 3 trial is negative or inconclusive, we may delay our filing. We may also choose to perform another Phase 3 trial on brain metastases, continue our Phase 3 trial on NSCLC or discontinue our development of RSR13 and focus our development efforts on other compounds. In either event, we expect to re-evaluate our development plans and cash expenditures once we know the results of our Phase 3 trial. Until we decide whether to submit an NDA to the FDA to seek approval of RSR13, likely during the second quarter of 2003, we expect our operating expenses to moderately increase during the first half of 2003. We intend to continue with certain clinical trials, pre-commercial scale-up in clinical manufacturing, and pre-marketing activities related to the planned commercialization of RSR13. However, if we decide to submit an NDA for RSR13, we expect to incur rising cash expenditures associated with developing a commercial organization, pre-launch marketing activities and executing the future development plans for our drug candidates.

We believe that our existing cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the calendar year 2003. However, our ability to execute our development and commercialization plan for RSR13 and our other drug candidates will require substantial capital beyond 2003. In order to fund our capital needs beyond 2003, we intend to seek capital through arrangements with corporate partners, equity or debt financings, or from other sources, including the proceeds of product sales, if any. If we are not able to raise sufficient additional funds, we expect to re-evaluate our level of activity and cash expenditures associated with the planned development and commercialization of RSR13 and our other drug candidates.

We have not derived any commercial revenues from product sales, and we do not expect to receive product revenues until at least 2004. There can be no assurance if or when we will become profitable. We expect to continue to incur significant operating losses over the next several years as we continue to incur increasing research and clinical development costs, in addition to costs related to manufacturing and commercialization activities. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our product candidates, and obtain required regulatory clearances and successfully manufacture and market our future products.

Critical Accounting Policies

Our results of operations and financial position are determined based on the application of our accounting policies, as discussed in the notes to the financial statements. Certain of our accounting policies represent a selection among acceptable alternatives under accounting principles generally accepted in the United States of America. We have not determined how reported amounts would differ based on the application of different accounting policies. We also have not determined the likelihood that materially different amounts could be reported under different conditions or using different assumptions.

Our critical accounting policies are important to fully understanding and evaluating our financial condition and results presented in the financial statements and require management to make judgments and estimates that are inherently uncertain.

We record the costs of clinical studies, clinical development, finished drug inventory, regulatory affairs, biostatistical data analysis, non-clinical studies, basic research and licensing fees as a component to research and development expenses. Clinical study costs represent internal costs for personnel, external costs incurred at clinical sites and contracted payments to third party clinical research organizations to perform certain clinical trials.

We are obligated to make certain upfront payments upon execution of certain research and development agreements. We record these upfront payments as prepaid research and development expenses. Such payments are expensed as services are performed or terms of the respective agreements are achieved.

We accrue research and development expenses for activity occurring during the fiscal year prior to receiving invoices from clinical sites and third party clinical research organizations. We accrue external costs for clinical studies based on the progress of the clinical trials, including patient enrollment, dosing levels of patients' enrolled, estimated costs to dose patients, and contracted costs with clinical research organizations and clinical sites. We record internal costs primarily related to personnel in clinical development, regulatory affairs and biostatistical data analysis and external costs related to non-clinical studies and basic research when incurred. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual costs incurred may or may not match the estimated costs for a given accounting period. Actual results could differ from those estimates under different assumptions.

We record the costs of upfront fees and milestone payments for our licensing agreements as a research and development expense as payments are made under the agreements.

Our finished drug inventory is expensed to research and development since we are still a development stage company and we have not received regulatory approval to market RSR13. After regulatory approval, we will be required to capitalize any future costs of our marketed products at the lower of cost or market. The timing of future payments for finished drug inventory in relation to the timing of regulatory approval may cause variability in our future cost of goods sold and clinical manufacturing expenses.

Results of Operations

Comparison of Years Ended December 31, 2002, 2001 and 2000

Research and Development. Research and development expenses include the costs of clinical trials, clinical development, data analysis, non-clinical studies, basic research and licensing fees for a new product candidate. Research and development expenses for 2002, 2001 and 2000 were $13.9 million, $12.7 million and $10.7 million, respectively. Excluding the impact of non-cash charges comprising amortization of deferred compensation and stock expense (see "Non-cash Charges" below), research and development expenses for 2002, 2001 and 2000 were $14.9 million, $11.4 million and $6.2 million, respectively. The $3.5 million increase in 2002 was due primarily to increased headcount to support our clinical trials and to develop a regulatory department, and paying an initial up-front license fee related to the in-licensing of the PDX compound. The $5.2 million increase in research and development spending in 2001 was due primarily to increased enrollment costs for our Phase 3 trial of RSR13 for brain metastasis and additional headcount required to support this trial.

We expect research and development expenses will continue to increase in 2003, due primarily to external costs associated with our planned Phase 3 clinical trial of RSR13 for non-small cell lung cancer. We plan to enroll approximately 600 patients in this trial over an estimated 3 year period. We expect this clinical trial to cost $25-30 million and take 5-7 years from commencement of the trial to completion. The extent and timing of the increased costs related to this clinical trial will be significantly influenced by the rate at which we enroll study participants. We expect our internal research and development costs to increase moderately in 2003 to support the expansion of our clinical development programs, including initiating several additional Phase 2 clinical trials of RSR13, the further development of PDX and BGP-15 and the continued development of our product pipeline through in-licensing of additional compounds. If we decide to delay the filing of an NDA with the FDA because the results of our Phase 3 trial of RSR13 in patients with brain metastasis are not sufficient or we are not able to raise sufficient additional funds, our research and development costs may decrease in the future if we have to curtail our development plans for RSR13 or any of our other compounds.

Clinical Manufacturing. Clinical manufacturing expenses include third-party manufacturing costs for RSR13 for use in clinical trials, costs associated with pre-commercial scale-up of manufacturing to support anticipated commercial requirements, and development activities for clinical trial material for PDX and BGP-15. Clinical manufacturing expenses for 2002, 2001 and 2000 were $3.8 million, $3.1 million and $3.2 million, respectively. The $633,000 increase in 2002 resulted from increased headcount and consulting expenses to support our anticipated NDA filing and pre-manufacturing costs for BGP-15. The $58,000 decrease in 2001 primarily resulted from decreased consulting and pre-manufacturing product formulation expenses.

We expect clinical manufacturing expenses to increase significantly in 2003 as we have entered into two purchase orders with third-party manufacturers to purchase approximately $8.0 million of bulk drug to meet our anticipated commercial requirements for RSR13 and develop clinical trial material for PDX and BGP-15. If we decide to terminate these purchase orders because our Phase 3 trial results are negative or inconclusive, or because RSR13 does not receive regulatory approval when anticipated, we could incur termination fees of up to

$6.0 million. The timing of future payments for finished drug inventory in relation to the timing of regulatory approval may cause variability in our future cost of goods sold and clinical manufacturing expenses.

General and Administrative. General and administrative expenses include costs for executive administration, corporate offices and related infrastructure, corporate development and pre-marketing activities. General and administrative expenses for 2002, 2001 and 2000 were $10.4 million, $9.3 million and $13.8 million, respectively. Excluding the impact of non-cash charges comprising amortization of deferred compensation and stock compensation expense (see "Non-cash Charges" below), general and administrative expenses for 2002, 2001 and 2000 were $9.0 million, $6.9 million and $3.6 million, respectively. The $2.1 million increase in 2002 and the $3.3 million increase in 2001 were both primarily due to additional costs associated with being a public company, personnel costs related to our administrative infrastructure and corporate development, and facility costs. If the results of our Phase 3 trial on RSR13 are positive, we expect these costs to continue to increase as personnel are hired to begin developing a commercial organization and pre-launch marketing activities. If the results of our Phase 3 trial are negative or inconclusive and we decide to forego or delay the filing of our NDA with the FDA, or if we are not able to raise sufficient additional funds, our general and administrative costs will likely decrease as we will be required to reduce our administrative infrastructure to conserve our capital resources.

Interest and Other Income, Net. Interest income, net of interest expense, for 2002, 2001 and 2000 was $2.3 million, $4.9 million and $4.4 million, respectively. The $2.6 million decrease in 2002 primarily resulted from lower average investment balances and lower yields on U.S. government securities, high-grade commercial paper and corporate notes and money market funds. The $584,000 increase in 2001 was attributable to increased average investment balances from the proceeds of our initial public offering and higher yields available on our investment funds.

Income Taxes. As of December 31, 2002, we had net operating loss carryforwards and research and development credit carryforwards of $78.0 million and $5.1 million, respectively, available to offset future regular and alternative taxable income. These carryforwards will expire beginning in 2009. The utilization of the loss carryforwards to reduce future income taxes will depend on our ability to generate sufficient taxable income prior to the expiration of the net operating loss carryforwards and research and development credit carryforwards. In addition, the availability of the net operating loss carryforwards to reduce U.S. federal taxable income is subject to various limitations in the event of an ownership change in our stock.

Non-cash Charges. We have recorded stock-based compensation expense resulting primarily from certain options granted prior to our initial public offering with exercise prices below the fair market value of our common stock on their respective grant dates. In 2002, we recorded $1.3 million in general and administrative, negative $1.0 million in research and development and $90,000 in clinical manufacturing. The negative balance recorded in research and development is the result of recovery of an expense of $1.2 million that was recorded in prior periods due to the cancellation of a former employee's unvested options. In 2001, we recorded $2.3 million in general and administrative, $1.0 million in research and development and $152,000 in clinical manufacturing. In 2000, we recorded $10.1 million in general and administrative, $4.5 million in research and development and $231,000 in clinical manufacturing. At December 31, 2002, we had $1.1 million of deferred compensation remaining to be expensed in future years.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private placements of common and preferred stock and a public equity financing, which have resulted in net proceeds to us of $137.8 million through December 31, 2002. We have used $74.6 million of cash for operating activities. Cash, cash equivalents, short-term investments and long-term marketable securities were $60.8 million, $69.6 million and $85.7 million at December 31, 2002, 2001 and 2000, respectively. Working capital was $48.7 million, $55.7 million and $59.2 million at December 31, 2002, 2001 and 2000, respectively. Net cash used in operating activities for 2002, 2001, and 2000 was $21.9 million, $14.3 million, and $7.9 million, respectively. Cash used in operating activities was primarily to fund net losses, excluding non-cash charges.

Net cash provided by investing activities for 2002 and 2001 was $7.6 million and $15.9 million, respectively, and consisted primarily of proceeds from the maturities of short-term investments, partially offset by the purchase of short-term investments, acquisition of property and equipment and the investment in equity of another company in 2002. Net cash used in investing activities during 2000 was $76.0 million and consisted primarily of net purchases of investments and acquisition of property and equipment.

Net cash provided by financing activities during 2002 was $15.3 million and resulted from the private sale of common stock to a single investor, exercise of common stock options, and the sale of stock under our employee stock purchase plan. Net cash used in financing activities during 2001 was $480,000 and consisted primarily of pledging collateral for a line of credit. Net cash provided by financing activities during 2000 was $82.8 million and consisted primarily of proceeds from our initial public offering.

We have no other material external sources of liquidity. Because we have not derived any commercial revenues from product sales and a significant amount of our capital resources are held in the form of short-term financial instruments, decreasing yields on instruments such as United States government securities, high-grade commercial paper and corporate notes and money market funds would reduce net cash provided by investing activities, which is our primary source of liquidity in the absence of additional capital raised through additional equity or debt financing.

During 2002, we signed two purchase orders to purchase approximately $8.0 million of commercial grade bulk drug material to be delivered in 2004. If we receive FDA approval for RSR13, our expenditures to secure commercial grade bulk drug material will increase substantially. If the results of our Phase 3 trial for RSR13 do not meet certain criteria, we may cancel one of the purchase orders totaling $6.0 million for the commercial grade bulk drug resulting in aggregate termination fees of up to $6.0 million. We may cancel the other purchase order totaling $2.0 million for commercial grade bulk drug, without penalty, if the results of our Phase 3 trial for RSR13 do not meet certain criteria.

Below is a schedule of contractual commitments as of December 31, 2002 related to our operating leases and other long-term obligations.

	Less than 1 year	1-3 years	3-5 years	More Than 5 years	Total
Operating leases	$ 577,911	$1,488,736	$1,476,556	$ 632,205	$ 4,175,408
Other long-term obligations	3,359,265	1,027,929	1,000,000	1,000,000	6,387,194
Total contractual cash obligations	$3,937,176	$2,516,665	2,476,556	$1,632,205	$10,562,602

Other long-term obligations includes the potential termination fees for the purchase orders for commercial grade bulk drug material, termination fees for contracts with clinical research organizations and future milestone payments under our in-licensing commitments which could be paid earlier depending on the timing of achieving the respective milestone.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the calendar year 2003. We anticipate continuing our current development programs and beginning other long-term development programs on new products and technologies. These projects will require many years and substantial expenditures to complete and may ultimately be unsuccessful. We will require significant levels of additional capital beyond 2003 from outside sources to continue research and development activities, fund operating expenses, pursue regulatory approvals and build commercial sales and marketing capabilities, as necessary. Our actual capital requirements will depend on many factors, including the results of our Phase 3 clinical trial in brain metastases; status of product development; the time and cost involved in conducting clinical trials and obtaining regulatory approvals; filing, prosecuting and enforcing patent claims; competing technological and market developments; and our ability to market and distribute our future products and establish new collaborative and licensing arrangements.

We intend to raise additional capital in the future through arrangements with corporate partners, equity or debt financings or from other sources, including product sales, if any. Such arrangements may be dilutive to existing stockholders. In addition, if additional funds are obtained through arrangements with collaborative partners or other sources, such arrangements may require us to relinquish rights to some of our technologies, product candidates or products under development that we would otherwise seek to develop or commercialize ourselves. There is no assurance that we will be successful in consummating any such arrangements. In the event we are not able to raise sufficient additional funds, we may be required to delay, scale back, or eliminate one or more of our product development programs.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ON MARKET RISK

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The investment portfolio is used to preserve our capital until it is required to fund operations. All of these market-risk sensitive instruments are classified as held-to-maturity. We do not own derivative financial instruments in our investment portfolio. Our investment portfolio contains instruments that are subject to the risk of a decline in interest rates. We maintain a non-trading investment portfolio of investment grade, liquid debt securities that limits the amount of credit exposure to any one issue, issuer or type of instrument. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

We prepared sensitivity analyses of our interest rate exposures and our exposure from anticipated investment for fiscal 2003 to assess the impact of hypothetical changes in interest rates. Based on the results of these analyses, a 10% adverse change in interest rates from the 2002 fiscal year-end rates would not have a material adverse effect on the fair value of investments and would not materially impact our results of operations, cash flows, or financial condition for the next 12 months.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

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

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item concerning our directors is incorporated by reference to the information set forth in the sections entitled "Proposal 1—Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's definitive Proxy Statement for the 2003 Annual Meeting of Stockholders to be filed with the Commission within 120 days after the end of our fiscal year ended December 31, 2002 (the "Proxy Statement"). The information required by this Item concerning our executive officers is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Executive Officers and Key Employees."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item regarding executive compensation is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Executive Compensation."

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

The information required by this Item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Security Ownership of Certain Beneficial Owners and Management." The information required by this Item regarding our equity compensations plans is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Equity Compensation Plan Information."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item regarding certain relationships and related transactions is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Certain Transactions."

ITEM 14. CONTROLS AND PROCEDURES

Within the 90-day period prior to the filing of this report, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-14(c) of the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based on that evaluation, the CEO and CFO have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Subsequent to the date of their evaluation, there were no significant changes in our internal controls or in other factors that could significantly affect the disclosure controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS, AND SCHEDULES AND REPORTS ON FORM 8-K

(a) The following documents are being filed as part of this report:

(1) Financial Statements

Reference is made to the Index to Financial Statements of Allos Therapeutics, Inc. appearing on page F-1 of this report.

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Financial Statements or the Notes thereto.

(3) Exhibits

Exhibit No.	Description
3.01 (1)	Amended and Restated Certificate of Incorporation.
3.02 (1)	Bylaws.
4.01 (1)	Form of Common Stock Certificate.
4.02 (1)	Reference is made to Exhibits 3.01 and 3.02.
10.01 (1)	Form of Indemnification Agreement between the Registrant and each of its directors and officers.
10.02 (1)+	Hemotech and CIT Amended and Restated Allosteric Modifiers of Hemoglobin Agreement with Center for Innovative Technology dated January 12, 1994.
10.03 (1)+	Amendment to Allos Therapeutics, Inc. and CIT Amended and Restated Allosteric Modifiers of Hemoglobin Agreement with Center for Innovative Technology dated January 17, 1995.
10.04 (1)	Amendment to Allos Therapeutics, Inc. and CIT Amended and Restated Allosteric Modifiers of Hemoglobin Agreement with Center for Innovative Technology dated March 12, 1996.
10.05 (1)+	Assignment and Assumption Agreement with Amendment with Center for Innovative Technology and Virginia Commonwealth University Intellectual Property Foundation dated July 28, 1997.
10.06 (1)	Exercise of Option to Nonheme Protein License Agreement with VCU-Intellectual Property Foundation dated March 23, 1998.
10.10 (1)	Allos Therapeutics, Inc. Fourth Amended and Restated Stockholder Rights Agreement dated October 4, 1999.
10.11 (1)(*)	Allos Therapeutics, Inc. 1995 Stock Option Plan, as amended to date.
10.17 (1)	Lease Agreement with Virginia Biotechnology Research Park Authority dated July 28, 1999.
10.18 (1)+	Term Sheet for Contract API Supply between Allos Therapeutics, Inc. and Hovione dated March 25, 1999.
10.19 (1)	Confirmatory letter agreement with Hovione Inter Limited dated January 13, 2000.
10.20 (1)+	Development and Investigational Supply Proposal between Taylor Pharmaceuticals and Allos Therapeutics, Inc. dated December 30, 1998.
10.23 (2)(*)	Employment Agreement between Michael E. Hart and Allos Therapeutics, Inc. dated December 17, 2001.
10.24 (3)(*)	Allos Therapeutics, Inc. Severance Benefit Plan, effective January 16, 2001, and related benefit schedule thereto.
10.26 (4)(*)	Allos Therapeutics, Inc. 2001 Employee Stock Purchase Plan and form of Offering.
10.27 (5)+	Office Lease with Catellus Development Corporation dated April, 2001.
10.27.1++	Amended and Restated Second Amendment to Lease with Catellus Development Corporation, dated December 9, 2002.
10.29 (6)(*)	2000 Stock Incentive Compensation Plan.
10.30 (7)(*)	2002 Broad Based Equity Incentive Plan.
10.31 (8)	Securities Purchase Agreement, dated April 24, 2002, between Allos Therapeutics, Inc. and Perseus-Soros BioPharmaceutical Fund, L.P.
10.32 (8)	Registration Rights Agreement, dated April 24, 2002, between Allos Therapeutics, Inc. and Perseus-Soros BioPharmaceutical Fund, L.P.
10.33 (9)(*)	Employment Agreement between Daniel R. Hudspeth and Allos Therapeutics, Inc., effective April 23, 2002.
10.34 (10)(*)	Employment Agreement between David A. DeLong and Allos Therapeutics, Inc., effective August 12, 2002.
10.35 (*)	Consultant Agreement between Stephen J. Hoffman, Ph.D., M.D. and Allos Therapeutics, Inc., effective February 28, 2003.
23.01	Consent of PricewaterhouseCoopers LLP, Independent Accountants.

Exhibit No.	Description
24.01	Power of Attorney (included on signature page herein).
99.01	Chief Executive Officer and Chief Financial Officer Certificate.

(*) Indicates Management Contract or Compensatory Plan or Arrangement.

+ Confidential treatment has been granted with respect to portions of these exhibits. Omitted portions have been filed with the Securities and Exchange Commission.

++ Confidential treatment has been requested with respect to portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(1) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-95439) and amendments thereto, declared effective March 27, 2000.

(2) Incorporated by reference to our Annual Report on Form 10-K (File No. 000-29815), as filed with the Commission on March 14, 2002.

(3) Incorporated by reference to our Annual Report on Form 10-K (File No. 000-29815), as filed with the Commission on March 7, 2001.

(4) Incorporated by reference to our Registration Statement on Form S-8 (File No. 333-60430), as filed with the Commission on May 8, 2001.

(5) Incorporated by reference to our Quarterly Report on Form 10-Q (File No. 000-29815), as filed with the Commission on August 14, 2001.

(6) Incorporated by reference to our Registration Statement on Form S-8 (File No. 333-38696), as filed with the Commission on June 6, 2000.

(7) Incorporated by reference to our Registration Statement on Form S-8 (File No. 333-76804), as filed with the Commission on January 16, 2002.

(8) Incorporated by reference to our Current Report on Form 8-K (File No. 000-29815), as filed with the Commission on April 30, 2002.

(9) Incorporated by reference to our Quarterly Report on Form 10-Q (File No. 000-29815), as filed with the Commission on July 23, 2002.

(10) Incorporated by reference to our Quarterly Report on Form 10-Q (File No. 000-29815), as filed with the Commission on November 12, 2002.

(b) Reports on Form 8-K:

No reports on Form 8-K were filed by us during the fourth quarter of 2002.

SIGNATURES

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

ALLOS THERAPEUTICS, INC.

Date: March 27, 2003

By: /s/ MICHAEL E. HART
Michael E. Hart
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Michael E. Hart and Daniel R. Hudspeth, and each of them, his true and lawful attorneys-in-fact and agents with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 27, 2003, and in the capacities indicated:

Name	Title
/s/ STEPHEN J. HOFFMAN Stephen J. Hoffman	Chairman of Board of Directors and Director
/s/ MICHAEL E. HART Michael E. Hart	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ DANIEL R. HUDSPETH Daniel R. Hudspeth	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ DONALD J. ABRAHAM Donald J. Abraham	Director
/s/ MICHAEL D. CASEY Michael D. Casey	Director
/s/ MARK G. EDWARDS Mark G. Edwards	Director
/s/ MARVIN E. JAFFE Marvin E. Jaffe	Director

Form 10-K Certification

I, Michael E. Hart, certify that:

1. I have reviewed this annual report on Form 10-K of Allos Therapeutics, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 27, 2003

/s/ MICHAEL E. HART

Michael E. Hart
President and Chief Executive Officer

Form 10-K Certification

I, Daniel R. Hudspeth, certify that:

1. I have reviewed this annual report on Form 10-K of Allos Therapeutics, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 27, 2003

/s/ DANIEL R. HUDSPETH

Daniel R. Hudspeth
Chief Financial Officer

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Allos Therapeutics, Inc.

Index to Financial Statements

REPORT OF INDEPENDENT ACCOUNTANTS

To the Stockholders and Board of Directors
of Allos Therapeutics, Inc.

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Allos Therapeutics, Inc. (a company in the development stage) at December 31, 2001 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002 and the cumulative period from September 1, 1992 (date of inception) through December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP
Denver, Colorado

February 18, 2003

ALLOS THERAPEUTICS, INC.

BALANCE SHEETS

	December 31, 2001	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,745,151	$ 3,756,951
Restricted cash	550,000	550,000
Short-term investments	56,473,499	50,676,010
Prepaid research and development expenses	787,627	534,287
Prepaids and other assets	121,186	240,789
Total current assets	60,677,463	55,758,037
Long-term marketable securities	9,843,198	5,816,529
Property and equipment, net	1,653,588	1,826,277
Long-term investment	—	1,000,000
Total assets	$ 72,174,249	$ 64,400,843
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable—related parties	$ 82,631	$ 111,656
Trade accounts payable and accrued expenses	359,552	408,879
Accrued research and development expenses	3,440,895	5,117,400
Accrued bonus and employee benefits	1,140,275	1,440,725
Total current liabilities	5,023,353	7,078,660
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2001 and 2002 respectively, no shares issued or outstanding	—	—
Common stock, $0.001 par value; 75,000,000 shares authorized at December 31, 2001 and 2002; 23,139,197 and 25,863,454 shares issued and outstanding at December 31, 2001 and 2002, respectively	23,139	25,863
Additional paid-in capital	156,925,292	171,020,705
Deferred compensation related to grant of options	(2,943,590)	(1,101,466)
Accumulated deficit	(86,853,945)	(112,622,919)
Total stockholders' equity	67,150,896	57,322,183
Total liabilities and stockholders' equity	$ 72,174,249	$ 64,400,843

The accompanying notes are an integral part of these financial statements.

ALLOS THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

	Years Ended December 31,			Cumulative Period From September 1, 1992 (date of inception) through December 31, 2002
	2000	2001	2002	
Operating expenses:				
Research and development	$ 10,736,503	$ 12,659,419	$ 13,860,208	$ 60,202,017
Clinical manufacturing	3,200,548	3,143,332	3,775,921	15,284,634
General and administrative	13,775,248	9,277,047	10,443,646	40,666,674
Total operating expenses	27,712,299	25,079,798	28,079,775	116,153,325
Loss from operations	(27,712,299)	(25,079,798)	(28,079,775)	(116,153,325)
Interest and other income, net	4,350,824	4,935,473	2,310,801	13,143,381
Net loss	(23,361,475)	(20,144,325)	(25,768,974)	(103,009,944)
Dividend related to beneficial conversion feature of preferred stock	—	—	—	(9,612,975)
Net loss attributable to common stockholders	$(23,361,475)	$(20,144,325)	$(25,768,974)	$(112,622,919)
Net loss per share:				
Basic and diluted	$ (1.29)	$ (0.88)	$ (1.03)	
Weighted average shares—basic and diluted	18,058,802	22,970,974	24,942,496	

The accompanying notes are an integral part of these financial statements.

ALLOS THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Convertible Preferred Stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Subscription receivable for common stock at $1.61 per share	—	$ 90	—	$ —	$ —	$ —	$ —	$ —	$ 90
Balance at December 31, 1992	—	90	—	—	—	—	—	—	90
Subscription receivable for common stock at $1.61 per share	—	10	—	—	—	—	—	—	10
Issuance of common stock for subscription receivable	992,000	892	—	—	(892)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(24,784)	(24,784)
Balance at December 31, 1993	992,000	992	—	—	(892)	—	—	(24,784)	(24,684)
Issuance of $.001 par value common stock in exchange for license agreement	248,000	248	—	—	39,752	—	—	—	40,000
Issuance of Series A convertible preferred stock ($.001 par value) together with Series A and Series B stock warrants at $1.00 per share	—	—	700,000	704	529,023	—	—	—	529,727
Issuance of Series A convertible preferred stock upon exercise of Series A warrants at $1.00 per share	—	—	1,300,000	1,300	1,298,700	—	—	—	1,300,000
Accretion to redemption value of preferred stock	—	—	—	—	58,839	—	—	(58,839)	—
Net loss	—	—	—	—	—	—	—	(898,929)	(898,929)
Balance at December 31, 1994	1,240,000	1,240	2,000,000	2,004	1,925,422	—	—	(982,552)	946,114
Issuance of Series A convertible preferred stock at $1.00 per share	—	—	3,000,000	3,000	2,973,454	—	—	—	2,976,454
Accretion to redemption value of preferred stock	—	—	—	—	229,837	—	—	(229,837)	—
Net loss	—	—	—	—	—	—	—	(2,384,176)	(2,384,176)
Balance at December 31, 1995	1,240,000	1,240	5,000,000	5,004	5,128,713	—	—	(3,596,565)	1,538,392
Issuance of Series B convertible preferred stock at $1.60 per share, net of issuance costs	—	—	5,032,500	5,033	7,992,705	—	—	—	7,997,738
Cancellation of Series B warrants previously issued with Series A	—	—	—	(4)	4	—	—	—	—
Cancellation of Series A redemption rights	—	—	—	—	(288,676)	—	—	288,676	—
Issuance of common stock upon exercise of stock options for cash of $4,024 and notes receivable of $90,000 at $0.16 per share	582,950	583	—	93,441	(90,000)	—	—	—	4,024
Net loss	—	—	—	—	—	—	—	(4,053,027)	(4,053,027)
Balance at December 31, 1996	1,822,950	1,823	10,032,500	10,033	12,926,187	(90,000)	—	(7,360,916)	5,487,127
Issuance of common stock upon exercise of stock options for cash of $20,288 and notes receivable of $49,687 at $0.16-$0.40 per share	175,770	176	—	—	69,799	(49,687)	—	—	20,288
Net loss	—	—	—	—	—	—	—	(6,512,591)	(6,512,591)
Balance at December 31, 1997	1,998,720	1,999	10,032,500	10,033	12,995,986	(139,687)	—	(13,873,507)	(1,005,176)
Issuance of Series C convertible preferred stock at $1.81 per share, net of issuance costs	—	—	9,944,750	9,945	17,937,102	—	—	—	17,947,047
Issuance of common stock upon exercise of stock options for cash of $3,464 at $0.16-$0.40 per share	13,239	13	—	—	3,451	—	—	—	3,464
Net loss	—	—	—	—	—	—	—	(8,573,923)	(8,573,923)
Balance at December 31, 1998	2,011,959	2,012	19,977,250	19,978	30,936,539	(139,687)	—	(22,447,430)	8,371,412

The accompanying notes are an integral part of these financial statements.

ALLOS THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(continued)

	Common Stock		Convertible Preferred Stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance at December 31, 1998	2,011,959	$ 2,012	19,977,250	$19,978	$ 30,936,539	$(139,687)	$ —	$ (22,447,430)	$ 8,371,412
Issuance of Series C convertible preferred stock at $1.81 per share, net of issuance costs	—	—	5,311,036	5,311	9,529,532	—	—	—	9,534,843
Issuance of common stock upon exercise of stock options for cash of $3,695 at $0.16-$0.56 per share	10,179	10	—	—	3,685	—	—	—	3,695
Deferred compensation related to options	—	—	—	—	6,811,055	—	(4,442,294)	—	2,368,761
Beneficial conversion feature related to issuance of preferred stock	—	—	—	—	9,612,975	—	—	(9,612,975)	—
Net loss	—	—	—	—	—	—	—	(11,287,740)	(11,287,740)
Balance at December 31, 1999	2,022,138	2,022	25,288,286	25,289	56,893,786	(139,687)	(4,442,294)	(43,348,145)	8,990,971
Issuance of 5,000,000 shares of common stock, net of issuance costs	5,000,000	5,000	—	—	82,764,396	—	—	—	82,769,396
Conversion of preferred stock to common stock upon IPO	15,678,737	15,679	(25,288,286)	(25,289)	9,610	—	—	—	—
Extinguishment of notes receivable	—	—	—	—	—	139,687	—	—	139,687
Issuance of common stock upon exercise of stock options for cash of $76,358 at $0.16—$0.56 per share	254,001	254	—	—	73,601	—	—	—	73,855
Deferred compensation related to options	—	—	—	—	16,860,998	—	(2,062,800)	—	14,798,198
Net loss	—	—	—	—	—	—	—	(23,361,475)	(23,361,475)
Balance at December 31, 2000	22,954,876	22,955	—	—	156,602,391	—	(6,505,094)	(66,709,620)	83,410,632
Issuance of common stock upon exercise of stock options for cash of $103,831 at $0.40—$2.42 per share	175,096	175	—	—	103,656	—	—	—	103,831
Issuance of common stock upon exercise of purchase rights at an exercise price of $3.84 per share	9,225	9	—	—	35,433	—	—	—	35,442
Stock compensation expense	—	—	—	—	283,512	—	—	—	283,512
Deferred compensation related to options	—	—	—	—	(99,700)	—	3,561,504	—	3,461,804
Net loss	—	—	—	—	—	—	—	(20,144,325)	(20,144,325)
Balance at December 31, 2001	23,139,197	23,139	—	—	156,925,292	—	(2,943,590)	(86,853,945)	67,150,896
Issuance of common stock in private placement for $6.00 per share	2,500,000	2,500	—	—	14,929,273	—	—	—	14,931,773
Issuance of common stock upon exercise of stock options for cash of $290,753 at $0.40—$7.38 per share	187,126	187	—	—	290,566	—	—	—	290,753
Issuance of common stock upon exercise of purchase rights at an exercise price of $3.84—$6.39 per share	27,446	27	—	—	120,252	—	—	—	120,279
Issuance of common stock upon exercise of warrants for equipment leaseline	9,685	10	—	—	21,521	—	—	—	21,531
Stock compensation expense	—	—	—	—	190,378	—	—	—	190,378
Deferred compensation related to options	—	—	—	—	(1,456,577)	—	1,842,124	—	385,547
Net loss	—	—	—	—	—	—	—	(25,768,974)	(25,768,974)
Balance at December 31, 2002	25,863,454	$25,863	—	$ —	$171,020,705	$ —	$(1,101,466)	$(112,622,919)	$ 57,322,183

The accompanying notes are an integral part of these financial statements.

ALLOS THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

	Years Ended December 31,			Cumulative Period From September 1, 1992 (date of inception) through December 31, 2002
	2000	2001	2002	
Cash Flows From Operating Activities:				
Net loss	$(23,361,475)	$(20,144,325)	$(25,768,974)	$(103,009,944)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	122,181	277,064	489,900	1,241,167
Stock-based compensation	14,888,198	3,745,316	575,925	21,578,200
Other	—	30,718	21,531	104,655
Changes in operating assets and liabilities:				
Prepaids and other assets	250,326	(659,173)	133,737	(775,077)
Interest receivable on investments	(1,472,798)	222,907	545,219	(799,164)
Accounts payable — related parties	89,802	1,397,649	29,025	3,469,921
Trade accounts payable and accrued expenses	146,892	147,537	49,327	408,879
Accrued research and development expenses	1,274,655	(15,258)	1,676,505	1,759,136
Accrued bonus and employee benefits	201,673	714,223	300,450	1,440,725
Net cash used in operating activities	(7,860,546)	(14,283,342)	(21,947,355)	(74,581,502)
Cash Flows From Investing Activities:				
Acquisition of property and equipment	(218,087)	(1,635,104)	(662,589)	(2,808,972)
Purchases of marketable securities	(97,994,487)	(45,994,641)	(46,028,561)	(237,954,867)
Proceeds from sales of marketable securities	22,227,033	63,572,592	55,307,500	182,261,492
Purchase of long-term investment	—	—	(1,000,000)	(1,000,000)
Payments received on notes receivable	49,687	—	—	49,687
Net cash provided by (used in) investing activities	(75,935,854)	15,942,847	7,616,350	(59,452,660)
Cash Flows From Financing Activities:				
Principal payments under capital leases	(79,042)	(69,320)	—	(422,088)
Proceeds from sales leaseback	—	—	—	120,492
Pledging restricted cash	—	(550,000)	—	(550,000)
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	—	—	40,285,809
Proceeds from issuance of common stock associated with stock options and purchase rights	—	—	411,032	655,731
Proceeds from issuance of common stock, net of issuance costs	82,843,251	139,273	14,931,773	97,701,169
Net cash provided by (used in) financing activities	82,764,209	(480,047)	15,342,805	137,791,113
Net increase (decrease) in cash and cash equivalents	(1,032,191)	(1,179,458)	1,011,800	3,756,951
Cash and cash equivalents, beginning of period	2,597,884	1,565,693	2,745,151	—
Cash and cash equivalents, end of period	$ 1,565,693	$ 2,745,151	$ 3,756,951	$ 3,756,951
Supplemental Schedule of Noncash Operating and Financing Activities:				
Cash paid for interest	$ 170,172	$ 694,641	$ 158,562	$ 1,033,375
Issuance of stock in exchange for license agreement	—	—	—	40,000
Capital lease obligations incurred for acquisition of property and equipment	—	—	—	422,088
Issuance of stock in exchange for notes receivable	—	—	—	139,687

The accompanying notes are an integral part of these financial statements.

1. Formation and Business of the Company

Allos Therapeutics, Inc. (the "Company") is a biopharmaceutical company focused on developing and commercializing innovative small molecule drugs for improving cancer treatments.

The Company was incorporated in the Commonwealth of Virginia on September 1, 1992 as HemoTech Sciences, Inc. and filed amended Articles of Incorporation to change its name to Allos Therapeutics, Inc. on October 19, 1994. The Company reincorporated in Delaware on October 28, 1996.

The Company's lead product candidate (RSR13, efaproxiral) is a synthetic small molecule that enhances the diffusion of oxygen to hypoxic (oxygen-deprived tumor tissues) from hemoglobin, the oxygen carrying protein contained within red blood cells. The Company is currently conducting clinical trials for RSR13. Prior to commercial sales of the product, the Company must complete the clinical trials and receive the necessary Food and Drug Administration ("FDA") approval. Should the Company be unable to obtain the necessary FDA approvals, there could be a materially adverse effect on the Company's financial condition, operating results and cash flows. In addition, the Company has in-licensed two additional compounds that it intends to develop.

To date, the Company has devoted substantially all of its resources to research and clinical development. The Company has not derived any commercial revenues from product sales, and does not expect to receive product revenues until at least 2004. The Company has incurred significant operating losses since its inception in 1992. The Company expects to continue to incur significant operating losses over the next several years as it continues to incur increasing research and development costs, in addition to costs related to clinical trials and manufacturing activities. There can be no assurance if or when the Company will become profitable.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and investments, will be adequate to satisfy our capital needs through at least the calendar year 2003. We anticipate continuing our current development programs and beginning other long-term development projects on new products or technologies. These projects will require many years and substantial expenditures to complete and may ultimately be unsuccessful. We will require significant levels of additional capital beyond 2003 from outside sources to continue research and development activities, fund operating expenses, pursue regulatory approvals and build sales and marketing capabilities, as necessary. Our actual capital requirements will depend on many factors, including the results of our Phase 3 clinical trial in brain metastases; status of product development; the time and cost involved in conducting clinical trials and obtaining regulatory approvals; filing, prosecuting and enforcing patent claims; competing technological and market developments; and our ability to market and distribute our future products and establish new collaborative and licensing arrangements.

We intend to raise additional capital in the future through additional arrangements with corporate partners, equity or debt financings, or from other sources, including product sales, if any. Such arrangements may be dilutive to existing stockholders. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, such arrangements may require us to relinquish rights to some of our technologies, product candidates or products under development that we would otherwise seek to develop or commercialize ourselves. There is no assurance that we will be successful in consummating any such arrangements. In the event we are not able to raise sufficient additional funds, we may be required to delay, scale back, or eliminate one or more of our product development programs.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company has not generated any revenue to date and its activities have consisted primarily of developing products, raising capital and recruiting personnel. Accordingly, the Company is considered to be in the development stage at December 31, 2002 as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, Accounting and Reporting by Development Stage Enterprises.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amount of expenses during the reporting period. Actual results could differ materially from these estimates.

Cash and Cash Equivalents, Short-term Investments and Marketable Securities

All highly liquid investments with a maturity of three months or less are considered to be cash equivalents. The carrying values of the Company's cash equivalents and short-term and long-term marketable securities approximate their market values based on quoted market prices. The Company accounts for marketable securities in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Short-term and long-term marketable securities are classified as held to maturity and are carried at cost plus accrued interest and consist of commercial paper, government obligations and corporate notes having maturities of longer than three months, held at financial institutions.

Prepaid Research and Development Expenses

In accordance with various research and development agreements, the Company is obligated to make certain up front payments upon execution. Such payments are expensed as services or terms of the agreement are achieved. The Company evaluates whether events and circumstances have occurred that may indicate impairment of remaining prepaid research expenses.

Property and Equipment

Property and equipment is recorded at cost and is depreciated using the straight-line method over estimated useful lives. Depreciation and amortization expense was $122,181, $277,064 and $489,900 for the years ended 2000, 2001 and 2002, respectively, and $1,241,167 for the cumulative period from inception.

The components of property and equipment are as follows:

	December 31,		Estimated Lives
	2001	2002	
Office furniture and equipment	$1,052,810	$1,129,687	5-7 years
Computer hardware and software	587,263	1,132,443	3 years
Lab equipment owned	103,224	103,224	5 years
Leasehold improvements	354,208	394,740	7 years
	2,097,505	2,760,094	
Less accumulated depreciation and amortization	(443,917)	(933,817)	
	$1,653,588	$1,826,277	

Long-lived Assets

The Company identifies and records impairment losses on long-lived assets when events and circumstances indicate that the assets might be impaired. No significant impairment losses have been recorded to date with respect to the Company's long-lived assets, which consist primarily of property and equipment, leasehold improvements, and long-term investment.

Accrued Research and Development Expenses

The Company records accruals for contracted third-party development activity, including estimated clinical study costs, which will be invoiced to us in a subsequent accounting period. Clinical study costs represent costs incurred by clinical research organizations and clinical sites. These costs are recorded as a component of research and development expenses. Management accrues costs for these clinical studies based on the progress of the

clinical trials, including patient enrollment, dosing levels of patients enrolled, estimated costs to dose patients, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates are made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates.

Bonus Plan

The Annual Bonus Program of the Company (the "Bonus Program") was adopted by the Board of Directors and is intended to promote both individual productivity and employee retention. The bonuses paid under the Bonus Plan are based on a number of criteria including, but not limited to, terms of employee agreements, that participants' individual performance and the corporate objectives established annually by the Board of Directors are achieved. Bonuses are paid in cash.

Stock-Based Compensation

The Company accounts for grants of stock options according to Accounting Principles Board Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* and related Interpretations. Proforma net loss information, as required by SFAS No. 123, *Accounting for Stock-Based Compensation*("SFAS 123"), is included in Note 5. Any deferred stock compensation calculated according to APB No. 25 is amortized over the vesting period of the individual options, generally four years, in accordance with FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option and Award Plans* ("FIN 28").

In December 2002, the FASB issued Statement No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. SFAS 148 amends SFAS 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of SFAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," to account for employee stock options.

The following table illustrates the effect on net loss and loss per share if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation for the years ended December 31, 2000, 2001 and 2002:

	2000	2001	2002
Net loss—as reported	$(23,361,475)	$(20,144,325)	$(25,768,974)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	7,180,823	3,745,316	575,925
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(7,827,842)	(5,215,838)	(2,392,223)
Pro forma net loss	$(24,008,494)	$(21,614,847)	$(27,585,272)
Loss per share:			
Basic and diluted—as reported	$ (1.29)	$ (0.88)	$ (1.03)
Basic and diluted—pro forma	$ (1.33)	$ (0.94)	$ (1.11)

Such pro forma disclosures may not be representative of the pro forma effect in future years because options vest over several years and additional grants may be made each year.

Research and Development

Research and development expenditures are charged to operations as incurred. Research and development expenses include the costs of basic research, nonclinical studies, clinical trials, regulatory affairs, biostatistical data analysis and licensing fees for new products.

Clinical Manufacturing

Clinical manufacturing expenses include primarily internal costs for personnel and external costs for third party manufacturing and product development, finished drug inventory and consulting expenses. Our finished drug inventory is expensed to research and development since we are still a development stage company and we have not received regulatory approval. After regulatory approval, we will be required to capitalize any future costs of our marketed products at the lower of cost or market and expense the inventory as a component of cost of goods sold.

Income Taxes

Income taxes are accounted for under SFAS No. 109, *Accounting for Income Taxes.* Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities at each year end and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount more likely than not to be realized.

Concentration of Credit

The Company's cash and cash equivalents, short-term investments and long-term marketable securities at December 31, 2001 and 2002 are maintained in two financial institutions in amounts that, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk in this area. It is the Company's policy to place its investments in high-quality securities.

Net Loss Per Share

Net loss per share is calculated in accordance with SFAS No. 128, *Earnings Per Share.* Under the provisions of SFAS 128, basic net loss per common share is computed by dividing the net loss for the period by the weighted average number of vested common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per share and is computed giving effect to all dilutive potential common stock, including options, non-vested common stock, convertible preferred stock and convertible preferred stock warrants.

Anti-dilutive securities as of December 31, 2000, 2001 and 2002 not included in the diluted net loss per share calculations, are as follows:

	2000	2001	2002
Non-vested common stock	171	—	—
Common stock options	1,859,903	2,442,301	3,023,852
Common stock warrants	14,275	14,275	—
	1,874,349	2,456,576	3,023,852

Fair Value of Financial Instruments

The Company's financial instruments include cash and cash equivalents, short-term investments, prepaid expenses, accounts payable and accrued liabilities. The carrying amounts of financial instruments approximate their fair value due to their short maturities. The fair value of the Company's long-term marketable securities approximates $5,500,000 at December 31, 2002.

Recent Accounting Pronouncements

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), *Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor's fiscal year-end. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FIN 45 has not had, nor do we believe it will have, a material impact on our current or prospective financial statements.

In July 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ("SFAS 146"). SFAS 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have a significant impact on the Company's financial statements.

In December 2002, the FASB issued Statement No. 148. *Accounting for Stock-Based Compensation—Transition and Disclosure*—an amendment of FASB Statement No. 123 ("SFAS 148"). This Statement amends FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of Statement 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The adoption of SFAS 148 has not had, nor does the Company believe it will have, a significant impact on the Company's financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), *Consolidation of Variable Interest Entities*. FIN 46 addresses consolidation by business enterprises of variable interest entities, which have certain characteristics. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 has not had, nor do we believe it will have, a material impact on our current or prospective financial statements.

3. Restricted Cash

On May 24, 2001, $550,000 of cash was pledged as collateral on a letter of credit related to a building lease and was classified as restricted cash on the balance sheet.

4. Marketable Securities

In accordance with SFAS No. 115, investments that the Company has the positive intent and ability to hold to maturity are reported at amortized cost, which approximates fair market value, and are classified as held-to-maturity. Substantially all of the Company's marketable securities are held in corporate notes with maturities ranging from three months to two years. Marketable securities as of December 31, 2001 and 2002 are as follows:

	2001	2002
Due in one year or less	$56,473,499	$50,676,010
Due after one year through two years	9,843,198	5,816,529
Total	$66,316,697	$56,492,539

5. Stockholders' Equity

Common Stock

On April 24, 2002, the Company completed a private placement of 2.5 million shares of common stock at a purchase price of $6.00 per share to Perseus-Soros BioPharmaceutical Fund, L.P. for an aggregate purchase price of $15.0 million, which resulted in net cash proceeds to the Company of approximately $14.9 million to be used to fund future clinical development and commercialization of RSR13 (efaproxiral) and BGP-15, a compound that was in-licensed in March 2002.

On March 27, 2000, the SEC declared effective the Company's Registration Statement on Form S-1. Pursuant to this Registration Statement, the Company completed an Initial Public Offering ("IPO") of 5,000,000 shares of its common stock at an IPO price of $18.00 per share (the "Offering"). Proceeds to the Company from the Offering, after calculation of the underwriters' discount and commission, totaled approximately $82.8 million, net of offering costs of approximately $1.0 million (excluding underwriters discounts and commissions). Concurrent with the closing of the IPO, all outstanding shares of the Company's convertible preferred stock were automatically converted into 15,678,737 shares of common stock.

At December 31, 2002, the Company has reserved shares of common stock for future issuance as follows:

1995 Stock Option Plan	1,220,413
2000 Stock Option Plan	1,685,502
2001 Employee Stock Purchase Plan	1,903,329
2002 Broad Based Equity Incentive Plan	1,000,000
Total	5,809,244

Concurrent with the close of the Company's initial public offering, the Company's Certificate of Incorporation was amended to authorize 10,000,000 shares of undesignated preferred stock, none of which are issued or outstanding. The Company's Board of Directors is authorized to fix the designation, powers, preferences, and rights of any such series. The Company's Certificate of Incorporation was also amended to increase the authorized number of shares of common stock to 75,000,000 shares.

Warrants

In April 1996, the Company issued warrants to purchase 17,500 shares of the Company's Series B convertible preferred stock in conjunction with an equipment lease line at an exercise price of $1.60 per share that were to expire on April 15, 2006. In May 1998, the Company issued warrants to purchase 5,524 shares of the Company's Series C convertible preferred stock in conjunction with an equipment lease with an exercise price of $1.81 per share that were to expire on May 5, 2008. Upon completing the IPO, the Series B and Series C warrants were converted to purchase 10,850 shares at $2.58 and 3,425 shares at $2.92, respectively, of the Company's common stock. In September 2002, all outstanding warrants were exercised.

Stock Options

During 1995, the Board of Directors terminated the 1992 Stock Plan (the "1992 Plan") and adopted the 1995 Stock Option Plan (the "1995 Plan"). The 1995 Plan was amended and restated in 1997. Termination of the 1992 Plan had no effect on the options outstanding under that plan, as they were assumed under the 1995 Plan. Under the 1995 Plan, the Company may grant fixed and performance-based stock options and stock appreciation rights to officers, employees, consultants and directors. The stock options are intended to qualify as "incentive stock options" under Section 422 of the Internal Revenue Code, unless specifically designated as non-qualifying stock options or unless exceeding the applicable statutory limit.

During 2000, concurrent with the Company's IPO, the Board suspended the 1995 Plan and adopted the 2000 Stock Incentive Compensation Plan (the "2000 Plan"). The 2000 Plan provides for the granting of stock options similar to the terms of the 1995 Plan as described above. Any shares remaining for future option grants and any future cancellations of options from our 1995 Plan will be available for future grant under the 2000 Plan.

Suspension of the 1995 Plan had no effect on the options outstanding under that plan. Under the 2000 Plan, the Company is authorized to increase the number of shares of common stock that shall be available annually on the first day of the Company's fiscal year beginning in 2001 in an amount equal to the lesser of 440,000 shares or 2% of the adjusted average common shares outstanding of the Company used to calculate fully diluted earning per share as reported in the Annual Report to stockholders for the preceding year, or alternatively, by any lesser amount determined by the Board.

In January 2002, the Board of Directors approved the Allos Therapeutics, Inc. 2002 Broad Based Equity Incentive Plan. Under this plan, the Company is authorized to issue up to 1,000,000 shares of common stock to employees, consultants and members of the Board of Directors. Under the terms of the plan, the aggregate number of shares underlying stock awards to officers and directors once employed by the Company cannot exceed 49 percent of the number of shares underlying all stock awards granted determined on specific dates. This plan will terminate on January 7, 2012.

As of December 31, 2002, the Company had 423,805 and 458,258 shares of common stock available for grant under the 2000 and 2002 Plans, respectively. The 1995, 2000 and 2002 Plans provide for appropriate adjustments in the number of shares reserved and granted options in the event of certain changes to the Company's outstanding common stock by reason of merger, recapitalization, stock split or other similar events. Options granted under the Plans may be exercised for a period of not more than ten years from the date of grant or any shorter period as determined by the Board of Directors. Options vest as determined by the Board of Directors, generally over a period of two to four years, subject to acceleration under certain events. The exercise price of any incentive stock option shall equal or exceed the fair market value per share on the date of grant, or 110% of the fair market value per share in the case of a 10% or greater stockholder.

The Company has granted to selected officers and other key employees stock option awards whose vesting is subject to acceleration upon achieving specific criteria. The options will vest based upon meeting certain clinical milestones, finalizing a corporate partnership and/or co-licensing of an additional compound for development. If such criteria are not met, these options will become fully vested after 7 years from the date of grant. For such options, deferred stock-based compensation was recorded at the date of grant, representing the difference between the exercise price and the fair value of the Company's common stock on the date these options were granted, as both the number of shares and the option price were fixed. Deferred stock-based compensation is amortized over the predefined vesting period until it becomes probable that the performance goals will be met; at that time, the amortization of the remaining deferred stock-based compensation will be accelerated so as to be amortized over the period to the date the performance goal is expected to be reached.

The Company recorded compensation charges resulting from certain options granted to employees with exercise prices below the fair market value of our common stock on their respective grant dates. For the years ended December 31, 2002, 2001 and 2000, we recorded amortization of deferred stock-based compensation of $386,000, $3,462,000 and $7,181,000, respectively. Of the $386,000 recorded for the year ended December 31, 2002, $1,327,000 related to general and administrative, negative $1,031,000 related to research and development and the remaining $90,000 related to clinical manufacturing. The negative balance for research and development is the result of recovery of an expense of $1,162,000 that was recorded in prior periods due to the cancellation of an employee's unvested options. Deferred compensation is included as a reduction of stockholders' equity and is being amortized in accordance with the accelerated method as described in *FIN 28* over the vesting periods of the related options, which is generally four years. At December 31, 2002, the Company had $1,101,466 in deferred stock-based compensation.

A summary of the Company's stock option activity, and related information follows:

	Options Outstanding		Options Exercisable	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 1999	1,225,170	$0.48	592,206	$0.48
Granted	898,171	4.14		
Exercised	(254,002)	0.34		
Canceled	(9,436)	3.90		
Outstanding at December 31, 2000	1,859,903	2.25	599,134	$0.55
Granted	860,379	5.66		
Exercised	(175,096)	0.59		
Canceled	(102,885)	8.45		
Outstanding at December 31, 2001	2,442,301	3.31	1,538,894	$1.80
Granted	977,644	6.76		
Exercised	(187,126)	1.56		
Canceled	(208,967)	3.08		
Outstanding at December 31, 2002	3,023,852	$4.55	1,591,069	$2.84

The following table summarizes information about options outstanding as of December 31, 2002:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number of Options	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$0.00 - $ 1.38	604,254	5.6	$ 0.50	604,254	$ 0.50
$1.39 - $ 5.50	1,127,222	7.8	3.63	672,256	2.77
$5.51 - $ 9.62	1,245,076	8.8	7.07	281,696	7.02
$9.63 - $13.75	47,300	7.5	11.87	32,863	11.76
	3,023,852	7.8	$ 4.55	1,591,069	$ 2.84

Employee Stock Purchase Plan

On February 28, 2001, the Board of Directors approved the Allos Therapeutics, Inc. 2001 Employee Stock Purchase Plan ("Purchase Plan"), which was also approved by the Company's stockholders on April 17, 2001. Under the Purchase Plan, the Company is authorized to issue up to 2,500,000 shares of common stock to qualified employees. Qualified employees can choose each offering to have up to 10 percent of their annual base earnings withheld to purchase the Company's common stock. The purchase price of the stock is 85 percent of the lower of the fair market value of a share of common stock on the first day of the offering or the fair market value of a share of common stock on the last day of the purchase period. The Company sold 9,225 and 27,446 shares to employees in 2001 and 2002, respectively. There are 1,903,329 shares available for sale at December 31, 2002. The Purchase Plan will terminate on February 27, 2011.

Pro Forma Disclosure

The weighted average estimated grant date fair value, as defined by SFAS 123, for options granted under the company's stock option plans during fiscal 2000, 2001 and 2002 was $6.76, $3.47 and $3.43 per share, respectively. The weighted average estimated grant date fair value of purchase awards under the Company's Purchase Plan during fiscal 2001 and 2002 was $1.55 and $1.76, respectively. The estimated grant date fair values were calculated using the Black-Scholes option-pricing model.

The following assumptions are included in the estimated grant date fair value calculations for the Company's stock option and purchase awards as of December 31, 2000, 2001 and 2002:

	2000	2001	2002
Stock option plans:			
Expected dividend yield	0%	0%	0%
Expected stock price volatility	73% - 90%	49% - 83%	33% - 63%
Risk free interest rate	5.63% - 6.5%	3.5% - 12.38%	3.38% - 7.88%
Expected life (years)	5.0	5.0	5.0
Stock purchase plan:			
Expected dividend yield	—	0%	0%
Expected stock price volatility	—	53%	44% - 56%
Risk free interest rate	—	3.49%	3.49%
Expected life (years)	—	2.0	1.2

6. Income Taxes

Income taxes computed using the federal statutory income tax rate differs from the Company's effective tax primarily due to the following for the years ended December 31, 2000, 2001 and 2002:

	2000	2001	2002
Federal income tax benefit at 35%	$(8,176,500)	$(7,050,500)	$(9,019,100)
State income tax, net of federal benefit	(254,400)	(525,300)	(781,462)
Stock-based compensation	4,966,000	1,075,200	47,600
Research and development credits	(685,300)	(1,121,100)	(1,333,900)
Change in valuation allowance	4,674,800	7,167,700	10,972,100
Other	(524,600)	(454,000)	114,762
Benefit for income taxes	$ —	$ —	$ —

The components of the Company's deferred tax assets under SFAS 109 as of December 31, 2001 and 2002 are as follows:

	2001	2002
Deferred tax assets:		
Temporary differences	$ 416,300	$ 528,100
Research and development credit carryforwards	3,746,100	5,080,000
Net operating loss carryforwards	20,123,900	29,650,300
Total deferred tax assets	24,286,300	35,258,400
Valuation allowance	(24,286,300)	(35,258,400)
Net deferred tax assets	$ —	$ —

The Company's deferred tax assets represent an unrecognized future tax benefit. A valuation allowance has been established for the entire tax benefit as the Company believes that it is more likely than not that such assets will not be realized.

At December 31, 2002, the Company has approximately $78.0 million of net operating loss ("NOL") carryforwards and approximately $5.1 million of research and development ("R&D") credit carryforwards. These carryforwards will expire beginning 2009. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the NOL and R&D credit carryforwards available for use in any given year upon the occurrence of certain events, including significant changes in ownership interest. A greater than 50% change in ownership of a company within a three-year period results in an annual limitation on the Company's ability to utilize its NOL and R&D credit carryforwards from tax periods prior to the ownership change. The Company's NOL and R&D credit

carryforwards as of December 31, 2002 are subject to annual limitation due to changes in ownership. Future ownership changes could further limit the utilization of the Company's NOL and R&D credit carryforwards.

7. Employee Benefit Plan

The Company maintains a defined contribution plan covering substantially all employees under Section 401(k) of the Internal Revenue Code. The Company amended the plan documents on January 1, 1999 to provide a 50% match of employees' contributions up to $2,000 per employee per year. The Company made total contributions of $118,383, $93,601 and $55,842 in 2002, 2001 and 2000, respectively.

8. Commitments and Contingencies

Lease Commitments

The Company leases offices, research and development facilities, as well as certain office and lab equipment under agreements that expire at various dates through 2008. Total rent expense in 2000, 2001 and 2002 and the cumulative period from inception was $207,389, $388,993, $629,793 and $1,738,247, respectively.

The aggregate future minimum rental commitments as of December 31, 2002, for noncancelable operating leases with initial or remaining terms in excess of one year are as follows:

	Operating Leases
Year Ending December 31:	
2003	$ 577,911
2004	767,427
2005	721,309
2006	717,910
2007	758,646
Thereafter	632,205
Total minimum lease payments	$4,175,408

Contingencies

The Company signed two purchase orders to purchase approximately $8.0 million of commercial grade bulk drug material to be delivered in 2004. The Company may cancel one of the purchase orders totaling $6.0 million for the commercial grade bulk drug resulting in aggregate termination fees of up to $6.0 million.

The Company enters into indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners, contractors, clinical sites and suppliers. Under these provisions the Company generally indemnifies and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2002.

9. Royalty and License Fee Commitments

On January 14, 1994, the Company entered into a license agreement with the Center for Innovative Technology ("CIT"), under which CIT grants to the Company an exclusive, worldwide license to practice, develop and use its technology and licensed patent rights to develop and market the Company's products. In exchange for the license agreement, the Company paid CIT $50,000 in cash and issued 248,000 shares of its common stock valued at $0.16 per share. This agreement was assigned by CIT to the Virginia Commonwealth University Intellectual Property Foundation ("VCUIPF") on June 30, 1997. Under the agreement, the Company has the right

to grant sublicenses, for which it must also pay royalties to VCUIPF for products produced by the sublicensees. VCUIPF has the primary responsibility to file, prosecute, and maintain intellectual property protection, but the Company has agreed to reimburse costs incurred by VCUIPF after July 1, 1993 related to obtaining and maintaining intellectual property protection. Also, pursuant to the agreement, the Company will pay VCUIPF a running royalty of 1.25% of our worldwide net revenue arising from the sale, lease or other commercialization of the allosteric hemoglobin modifier compounds. This agreement terminates on the date the last United States patent licensed to the Company under the agreement expires, which is October, 2016. Quarterly royalty payments are due within 60 days from the end of each calendar quarter. As of December 31, 2002, no royalty payments have been incurred.

In addition, the CIT license agreement requires the Company to sponsor research at Virginia Commonwealth University ("VCU"). As of December 31, 2002, the Company entered into sponsored research agreements with VCU, which extend through June 30, 2003. The Company has an aggregate remaining commitment of $200,116 under the agreement.

In March 2002, the Company entered into an agreement with N-Gene Research Laboratories, Inc., under which the Company obtained an exclusive U.S. license to intellectual property surrounding BGP-15, a novel, orally bioavailable small molecule that reduces cellular stress induced by chemotherapy. The Company has the right to develop and market BGP-15 in the field of oncology and certain cardiovascular conditions. In connection with the license, the Company made an upfront equity investment of $1,000,000 in the licensor, and is required to make a subsequent equity investment upon the achievement of certain development milestones, as well as a cash payment based on issuance of certain patents. In addition, the Company will pay the licensor a royalty based on a percentage of net revenue arising from sales of BGP-15 in the U.S., if and when such sales occur. No royalty payments have been made as of December 31, 2002. The agreement also requires the Company to expend certain minimum funds in connection with pre-launch marketing efforts conducted during the 2-year period prior to the launch of the first FDA-approved product derived from BGP-15. The Company is accounting for the investment under the cost method of accounting as it has no control or significant influence over the licensor.

In December 2002, the Company entered into an agreement under which the Company obtained exclusive worldwide rights to a novel, proprietary anti-folate, known as PDX, from Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute. The Company has obtained worldwide rights to develop and market the product in all potential diagnostic and therapeutic areas. Under the terms of the agreement, the Company made an upfront payment and will also make subsequent payments at the earlier of the achievement of certain development milestones or the passage of certain time periods after the effective date of the agreement, Such subsequent payments will be expensed as incurred. The Company will fund all development programs and will have sole responsibility for all commercialization activities. In addition, the Company will pay the licensor a royalty based on a percentage of net revenues from sales, if and when such sales occur. As of December 31, 2002 no royalty payments have been made.

10. Related Party Transactions

In December 1994, the Company renegotiated a consulting agreement for scientific advisory services with Dr. Marvin Jaffe, a director of the Company. Under the agreement, the Company paid Dr. Jaffe consulting fees of $2,000 per month. In March 2002, this contract was terminated. For 2000, 2001 and 2002 and the cumulative period from inception, the Company paid Dr. Jaffe consulting fees of $24,000, $24,000, $6,000 and $215,017, respectively. Since inception, the Company has granted to Dr. Jaffe stock options to purchase a total of 75,800 shares of the Company's common stock under the Company's stock option plans at exercise prices ranging from $0.16 to $7.20 per share.

In January 2001, the Company entered into a consulting agreement for scientific advisory services with Dr. Donald Abraham, a director of the Company. Under the one-year agreement, which was renewable upon mutual consent, the Company paid Dr. Abraham consulting fees of $2,000 per month. In March 2002, this contract was terminated. For 2001, 2002 and the cumulative period from inception, the Company paid Dr. Abraham consulting fees of $42,000, $6,000 and $48,000 respectively. Since inception, the Company has granted to Dr. Abraham stock options to purchase a total of 20,000 shares of the Company's common stock under the Company's stock option plans at exercise prices ranging from $6.73 to $7.20 per share.

The Company entered into several research and development contracts during 1996. Under these contracts, Dr. Abraham acted as Principal Investigator for the contracts with VCU. During 2000, 2001 and 2002, services provided under these contracts totaled $487,557, $457,474, and $412,921, respectively, of which $66,706 was included in accounts payable at December 31, 2002.

During 2000, we recorded $7.6 million in stock-based compensation expense in connection with the forgiveness of certain recourse notes receivable from two officers of the Company: $5.4 million in general and administrative and $2.2 million in research and development. Upon forgiveness of the notes in March 2000, we recorded stock-based compensation expense based upon the difference between the fair market value of the underlying common stock and option exercise price on date of forgiveness. In addition, we recorded $120,000 of stock-based compensation expense due to the ultimate extinguishment of the notes: $35,000 in general and administrative and $85,000 in research and development.

11. Quarterly Information (Unaudited)

The results of operations on a quarterly basis for the years ended December 31, 2001 and 2002 were as follows:

	March 31, 2001	June 30, 2001	September 30, 2001	December 31, 2001	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002
Operating expenses:								
Research and development	$ 2,781,784	$ 3,064,636	$ 3,344,297	$ 3,468,702	$ 3,938,887	$ 4,289,787	$ 1,937,299	$ 3,694,235
Clinical manufacturing	1,014,829	1,190,679	640,348	297,477	445,164	726,115	1,242,430	1,362,212
General and administrative	2,135,434	2,259,710	2,412,052	2,469,851	2,688,019	2,537,046	2,657,133	2,561,448
Total operating expenses	5,932,047	6,515,025	6,396,697	6,236,030	7,072,070	7,552,948	5,836,862	7,617,895
Loss from operations	(5,932,047)	(6,515,025)	(6,396,697)	(6,236,030)	(7,072,070)	(7,552,948)	(5,836,862)	(7,617,895)
Interest and other income, net	1,553,155	1,256,154	1,268,233	857,931	611,942	674,890	548,545	475,424
Net loss attributable to common Stockholders	$(4,378,892)	$(5,258,871)	$(5,128,464)	$(5,378,099)	$(6,460,128)	$(6,878,058)	$(5,288,317)	$(7,142,471)
Net loss per share:								
Basic and diluted	$ (0.19)	$ (0.23)	$ (0.22)	$ (0.23)	$ (0.28)	$ (0.27)	$ (0.21)	$ (0.27)
Weighted average shares—basic and diluted	22,959,975	22,958,087	22,961,185	23,007,206	23,129,771	25,040,790	25,724,192	25,836,893

12. Subsequent Events

During February 2003, the Company entered into a consulting agreement with the Chairman and terminated the employment agreement as executive Chairman previously entered into with him in January 2001. The Chairman will serve the Company as non-executive Chairman of the Board and is required to provide consulting services as requested from time to time by the Company. The consulting agreement is for a term of two years commencing February 28, 2003, unless terminated earlier pursuant to its terms.

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CORPORATE INFORMATION

BOARD OF DIRECTORS

Stephen J. Hoffman, Ph.D., M.D.
Chairman of the Board of Directors

Michael E. Hart
President and Chief Executive Officer

Donald J. Abraham, Ph.D.
Chairman of the Department of Medicinal Chemistry, Virginia

Michael D. Casey
Pharmaceutical Industry Consultant

Mark G. Edwards
Managing Director, Recombinant Capital, Inc.

Marvin E. Jaffe, M.D.
Pharmaceutical Industry Consultant

CORPORATE HEADQUARTERS

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INVESTOR RELATIONS

Allos invites stockholders, security analysts, representatives of the financial community and members of the business media to contact:

Monique M. Greer
Vice President, Corporate Communications & Investor Relations
mgreer@allos.com
303-426-6262

Interested parties may view Press releases and other information about Allos by visiting *www.allos.com* or by direct request to the company's Investor Relations office.

SEC FORM 10-K

Enclosed is a copy of the company's Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission. Additional copies are available without charge by contacting Allos' Investor Relations office at 303-426-6262.

STOCK LISTING

Allos' stock is traded on the Nasdaq National Market® under the symbol "ALTH". For more information, please visit *www.allos.com.*

REGISTRAR & TRANSFER AGENT

Mellon Investor Services LLC
85 Challenger Road
Ridgefield Park, NJ 07660

ANNUAL MEETING

Allos shareholders are invited to attend our annual meeting, which will be held at 8:30 a.m. on May 23, 2003 at the corporate headquarters of Allos Therapeutics, Inc., Westminster, CO.

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