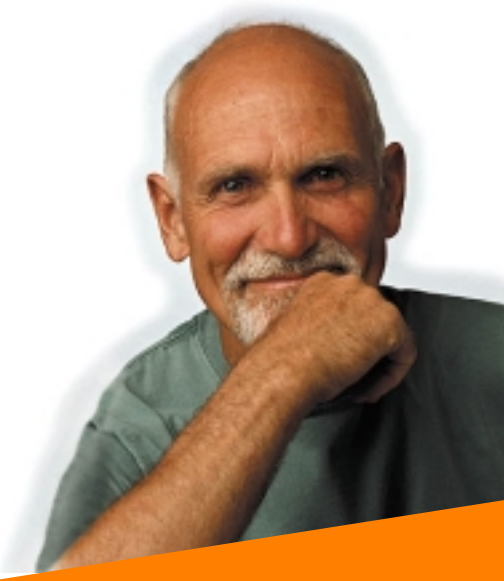
Breathing New Life into Cancer Therapy.



Allos THERAPEUTICS, INC.

'03

Allos Therapeutics, Inc.

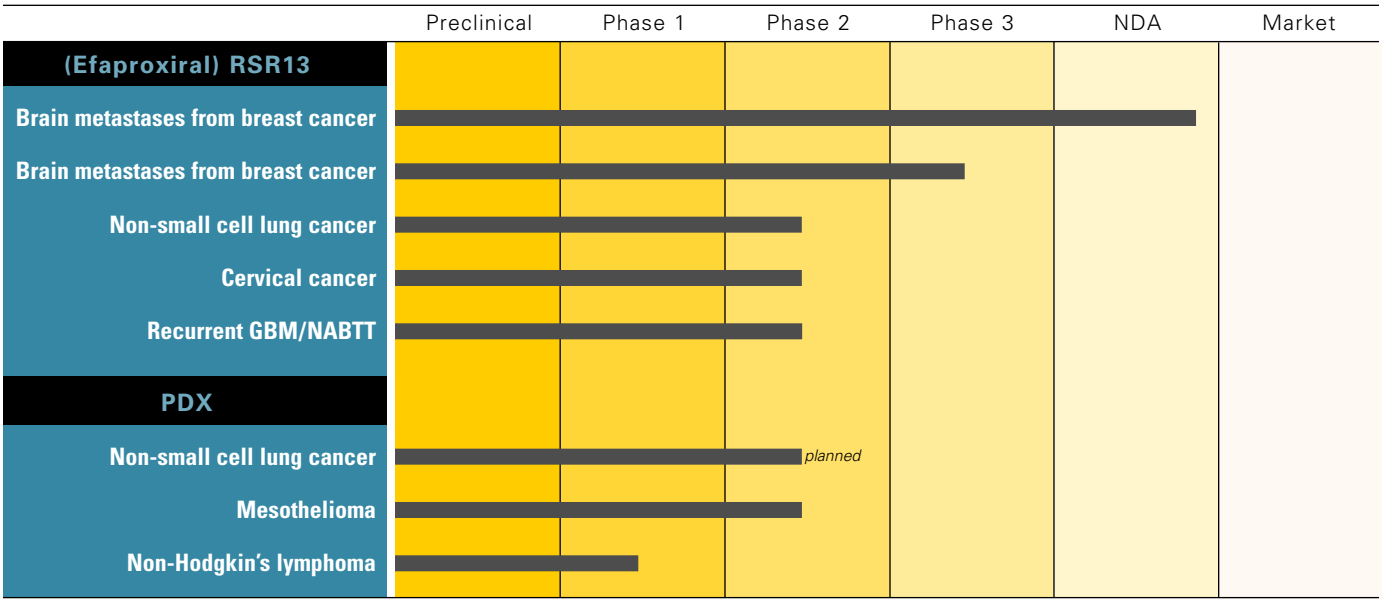
Key Events in 2004

- Initiate new investigative sites and enroll women with brain metastases from breast cancer in the ENRICH clinical trial
- Expect FDA decision by June 4, 2004 on NDA to market RSR13 in patients with brain metastases from breast cancer
- Submit MAA in Europe for RSR13
- Launch Phase 1 clinical trial of RSR13 with concurrent chemoradiation therapy in patients with locally advanced, unresectable non-small cell lung cancer
- Launch multi-center Phase 1/2 study of PDX in patients with non-small cell lung cancer

Allos Therapeutics, Inc. (NASDAQ: ALTH) is a biopharmaceutical company focused on developing and commercializing innovative drugs for improving cancer treatments.

Our lead clinical candidate, RSR13 (efaproxiral), is a synthetic small molecule that has the potential to sensitize hypoxic, or oxygen deprived, tumor tissues and enhance the efficacy of standard radiation therapy. In addition, we are developing PDX, an injectable small molecule chemotherapeutic agent that has a superior potency and toxicity profile relative to methotrexate and other dihydrofolate reductase, or DHFR, inhibitors.

Innovative Pipeline Targets Unmet Medical Needs



Note: All studies ongoing or planned as noted.

2003 ACHIEVEMENTS

1/03 — *Licensed exclusive worldwide rights to a novel analog of methotrexate, known as PDX, from the Memorial Sloan-Kettering Cancer Center, Southern Research Institute and SRI International.*

4/03 — *Announced preliminary results of a pivotal Phase 3 trial that evaluated RSR13 and whole brain radiation therapy in patients with brain metastases.*

5/03 — *Announced the decision to submit a rolling New Drug Application (NDA) to market RSR13 as an adjunct to whole brain radiation therapy for the treatment of brain metastases from breast cancer.*

Tenacious, Responsible & Optimistic

Dear Stockholders,

2003 was a year of important achievements for Allos, and I am pleased to report that we made progress on many fronts: we advanced our compounds in the clinic, we met several regulatory milestones, and we took decisive steps to strengthen our company and improve our prospects for commercial success. Our long-term goal remains to build a sustainable oncology company.

"When used with whole-brain radiation therapy in clinical trials, RSR13 has shown considerable efficacy in reducing the size and number of tumors in patients suffering from breast cancer that has metastasized to the brain. This combination of therapies offers much needed hope for these patients."

– John H. Suh, M.D.

Clinical Director, Radiation Oncology, Brain Tumor Institute at the Cleveland Clinic

Several companies, most notably Genentech, Amgen, and IDEC, have demonstrated how the success of one product can transform a company. We have an opportunity with RSR13 to shift the treatment paradigm for patients receiving radiation therapy. Our progress over the past year has put us right on the cusp of this transformation.

The most significant events for us in 2003 were the conclusion of the REACH study and subsequent filing of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for approval of RSR13 as an adjunct to whole brain radiation therapy for the treatment of brain metastases from breast cancer. While the overall results of the REACH study were not exactly what we had hoped for, it became clear to us through analysis of the data that RSR13 plus whole brain radiation therapy provides a statistically significant benefit to patients with brain metastases from breast cancer. The survival data are impressive and, in the interest of all patients, merit further review.

The completion of the NDA for RSR13 was a decade in the making. This was not a trivial exercise for a company of 60 employees; it represented a major milestone for Allos. We are gratified that the FDA granted priority review to the NDA, and further, that the FDA's Oncologic Drugs Advisory Committee (ODAC) plans to review RSR13 on May 3, 2004. The FDA will take into consideration ODAC's opinion when they make their final decision on the NDA, which we expect to occur in June 2004.

Last June, after the results of the REACH trial became known, we acted quickly and responsibly to reduce our burn rate and terminate development programs that were not critical to our short-term business objectives. It is a testament to the fortitude and determination of the entire Allos team that we were able to put this behind us and focus on completing several important objectives in the second half of the year. In November, we further enhanced our balance sheet by completing a $12 million private placement of securities to provide additional working capital to support our ongoing development programs.

We remain committed to continuing our clinical research with RSR13 in patients with brain metastases. As a follow-on to the REACH study, we initiated the ENRICH study which is

6/03 – *Findings from a Phase 2 clinical trial of RSR13 for the treatment of patients with brain metastases published in the Journal of Clinical Oncology.*

6/03 – *Clinical Cancer Research published results of a Memorial Sloan-Kettering Cancer Center study that showed PDX may be an effective chemotherapy treatment for patients with non-small cell lung cancer.*

8/03 – *Submitted the first part of the NDA containing non-clinical information.*

10/03 – *Submitted the second part of the NDA containing information about RSR13's chemistry, manufacture and controls (CMC).*

10/03 – *Dr. John H. Suh, Clinical Director, Radiation Oncology, Brain Tumor Institute at the Cleveland Clinic, presented with National Tumor Foundation Research Award at Society for Neuro-Oncology Annual Meeting for work on RSR13.*

10/03 – *Presented results from the pivotal Phase 3 trial of RSR13 for the treatment of patients with brain metastases at the Eighth Annual Meeting of The Society for Neuro-Oncology.*

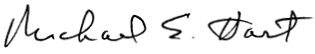
designed to evaluate RSR13 plus whole brain radiation therapy in women with brain metastases originating from breast cancer. We initiated several clinical sites for the ENRICH study in late 2003, leading to the enrollment of the first patient in February 2004. If supplemental data are needed to support RSR13 marketing approval in this indication, we expect the ENRICH study to provide such data over the next 18-24 months.

We also believe RSR13 as an adjunct to radiation therapy may provide clinical benefit to patients with primary cancer. In January 2004, we initiated a new study in patients with primary non-small cell lung cancer (NSCLC). Use of radiation therapy in the treatment of primary cancers typically involves six weeks of daily therapy, making the safety of an adjunct like RSR13 very important. Ongoing studies in cervical cancer and NSCLC are designed to re-confirm the maximum tolerated dose of RSR13 for a given chemoradiation regimen before evaluating efficacy. Results of earlier studies in patients with NSCLC and glioblastoma provide us with a great deal of optimism for improving patient outcomes.

Early in 2003, we expanded our oncology portfolio by licensing exclusive worldwide rights to a novel, proprietary antifolate (DHFR inhibitor) known as PDX from the Memorial Sloan-Kettering Cancer Center, Southern Research Institute and SRI International. PDX is an analog of methotrexate that has demonstrated a superior therapeutic index to its predecessor and has shown significant single-agent activity. We are eager to move this program forward and plan to launch a multi-center Phase 1/2 study of PDX in patients with refractory NSCLC in mid-2004.

2004 will undoubtedly be another exciting and challenging year for Allos. The FDA decision on whether or not to approve RSR13 for marketing will greatly influence our direction for the second half of the year and beyond. Should RSR13 be approved, we will move aggressively to market it to the broadest range of medical professionals thus ensuring the patients who need it are served. If not, we will stay the course and seek to complete enrollment in the ENRICH study as rapidly as possible. Our talented and dedicated team is prepared for either challenge.

In conclusion, we remain committed to our mission of developing, acquiring and commercializing therapeutic compounds that enhance current cancer therapies in patients for whom there are no other treatment alternatives. On behalf of our Board of Directors and management team, I would like to express our sincere appreciation to all of our employees, clinical collaborators and partners for their dedication and hard work over the past year. We look forward to their continued contributions and to your ongoing support in the year ahead.



Michael E. Hart
President and Chief Executive Officer

"Our findings to date suggest that RSR13, when combined with whole brain radiation therapy, is an important and significant advance in the treatment of patients with brain metastases for whom there are few therapeutic options. In our experience, RSR13 also has an acceptable safety profile."

– Baldassare Stea, M.D., Ph.D.,
Head of the Department of Radiation Oncology
Arizona Health Sciences Center in Tucson

Completed a $12 million private placement of securities with institutional investors.

10/03

12/03

Presented positive survival and quality of life data from the pivotal Phase 3 trial of RSR13 for the treatment of patients with brain metastases from breast cancer at the 26th Annual San Antonio Breast Cancer Symposium.

Completed the submission of the NDA to market RSR13 as an adjunct to whole brain radiation therapy for the treatment of brain metastases from breast cancer.

12/03

12/03

Entered into a long-term development and supply agreement with Baxter Healthcare for the commercial manufacture of RSR13 injection.

Allos THERAPEUTICS, INC.

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

FORM 10-K/A
(Amendment No. 1)

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the fiscal year ended December 31, 2003.

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the transition period from to

Commission File Number
00029815

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 2, 2004, there were 31,104,447 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 30, 2003) was approximately $82,617,639. 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, 2003. 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 2004 Annual Meeting of Stockholders to be filed within 120 days after the end of the Registrant's fiscal year ended December 31, 2003 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, Annual Report on Form 10-K (File No. 000-29815) for the fiscal year ended December 31, 2002, 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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EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A to our Annual Report on Form 10-K for the fiscal year ended December 31, 2003, originally filed with the Securities and Exchange Commission on March 5, 2004, amends Item 7 of Part II and Item 15 of Part IV of our Annual Report on Form 10-K. This Form 10-K/A is filed in response to comments received from the Division of Corporation Finance of the Securities and Exchange Commission. Consent of our independent auditors is attached to this Form 10-K/A as Exhibit 23.01 and certifications from our Chief Executive Officer and Chief Financial Officer required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 are attached to this Form 10-K/A as Exhibits 31.01 and 32.01.

While this Amendment No. 1 also sets forth the complete text of each other item of the Company's Form 10-K for the year ended December 31, 2003, it does not change any information contained in these other items as originally filed on March 5, 2004. This Amendment No. 1 also does not reflect events that have occurred after the original filing of the Form 10-K.

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

Allos Therapeutics, Inc. is a biopharmaceutical company that is 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 biological methods. We strive to develop drugs that improve the treatment of cancer and enhance the power of current therapies. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or together with one or more potential strategic partners. Our focus is on product opportunities that build on our internal clinical development and regulatory expertise and address important medical markets. We endeavor to grow our existing portfolio of oncology product candidates through further clinical development of current small molecules and ongoing product acquisition and in-licensing efforts.

We have two product candidates that are currently under development, RSR13 (efaproxiral) and PDX (10-propargyl-10-deazaaminopterin).

- RSR13 is the first synthetic small molecule designed to sensitize hypoxic, or oxygen-deprived, areas of tumors prior to radiation therapy by facilitating the release of oxygen from hemoglobin, the oxygen-carrying protein contained within red blood cells, and increasing the level of oxygen in tumors. The presence of oxygen in tumors is an essential element for the effectiveness of radiation therapy. By increasing tumor oxygenation, we believe RSR13 has the potential to enhance the efficacy of standard radiation therapy.

  We have completed a pivotal Phase 3 trial of RSR13 plus whole brain radiation therapy in 538 patients with brain metastases. On April 23, 2003, we announced the preliminary results of this trial in which the survival benefit observed did not reach statistical significance in either of the pre-specified intent-to-treat groups. However, the results demonstrated a statistically significant survival benefit in patients with brain metastases originating from breast cancer. Based on these findings, in December 2003, we submitted a New Drug Application, or NDA, to the United States Food and Drug Administration, or FDA, for approval to market RSR13 as an adjunct to whole brain radiation therapy for the treatment of brain metastases originating from breast cancer. In February 2004, the FDA accepted our NDA with priority review and established an action date by June 2004. We also intend to submit a Marketing Authorization Application, or MAA, in Europe for approval to market RSR13 in this indication in the first half of 2004.

  We have also demonstrated in Phase 2 clinical trials that RSR13 plus radiation therapy improves survival in patients with glioblastoma multiforme, or GBM, a highly aggressive form of primary brain cancer, and in patients with non-small cell lung cancer, or NSCLC. In February 2004, we initiated a randomized, open-label Phase 3 trial of RSR13 as an adjunct to radiation therapy for the treatment of brain metastases originating from breast cancer. We also are evaluating or plan to evaluate RSR13 in many other tumor types and clinical situations requiring radiation therapy, such as non-small cell lung cancer, cervical cancer, esophageal and head and neck cancers.

- PDX is an injectable small molecule chemotherapeutic agent that has a superior potency and toxicity profile relative to methotrexate and other related dihydrofolate reductase, or DHFR, inhibitors. Drugs that inhibit DHFR, such as methotrexate, were among the first chemotherapeutic agents discovered. Methotrexate remains one of the most widely applied chemotherapy drugs and is used to treat breast, bladder and head and neck cancers, leukemias and other cancers.

  PDX is the subject of several published articles and studies, the latest of which is a Phase 2 study of PDX as a single agent in 39 pretreated patients with advanced-stage non-small cell lung cancer. Current clinical trials include a single-agent study in non-Hodgkin's lymphoma (Phase 1/2), mesothelioma (Phase 2), and a combination study with docetaxel in NSCLC patients (Phase 1).

Current Cancer Therapies

According to an independent healthcare research company, the worldwide oncology drug market was estimated at approximately $25 billion in 2003. 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 1.3 million new cases of cancer are diagnosed each year in the United States, and approximately 556,000 patients die each year of cancer.

The appropriate cancer therapy for each patient depends on the cancer type and careful assessment of the size and location of the tumor and extent to which the tumor has spread, or metastasized, to other parts of the body. Effective therapy must eliminate or control the growth of the cancer both at its site of origin and at sites of metastases. Treatment options may include a combination of surgery, radiation therapy, chemotherapy, hormone therapy and immunotherapy.

Radiation therapy is the principal non-surgical means of treating malignant tumors in patients with cancer. Currently more than half of all cancer patients receive radiation therapy at some point during their cancer treatment. The estimated 750,000 cancer patients who receive radiation therapy annually are approximately twice the number of cancer patients who are treated with 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. Although radiation therapy can be effective in treating certain types of cancer, there are currently no drugs on the market that increase the effectiveness of radiation therapy.

Chemotherapy involves using chemical agents to help control or prevent the growth of cancerous tumors, while attempting to limit the damage to normal cells. Chemotherapy is useful in fighting cancer that has spread to other parts of the body and cannot be easily detected or treated with surgery or radiation therapy. In this way, chemotherapy is different from local treatments such as surgery or radiation therapy, which target only specific areas of the body. Chemotherapy can be used in combination with surgery and/or radiation therapy.

Our Business Strategy

Our goal is to become a profitable biopharmaceutical development and marketing company that generates significant cash flow. The key elements of our business strategy are to:

- *Obtain regulatory approval to market RSR13.* We are currently focused on obtaining regulatory approval in the United States and Europe to market RSR13 as an adjunct to radiation therapy for the treatment of brain metastases originating from breast cancer. We are also actively developing RSR13 in combination with radiation therapy in several other indications, including cervical cancer and NSCLC.
- *Develop PDX.* We plan to evaluate PDX for oncology as a novel chemotherapeutic and in combination with other therapies. We also plan to evaluate PDX in other therapeutic indications where methotrexate is used.
- *In-license or acquire complementary products, technologies or companies.* We continue to seek opportunities to expand our product portfolio by identifying and evaluating potential compounds and technologies developed by third parties that would enhance our current oncology portfolio.
- *Develop sales and marketing and manufacturing capabilities.* We currently retain exclusive, worldwide commercial rights to RSR13 and PDX for all target indications. We intend to develop sales and marketing capabilities, either internally or through contract relationships or strategic collaborations. We also intend to develop pre-launch and commercial-scale production capabilities through agreements with contract manufacturers.

Our Product Candidates

The following table summarizes the target indications and clinical development status of our product candidates:

Product Candidate	Target Indications	Clinical Program Status
RSR13 (efaproxiral)		
Radiation Sensitizer	Brain metastases from breast cancer	NDA in Priority Review
	Brain metastases from breast cancer	Phase 3
	Non-small cell lung cancer with sequential chemotherapy	Phase 2 complete
	Non-small cell lung cancer with concurrent chemotherapy	Phase 1b/2
	Glioblastoma multiforme	Phase 2 complete
	Cervical cancer	Phase 1b/2
Chemotherapy Enhancer	Recurrent malignant glioma	Phase 1b/2
PDX		
Chemotherapy	Non-small cell lung cancer	Phase 2 complete
	Mesothelioma	Phase 2
	Non-Hodgkin's lymphoma	Phase 1b/2

RSR13 (efaproxiral)

RSR13 as a Radiation Sensitizer

RSR13 is a synthetic small molecule being developed for use as an adjunct to radiation therapy in the treatment of cancer. Over 700 patients have been treated with RSR13 in conjunction with radiation therapy in nine clinical trials. The results have shown that RSR13 is generally well tolerated and has an acceptable safety profile for use in cancer patients.

Scientific Rationale

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. 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 cancer, 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 effectiveness of radiation therapy in killing tumor cells.

Radiation therapy generally works well at the periphery of tumors where cells are small in number and well oxygenated. However, radiation therapy is less effective in the center of the tumor where there is a large volume of cells, often under hypoxic, or oxygen-deprived, conditions. Tumors become hypoxic because they have a poorly regulated blood supply caused by the disorganized growth of new blood vessels into the tumor. In most tumors studied, 10% to 20% of the cells were hypoxic. While

hypoxia is deadly to most cells, cancer cells undergo genetic and adaptive changes that allow them to survive and even proliferate in a hypoxic environment.

Small molecule drugs, like RSR13, can be used to modify a protein's function by altering the protein's 3-dimensional structure. Known as allosteric modification, a small molecule drug alters a protein's 3-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.

RSR13 binds in the central water cavity of the hemoglobin tetramer and decreases hemoglobin-oxygen binding affinity, which is reflected as an increase in p50 (i.e., the partial pressure of oxygen that results in 50 percent hemoglobin saturation). By this action, RSR13 facilitates the release of oxygen from hemoglobin and increases the level of oxygen in tumors. In addition, by facilitating the release of oxygen from hemoglobin, we believe RSR13 has the potential to treat a variety of other diseases and clinical conditions caused by tissue hypoxia.

Unlike existing drugs and other attempts to enhance the effectiveness of radiation therapy, the radiation-enhancing effect of RSR13 is not dependent on its direct diffusion into the cancerous tumor. Instead, RSR13 works by increasing oxygen uptake within the tumor. It is the oxygen, and not RSR13, 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.

RSR13 is administered in an outpatient setting and has several distinguishing characteristics that make it well suited as a radiation sensitizer:

- RSR13 is not cytotoxic;
- RSR13 stays in the bloodstream bound to hemoglobin;
- RSR13 does not need to cross the blood-brain barrier to be effective; and
- RSR13 has a rapid onset of action and a short half-life.

RSR13 and Whole Brain Radiation Therapy (WBRT) in the Treatment of Brain Metastases

WBRT for the treatment of brain metastases is administered to approximately 175,000 patients per year in the United States and is intended to prevent or reduce complications and increase survival. Cancers that metastasize to the brain most often originate in the breast, lungs, kidneys or melanomas in the skin.

The median survival of patients with brain metastases who receive WBRT is about four to six months. A patient's survival time 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 die from disease progression in the brain, and the remainder die from disease progression in other regions in the body. Although WBRT is the primary therapy for these patients, the effectiveness of WBRT may be limited by tumor hypoxia, which has been shown to decrease radiation sensitivity of solid tumors and their metastases. As a result, we believe the addition of RSR13 to WBRT may decrease tumor hypoxia and improve the sensitivity of solid tumors to radiation therapy, thereby leading to improved patient outcomes.

In February 2000, we initiated a randomized, open label Phase 3 clinical trial, called REACH, designed to demonstrate that RSR13 is safe and effective for treating patients with brain metastases resulting from heterogeneous primary tumor types, i.e., breast, NSCLC, melanoma. The study enrolled 538 patients and compared the efficacy and safety of RSR13 plus WBRT and supplemental oxygen

versus WBRT and supplemental oxygen in patients with brain metastases. The FDA granted Fast Track Product designation for RSR13 in November 2000.

In April 2003, we announced the preliminary results from the REACH trial. Although the survival benefit observed did not achieve statistical significance in either of the pre-specified intent-to-treat groups, the results demonstrated a statistically significant survival benefit in patients with brain metastases originating from breast cancer. Patients with brain metastases originating from breast cancer represent a subset of patients that was not prospectively defined as an intent-to-treat subgroup in the Phase 3 trial. For these patients, the addition of RSR13 to radiation therapy nearly doubled the median survival rate. Patients receiving RSR13 plus WBRT achieved a median survival of 8.67 months versus 4.57 months when receiving WBRT alone. Patients who were treated with RSR13 plus WBRT also achieved a higher response rate in the brain than the control group (71.7% versus 49.1%). Overall, patients with brain metastases from breast cancer experienced a 51% reduction in risk of death when administered RSR13. Risk of death is the relative reduction in death at any time point between the control arm and the RSR13 arm. A statistically significant quality of life benefit at three months was observed in patients receiving RSR13. In general, patients experienced minimal serious adverse events with the most common being hypoxemia, which is dose-dependent and effectively managed with supplemental oxygen.

Based on the findings from this study, we submitted an NDA to the FDA for approval to market RSR13 as an adjunct to WBRT for the treatment of brain metastases originating from breast cancer. In February 2004, the FDA accepted our NDA with priority review and established an action date by June 2004. We also intend to submit an MAA in Europe for approval to market RSR13 in this indication in the first half of 2004. Over 200,000 women are diagnosed with breast cancer each year in the United States. Breast cancer is the second most common cause of brain metastases after lung cancer, accounting for 14% to 20% of the total incidence of brain metastases.

In February 2004, we initiated a randomized, open-label, multi-center Phase 3 trial of RSR13 as an adjunct to WBRT for the treatment of brain metastases originating from breast cancer. Called ENRICH, the study will seek to enroll approximately 360 patients at up to 50 cancer centers across North America and compare WBRT plus supplemental oxygen with or without RSR13. The primary endpoint of the study will measure the difference in survival between the two arms. We initiated the ENRICH study in the event additional data may be required to support approval to market RSR13 in this indication.

RSR13 and Thoracic Radiation Therapy 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 the 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 9 to 12 months.

In November 2000, we completed 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 two-year follow-up results showed a median survival rate of 20.6 months, a one-year survival rate of 67% and a two-year survival rate of 37%. Analyzing the response data from patients receiving RSR13 plus radiation therapy demonstrated an overall response rate of 89%, with 80% partial responses and 9% complete responses. The results of this trial were first presented at the May 2001 Annual Meeting of the American Society of Clinical Oncology (ASCO) and most recently at the European Society for Therapeutics Radiology and Oncology (ESTRO) in September 2002.

In January 2003, we initiated a Phase 3 clinical trial of induction chemotherapy followed by chest radiation therapy with or without RSR13 for Stage IIIA/IIIB NSCLC. In June 2003, we implemented certain expense reduction measures and terminated this trial as a result of a re-prioritization of our clinical programs.

In January 2004, we initiated a Phase 1b/2 clinical trial in patients with locally advanced NSCLC receiving concurrent chemoradiotherapy (chemotherapy and radiation therapy administered at the same time) in combination with RSR13. Treatment of these patients with concurrent chemoradiotherapy is a more accepted treatment regimen within the United States than induction chemotherapy followed by chest radiation therapy.

RSR13 and WBRT 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 9 to 10 months. WBRT is administered to most patients with GBM and is intended to prevent or reduce complications and improve survival time.

We have completed three clinical studies of RSR13 in GBM. We collaborated with the National Cancer Institute, or NCI, sponsored New Approaches to Brain Tumor Therapy, or NABTT, Consortium on Phase 1b and Phase 2 clinical trials of RSR13 in patients with GBM. The trials were initiated in February 1998 and completed in March 1999. Based on the 19-patient Phase 1b study, which showed that RSR13 was safe and well tolerated, the NABTT Consortium conducted the 50-patient, multi-center, Phase 2 study of RSR13 combined with a standard six-week course of WBRT in newly diagnosed GBM patients. The RSR13-treated patients demonstrated an 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% versus 72%, 35% and 6% for the NABTT control group. In addition, a 67-patient, multi-center, Phase 2 companion trial of RSR13 plus WBRT was conducted in patients with newly diagnosed GBM patients was conducted from April 1998 to May 1999. In this trial, which was comparable in design and methods to the NABTT Phase 2 trial, RSR13 was found to be safe and well tolerated, although a statistically significant difference in survival was not observed.

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; however, we do not intend to conduct additional clinical studies in this indication at this time.

RSR13 and Standard Radiation Therapy 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 treatments for patients with advanced cervical cancer.

In August 2002, we initiated a Phase 1b/2 clinical trial of RSR13 for patients with locally advanced cancer of the cervix receiving concurrent chemoradiotherapy. 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 purpose of the Phase 1 portion 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 portion 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 as a Chemotherapy Enhancer

As with radiation therapy, certain types of chemotherapy drugs require the presence of oxygen for optimal cytotoxic effects on cancer cells. Thus, by stimulating the release of oxygen from hemoglobin to hypoxic tumor tissue, RSR13 may also enhance the beneficial effects of certain types of chemotherapy.

We have conducted preclinical studies that suggest RSR13, when used in conjunction with certain chemotherapy agents, may enhance the effects of chemotherapy. Based on these results, in December 2000, the NCI-sponsored NABTT Consortium initiated a Phase 1b/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 is conducting the study.

RSR13 in Non-Oncology Indications

We believe RSR13 can also be used to treat many other diseases and clinical conditions where tissue hypoxia is a factor. For example, for 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 cardiopulmonary bypass surgery, or 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.

We also believe that RSR13 could play a beneficial role in the treatment of patients with acute coronary syndrome and stroke. Preclinical studies led to an initial Phase 1b safety study in patients with chronic angina, which demonstrated that RSR13 was safe and well tolerated.

We currently anticipate that development of RSR13 for these or any other non-oncology indications would be in cooperation with a corporate partner.

Manufacturing

We have entered into arrangements with two contract manufacturers for the supply of RSR13 bulk drug substance, efaproxiral sodium, and a third contract manufacturer for the supply of 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, (Hovione) 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. manufactured our formulated drug product for our clinical trials. Akorn specializes in parenteral products and manufactured the first NDA stability batches. Because

efaproxiral injection is a large volume parenteral with relatively high projected annual units, we have identified a manufacturer with greater capacity. In December 2003, we entered into a long-term development and supply agreement with Baxter Healthcare for commercial manufacture of efaproxiral injection. Baxter Healthcare has significant experience in the manufacture of large volume injectables of this type. Under the terms of the contract, Baxter has agreed to manufacture sufficient quantities of efaproxiral injection to support our commercial requirements. Baxter is in good standing with the FDA, having passed recent inspections. NDA stability batches have been manufactured by Baxter to demonstrate equivalence to those manufactured during clinical development at Akorn. In addition, we are also seeking to establish an alternate supplier of efaproxiral injection.

Sales and Marketing

If and when we obtain FDA approval, we intend to commercialize RSR13 by building a focused sales and marketing organization complemented by co-promotion arrangements with pharmaceutical or biotechnology partners, where appropriate. Our sales and marketing strategy is to:

- *Build a direct United States sales force.* We believe that a relatively small sales force could effectively reach the oncologists and medical institutions that treat the majority of patients with brain metastases in the United States. We intend to build this sales force internally.
- *Build a marketing organization.* We also plan to build an internal marketing and sales management organization to develop and implement product plans and support our sales force.
- *Establish co-promotion alliances.* We intend to enter into co-promotion arrangements with larger pharmaceutical or biotechnology firms when necessary to reach larger markets than would be possible with our internal sales force, as well as all markets outside the United States.

PDX (10-propargyl-10-deazaaminopterin)

In December 2002, we obtained an exclusive worldwide license from Memorial Sloan-Kettering Cancer Center (MSKCC), SRI International and Southern Research Institute to intellectual property covering a novel, small molecule cytotoxic injectable anti-folate identified as PDX. PDX is an injectable small molecule cytotoxic agent that has a superior potency and toxicity profile relative to methotrexate and other related DHFR inhibitors. Drugs that inhibit DHFR, such as methotrexate, were among the first chemotherapeutic agents discovered. We believe PDX is a more effective permeant and substrate for the folate transporter (RFC-1) and the enzyme FPGS than methotrexate, resulting in increased intracellular accumulation of polyglutamylated metabolites. Due to its unique toxicity profile, PDX has the potential to be delivered in combination therapy regimens.

Methotrexate has been available for use in the treatment of cancer for over 35 years. During this time, it has been used in the treatment of NSCLC, non-Hodgkin's lymphoma (NHL), head and neck cancer and breast cancer. We believe PDX has the potential to be used in the treatment of several tumor types.

Scientific Rationale

The antimetabolites are a group of low-molecular weight compounds that exert their effect by virtue of their structural or functional similarity to naturally occurring molecules involved in nucleic acid (DNA) synthesis. Because the cell mistakes them for a normal metabolite, they either inhibit critical enzymes involved in DNA synthesis or become incorporated into the nucleic acid, producing incorrect codes. Both mechanisms result in inhibition of DNA synthesis and ultimately, cell death. Because of their primary effect on DNA synthesis, the antimetabolites are most effective against actively dividing cells and are largely cell-cycle phase specific. There are three classes of

antimetabolites; purine analogs, pyrimidine analogs and folic acid analogs, also termed antifolates. PDX, like methotrexate, is a folic acid analog.

The selectivity of methotrexate for tumor cells involves its conversion to a polyglutamated form by the enzyme folypolyglutamyl synthetase (FPGS). Polyglutamation is a time and concentration dependant process that occurs in tumor cells, and to a lesser extent, normal tissues. The selective activity in malignant cells versus normal cells likely is due to the relative difference in polyglutamate formation. Polyglutamated metabolites have prolonged intracellular half-life, increased duration of drug action and are potent inhibitors of several folate-dependent enzymes, including DHFR. Up to 80% of methotrexate found in malignant tissues has been converted to polyglutamated metabolites. This action results in depletion of intracellular reduced folate pools needed for purine and thymidine biosynthesis, ultimately resulting in cell death.

PDX in the treatment of 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 about 80% of all lung cancers. Over the last decade, oncologists have begun treating advanced NSCLC patients more aggressively, typically administering a potent combination of Taxol® and Paraplatin®. Other drugs used in this setting include Gemzar®, Navelbine®, Taxotere® and cisplatin. Despite aggressive therapy, the expected survival of patients with Phase IIIB or IV NSCLC is only eight to ten months. The one-year survival rate is approximately 40%.

A Phase 2 trial of PDX as a single agent for the second-line treatment of NSCLC was completed in 2001. The study enrolled 39 patients with Stage IIIB or IV NSCLC who had either progressed after initial response or had stable disease to one previous chemotherapy regimen (92%) or had no previous chemotherapy (8%). Results showed a median survival time of 13.5 months, with one and two-year survival rates of 56% and 36%, respectively. Ten percent of the patients treated with PDX had confirmed durable responses and 31% had stable disease. The response rate and symptomatic benefit are comparable to docetaxel (Taxotere®), the FDA approved drug for second-line treatment of NSCLC, which demonstrated response rates of between 6% and 11% in Phase 3 trials. The primary side effect of PDX was stomatitis (mouth sores). No clinically significant myelosuppression occurred.

A Phase 1 trial of PDX in combination with docetaxel in NSCLC patients is currently being conducted at MSKCC. We intend to initiate a confirmatory multi-center study of PDX in patients with refractory NSCLC patients in the first half of 2004.

PDX in the treatment of Mesothelioma

Mesothelioma is a chemoresistant tumor whose epidemiology has been linked with exposure to asbestos. Many agents such as adriamycin, cisplatin, mitomycin, cyclophosphamide and ifosfamide have demonstrated some efficacy in mesothelioima, but none has consistently achieved response rates over 20%.

The anti-folates, namely high dose methotrexate and edatrexate, are among the most active drugs for this disease. PDX has demonstrated greater anti-tumor effects than methotrexate and edatrexate against murine tumor models and human tumor xenografts in nude mice due to the more effective internalization by the one carbon, reduced folate transporter and the subsequent accumulation in tumor cells through the formation of polyglutamylated metabolites. *In vitro* studies documented 25-30-fold and 3-fold, respectively, greater cytotoxic potency of PDX compared with methotrexate and edatrexate against VAMT-1 and JMN cell lines derived from human mesothelioma. Against the JMN tumor xenografted in nude mice, whereas methotrexate and edarexate were potently growth inhibitory, only PDX brought about substantial regression. When combined with cisplatin or carboplatin, PDX achieved 2-fold greater overall regression of the JMN tumor with a 3-4-fold increase in complete regressions,

although some attenuation of dosages of each was required in the combination. These results suggest that PDX has potential in the treatment of human pleural mesothelioma.

A Phase 2 single-agent study of PDX in patients with unresectable malignant pleural mesothelioma is currently being conducted at MSKCC.

PDX in the treatment of Non-Hodgkin's Lymphoma (NHL)

The incidence of NHL has increased significantly over the last 25 years and is currently growing at greater than 2% per year. Patients with indolent or low-grade NHL typically have long survival rates of 8-10 years, yet the disease is considered incurable. Intermediate and high-grade lymphomas are much more aggressive and result in shorter median survival times; however, patients with these malignancies can be cured in 50% to 60% of cases.

Standard chemotherapy for NHL involves an initial combination of cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP). Recently, Rituxan® has been added to this combination and increased response rates to nearly 100%. Even so, about 40% of patients will eventually relapse and are candidates for salvage chemotherapy.

A Phase 1/2 single-agent study of PDX in patients with NHL is currently being conducted at MSKCC.

Manufacturing

We have entered into arrangements with two third party manufacturers to produce PDX bulk drug substance and formulated drug product for use in our clinical development programs.

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.

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.

RSR13

Under a 1994 agreement with the Center for Innovative Technology, or CIT, we have obtained exclusive worldwide rights to 17 United States patents, a European patent which has been validated in the United Kingdom, France, Italy, and Germany, one pending patent application in Canada, one issued patent in Canada, two issued patents in Japan, and two pending patent applications which have been approved in Europe. 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 1-1.25% 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:

- storing blood;
- restoring the oxygen affinity of red blood cells;
- treating carbon monoxide exposure;
- treating cancerous tumors;
- treating ischemia or oxygen deprivation;
- treating stroke or cerebral ischemia;
- treating surgical blood loss;
- performing cardiopulmonary bypass surgery; and
- treating hypoxia.

We are co-owners, along with VCUIPF, of a patent family directed to chiral allosteric hemoglobin modifier compounds. This family includes one issued United States patent, one pending United States patent application, and pending applications in Japan, Canada, Europe, and Australia.

We exclusively own two patent families with pending applications directed to a formulation of RSR13 and to methods of use of RSR13 in BOLD MRI applications. The formulation application is

pending in the United States, and an international patent application is also pending. BOLD MRI patent applications are pending in the United States, Canada, and Europe.

PDX

Under a December 2002 license agreement with MSKCC, SRI International and Southern Research Institute, we have obtained exclusive worldwide rights to three United States patents and 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.

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.

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, 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.

Our product candidates and we 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.

Employees

As of March 2, 2004, we had a total of 60 full-time employees and one part-time employee. Of those, 44 are engaged in clinical development, regulatory affairs, biostatistics, manufacturing and preclinical development. The remaining 17 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. In May 2003, as part of our revised operating plan, we implemented expense reduction measures, including a reduction in workforce by approximately 30 percent.

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 mailing address is 11080 CirclePoint Road, Suite 200, Westminster, Colorado 80020.

Our website address is *www.allos.com*; however, information found on our website is not incorporated by reference into this report. Our web site address is included in this report as an inactive textual reference only. 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.

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 net losses and an accumulated deficit, and we may never achieve or maintain revenue or profitability in the future.

We have never generated revenue from product sales, and we have experienced significant net losses since our inception in 1992. To date, we have financed our operations primarily through the private sale of securities and our initial public offering of common stock in March 2000. For the years ended December 31, 2001, 2002 and 2003, we had net losses of $20.1 million, $25.8 million and $23.1 million, respectively. As of December 31, 2003, we had an accumulated deficit of approximately $135.7 million. We have incurred these losses principally from costs incurred in our research and development programs and from our general and administrative costs. We expect to continue incurring net losses for the foreseeable future. The presence and size of these potential net losses will depend, in large part, on if and when we receive regulatory approval in the United States or Europe to market RSR13 as an adjunct to radiation therapy for the treatment of brain metastases from breast cancer. Our ability to generate revenue and achieve 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. We may never generate revenue from product sales or become profitable.

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.

We currently have no products that are approved 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 over the next few years will be devoted to RSR13. Accordingly, our future prospects are substantially dependent on obtaining regulatory approval in the United States or Europe to market RSR13 as an adjunct to radiation therapy for the treatment of brain metastases from breast cancer. Neither RSR13 nor PDX is expected to be commercially available for other indications until at least 2007. If we are unable to successfully commercialize our product candidates, we will be unable to generate any revenue from product sales 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.

The FDA may not approve our NDA to market RSR13 as an adjunct to radiation therapy for the treatment of brain metastases from breast cancer.

On April 23, 2003, we announced the preliminary results of our pivotal Phase 3 trial of RSR13 in patients with brain metastases in which the survival benefit observed did not reach statistical significance in either of the pre-specified intent-to-treat groups. However, the results demonstrated a statistically significant survival benefit in patients with brain metastases originating from breast cancer. Based on these findings, in December 2003, we submitted our NDA to the FDA for approval to market RSR as an adjunct to radiation therapy for the treatment of brain metastases originating from breast cancer. In February 2004, the FDA accepted our NDA with priority review and established an action date by June 2004. Patients with brain metastases originating from breast cancer represent a subset of patients that was not prospectively defined as an intent-to-treat subgroup in the Phase 3 trial. To our

knowledge, the FDA has never approved a drug for marketing based upon an analysis of a subset of patients that was not prospectively defined as an intent-to-treat subgroup. As a result, there can be no assurance that the FDA will approve RSR13 for marketing based on our NDA submission. If the FDA does not approve RSR13 for marketing or requires us to conduct an additional trial using RSR13 for patients with brain metastases from breast cancer, we would incur substantial additional costs and our ability to commercialize RSR13 would be substantially delayed. Any delay in or failure to receive regulatory approval to market RSR13 for the treatment of brain metastases from breast cancer would have a material adverse effect on our business, financial condition and future prospects.

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.

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 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. If we have to conduct additional clinical trials, whether for RSR13, PDX or any future product candidate, it would significantly increase our expenses and delay marketing of our product candidates.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and review.

Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, we or our third-party manufacturers will be required to adhere to regulations setting forth current good manufacturing practices. These regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. Furthermore, we or our third-party manufacturers must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign authorities before obtaining marketing approval and will be subject to periodic inspection by these regulatory authorities. Such inspections may result in compliance issues that could prevent or delay marketing approval, or require the expenditure of financial or other resources to address. If we or our third-party manufacturers fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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

We expect that significant additional capital will be required in the future to continue our research and development efforts and to commercialize our product candidates, if approved for marketing. Our actual capital requirements will depend on many factors, including the outcome of our current NDA filing, costs associated with the commercialization of RSR13, if approved for marketing, our evaluation of, and decisions with respect to, our strategic alternatives, and costs associated with securing in-license opportunities, purchasing product candidates and conducting preclinical research and clinical development for our current and future product candidates, among other factors. If RSR13 is approved for marketing in the United States or Europe in 2004, we expect to incur large cash expenditures associated with developing a commercial organization and pre-launch marketing activities. We intend to raise additional capital in the future through arrangements with corporate partners, equity or debt financings, or from other sources, including the proceeds of product sales, if any. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or us. 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. 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.

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 the FDA or us 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 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.

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. 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 uncertainty. 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.

We do not have manufacturing expertise or capabilities and are dependent on third parties to fulfill our manufacturing needs, which could result in the delay of clinical trials, regulatory approval and product introductions.

We are dependent on third parties for the manufacture and storage of our product candidates for clinical trials and, if approved, for commercial sale. If we are unable to contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the

manufacturing process or our relationships with our manufacturers, we may not have sufficient product to conduct or complete our clinical trials or support commercial requirements for our product candidates, if approved.

We have entered into arrangements with two contract manufacturers for the supply of RSR13 bulk drug substance, and a third contract manufacturer for the supply of RSR13 formulated drug product. In December 2003, we entered into a long-term development and supply agreement with Baxter Healthcare for commercial manufacture of formulated drug product and development of alternative packaging. These manufacturers are currently our only source for the production and formulation of RSR13. To date, these contract manufacturers have produced only small quantities of RSR13 relative to those needed for commercialization.

Even if we obtain approval to market RSR13 in one or more indications, our current or future manufacturers may be unable to scale production when necessary to enable commercial launch or accurately and reliably manufacture commercial quantities of RSR13 at reasonable costs, on a timely basis and in compliance with the FDA's current Good Manufacturing Practices. If our current or future contract manufacturers fail in any of these respects, our ability to timely complete our clinical trials, obtain required regulatory approvals and successfully commercialize RSR13 will be materially and adversely affected.

Our reliance on contract manufacturers exposes us to additional risks, including:

- delays in scale-up to quantities needed for clinical trails or failure to manufacture such quantities to our specifications, or to deliver such quantities on the dates we require;
- our current and future manufacturers are subject to ongoing, periodic, unannounced inspections by the FDA and corresponding state and international regulatory authorities for compliance with strictly enforced current Good Manufacturing Practice regulations and similar foreign standards, and we do not have control over our contract manufacturer's compliance with these regulations and standards;
- our current and future manufacturers may not be able to comply with applicable regulatory requirements, which would prohibit them from manufacturing products for us;
- if we need to change to other commercial manufacturing contractors, the FDA and comparable foreign regulators must approve these contractors prior to our use, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in, or themselves develop substantially equivalent processes necessary for, the production of our products;
- our manufacturers might not be able to fulfill our commercial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demands; and
- we may not have intellectual property rights, or may have to share intellectual property rights, to any improvements in the manufacturing processes or new manufacturing processes for our products.

Any of these factors could cause us to delay or suspend clinical trials, regulatory submission, required approvals or commercialization of our products under development, entail higher costs and result in our being unable to effectively commercialize our products.

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 payers such as insurance companies, health maintenance organizations and other plan administrators; and
- the effectiveness of our sales and marketing efforts.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our products.

If we are unable to develop adequate sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, we will not be able to commercialize our products effectively.

In order to commercialize any products, we must develop sales, marketing and distribution capabilities or make arrangements with one or more third parties to perform these services. For some market opportunities, we may need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our products. We may not be able to establish sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful. Additionally, building marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

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 any 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.

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.

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 60 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.

We cannot guarantee that we will be in compliance with all applicable regulations.

The development, manufacturing, pricing, sales and reimbursement of our products, together with our general obligations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We are a small company with 60 employees. We also have significantly fewer employees than many other companies that have the same or fewer product candidates in late stage clinical development and we rely heavily on third parties to conduct many important functions. Further, as a publicly-traded company, we are subject to additional regulations, some of which have either only recently been adopted or are currently proposals subject to change. For example, we are currently reviewing and testing our material internal control systems, processes and procedures in compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We cannot assure that such a review will not result in the identification of significant control deficiencies or that our auditors will be able to attest to the adequacy of our internal controls. Further, we cannot assure that we are or will be in compliance with all other potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including the de-listing of our common stock from the Nasdaq National Market, suspension or termination of our clinical trials, failure to receive approval to market a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

The market price for our common stock may be highly volatile.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated results of our clinical trials;
- actual or anticipated regulatory approvals or non-approvals of our product candidates or of competing product candidates;
- changes in laws or regulations applicable to our product candidates;

- changes in the expected or actual timing of our development programs;
- actual or anticipated variations in quarterly operating results;
- announcements of technological innovations by us or our competitors;
- changes in financial estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- developments concerning any research and development, manufacturing, and marketing collaborations;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and five percent stockholders; and
- economic and other external factors, including disasters or crises.

In addition, the stock market in general, the Nasdaq National Market® and the market for technology companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of biotechnology and life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent an acquisition of us, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- authorizing the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares or change the balance of voting control and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

We have adopted a stockholder rights plan that may discourage, delay or prevent a merger or acquisition that is beneficial to our stockholders.

In May 2003, our board of directors adopted a stockholder rights plan that may have the effect of discouraging, delaying or preventing a merger or acquisition of us that is beneficial to our stockholders by diluting the ability of a potential acquirer to acquire us. Pursuant to the terms of our plan, when a person or group, except under certain circumstances, acquires 15% or more of our outstanding common stock or 10 business days after announcement of a tender or exchange offer for 15% or more of our outstanding common stock, the rights (except those rights held by the person or group who has acquired or announced an offer to acquire 15% or more of our outstanding common stock) would generally become exercisable for shares of our common stock at a discount. Because the potential acquirer's rights would not become exercisable for our shares of common stock at a discount, the potential acquirer would suffer substantial dilution and may lose its ability to acquire us. In addition, the existence of the plan itself may deter a potential acquirer from acquiring us. As a result, either by operation of the plan or by its potential deterrent effect, mergers and acquisitions of us that our stockholders may consider in their best interests may not occur.

ITEM 2. PROPERTIES

Our corporate headquarters facility consists of approximately 43,956 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 three 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 January 2005.

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 2003.

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, 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

Year Ended December 31, 2003	HIGH	LOW
First Quarter	$8.05	$3.65
Second Quarter	$4.42	$1.66
Third Quarter	$3.48	$2.20
Fourth Quarter	$3.75	$2.52

On March 2, 2004, we had approximately 84 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 November 20, 2003, we completed a $12 million private placement of securities with several institutional investors. Pursuant to the terms of the securities purchase agreement, we sold 5,172,412 shares of common stock at a purchaser price of $2.32 per share, and issued warrants to purchase up to 1,706,893 shares of common stock with an exercise price of $3.14 per share. The purchase price for the common stock was privately negotiated with the purchasers to represent an approximately 16% discount to the market value of our common stock on November 14, 2003. The warrants first become exercisable on May 20, 2004, and expire on November 20, 2007. The shares and warrants were issued to the purchasers 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.

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, 2003, we have used an estimated $73.9 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 this Item concerning securities authorized for issuance under equity compensation plans is incorporated by reference to the information set forth in the section entitled "Equity Compensation Plan Information" in our definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed with the Commission within 120 days after the end of our fiscal year ended December 31, 2003 (the "Proxy Statement").

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, 2001, 2002, 2003, and cumulative period from September 1, 1992 through December 31, 2003, and the balance sheet data as of December 31, 2002 and 2003, 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, 1999 and 2000, and the balance sheet data as of December 31, 1999, 2000 and 2001, 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 (date of inception) through December 31, 2003
	1999	2000	2001	2002	2003	
	(in thousands, except share and per share data)					
Statement of Operations Data:						
Operating expenses:						
Research and development	$ 7,836	$ 10,737	$ 12,660	$ 13,860	$ 11,957	$ 72,159
Clinical manufacturing	1,382	3,200	3,143	3,776	7,252	22,537
Marketing, general and administrative	2,379	13,775	9,277	10,444	9,378	50,045
Restructuring costs	—	—	—	—	638	638
Total operating expenses	11,597	27,712	25,080	28,080	29,225	145,379
Loss from operations	(11,597)	(27,712)	(25,080)	(28,080)	(29,225)	(145,379)
Gain on settlement claims	—	—	—	—	5,110	5,110
Interest and other income, net	309	4,351	4,936	2,311	988	14,132
Net loss	(11,288)	(23,361)	(20,144)	(25,769)	(23,127)	(126,137)
Dividend related to beneficial conversion feature of preferred stock	(9,613)	—	—	—	—	(9,613)
Net loss attributable to common stockholders	$ (20,901)	$ (23,361)	$ (20,144)	$ (25,769)	$ (23,127)	$(135,750)
Weighted-average basic and diluted net loss per share	$ (10.48)	$ (1.29)	$ (0.88)	$ (1.03)	$ (0.87)	
Weighted-average shares used in computing basic and diluted net loss per share	1,994,764	18,058,802	22,970,974	24,942,496	26,493,861	

	As of December 31,				
	1999	2000	2001	2002	2003
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 9,475	$ 61,777	$ 59,769	$ 54,983	$ 39,819
Long-term marketable securities	—	23,906	9,843	5,816	5,778
Working capital	8,784	59,170	55,650	48,679	38,178
Total assets	10,206	86,259	72,174	64,401	48,174
Long-term obligations, less current portion	69	8	—	—	—
Convertible preferred stock	49,899	—	—	—	—
Common stock	7,022	156,625	156,948	171,046	181,446
Accumulated deficit	(43,348)	(66,710)	(86,854)	(112,623)	(135,750)
Total stockholders' equity	8,991	83,411	67,151	57,322	45,411

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

Overview

Allos Therapeutics, Inc. is a biopharmaceutical company that is 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 biological methods. We strive to develop drugs that improve the treatment of cancer and enhance the power of current therapies. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or together with one or more potential strategic partners. Our focus is on product opportunities that leverage our internal clinical development and regulatory expertise and address important medical markets. We have two product candidates that are currently under development, RSR13 (efaproxiral) and PDX (10-propargyl-10-deazaaminopterin). In addition, we endeavor to grow our existing portfolio of product candidates through ongoing product acquisition and in-licensing efforts.

We have devoted substantially all of our resources to research and clinical development. We have never generated any revenue from product sales, and have experienced significant net losses since our inception in 1992. For the years ended December 31, 2001, 2002 and 2003, we had net losses of $20.1 million, $25.8 million and $23.1 million, respectively. As of December 31, 2003, we had an accumulated deficit of approximately $135.7 million. We expect to continue incurring net losses for the foreseeable future. The presence and size of these potential net losses will depend, in large part, on if and when we receive regulatory approval in the United States or Europe to market RSR13 as an adjunct to radiation therapy for the treatment of brain metastases from breast cancer. Our ability to generate revenue and achieve 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.

On April 23, 2003, we announced the preliminary results of our pivotal Phase 3 trial of RSR13 in patients with brain metastases in which the survival benefit observed did not reach statistical significance in either of the pre-specified intent-to-treat groups. However, the results demonstrated a statistically significant survival benefit in patients with brain metastases originating from breast cancer. Based on these findings, in December 2003, we submitted an NDA to the FDA for approval to market RSR13 as an adjunct to radiation therapy for the treatment of brain metastases from breast cancer. In February 2004, the FDA accepted our NDA with priority review and established an action date by June 2004. We also intend to submit an MAA in Europe for approval to market RSR13 in this indication in the first half of 2004.

In June 2003, given the uncertainty provided by the results of our pivotal Phase 3 trial of RSR13 in patients with brain metastases and the potential impact on our business, we implemented certain cost reduction measures and reduced our quarterly operating expenses to approximately $6.5 million. In connection with this restructuring, we reduced the size of our organization from 93 to 60 employees, cancelled certain purchase orders for RSR13 bulk drug substance and terminated our Phase 3 trial of RSR13 in NSCLC.

In October 2003, we entered into a Settlement and Termination Agreement and Mutual Release of Claims with N-Gene Research Laboratories, Inc., which terminated all of our rights and licenses to the intellectual property surrounding BGP-15, an investigational compound that we in-licensed from N-Gene in March 2002, and settled certain disputes between the parties under the original license agreement. Under the terms of the settlement agreement, we paid N-Gene an aggregate of $591,000 in settlement fees and expenses and relinquished our equity investment in N-Gene, which had a book value of $1.0 million and was recorded as an impairment charge in 2003.

Also in October 2003, we entered into a Settlement Agreement and Mutual Release with Durus Life Sciences Master Fund, Ltd. (the "Fund"), pursuant to which we settled certain claims against the Fund and certain of its affiliates under Section 16(b) of the Securities Exchange Act of 1934. Such claims arose out of the Funds' transactions in our common stock during the period from June 4, 2002 through July 29, 2003, during which time it was a beneficial owner of 10% or more of our outstanding common stock. Under the terms of the settlement agreement, the Fund paid us a one-time settlement fee of approximately $5.1 million, and we released and discharged the Fund and certain of its affiliates from any and all further claims by us and/or our shareholders arising under Section 16(b) with respect to these transactions.

On November 20, 2003, we completed a $12 million private placement of securities with several institutional investors. Pursuant to the terms of the securities purchase agreement, we sold 5,172,412 shares of common stock at a purchaser price of $2.32 per share, and issued warrants to purchase up to 1,706,893 shares of common stock with an exercise price of $3.14 per share. The purchase price for the common stock was privately negotiated with the purchasers to represent an approximately 16% discount to the market value of our common stock on November 14, 2003. The warrants first become exercisable on May 20, 2004, and expire on November 20, 2007.

In February 2004, we announced the initiation of a Phase 3 trial of RSR13 plus WBRT in the treatment of patients with brain metastases originating from breast cancer. In 2004, the financial impact of this study is expected to represent approximately 10% of our anticipated research and development expenses.

As of December 31, 2003, we had $45.6 million in cash, cash equivalents, short-term marketable securities and long-term marketable securities. We believe that our existing cash, cash equivalents and investments will be adequate to satisfy our capital needs through at least the calendar year 2004. However, we will require significant levels of additional capital beyond 2004 from outside sources to continue research and development activities, fund operating expenses, pursue regulatory approvals and build sales and marketing capabilities, as necessary. If RSR13 is approved for marketing in the United States, we would expect to increase our operating expenses by at least $15 to $20 million during the first 12 months after launch in order to develop a commercial organization and to engage in marketing activities. In Europe, we anticipate engaging a corporate partner that would, upon marketing approval of RSR13, incur the majority of launch-related expenses.

Results of Operations

Comparison of Years Ended December 31, 2001, 2002 and 2003

Research and Development. Research and development expenses include the costs of basic research, nonclinical studies, clinical trials, regulatory affairs, biostatistical data analysis, patents and licensing fees for new products.

	Years Ended December 31,		
	2001	2002	2003
	(in millions)		
Research and development expenses, as reported	$12.7	$13.9	$12.0
Non-cash charges (recoveries)	1.3	(1.0)	—
	$11.4	$14.9	$12.0

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 $2.9 million decrease in 2003 was due primarily to the termination of our Phase 3 trial of RSR13 in NSCLC, determining our final site payments for our

Phase 3 trial of RSR13 in brain metastases, lower patient enrollment in our clinical trials and a reduction in our license fee payments for the PDX compound.

We expect research and development expenses to increase moderately in 2004, due primarily to costs associated with our Phase 3 clinical trial of RSR13 for brain metastases from breast cancer, the Phase 1b/2 study of RSR13 in patients with NSCLC, the commencement of a multi-site study of PDX for NSCLC, and a milestone payment for PDX due in June 2004. The amount and timing of the increased costs related to our clinical trials is difficult to predict due to the uncertainty inherent in the timing of clinical trial initiations, the rate of patient enrollment and the detailed design of future trials. In addition, if we receive approval in the United States or Europe in 2004 to market RSR13 as an adjunct to radiation therapy for the treatment of brain metastases from breast cancer, we expect to incur additional research and development expenses as we build clinical infrastructure to support our commercialization efforts. In order to fund our research and development programs after 2004, we will require significant levels of additional capital. If we do not receive approval to market RSR13 in the United States or Europe and are otherwise unable to raise sufficient additional funds, we may be forced to curtail our development plans for one or more of our product candidates, including RSR13, in which case our research and development expenses may decrease materially.

Since our inception through December 31, 2003, we have incurred costs of approximately $27.0 million and $2.6 million associated with the research and development expenses of RSR13 and PDX, respectively, and an aggregate of approximately $5.5 million associated with our other research and development programs, including programs that have been discontinued. Unallocated costs since inception represent an aggregate of approximately $37.0 million of research and development expenses incurred during such period. We charge direct internal and external program costs to the respective development programs. We also incur indirect costs that are not allocated to specific programs because such costs benefit multiple development programs. These consist primarily of salaries and benefits, facilities costs and other internal-shared resources related to the development and maintenance of systems and processes applicable to all of our programs.

The following table summarizes our research and development expenses for the years ended December 31, 2001, 2002 and 2003 (in millions):

	Years Ended December 31,		
	2001	2002	2003
RSR13	$ 6.2	$ 5.5	$ 2.9
PDX	—	2.0	0.6
Other programs	0.5	0.5	1.6
Unallocated	6.0	5.9	6.9
Total research and development expenses	$12.7	$13.9	$12.0

The timing and costs to complete the successful development of any of our product candidates are highly uncertain, and therefore difficult to estimate. The lengthy process of seeking regulatory approvals for our product candidates, and the subsequent compliance with applicable regulations, require the expenditure of substantial resources. For a more complete discussion of the regulatory approval process, please refer to the "Government Regulation" section of Item I above. Clinical development timelines, likelihood of success and total costs vary widely and are impacted by a variety of factors discussed in the "Risk Factors" section of Item I above. Because of these risks and uncertainties, we cannot predict when or whether we will successfully complete the development of any of our product candidates or the ultimate costs of such efforts. Due to these same factors, we cannot be certain when any net cash inflow from any of our current product candidates will commence.

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.

	Years Ended December 31,		
	2001	2002	2003
	(in millions)		
Clinical manufacturing, as reported	$3.1	$3.8	$7.3

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 $3.5 million increase in 2003 was due primarily to a $3 million termination fee associated with the cancellation of our purchase orders for RSR13 bulk drug substance and increased development work to produce clinical trial drug material for PDX.

We currently have a sufficient supply of RSR13 bulk drug substance and formulated drug product to support all of our currently pending and/or planned clinical trials involving RSR13. As a result, we expect clinical manufacturing expenses to decrease significantly in 2004 until such time, if any, as we initiate manufacturing efforts for commercialization of RSR13. If FDA approval is received, we anticipate a moderate increase of clinical manufacturing expenses to establish a supply of finished goods inventory. The timing of future payments for finished goods inventory in relation to the timing of regulatory approval may cause variability in our future cost of goods sold and clinical manufacturing expenses.

Marketing, General and Administrative. Marketing, general and administrative expenses include costs for pre-marketing activities, executive administration, corporate offices and related infrastructure and corporate development.

	Years Ended December 31,		
	2001	2002	2003
	(in millions)		
Marketing, general and administrative, as reported	$9.3	$10.4	$ 9.4
Non-cash charges (recoveries)	2.4	1.4	(0.2)
	$6.9	$ 9.0	$ 9.6

The $2.1 million increase in 2002 was primarily due to costs associated with relocating our company headquarters, additional personnel costs related to our administrative infrastructure and corporate development, and increased facility costs. The $646,000 increase in 2003 was primarily attributable to the fees and expenses incurred in connection with our settlement of claims with N-Gene Research Laboratories.

If we obtain regulatory approval for RSR13, we expect marketing, general and administrative expenses to increase significantly as personnel are hired to develop a commercial organization and expenses are incurred to support pre-launch marketing activities. If we do not obtain regulatory approval for RSR13 or if we are not able to raise sufficient additional funds to support our operations, our marketing, general and administrative costs will likely decrease as we may be required to reduce our administrative infrastructure to conserve our capital resources.

Restructuring Costs. We recorded $638,000 in restructuring costs during the year ended December 31, 2003. The restructuring expenses include severance and other employee termination costs

of approximately $634,000 and legal fees of $4,000. As of December 31, 2003, there was no remaining liability related to the restructuring.

Gain on Settlement Claims. In 2003, we recognized a gain on settlement claims of approximately $5.1 million in connection with our receipt of the one-time settlement fee from Durus Life Sciences Master Fund, Ltd.

Interest and Other Income, Net. Interest income, net of interest expense, for 2001, 2002 and 2003 was $4.9 million, $2.3 million and $988,000, respectively. The $2.6 million and $1.3 million decrease in 2002 and 2003, respectively, primarily resulted from lower average investment balances and lower yields on United States government securities, high-grade commercial paper and corporate notes and money market funds.

Income Taxes. As of December 31, 2003, we had net operating loss carryforwards and research and development credit carryforwards of $99.7 million and $6.5 million, respectively, available to offset future regular and alternative taxable income. These carryforwards will expire beginning 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 United States 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. During 2001, we recorded $2.3 million in marketing, general and administrative, $1.2 million in research and development and $152,000 in clinical manufacturing. During 2002, we recorded $1.5 million in marketing, 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 a 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. During 2003, we recorded a negative $210,000 in marketing, general and administrative, $17,000 in research and development and $50,000 in clinical manufacturing. The negative balance recorded in marketing, general and administrative is due to the change in employment status of our Chairman from an employee to a consultant, resulting in the recovery of expenses totaling $762,000 related to stock-based compensation expense on unvested stock options recorded in prior periods. At December 31, 2003, we had $286,000 of unamortized 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, a public equity financing, and interest income, which have resulted in net proceeds to us of $149.2 million through December 31, 2003. We have used $100.7 million of cash for operating activities through December 31, 2003. Cash, cash equivalents, short-term investments and long-term marketable securities were $69.6 million, $60.8 million and $45.6 million at December 31, 2001, 2002 and 2003, respectively. Working capital was $48.7 million and $38.2 million at December 31, 2002 and 2003, respectively. Net cash used in operating activities for 2001, 2002 and 2003 was $14.3 million, $21.9 million and $26.2 million, respectively. Cash used in operating activities was primarily to fund net losses, excluding non-cash charges.

Net cash provided by investing activities for 2001, 2002 and 2003 was $15.9 million, $7.6 million and $15.7 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 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 2002 and 2003 was $15.3 million and $11.4 million, respectively, and resulted from the private sale of common stock, exercise of common stock options, and proceeds from sales of stock under our employee stock purchase plan.

Below is a schedule of timing of contractual commitments related to our leases and service contracts. We currently have no off-balance sheet arrangements.

	Less than 1 year	1-3 Years	3-5 Years	More than 5 Years	Total
Operating leases	$ 773,916	$1,454,998	$1,406,243	$ —	$3,635,157
Other long-term obligations	1,000,000	500,000	1,000,000	500,000	3,000,000
Total contractual cash obligations	$1,773,916	$1,954,998	$2,406,243	$500,000	$6,635,157

Other long-term obligations represent future milestone payments under our in-licensing commitments, which could be paid earlier depending on the timing of achieving the pertinent 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 2004. We anticipate continuing our current development programs and beginning other long-term development projects on new products or technologies. These projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. Therefore, we will need to obtain additional funds from outside sources to continue research and development activities, fund operating expenses, pursue regulatory approvals and build sales and marketing capabilities, as necessary. However, our actual capital requirements will depend on many factors, including the status of our product development programs; the time and cost involved in conducting clinical trials and obtaining regulatory approvals; the time and cost involved in 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 the proceeds of product sales, if any. Such arrangements, if successfully consummated, may be dilutive to our existing stockholders. However, there is no assurance that we will be successful in consummating any such arrangements. 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. In the event we are not able to raise sufficient additional funds, 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.

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.

Our critical accounting policies are important to fully understand and evaluate our financial condition and the results presented in the financial statements 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 from personnel; external costs incurred at clinical sites and contracted payments third party clinical research organizations to perform certain clinical trials.

We are obligated to make certain upfront payments upon execution of certain research and developments 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 as incurred during the fiscal year and 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 as incurred. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. We performed a sensitivity analysis on our accrual for external costs related to our clinical studies as of December 31, 2003. We considered the timing of patient dosing and determined that the effect was immaterial when accruing at enrollment or upon final dosing in comparison to our policy.

We record upfront fees and milestone payments made under our licensing agreements as a research and development expense.

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ON MARKET RISK

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk and all are classified as held-to-maturity. We do not own derivative financial instruments in our investment portfolio. This means that a change in prevailing interest rates may cause the fair value of the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk in the future, 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. The average duration of all of our investments is less than one year. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments. Therefore, no quantitative tabular disclosure is provided.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by 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 AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

As of the end of the period covering this report, an evaluation was carried out under the supervision and with the participation of our management, including our principal executive and financial officer (the "Evaluating Officer"), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based on that evaluation, our management, including the Evaluating Officer, concluded that our disclosure controls and procedures were 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's rules and forms, and that such information is accumulated and communicated to our management, including the Evaluating Officer, as appropriate, to allow timely decisions regarding required disclosure.

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 of the Proxy Statement entitled "Proposal 1—Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance." 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. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section of the Proxy Statement entitled "Independent Auditor's Fees."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT 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.

The following is a list of exhibits filed as part of this report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference.

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.
4.03(11)	Certificate of Designation of Series A Junior Participating Preferred Stock.
4.04(11)	Rights Agreement dated as of May 6, 2003 among Allos Therapeutics, Inc. and Mellon Investor Services LLC.
4.05(11)	Form of Rights Certificate.
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.

Exhibit No.	Description
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(12)+	Amended and Restated Second Amendment to Lease with Catellus Development Corporation, dated December 9, 2002.
10.27.2**++	Third Amendment to Lease with Catellus Development Corporation, dated November 28, 2003.
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(12)(*)	Consultant Agreement between Stephen J. Hoffman, Ph.D., M.D. and Allos Therapeutics, Inc., effective February 28, 2003.
10.36**(*)	Employment Agreement between Pablo Cagnoni, M.D. and Allos Therapeutics, Inc., effective September 30, 2003.
10.37**++	Development and Supply Agreement between Baxter Healthcare Corporation and Allos Therapeutics, Inc., effective December 19, 2003.
10.38**(*)	Separation Agreement between Daniel R. Hudspeth and Allos Therapeutics, Inc., effective May 30, 2003.
10.39(13)	Securities Purchase Agreement dated as of November 20, 2003.

Exhibit No.	Description
10.40(13)	Form of Warrant issued pursuant to Securities Purchase Agreement dated November 20, 2003.
23.01	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
24.01**	Power of Attorney.
31.01	Rule 13a-14(a)/15d-14(a) Certification.
32.01	Section 1350 Certification.

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

** Previously filed.

+ 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.

(11) Incorporated by reference to our Current Report on Form 8-K (File No. 000-29815), as filed with the Commission on May 9, 2003.

(12) Incorporated by reference to our Annual Report on Form 10-K (File No. 000-29815), as filed with the Commission on March 28, 2003.

(13) Incorporated by reference to our Current Report on Form 8-K (File No. 000-29815), as filed with the Commission on November 21, 2003.

(b) Reports on Form 8-K:

On November 6, 2003, we furnished a report on Form 8-K reporting under Items 9 and 12 that we had issued an announcement of our third quarter 2003 financial results.

On November 21, 2003, we filed a report on Form 8-K reporting under Items 5 and 7 that we had executed a securities purchase agreement with certain investors.

SIGNATURES

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

ALLOS THERAPEUTICS, INC.

Date: March 30, 2004

By: /s/ MICHAEL E. HART

Michael E. Hart
President, Chief Executive Officer and Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant on March 30, 2004, and in the capacities indicated:

Name	Title
* Stephen J. Hoffman	Chairman of Board of Directors and Director
/s/ MICHAEL E. HART Michael E. Hart	President, Chief Executive Officer, Chief Financial Officer and Director (Principal Executive Officer and Principal Financial Officer)
* Paulette M. Wilson	Corporate Controller, Treasurer and Secretary (Principal Accounting Officer)
* Donald J. Abraham	Director
* Michael D. Casey	Director
* Mark G. Edwards	Director
* Marvin E. Jaffe	Director

*By: /s/ MICHAEL E. HART

Michael E. Hart
Attorney-in-fact

Allos Therapeutics, Inc.

Index to Financial Statements

REPORT OF INDEPENDENT AUDITORS

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, 2002 and 2003 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 and the cumulative period from September 1, 1992 (date of inception) through December 31, 2003, 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
March 2, 2004

ALLOS THERAPEUTICS, INC.

BALANCE SHEETS

	December 31, 2002	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,756,951	$ 4,642,305
Restricted cash	550,000	550,000
Short-term investments	50,676,010	34,627,187
Prepaid research and development expenses	534,287	286,573
Prepaid expenses and other assets	240,789	834,249
Total current assets	55,758,037	40,940,314
Long-term marketable securities	5,816,529	5,777,930
Property and equipment, net	1,826,277	1,455,486
Long-term investment	1,000,000	—
Total assets	$ 64,400,843	$ 48,173,730
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable—related parties	$ 111,656	$ 114,483
Trade accounts payable and accrued expenses	408,879	462,774
Accrued research and development expenses	5,117,400	1,173,856
Accrued bonus and employee benefits	1,440,725	1,011,340
Total current liabilities	7,078,660	2,762,453
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2002 and December 31, 2003; no shares issued or outstanding	—	—
Series A Junior Participating Preferred Stock, $0.001 par value; 1,000,000 shares designated from authorized preferred stock at December 31, 2003; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 75,000,000 shares authorized at December 31, 2002 and December 31, 2003; 25,863,454 and 31,103,455 shares issued and outstanding at December 31, 2002 and December 31, 2003, respectively	25,863	31,104
Additional paid-in capital	171,020,705	181,415,293
Deferred compensation related to stock-based compensation	(1,101,466)	(285,576)
Deficit accumulated during the development stage	(112,622,919)	(135,749,544)
Total stockholders' equity	57,322,183	45,411,277
Total liabilities and stockholders' equity	$ 64,400,843	$ 48,173,730

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, 2003
	2001	2002	2003	
Operating expenses:				
Research and development	$ 12,659,419	$ 13,860,208	$ 11,957,249	$ 72,159,266
Clinical manufacturing	3,143,332	3,775,921	7,251,807	22,536,441
Marketing, general and administrative	9,277,047	10,443,646	9,378,093	50,044,767
Restructuring costs	—	—	638,070	638,070
Total operating expenses	25,079,798	28,079,775	29,225,219	145,378,544
Loss from operations	(25,079,798)	(28,079,775)	(29,225,219)	(145,378,544)
Gain on settlement claims	—	—	5,110,083	5,110,083
Interest and other income, net	4,935,473	2,310,801	988,511	14,131,892
Net loss	(20,144,325)	(25,768,974)	(23,126,625)	(126,136,569)
Dividend related to beneficial conversion feature of preferred stock	—	—	—	(9,612,975)
Net loss attributable to common stockholders	$(20,144,325)	$(25,768,974)	$(23,126,625)	$(135,749,544)
Net loss per share:				
Basic and diluted	$ (0.88)	$ (1.03)	$ (0.87)	
Weighted average shares: basic and diluted	22,970,974	24,942,496	26,493,861	

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)

	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, 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
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	—	—	—	—
Extinguishments 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

	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, 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, net of issuance costs	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 lease line	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
Issuance of common stock upon exercise of stock options for cash of $75,686 at $.56 - $2.42 per share	35,400	35	—	—	75,651	—	—	—	75,686
Issuance of common stock upon exercise of purchase rights at an exercise price of $2.48 - $2.58 per share	32,189	33	—	—	81,466	—	—	—	81,499
Issuance of common stock in private placement for $2.32 per share together with common stock warrants for $3.14 per share, net of issuance costs	5,172,412	5,173	—	—	11,196,549	—	—	—	11,201,722
Stock compensation expense	—	—	—	—	178,166	—	—	—	178,166
Deferred compensation related to options	—	—	—	—	(1,137,244)	—	815,890	—	(321,354)
Net loss	—	—	—	—	—	—	—	(23,126,625)	(23,126,625)
Balance at December 31, 2003	31,103,455	$31,104	—	$ —	$181,415,293	$ —	$ (285,576)	$(135,749,544)	$45,411,277

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, 2003
	2001	2002	2003	
Cash Flows From Operating Activities:				
Net loss	$(20,144,325)	$(25,768,974)	$(23,126,625)	$(126,136,569)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	277,064	489,900	602,354	1,843,521
Stock-based compensation	3,745,316	575,925	(143,188)	21,435,012
Write-off of long-term investment	—	—	1,000,000	1,000,000
Other	30,718	21,531	(6,271)	98,384
Changes in operating assets and liabilities:				
Prepaids and other assets	(659,173)	133,737	(335,746)	(1,110,823)
Interest receivable on investments	222,907	545,219	175,258	(623,906)
Accounts payable—related parties	1,397,649	29,025	2,827	3,472,748
Trade accounts payable and accrued expenses	147,537	49,327	53,895	462,774
Accrued research and development expenses	(15,258)	1,676,505	(3,943,544)	(2,184,408)
Accrued compensation and restructuring costs	714,223	300,450	(429,385)	1,011,340
Net cash used in operating activities	(14,283,342)	(21,947,355)	(26,150,425)	(100,731,927)
Cash Flows From Investing Activities:				
Acquisition of property and equipment	(1,635,104)	(662,589)	(235,292)	(3,044,264)
Purchases of marketable securities	(45,994,641)	(46,028,561)	(45,204,196)	(283,159,063)
Proceeds from sales of marketable securities	63,572,592	55,307,500	61,116,360	243,377,852
Purchase of long-term investment	—	(1,000,000)	—	(1,000,000)
Payments received on notes receivable	—	—	—	49,687
Net cash provided by (used in) investing activities	15,942,847	7,616,350	15,676,872	(43,775,788)
Cash Flows From Financing Activities:				
Principal payments under capital leases	(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 employee stock purchase plan	139,273	411,032	157,185	812,916
Proceeds from issuance of common stock, net of issuance costs	—	14,931,773	11,201,722	108,902,891
Net cash provided by (used in) financing activities	(480,047)	15,342,805	11,358,907	149,150,020
Net increase in cash and cash equivalents	1,179,458	1,011,800	885,354	4,642,305
Cash and cash equivalents, beginning of period	1,565,693	2,745,151	3,756,951	—
Cash and cash equivalents, end of period	$ 2,745,151	$ 3,756,951	$ 4,642,305	$ 4,642,305
Supplemental Schedule of Non-cash Operating and Financing Activities:				
Cash paid for interest	$ 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.

ALLOS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

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

1. Formation and Business of the Company

Allos Therapeutics, Inc. is a biopharmaceutical company that is focused on developing and commercializing innovative small molecule drugs for improving cancer treatments.

We have two product candidates that are currently under development, RSR13 (efaproxiral) and PDX (10-propargyl-10-deazaaminopterin).

- RSR13 is the first synthetic small molecule designed to "sensitize" hypoxic (oxygen-deprived) areas of tumors prior to radiation therapy by facilitating the release of oxygen from hemoglobin, the oxygen-carrying protein contained within red blood cells, and increasing the level of oxygen in tumors. The presence of oxygen in tumors is an essential element for the effectiveness of radiation therapy. By increasing tumor oxygenation, RSR13 has the potential to enhance the efficacy of standard radiation therapy.
- PDX is an injectable small molecule chemotherapeutic agent that has a superior potency and toxicity profile relative to methotrexate and other related dihydrofolate reductase, or DHFR, inhibitors. Drugs that inhibit DHFR, such as methotrexate, were among the first chemotherapeutic agents discovered. Methotrexate remains one of the most widely applied chemotherapy drugs and is used to treat breast, bladder and head and neck cancers, leukemias and other cancers.

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

To date, we have devoted substantially all of our resources to research and clinical development. We have not derived any commercial revenues from product sales, and do not expect to receive product revenues until at least the second half of 2004, at the earliest. We have incurred significant operating losses since our inception in 1992. We expect to continue to incur significant operating losses over the next several years as we continue 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 we 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 end of the calendar year 2004. 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 2004 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, 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 equity or debt financings, collaborative arrangements with corporate partners 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

We have not generated any revenue to date and our activities have consisted primarily of developing products, raising capital and recruiting personnel. Accordingly, we are considered to be in the development stage at December 31, 2003 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 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 our cash equivalents and short-term and long-term marketable securities approximate their market values based on quoted market prices. We account 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.

In accordance with SFAS No. 115, investments that we have 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 our marketable securities are held in corporate notes with maturities ranging from three months to seven years. Marketable securities as of December 31, 2002 and 2003 are as follows:

	2002	2003
Short-term	$50,676,010	$34,627,187
Long-term	5,816,529	5,777,930
Total	$56,492,539	$40,405,117

Prepaid Research and Development Expenses

In accordance with various research and development agreements, we are obligated to make certain up front payments upon execution. Such payments are expensed as services are performed or over the contractual period of the agreement. We evaluate on a quarterly basis 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 $277,064, $489,900 and $602,354, for the years ended 2001, 2002, and 2003 respectively, and $1,843,521 for the cumulative period from inception.

The components of property and equipment are as follows:

	December 31,		Estimated Lives
	2002	2003	
Office furniture and equipment	$1,129,687	$ 1,209,271	5-7 years
Computer hardware and software	1,132,443	1,199,275	3 years
Lab equipment	103,224	103,224	5 years
Leasehold improvements	394,740	394,740	7 years
	2,760,094	2,906,510	
Less accumulated depreciation and amortization	(933,817)	(1,451,024)	
	$1,826,277	$ 1,455,486	

Long-lived Assets

Long-lived assets are reviewed for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed the projected discounted future net cash flows arising from the assets. Our long-lived assets consist primarily of property and equipment, leasehold improvements, and long-term investment. During 2003, we wrote off our long-term investment in N-Gene Research Laboratories, Inc., as more fully described in Note 4 below.

Accrued Research and Development Expenses

We record 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 these estimates.

Bonus Plan

Our Annual Bonus Program (the "Bonus Program") was adopted by the Board of Directors in September 1998, and is intended to promote both individual productivity and employee retention. The bonuses paid under the Bonus Program are based on a number of criteria including, but not limited to, terms of employment, participants' individual performance and success in achieving corporate objectives established annually by the Board of Directors are achieved. Bonuses are paid in cash.

Stock-Based Compensation

We account for grants of stock options according to Accounting Principles Board Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and related Interpretations. Pro forma net loss information, as required by SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), is presented below. Any deferred stock-based 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")*. 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 APB 25 to account for employee stock options.

The following table illustrates the effect on net loss and net 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, 2001, 2002 and 2003:

	2001	2002	2003	Cumulative Period from September 1, 1992 (date of inception) through December 31, 2003
Net loss attributable to common stockholders—as reported	$(20,144,325)	$(25,768,974)	$(23,126,625)	$(135,749,544)
Add: Stock-based employee compensation expense included in reported net loss	3,745,316	1,738,079	619,007	15,651,986
Deduct: Recovery of stock-based compensation expense included in reported net loss	—	(1,162,154)	(762,195)	(1,924,349)
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards	(5,215,838)	(2,392,223)	(3,150,362)	(22,599,209)
Pro forma net loss attributable to common stockholders	$(21,614,847)	$(27,585,272)	$(26,420,175)	$(144,621,116)
Net loss per share:				
Basic and diluted—as reported	$ (0.88)	$ (1.03)	$ (0.87)	
Basic and diluted—pro forma	$ (0.94)	$ (1.11)	$ (1.00)	

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, patents and licensing fees for new products.

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. 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

Our cash and cash equivalents, short-term investments and long-term marketable securities at December 31, 2002 and 2003 are maintained in two financial institutions in amounts that, at times, may exceed federally insured limits. We have not experienced any losses in such accounts and believe it is not exposed to any significant credit risk in this area. It is our policy to place 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, 2001, 2002 and 2003 not included in the diluted net loss per share calculations, are as follows:

	2001	2002	2003
Common stock options	2,442,301	3,023,852	3,539,818
Common stock warrants	14,275	—	1,706,893
	2,456,576	3,023,852	5,246,711

Fair Value of Financial Instruments

Our 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 our long-term marketable securities approximates $5,600,000 at December 31, 2003.

Recent Accounting Pronouncements

In January 2003, the Emerging Issues Task Force ("EITF") addressed EITF Statement No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). EITF 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for purposes of revenue recognition and how the revenue arrangement consideration should be measured and allocated to the separate units of accounting. EITF 00-21 applies to all revenue arrangements that are executed after June 28, 2003. The adoption of EITF 00-21 has not had, nor do we believe it will have, a material impact on our current or prospective 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. 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.

In May 2003, the FASB issued Statement No. 150 ("SFAS 150"), *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity.* The Statement addresses the classification of certain financial instruments embodying obligations that could be settled by the issuance of an entity's own shares. SFAS 150 improves the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity and requires that those instruments be classified as liabilities (or assets in certain circumstances) in statements of financial position. SFAS 150 is generally effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 has not had, nor do we believe it will have, a material impact on our current or prospective financial statements.

In December 2003, the Staff of the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 104 ("SAB 104"), *Revenue Recognition*, which supersedes SAB 101, *Revenue Recognition in Financial Statements*. SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements and to rescind the SEC's "Revenue Recognition in Financial Statements Frequently Asked Questions and Answers" ("FAQ") issued with SAB 101. Selected portions of the FAQ have been incorporated into SAB 104. The adoption of SAB 104 has not had, nor do we believe it will have, a material impact on our current of 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. Impairment of Long-term Investment

We identify and record impairment losses on long-lived assets when events and circumstances indicate that the assets might be impaired. On October 9, 2003, we entered into a Settlement and Termination Agreement and Mutual Release of Claims with N-Gene Research Laboratories, Inc., which terminated the business relationship and settled certain disputes between the parties. Under the terms

of this settlement agreement, we surrendered all rights and licenses to the intellectual property surrounding BGP-15, an investigational compound that we in-licensed from N-Gene in March 2002, and paid N-Gene an aggregate of $591,000 in settlement fees and expenses. We also relinquished our equity investment in N-Gene, which had a carrying value of $1.0 million. In addition, each party released the other party from all further claims, damages and obligations of any kind arising under the initial license agreement and related stock purchase agreement between the parties. As a result, the investment was written off during 2003 to research and development expense.

5. Stockholders' Equity

Common Stock

On November 20, 2003, we completed a private placement of 5,172,412 shares of common stock at a purchase price of $2.32 per share to various purchasers for an aggregate purchase price of $12.0 million, net of $800,000 in issuance costs, which resulted in net cash proceeds to us of approximately $11.2 million to be used to fund future clinical development and commercialization of RSR13 and other in-licensing product candidates. The purchase price was privately negotiated with the purchasers to represent an approximately 16% discount to the market value of our common stock on November 14, 2003.

On April 24, 2002, we 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, net of $100,000 in issuance costs, which resulted in net cash proceeds to us 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 our Registration Statement on Form S-1. Pursuant to this Registration Statement, we completed an Initial Public Offering ("IPO") of 5,000,000 shares of our common stock at an IPO price of $18.00 per share (the "Offering"). Proceeds to us 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 our convertible preferred stock were automatically converted into 15,678,737 shares of common stock.

At December 31, 2003, we have reserved shares of common stock for future issuance as follows:

1995 Stock Option Plan	1,175,500
2000 Stock Option Plan	2,139,515
2001 Employee Stock Purchase Plan	2,311,140
2002 Broad Based Equity Incentive Plan	995,500
Total	6,621,655

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

Stock Warrants

On November 20, 2003, we issued warrants to purchase 1,706,893 shares of common stock in conjunction with the private placement at an exercise price of $3.14 per share with a life of four years. As of December 31, 2003, these warrants were outstanding.

In April 1996, we issued warrants to purchase 17,500 shares of our 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, we issued warrants to purchase 5,524 shares of our 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 our common stock. In September 2002, these warrants were exercised.

Stockholder Rights Plan

In May 2003, we designated 1,000,000 shares of our authorized preferred stock as Series A Junior Participating Preferred Stock, par value $0.001 per share pursuant to a Stockholder Rights Plan approved by the Board of Directors under which all stockholders of record as of May 28, 2003 received a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of our common stock. The Rights trade with the common stock and no separate Right certificates will be distributed until such time as the Rights become exercisable in accordance with the Stockholder Rights Plan. The Stockholder Rights Plan is intended as a means to guard against abusive takeover tactics and to provide for fair and equal treatment for all stockholders in the event that an unsolicited attempt is made to acquire us.

Until the Rights become exercisable, the Rights will have no dilutive impact on our earnings per share data. The Rights are protected by customary anti-dilution provisions. As of December 31, 2003, no shares of Series A Junior Participating Preferred Stock were issued or outstanding.

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, we 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 our 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, we are authorized to increase the number of shares of common stock that shall be available annually on the first day of our 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 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, we are 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 us 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, 2003, we had 355,401 and 415,296 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 our 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 10 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.

We record 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, 2003, 2002 and 2001, we recorded amortization of deferred stock-based compensation of a negative $143,000, $576,000 and $3,745,000, respectively. Of the negative $143,000 recorded for the year ended December 31, 2003, we recorded a negative $210,000 in marketing, general and administrative, $17,000 in research and development and $50,000 in clinical manufacturing. The negative balance recorded in marketing, general and administrative is due to the change in employment status of our Chairman from an employee to a consultant, resulting in the recovery of expenses totaling $762,000 related to stock-based compensation expense on unvested stock options recorded in prior periods. 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 remaining vesting periods of the related options, which is generally four years. As of December 31, 2003, we had $286,000 in deferred stock-based compensation.

A summary of our 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, 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
Granted	1,076,256	4.02		
Exercised	(35,400)	2.14		
Canceled	(524,890)	6.39		
Outstanding at December 31, 2003	3,539,818	$4.14	2,161,725	$3.60

The following table summarizes information about options outstanding as of December 31, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Outstanding as of December 31, 2003	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable as of December 31, 2003	Weighted Average Exercise Price
$0.00 - $1.38	599,468	4.6	$ 0.50	599,468	$0.50
$1.39 - $2.75	526,432	6.0	2.42	526,432	2.42
$2.76 - $4.13	578,315	9.4	3.19	122,759	3.20
$4.14 - $5.50	849,662	8.2	4.83	353,003	4.83
$5.51 - $6.88	580,295	7.4	6.18	340,604	6.22
$6.89 - $8.25	116,541	8.6	7.28	55,184	7.27
$8.26 - $9.63	242,805	8.0	8.84	122,982	8.94
$9.64 - $13.75	46,300	6.5	11.91	41,293	11.88
	3,539,818	7.3	$ 4.14	2,161,725	$3.60

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 our stockholders on April 17, 2001. Under the Purchase Plan, we are 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 our 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. We sold 27,446 and 32,189 shares to employees in 2002 and 2003, respectively. There are 2,311,140 shares available for sale at December 31, 2003. 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 our stock option plans during fiscal 2001, 2002 and 2003 was $3.47, $3.43 and $2.80 per share, respectively. The weighted average estimated grant date fair value of purchase awards under our Purchase Plan during fiscal 2001, 2002 and 2003 was $1.55, $1.76 and $3.02 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 our stock option and purchase awards as of December 31, 2001, 2002 and 2003:

	2001	2002	2003
Stock option plans:			
Expected dividend yield	0%	0%	0%
Expected stock price volatility	49% - 83%	33% - 63%	62% - 175%
Risk free interest rate	3.5% - 12.38%	3.38% - 7.88%	3.38% - 7.0%
Expected life (years)	5.0	5.0	2.0 - 5.0
Stock purchase plan:			
Expected dividend yield	0%	0%	0%
Expected stock price volatility	53%	44% - 56%	64% - 131%
Risk free interest rate	3.49%	3.49%	0.94% - 3.49%
Expected life (years)	2.0	1.2	2.0

6. Restructuring Costs

On May 28, 2003, as part of a revised operating plan, we implemented expense reduction measures, including a reduction in workforce by approximately 30 percent, in an effort to conserve sufficient resources to operate our business under a revised operating plan through 2004. During the year ended December 31, 2003, we recorded $638,070 in restructuring costs which consist primarily of severance, payroll taxes and employee benefits which were recorded to expense as follows:

Research and development	$246,670
Clinical manufacturing	50,021
Marketing, general and administrative	341,379
Total	$638,070

We expect to realize cost savings going forward as a result of these expense reduction measures and other cost saving initiatives that have been implemented. We believe our restructuring plan is substantially complete with these actions. The nature of the restructuring charges and the amounts paid as of December 31, 2003 are summarized as follows:

	Total Expense	Paid	Accrued as of December 31, 2003
Severance, payroll taxes and other employee benefits	$633,799	$633,799	$—
Legal	4,271	4,271	—
Total	$638,070	$638,070	$—

7. Income Taxes

Income taxes computed using the federal statutory income tax rate differs from our effective tax primarily due to the following for the years ended December 31, 2001, 2002 and 2003:

	2001	2002	2003
Federal income tax benefit at 35%	$(7,050,500)	$(9,019,100)	$(8,094,300)
State income tax, net of federal benefit	(525,300)	(781,462)	(658,105)
Stock-based compensation	1,085,322	(325,769)	(25,259)
Research and development credits	(728,712)	(867,038)	(947,096)
Change in valuation allowance	7,167,700	10,972,100	9,651,700
Other	51,490	21,269	73,060
Benefit for income taxes	$ —	$ —	$ —

The components of our deferred tax assets under SFAS 109 as of December 31, 2002 and 2003 are as follows:

	2002	2003
Deferred tax assets:		
Temporary differences	$ 528,100	$ 465,300
Research and development credit carryforwards	5,080,000	6,537,100
Net operating loss carryforwards	29,650,300	37,907,700
Total deferred tax assets	35,258,400	44,910,100
Valuation allowance	(35,258,400)	(44,910,100)
Net deferred tax assets	$ —	$ —

Our deferred tax assets represent an unrecognized future tax benefit. A valuation allowance has been established for the entire tax benefit as we believe that it is more likely than not that such assets will not be realized.

As of December 31, 2003, we have approximately $99.7 million of net operating loss ("NOL") carryforwards and approximately $6.5 million of research and development ("R&D") credit carryforwards. These carryforwards will expire beginning in 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 our ability to utilize our NOL and R&D credit carryforwards from tax periods prior to the ownership change. Our NOL and R&D credit carryforwards as of December 31, 2003 are subject to annual limitation due to changes in ownership. Future ownership changes could further limit the utilization of our NOL and R&D credit carryforwards.

8. Employee Benefit Plan

We maintain a defined contribution plan covering substantially all employees under Section 401(k) of the Internal Revenue Code. We amended the plan documents on January 1, 1999 to provide a 50% match of employees' contributions up to $2,000 per employee per year. We made total contributions of $93,601, $118,383 and $130,731 in 2001, 2002 and 2003, respectively.

9. Commitments and Contingencies

Lease Commitments

We lease offices and 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 2001, 2002 and 2003 and the cumulative period from inception was $388,993, $629,793, $697,930, and $2,436,177, respectively.

The aggregate future minimum rental commitments as of December 31, 2003, for noncancelable operating leases with initial or remaining terms in excess of one year are as follows:

	Operating Leases
Year Ending December 31:	
2004	$ 773,916
2005	729,126
2006	725,872
2007	767,042
2008	639,201
Total minimum lease payments	$3,635,157

Contingencies

In 2002, we signed two purchase orders to purchase approximately $8.0 million of commercial grade bulk drug material to be delivered in 2004. In April 2003, we elected to cancel these purchase orders and recorded and paid a termination fee of $3.0 million included in clinical manufacturing expense in the Statements of Operations, during 2003.

In December 2003, we entered into an agreement with Baxter Healthcare Corporation for certain development and manufacturing services for the clinical and commercialization production of RSR13. We currently have no commitments to Baxter under this agreement. The minimum purchase obligations are subject to FDA approval of RSR13.

We enter into indemnification provisions under our agreements with other companies in our ordinary course of business, typically with business partners, contractors, clinical sites and suppliers. Under these provisions we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have 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, we have no liabilities recorded for these agreements as of December 31, 2003.

10. Royalty and License Fee Commitments

On January 14, 1994, we entered into a license agreement with the Center for Innovative Technology (“CIT”), under which CIT grants us an exclusive, worldwide license to practice, develop and use its technology and licensed patent rights to develop and market our products. In exchange for the license agreement, we paid CIT $50,000 in cash and issued 248,000 shares of our 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, 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. Quarterly royalty payments are due within 60 days from the end of each calendar quarter. As of December 31, 2003, no royalty payments have been incurred.

In March 2002, we entered into an agreement with N-Gene Research Laboratories, Inc., under which we obtained an exclusive United States license to intellectual property surrounding BGP-15, a novel, orally bioavailable small molecule that reduces cellular stress induced by chemotherapy. In connection with the license, we made an upfront equity investment of $1,000,000 to the licensor. On October 9, 2003 we entered into a Settlement and Termination Agreement and Mutual Release of Claims with N-Gene Research Laboratories, Inc., which terminated the business relationship and settled certain disputes between the parties. Under the terms of this settlement agreement, we surrendered all rights and licenses to the intellectual property surrounding BGP-15, and investigational compound that we in-licensed from N-Gene in March 2002, and paid N-Gene an aggregate of $591,000 in settlement fees and expenses. We also relinquished our equity investment in N-Gene, which had a carrying value of $1.0 million. In addition, each party released the other party from all further claims, damages and obligations of any kind arising under the initial license agreement and related stock purchase agreement between the parties.

In December 2002, we entered into an agreement under which we 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. We have obtained worldwide rights to develop and market the product in all potential diagnostic and therapeutic areas. Under the terms of the agreement, we made an up-front 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. We will fund all development programs and will have sole responsibility for all commercialization activities. In addition, we 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, 2003 no royalty payments have been made.

11. Related Party Transactions

In December 1994, we renegotiated a consulting agreement for scientific advisory services with Dr. Marvin Jaffe, a director of the Company. Under the agreement, we paid Dr. Jaffe consulting fees of $2,000 per month. In March 2002, this contract was terminated. For 2001 and 2002 and the cumulative period from inception, we paid Dr. Jaffe consulting fees of $24,000, $6,000 and $215,017, respectively. Since inception through December 31, 2002, we have granted to Dr. Jaffe stock options to purchase a total of 75,800 shares of our common stock under our stock option plans at exercise prices ranging from $0.16 to $7.20 per share. Stock options granted in 2003 related to Board of Director services.

In January 2001, we 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, we 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, we paid Dr. Abraham consulting fees of $42,000, $6,000 and $48,000 respectively. Since inception through December 31, 2002, we have granted to Dr. Abraham stock options to purchase a total of 20,000 shares of our common stock under our stock option plans at exercise prices ranging from $6.73 to $7.20 per share. Stock options granted in 2003 related to Board of Director services.

We entered into several research and development contracts during 1996. Under these contracts, Dr. Abraham acted as Principal Investigator for the contracts with VCU. During 2001, 2002 and 2003, services provided under these contracts totaled $457,474, $412,921 and $200,116 respectively, all of which was paid prior to December 31, 2003.

In February 2003, we entered into a consulting agreement with Dr. Stephen Hoffman and terminated his employment agreement. Pursuant to the consulting agreement, Dr. Hoffman will serve us as non-executive Chairman of the Board and is required to provide consulting services as requested

by us from time to time. The consulting agreement provides for an annual consulting fee of $150,000, paid monthly, so long as Dr. Hoffman provides consulting services in accordance with the agreement. The consulting agreement also provides for a minimum guaranteed incentive payment of $45,000 per year payable to Dr. Hoffman for each full year of consulting services provided under the agreement. The consulting agreement is for a term of two years commencing February 28, 2003, unless terminated earlier pursuant to our terms. The consulting agreement will terminate automatically upon Dr. Hoffman's failure to be re-elected to our Board of Directors, just cause or consummation of a change in control. For 2003, we paid Dr. Hoffman consulting fees of $125,000 and have accrued $45,000 of incentive compensation as of December 31, 2003. Stock options granted in 2003 related to Board of Director services. According to the consulting agreement Dr. Hoffman's options will continue to vest for the life of the agreement. We account for the continued vesting of the stock options using variable accounting as prescribed by FIN 44, *Accounting for Certain Transactions Involving Stock Compensation*. We recorded non-cash stock-based compensation of $173,963 as of December 31, 2003 related to these options.

12. Gain on Settlement Claims

On October 23, 2003, we entered into a Settlement Agreement and Mutual Release with Durus Life Sciences Master Fund, Ltd. (the ''Fund), pursuant to which we settled certain claims against the Fund and certain of its affiliates under Section 16(b) of the Securities and Exchange Act of 1934 (the "Exchange Act"). Such claims arose out of transactions by the Fund in our common stock during the period from June 4, 2002 through July 29, 2003, during which time the Fund was a beneficial owner of 10% or more of our outstanding common stock. Under the terms of this settlement agreement, the Fund paid us approximately $5.1 million in cash, and we released and discharged the Fund and certain of its affiliates from any and all further claims by us and/or our stockholders arising under Section 16(b) of the Exchange Act with respect to these transactions. This amount was recognized in the fourth quarter of 2003.

13. Quarterly Information (Unaudited)

The results of operations on a quarterly basis for the years ended December 31, 2002 and 2003 were as follows:

	March 31, 2002	June 30, 2002	Sept. 30, 2002	Dec. 31, 2002	March 31, 2003	June 30, 2003	Sept. 30, 2003	Dec. 31, 2003
Operating expenses:								
Research and development	$ 3,938,887	$ 4,289,787	$ 1,937,299	$ 3,694,235	$ 3,405,572	$ 5,081,232	$ 1,629,139	$1,841,306
Clinical manufacturing	445,164	726,115	1,242,430	1,362,212	2,080,207	3,865,872	707,431	598,297
Marketing, general and administrative	2,688,019	2,537,046	2,657,133	2,561,448	2,019,254	2,522,994	2,796,971	2,038,875
Restructuring costs	—	—	—	—	—	577,665	59,934	470
Total operating expenses	7,072,070	7,552,948	5,836,862	7,617,895	7,505,033	12,047,763	5,193,475	4,478,948
Loss from operations	(7,072,070)	(7,552,948)	(5,836,862)	(7,617,895)	(7,505,033)	(12,047,763)	(5,193,475)	(4,478,948)
Gain on settlement claims	—	—	—	—	—	—	—	5,110,083
Interest and other income, net	611,942	674,890	548,545	475,424	371,684	276,983	179,828	160,016
Net income (loss) attributable to common stockholders	$(6,460,128)	$(6,878,058)	$(5,288,317)	$(7,142,471)	$(7,133,349)	$(11,770,780)	$(5,013,647)	$ 791,151
Net income (loss) per share:								
Basic and diluted	$ (0.28)	$ (0.27)	$ (0.21)	$ $(0.28)	$ (0.28)	$ (0.45)	$ (0.19)	$ 0.03
Weighted average shares: basic	23,129,771	25,040,790	25,724,192	25,836,893	25,880,216	25,888,500	25,911,309	28,275,497
Weighted average shares: diluted	23,129,771	25,040,790	25,724,192	25,836,893	25,880,216	25,888,500	25,911,309	28,807,281

14. Subsequent Events

In January 2004, we signed an office lease with Catellus Development Corporation for 579 square feet of additional contiguous space in our corporate offices located in Westminster, Colorado. The lease has a term of four years with aggregate future payments of $39,000.

In January 2004, we executed a one-year Services Agreement with Abraham Consulting to provide scientific and technical services for our clinical trials effective July 1, 2003. Dr. Abraham, a director of the Company, owns Abraham Consulting. Total payments under the Services Agreement amount to $60,000.

Corporate Information

BOARD OF DIRECTORS

Stephen J. Hoffman, Ph.D., M.D.
Chairman of the Board; Principal, Techno Venture Management

Michael E. Hart
President and Chief Executive Officer

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

Michael D. Casey
Pharmaceutical Industry Consultant

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

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

CORPORATE HEADQUARTERS

Allos Therapeutics, Inc.
11080 CirclePoint Road
Westminster, CO 80020
Phone: 303-426-6262
Fax: 303-426-4731
Website: www.allos.com

SEC FORM 10-K

Enclosed is a copy of our Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission. Additional copies are available without charge upon request to:
Attn: Investor Relations
Allos Therapeutics, Inc.
11080 CirclePoint Road
Suite 200
Westminster, CO 80020
Phone: 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 11, 2004 at corporate headquarters in Westminster, CO.

LEGAL COUNSEL

Cooley Godward LLP
380 Interlocken Crescent
Suite 900
Broomfield, CO 80021-8023

INDEPENDENT AUDITORS

PricewaterhouseCoopers LLP
1670 Broadway
Suite 1000
Denver, CO 80202

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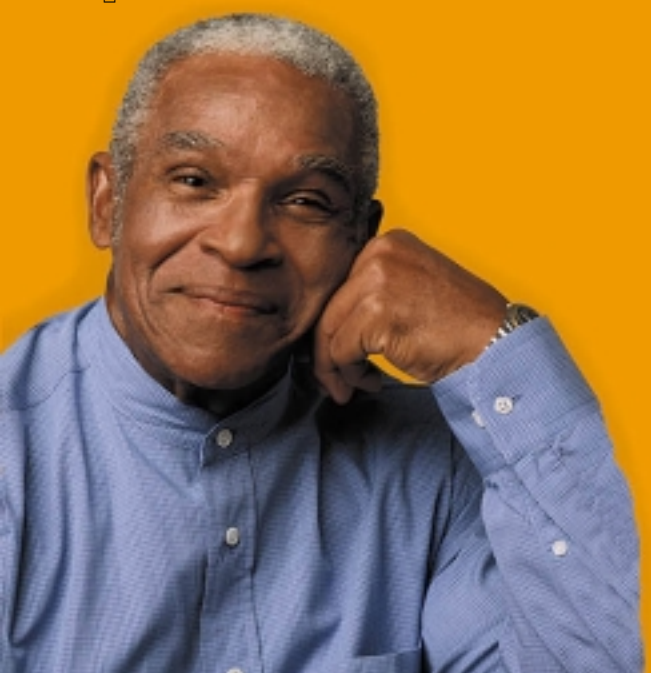

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THERAPEUTICS, INC.