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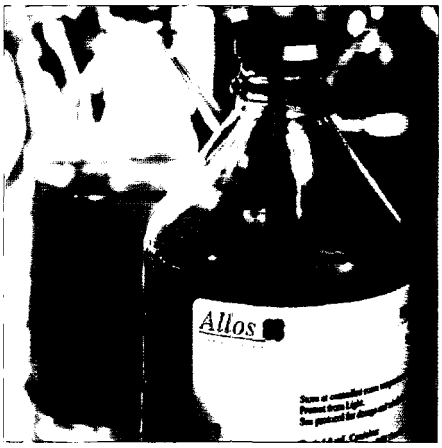
At the Forefront of

New CANCER *Therapies*

Allos THERAPEUTICS, INC.

2004 ANNUAL REPORT



therapeutic potential and plan to launch a multi-center Phase 2 study this year to evaluate the efficacy of PDX with vitamin supplementation in patients with refractory NSCLC.

We recently expanded our portfolio by acquiring exclusive worldwide rights to a new chemotherapeutic agent, known as RH1, from the University of Colorado Health Sciences Center, the University of Salford and Cancer Research Technology. RH1 is a small molecule chemotherapeutic agent that is bioactivated by the enzyme DT-diaphorase (DTD), which is overexpressed in many tumors relative to normal tissue, including lung, colon, breast and liver tumors. The drug exhibits a similar mechanism of action to the potent chemotherapeutic agent Mitomycin C, with the potential to be more effective in killing tumor cells expressing high levels of DTD and a potentially more favorable safety profile. RH1 is currently being evaluated in an open-label Phase 1 dose-escalation study in patients with advanced solid tumors.

With the completion of a $52 million financing in March 2005, we have reduced the financial risk associated with reaching the conclusion of the ENRICH study and provided the additional resources necessary to move our other compounds forward in their respective development programs. As part of this transaction, we are also pleased to add Warburg Pincus LLC, one of the premier investors in healthcare, to our investor base and board of directors.

Our focus on developing novel cancer therapies has us working in one of the most exciting areas of medical research today. I am grateful to our employees, clinical collaborators and partners for their dedication and hard work in advancing our pipeline of drug candidates over the past year, and look forward to their continued contributions and support in the year ahead.

Michael E. Hart
President, CEO & CFO

Received an "approvable" letter from FDA for EFAPROXYN for use as an adjunct to whole brain radiation therapy for the treatment of patients with brain metastases originating from breast cancer.

6/04

8/04

Received Orphan Drug Status from FDA for EFAPROXYN for use as an adjunct to whole brain radiation therapy for the treatment of patients with brain metastases originating from breast cancer.

In-licensed RH1, a targeted cytotoxic prodrug with potential application in various solid tumors.

12/04

Letter to

STOCKHOLDERS

"With an 'approvable' letter from the U.S. Food and Drug Administration for our lead clinical candidate, EFAPROXYN, two next-generation anti-cancer compounds with established proof-of-principle, expanding clinical programs and a revitalized balance sheet, Allos faces the year ahead with renewed optimism."

Michael E. Hart

With an "approvable" letter from the U.S. Food and Drug Administration (FDA) for our lead clinical candidate, EFAPROXYN, two next-generation anti-cancer compounds with established proof-of-principle, expanding clinical programs and a revitalized balance sheet, Allos faces the year ahead with renewed optimism.

We are continuing Phase 3 clinical development of EFAPROXYN with a solid understanding of the steps needed to obtain clearance to market the drug in the United States, and with confidence that positive findings from the ongoing ENRICH clinical trial will support our case for approval of EFAPROXYN to treat patients with brain metastases originating from breast cancer. Results from the previous Phase 3 study of EFAPROXYN (REACH) showed a positive survival benefit among patients with brain metastases originating from breast cancer and a favorable drug safety profile. The FDA's review of our New Drug Application (NDA) for EFAPROXYN last year and subsequent issuance of an "approvable" letter indicated that the successful completion of our ongoing Phase 3 ENRICH study should be sufficient to support approval of EFAPROXYN in this indication.

With the support of leading oncologists and patient groups, we plan to enroll 360 women with brain metastases originating from breast cancer in our Phase 3 ENRICH trial at up to 125 cancer centers across North America, Europe and South America. As of March 2005, 50 percent of planned investigative sites were open for enrollment, with patient enrollment expected to complete by the second half of 2006. To date, our progress is consistent with what we experienced in the REACH study, which leads us to believe that we can complete the study on time and on budget. Importantly, our receipt of an "approvable" letter, coupled with our NDA on file, ensures a maximum of a six-month regulatory review cycle once final results from the ENRICH study have been submitted.

We have also continued to make steady progress with our other product candidates. Clinical development work for PDX, a novel antifolate (DHFR inhibitor), has continued at Memorial Sloan-Kettering Cancer Center in patients with non-small cell lung cancer (NSCLC), mesothelioma and lymphoma. We are excited about this compound's

2004

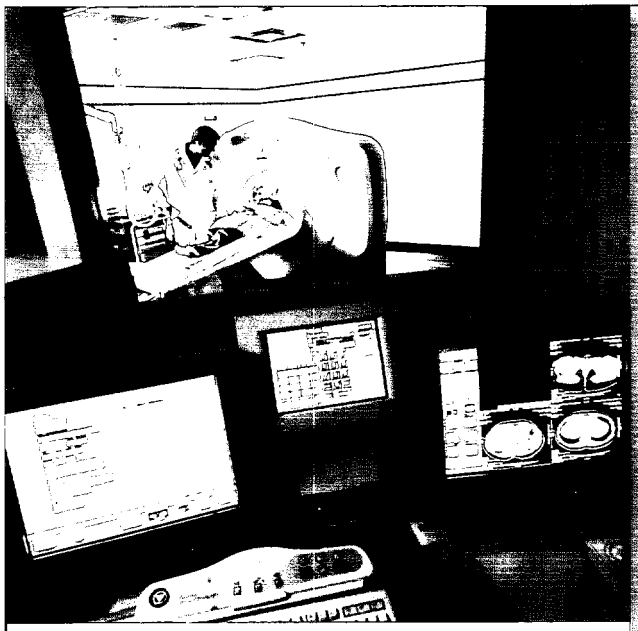
MILESTONES

2/04

Initiated ENRICH, a pivotal Phase 3 study of EFAPROXYN as an adjunct to whole brain radiation therapy for the treatment of women with brain metastases originating from breast cancer.

6/04

Filed application with the European Medicines Agency to market EFAPROXYN as an adjunct to whole brain radiation therapy for the treatment of patients with brain metastases originating from breast cancer.



Allos Therapeutics, Inc. (NASDAQ: ALTH) is a biopharmaceutical company focused on developing and commercializing small molecule therapeutics for the treatment of cancer. Since our founding in 1992, we have looked to leverage advances in the field of oncology to build and develop a pipeline of products designed to address different aspects in the growth and spread of cancer.

2005

Product Portfolio

- EFAPROXYN™ (efaproxiral) is the first synthetic small molecule designed to sensitize hypoxic, or oxygen-deprived, areas of tumors during 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 EFAPROXYN has the potential to enhance the efficacy of standard radiation therapy.

- PDX is a small molecule chemotherapeutic agent that inhibits dihydrofolate reductase, or DHFR, a folic acid (folate)-dependent enzyme involved in the building of nucleic acid, or DNA, and other processes. Preclinical data suggests that PDX has an enhanced potency and toxicity profile relative to methotrexate and other related DHFR inhibitors. Drugs that inhibit DHFR, such as methotrexate, were among the first antifolate chemotherapeutic agents discovered. Methotrexate remains one of the most widely applied antifolate chemotherapeutics and has been used to treat leukemia, breast, bladder, gastric, esophageal, head and neck cancers. We believe PDX has the potential to be delivered as a single agent or in combination therapy regimens.

- RH1 is a small molecule chemotherapeutic agent that is bioactivated by the enzyme DT-diaphorase, or DTD, which is over-expressed in many tumors relative to normal tissue, including lung, colon, breast and liver tumors. Because RH1 is bioactivated in the presence of DTD, it has the potential to provide targeted drug delivery to these tumor types while limiting the toxicity to normal tissue. RH1 has undergone in vivo efficacy testing by the Developmental Therapeutics Program of the National Cancer Institute and has demonstrated significant activity in both NSCLC and ovarian xenograft models.

Product Candidate	Target Indications	Clinical Program Status
EFAPROXYN		
Radiation Sensitizer	Brain metastases from breast cancer	Phase 3
	Stage III non-small cell lung cancer	Phase 1
	Cervical cancer	Phase 1b/2
Chemotherapy Enhancer	Recurrent malignant glioma	Phase 1b/2
PDX		
Chemotherapy	Stage IIIB-IV non-small cell lung cancer	Phase 1
	Advanced cancer	Phase 1
	Non-Hodgkin's lymphoma	Phase 1/2
RH1		
Chemotherapy	Solid tumors	Phase 1

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

FORM 10-K

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

For the fiscal year ended December 31, 2004.

☐ **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 7, 2005, there were 31,175,783 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, 2004) was approximately $69,505,884. 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, 2004. 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 2005 Annual Meeting of Stockholders to be filed within 120 days after the end of the Registrant's fiscal year ended December 31, 2004 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein.

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PART I

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

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements concerning our plans to continue development of our current product candidates; conduct clinical trials with respect to our product candidates; seek regulatory approvals; address certain markets; initiate marketing activities related to commercialization of our products; 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.

Allos Therapeutics, Inc., the Allos Therapeutics, Inc. logo, EFAPROXYN™ (efaproxiral), formerly known as RSR13, and all other Allos names are trademarks of Allos Therapeutics, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders.

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 leverage our internal clinical development and regulatory expertise and address important medical markets. We endeavor to grow our existing portfolio of product candidates through ongoing product acquisition and in-licensing efforts.

We have never generated any revenue from product sales and have experienced significant net losses since our inception in 1992. We have incurred these losses principally from costs incurred in our research and development programs and from our general and administrative expenses. 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 obtain regulatory approval in the United States or Europe to market our lead product candidate, EFAPROXYN (efaproxiral), as an adjunct to radiation therapy for the treatment of brain metastases originating 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 have three product candidates that are currently under development, EFAPROXYN (efaproxiral), formerly known as RSR13, PDX (pralatrexate) and RH1.

- **EFAPROXYN** is the first synthetic small molecule designed to sensitize hypoxic, or oxygen-deprived, areas of tumors during 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 EFAPROXYN has the potential to enhance the efficacy of standard radiation therapy.

  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 EFAPROXYN in the United States as an adjunct to whole brain radiation therapy, or WBRT, for the treatment of patients with brain metastases originating from breast cancer. The NDA was based on the findings from our randomized, open label Phase 3 clinical trial of EFAPROXYN in patients with brain metastases, which we called REACH. The results from the REACH trial were announced in April 2003. In May 2004, the FDA's Oncologic Drug Advisory Committee reviewed the NDA and voted not to recommend approval of EFAPROXYN for this indication based on the data from the REACH trial. However, in June 2004, the FDA issued an "approvable letter" in which it indicated that before the NDA may be approved, it would be necessary for us to successfully complete our ongoing Phase 3 clinical trial of EFAPROXYN in patients with brain metastases originating from breast cancer and submit the results as a NDA amendment for the FDA's review. In the letter, the FDA stated, "if the study shows effectiveness in this population (increased survival) using the pre specified analysis, and the study is otherwise satisfactory, we believe it would, together with the subset result in the [REACH trial], support approval."

  The ongoing Phase 3 trial referenced in the FDA's approvable letter was initiated in February 2004. This pivotal Phase 3 trial, which is called ENRICH (**EN**hancing whole brain **R**adiation therapy **I**n patients with breast **C**ancer and **H**ypoxic brain metastases), will seek to enroll approximately 360 patients at up to 125 cancer centers across North America, Europe and South America. The primary endpoint of the trial will measure the difference in survival between patients receiving whole brain radiation therapy, or WBRT, plus supplemental oxygen, with or without EFAPROXYN. We currently anticipate that enrollment in the trial will be completed during the second half of 2006.

  In June 2004, we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMEA, for approval to market EFAPROXYN in Europe as an adjunct to WBRT for the treatment of patients with brain metastases originating from breast cancer. The MAA was filed under the EMEA's centralized procedure, which is used when marketing authorization is applied for in all EMEA member states simultaneously. In October 2004, we received the EMEA's Day 120 List of Questions relating to the MAA, to which we must respond by April 2005.

  In August 2004, the FDA awarded orphan drug status to EFAPROXYN for use as an adjunct to WBRT for the treatment of patients with brain metastases originating from breast cancer. The FDA may award orphan drug designation to drugs that target conditions affecting 200,000 or fewer U.S. patients per year and provide a significant therapeutic advantage over existing treatments. The orphan drug designation provides for U.S. marketing exclusivity for seven years following marketing approval by the FDA.

In addition to the Phase 3 ENRICH trial, other current clinical trials involving EFAPROXYN include (i) a Phase 1 clinical trial in patients with locally advanced non-small cell lung cancer, or NSCLC, receiving concurrent chemoradiotherapy (chemotherapy and radiation therapy administered at the same time) in combination with EFAPROXYN, (ii) a Phase 1b/2 clinical trial of EFAPROXYN in patients with locally advanced cancer of the cervix receiving concurrent chemoradiotherapy, and (iii) a Phase 1b/2 study of EFAPROXYN administered with BCNU (carmustine) chemotherapy for the treatment of patients with recurrent malignant glioma, a type of primary brain cancer.

- **PDX** is a small molecule chemotherapeutic agent that inhibits dihydrofolate reductase, or DHFR, a folic acid (folate)-dependent enzyme involved in the building of nucleic acid, or DNA, and other processes. Preclinical data suggests that PDX has an enhanced potency and toxicity profile relative to methotrexate and other related DHFR inhibitors. Drugs that inhibit DHFR, such as methotrexate, were among the first antifolate chemotherapeutic agents discovered. Methotrexate remains one of the most widely applied antifolate chemotherapeutics and has been used to treat leukemia, breast, bladder, gastric, esophageal, head, and neck cancers. We believe PDX has the potential to be delivered as a single agent or in combination therapy regimens.

  Current clinical trials involving PDX include (i) a Phase 1/2 single-agent study in patients with non-Hodgkin's lymphoma, (ii) a Phase 1 combination study with docetaxel in patients with advanced cancer, including NSCLC, and (iii) a Phase 1 single-agent study to determine the maximum tolerated dose of PDX in patients with NSCLC.

- **RH1** is a small molecule chemotherapeutic agent that is bioactivated by the enzyme DT-diaphorase, or DTD, which is over-expressed in many tumors relative to normal tissue, including lung, colon, breast and liver tumors. Because RH1 is bioactivated in the presence of DTD, it has the potential to provide targeted drug delivery to these tumor types while limiting the toxicity to normal tissue. RH1 has undergone in vivo efficacy testing by the Developmental Therapeutics Program of the National Cancer Institute and has demonstrated significant activity in both NSCLC and ovarian xenograft models.

  RH1 is currently being evaluated in patients with advanced solid tumors refractory to other chemotherapy regimens in an open label, Phase 1 dose escalation study to test the safety, tolerability and pharmacokinetics of escalating doses of RH1.

Current Cancer Therapies

According to an independent healthcare research company, the worldwide oncology drug market is expected to reach $38.5 billion in 2005. Despite the enormous effort undertaken by the pharmaceutical industry to develop oncology products, cancer is the leading cause of death of Americans under 85 and remains a largely unmet medical need. Over 1.5 million new cases of cancer are diagnosed each year in the United States, and approximately 628,000 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, biologic drug therapy, hormone therapy and immunotherapy.

Radiation therapy is one of the principal non-surgical means of treating malignant tumors in patients with cancer. Radiation therapy (sometimes called radiotherapy) is the treatment of disease using penetrating beams of high-energy waves or streams of particles called radiation. Currently more than half of all cancer patients receive radiation therapy at some point during their cancer treatment

and an estimated 750,000 cancer patients receive radiation therapy each year. Radiation therapy is used to cure certain cancers, to control local tumor invasion and thus prolong life, and to treat symptomatic problems in patients who are expected to die of their cancer.

Chemotherapy involves the systemic use of chemical agents to help kill tumor cells, 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. An estimated 627,000 to 844,000 cancer patients are treated with chemotherapy each year.

Our Business Strategy

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

- *Focus on the oncology market.* We intend to continue to focus our drug development efforts on the oncology market. We believe the oncology market is attractive due to its large market size, continual demand for safer and more effective cancer treatments, well-characterized endpoints, and potential for expedited regulatory review.
- *Obtain regulatory approval to market EFAPROXYN.* We are currently focused on completing our Phase 3 ENRICH trial and, if the results are positive, obtaining regulatory approval in the United States to market EFAPROXYN as an adjunct to WBRT for the treatment of brain metastases originating from breast cancer. We have also filed a MAA with the EMEA for approval to market EFAPROXYN in Europe for this target indication, and may pursue regulatory approvals in other countries if deemed strategically and economically feasible.
- *Advance the development of PDX and RH1.* We plan to evaluate PDX and RH1 for oncology use as single agents or in combination with other therapies in target indications that we believe will yield the highest probability of success. We believe the clinical and regulatory expertise gained in our EFAPROXYN-related efforts will enable us to accelerate the development of PDX and RH1.
- *Expand our product candidate portfolio.* We plan to continue pursuing opportunities to expand our product candidate portfolio by identifying and evaluating new compounds that have demonstrated potential in preclinical or clinical studies and are synergistic with our existing oncology portfolio. Our intent is to build a strong and continual pipeline of novel and powerful drug candidates.
- *Develop sales and marketing capabilities to maximize the commercial potential of our product candidates.* We currently retain exclusive worldwide commercial rights to EFAPROXYN, PDX and RH1 for all target indications. We intend to develop sales and marketing capabilities, either internally or through a combination of contract relationships or strategic collaborations, to market our products in the United States. We intend to enter into co-promotion or out-licensing arrangements to reach all markets outside the United States.

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
EFAPROXYN (efaproxiral)		
Radiation Sensitizer	Brain metastases from breast cancer	Phase 3
	Stage III NSCLC	Phase 1
	Cervical cancer	Phase 1b/2
Chemotherapy Enhancer	Recurrent malignant glioma	Phase 1b/2
PDX		
Chemotherapy	Stage IIIB-IV NSCLC	Phase 1
	Advanced cancer	Phase 1
	Non-Hodgkin's lymphoma	Phase 1/2
RH1		
Chemotherapy	Solid tumors	Phase 1

EFAPROXYN (efaproxiral)

EFAPROXYN as a Radiation Sensitizer

EFAPROXYN is a synthetic small molecule being developed for use as an adjunct to radiation therapy in the treatment of cancer. Approximately 600 patients have been treated with EFAPROXYN in conjunction with radiation therapy in 11 clinical trials. The results have shown that EFAPROXYN 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 therapy therefore have the potential to enhance the effectiveness of radiation therapy in killing tumor cells.

Malignant tumors often have a poorly regulated blood supply, caused by the disorganized and disordered growth of new blood vessels into the tumor. This results in a large number of tumor cells being further away from a blood vessel, resulting in an increased diffusion distance from the vessel to the cells. In addition, because malignant tumors often grow rapidly, they consume high levels of oxygen. This high level of oxygen consumption, combined with the poorly regulated blood supply and increased oxygen diffusion distances from the vessels to the cells, generally results in tumor hypoxia, or oxygen-deprived regions of the tumor. In most tumors studied, up to 80% of the tumor is 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. Because oxygen is a necessary component for

the effectiveness of radiation therapy, tumor hypoxia may limit the effectiveness of radiation therapy in controlling tumor growth and killing cancer cells.

Small molecule drugs, like EFAPROXYN, 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.

EFAPROXYN 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, EFAPROXYN facilitates the release of oxygen from hemoglobin and increases the level of oxygen in malignant and non-malignant tissue. In addition, by facilitating the release of oxygen from hemoglobin, we believe EFAPROXYN 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 EFAPROXYN is not dependent on the direct diffusion of the drug into the cancerous tumor. Instead, EFAPROXYN works by increasing the release of oxygen from hemoglobin circulating within and around the tumor. It is the oxygen, and not EFAPROXYN, which diffuses across the cancer cell membranes to oxygenate the tumor. 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.

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

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

EFAPROXYN and WBRT in the treatment of Brain Metastases Originating from Breast Cancer

Brain metastases occur in up to 175,000 patients per year in the United States. WBRT for the treatment of brain metastases is administered to approximately 125,000 patients per year in the United States and is intended to prevent or reduce complications and extend survival. Cancers that metastasize to the brain most often originate in the breast, lungs, kidneys or melanomas in the skin. Breast cancer is the second most common cause of brain metastases, accounting for 14% to 20% of the total incidence of brain metastases. Over 200,000 women are diagnosed with breast cancer each year in the United States. The median survival of patients with brain metastases who receive WBRT is about 4.5 months. It should be noted that over the past 25 years, no improvement in median survival has been observed for patients with brain metastases receiving WBRT. 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 half 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 the radiation sensitivity of solid tumors. As a result, we believe the addition of EFAPROXYN 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 EFAPROXYN is safe and effective for treating patients with brain metastases resulting from different primary tumor types, such as, breast, NSCLC and melanoma. The study enrolled 538 patients and compared the efficacy and safety of WBRT and supplemental oxygen with or without EFAPROXYN in patients with brain metastases.

In April 2003, we announced the 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 those patients, the addition of EFAPROXYN to WBRT nearly doubled median survival from 4.57 months for the control arm to 8.67 months for the EFAPROXYN arm, and improved response rate, or the percentage of patients experiencing at least a 50% decrease in the amount of cancer following treatment, from 49.1% in the control arm to 71.7% in the EFAPROYXN arm. Overall, patients with brain metastases from breast cancer who received EFAPROXYN experienced approximately a 49% reduction in risk of death. Risk of death is the relative effect on death at any time point between the control arm and the EFAPROXYN arm. In addition, a statistically significant quality of life benefit (as determined by Karnofsky Performance Status, or KPS, and Spitzer Questionnaire) at three and six months was observed in patients treated with EFAPROXYN.

In general, patients treated with EFAPROXYN experienced relatively few serious adverse events. The most common treatment-related adverse event was hypoxemia, or reduced oxygen in the blood, which occurred in 41% of the patients. The level of hypoxemia was dose-dependent and effectively managed with supplemental oxygen. Furthermore, these adverse events of hypoxemia were predominately asymptomatic, meaning that the patients did not express or exhibit any symptoms and were unaware of the hypoxemia. It is important to recognize that the adverse event of hypoxemia is unrelated to tissue hypoxia or ischemia, which have potentially life-threatening consequences.

Based on the findings from the REACH trial, in December 2003, we submitted a NDA to the FDA for approval to market EFAPROXYN in the United States as an adjunct to WBRT for the treatment of patients with brain metastases originating from breast cancer. In May 2004, the FDA's Oncologic Drug Advisory Committee reviewed the NDA and voted not to recommend approval of EFAPROXYN for this indication based on the results of the REACH trial. However, in June 2004, the FDA issued an "approvable letter" in which it indicated that before the NDA may be approved, it would be necessary for us to successfully complete our ongoing Phase 3 clinical trial of EFAPROXYN in patients with brain metastases originating from breast cancer and submit the results as a NDA amendment for the FDA's review. In the letter, the FDA stated, "if the study shows effectiveness in this population (increased survival) using the pre specified analysis, and the study is otherwise satisfactory, we believe it would, together with the subset result in the [REACH trial], support approval."

The ongoing Phase 3 trial referenced in the FDA's approvable letter was initiated in February 2004. This pivotal Phase 3 trial, which is called ENRICH (ENhancing Whole Brain Radiation Therapy In Patients with Breast Cancer and Hypoxic Brain Metastases), will seek to enroll approximately 360 patients at up to 125 cancer centers across North America, Europe and South America. The primary endpoint of the trial will measure the difference in survival between patients receiving WBRT plus supplemental oxygen, with or without EFAPROXYN. Under the trial protocol, the primary endpoint will be achieved if the EFAPROXYN arm demonstrates a statistically significant increase in overall survival versus the control arm. The study design has an 80% power to detect a 40% increase in overall survival. Secondary efficacy endpoints of the trial include the response rate in the brain at 3 months and KPS, neurologic signs, and symptoms assessment. An independent Data Monitoring Committee, or DMC, will provide an expert review of cumulative data from the trial to determine, at either of two interim analyses of the primary endpoint (survival), if sufficient evidence

exists to stop the trial early due to overwhelming evidence of improved survival in the EFAPROXYN arm. The DMC will perform the interim analyses of the primary endpoint at its first scheduled meeting following the occurrence of 94 and 188 patient deaths, respectively. We will perform the final analysis of both the primary and secondary endpoints following the occurrence of 281 patient deaths. A number of factors will influence the actual timing of the interim and final analyses, including patient accrual rates and individual survival rates. We currently anticipate that enrollment in the trial will be completed during the second half of 2006. The FDA completed a Special Protocol Assessment for the ENRICH trial in September 2003. A Special Protocol Assessment is an agreement between the sponsor and the FDA that the design and planned analysis of a Phase 3 trial, as reflected in the trial protocol, adequately addresses the objectives of the trial in support of a NDA submission.

In June 2004, we filed a MAA with the EMEA to market EFAPROXYN in Europe as an adjunct to WBRT for the treatment of patients with brain metastases originating from breast cancer. The MAA for EFAPROXYN was filed under the EMEA's centralized procedure, which is used when marketing authorization is applied for in all EMEA member states simultaneously. In October 2004, we received the EMEA's Day 120 List of Questions relating to the MAA, to which we must respond by April 2005.

In August 2004, the FDA awarded orphan drug status to EFAPROXYN for use as an adjunct to WBRT for the treatment of patients with brain metastases originating from breast cancer. The FDA may award orphan drug designation to drugs that target conditions affecting 200,000 or fewer U.S. patients per year and provide a significant therapeutic advantage over existing treatments. The orphan drug designation provides for U.S. marketing exclusivity for seven years following marketing approval by the FDA. In addition, the designation qualifies a product for up to $350,000 per year of potential funding to support clinical trials and study design assistance from the FDA during development. We plan to apply for orphan drug funding to support the ENRICH trial.

EFAPROXYN and Thoracic Radiation Therapy in the treatment of NSCLC

NSCLC is the most common type of lung cancer and occurs in approximately 160,000 patients per year in the United States. NSCLC accounts for almost 85% of all lung cancer cases. We are currently evaluating EFAPROXYN 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 44,000 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 10 to 12 months.

In November 2000, we completed a 52-patient, open-label, multi-center, Phase 2 clinical trial of induction chemotherapy followed by sequential chest radiation therapy in combination with EFAPROXYN 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%. The analysis of response data from the 44 patients who had a follow-up scan at the two-month visit and who received EFAPROXYN plus radiation therapy demonstrated an overall response rate of 89%, with 80% partial responses and 9% complete responses.

In January 2003, we initiated a Phase 3 clinical trial of induction chemotherapy followed by chest radiation therapy with or without EFAPROXYN in patients with Stage IIIA/IIIB NSCLC. In June 2003, we implemented certain expense reduction measures and terminated this trial prior to the first patient being dosed.

In January 2004, we initiated a Phase 1 clinical trial in patients with Stage III NSCLC receiving concurrent chemoradiotherapy (chemotherapy and radiation therapy administered at the same time) in combination with EFAPROXYN. 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. We expect to complete enrollment in this trial in 2006, and will evaluate the

data from this and our other ongoing clinical trials to determine our future development plans in this indication.

EFAPROXYN and Standard Radiation Therapy in the treatment of Cervical Cancer

Cervical cancer is the third most common form of cancer in women worldwide, and the leading cause of cancer-related death for women in developing countries. An estimated 230,000 women die from cervical cancer each year. Cancer of the cervix can often be cured if detected and treated at an early stage, and five-year survival rates for all stages of cervical cancer are approximately 70%. Surgery, radiation therapy and chemotherapy are the primary treatments for patients with advanced cervical cancer.

In August 2002, we initiated a Phase 1b/2 clinical trial of EFAPROXYN for patients with locally advanced cancer of the cervix receiving concurrent chemoradiotherapy. This clinical trial is an open-label, multi-center study of EFAPROXYN 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 EFAPROXYN in this combination and to determine the maximum tolerated dose, or MTD, of EFAPROXYN 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 EFAPROXYN at the MTD in combination with cisplatin and radiation therapy as determined by the progression rate at two years. We expect to complete enrollment in this trial in 2006, and will evaluate the data from this and our other ongoing clinical trials to determine our future development plans in this indication.

EFAPROXYN and WBRT in the treatment of Glioblastoma Multiforme

Glioblastoma multiforme, or GBM, is a deadly form of primary brain cancer. This condition occurs in approximately 12,000 patients per year in the United States. The median survival time of patients with GBM is approximately 7 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 EFAPROXYN 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 EFAPROXYN 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 EFAPROXYN was safe and well tolerated, the NABTT Consortium conducted the 50-patient, multi-center, Phase 2 study of EFAPROXYN combined with a standard six-week course of WBRT in patients with newly diagnosed GBM. The EFAPROXYN-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 EFAPROXYN 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 EFAPROXYN plus WBRT was conducted in patients with newly diagnosed GBM from April 1998 to May 1999. In this trial, which was comparable in design and methods to the NABTT Phase 2 trial, EFAPROXYN 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 EFAPROXYN in patients receiving radiation therapy for the treatment of GBM; however, we do not intend to conduct additional clinical studies in this indication at the present time as we are concentrating our efforts on the other potential target indications for EFAPROXYN.

EFAPROXYN 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, EFAPROXYN may also enhance the beneficial effects of certain types of chemotherapy.

We have conducted preclinical studies that suggest EFAPROXYN, 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 EFAPROXYN administered with BCNU (carmustine) chemotherapy for the treatment of patients with recurrent malignant glioma, a type of primary brain cancer. This study is an ongoing, nonrandomized, open-label, multi-center study of escalating doses of EFAPROXYN given with a fixed dose of BCNU. Enrollment in the Phase 1b portion of this study was completed in 2004 and we are currently evaluating the results to determine our future development plans.

EFAPROXYN in Non-Oncology Indications

We believe EFAPROXYN could potentially be useful in treating 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 EFAPROXYN could potentially 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 EFAPROXYN in CPB and a successful Phase 1b study in elective surgery patients, we conducted a randomized 30-patient Phase 2 clinical trial of EFAPROXYN in patients undergoing CPB for first time coronary artery bypass grafting. This study demonstrated that EFAPROXYN can be safely given during CPB and provided preliminary evidence of a protective effect on heart function.

We also believe that EFAPROXYN 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 EFAPROXYN was safe and well tolerated.

We currently anticipate that development of EFAPROXYN for these, or any other, non-oncology indications would be conducted in cooperation with a strategic partner.

Manufacturing

We have a contract with Hovione FarmaCiencia SA for the supply of EFAPROXYN bulk drug substance (efaproxiral sodium), and a contract with Baxter Healthcare Corporation for the supply of EFAPROXYN formulated drug product (efaproxiral injection). These contracts enable us to minimize fixed costs and capital expenditures, and gain access to advanced manufacturing process capabilities and expertise.

Hovione is our primary supplier of efaproxiral sodium. Hovione operates under current Good Manufacturing Practices 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.

After manufacture, efaproxiral sodium is formulated under contract for us into the drug product, efaproxiral injection. In December 2003, we entered into a long-term development and supply agreement with Baxter for commercial manufacture of efaproxiral injection. Baxter operates under

current Good Manufacturing Practices and has significant experience in the manufacture of large volume injectables of this type. Under the terms of our contract, Baxter has agreed to manufacture sufficient quantities of efaproxiral injection to support our anticipated commercial requirements. Baxter is in good standing with the FDA, having passed recent inspections, including a pre-approval inspection for efaproxiral injection. In addition, we also plan to establish an alternate supplier of efaproxiral injection.

Sales and Marketing

If and when we obtain FDA approval, we intend to commercialize EFAPROXYN by building a focused United States 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 moderate sized 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 and manage 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 and marketing partners.
- *Establish co-promotion alliances.* We intend to enter into co-promotion or out-licensing arrangements with other pharmaceutical or biotechnology firms, where necessary, to reach domestic and foreign market segments that are not reachable with our internal sales force.

PDX (pralatrexate)

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 PDX. PDX is a small molecule chemotherapeutic agent that inhibits dihydrofolate reductase, or DHFR, a folic acid (folate)-dependent enzyme involved in the building of nucleic acid, or DNA, and other processes. Preclinical data suggests that PDX has an enhanced potency and toxicity profile relative to methotrexate and other related DHFR inhibitors. Drugs that inhibit DHFR, such as methotrexate, were among the first antifolate chemotherapeutic agents discovered. Methotrexate remains one of the most widely applied antifolate chemotherapeutics and has been used to treat leukemia, breast, bladder, gastric, esophageal, head, and neck cancers. We believe PDX has the potential to be delivered as a single agent or in combination therapy regimens.

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, or 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 is a folic acid analog.

The selectivity of antifolates for tumor cells involves their conversion to a polyglutamated form by the enzyme folypolyglutamyl synthetase, or FPGS. Polyglutamation is a time and concentration dependant process that occurs in tumor cells, and to a lesser extent, normal tissues. The selective

activity of the folic acid analogs 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.

It is thought that the resistance of malignant cells to the effects of the folic acid analogs may, in part, be due to impaired polyglutamation. The improved antitumor effects of PDX in comparison to methotrextate, as observed in preclinical studies, is likely due to the more effective uptake and transport of PDX into the cell followed by the greater accumulation of PDX and its metabolites within the tumor cell through the formation of the polyglutamated derivatives.

PDX in the treatment of NSCLC

NSCLC is the most common type of lung cancer and occurs in approximately 160,000 patients per year in the United States. NSCLC accounts for almost 85% of all lung cancer cases. Over the last decade, oncologists have begun treating advanced NSCLC patients more aggressively, typically administering a potent combination of paclitaxel and carboplatin. Other drugs used in this setting include gemcitabine, vinorelbine, docetaxel and cisplatin. Despite aggressive therapy, the expected survival of patients with Stage IIIB or IV NSCLC is only 8 to 10 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 primary side effect of PDX was stomatitis (mouth sores), which was treated with a dose reduction. Patients were not supplemented with folic acid and vitamin B12 in this study. In addition, no clinically significant myelosuppression was observed. Myelosuppression, which is a side effect of certain chemotherapy agents, is a condition in which bone marrow activity is decreased, resulting in fewer red blood cells, white blood cells, and platelets.

A Phase 1 trial of PDX in combination with docetaxel in patients with advanced cancer, including NSCLC, that have failed prior chemotherapy is currently being conducted at MSKCC. Docetaxel is approved for the second-line treatment of advanced NSCLC. We expect to complete this study in the first half of 2005.

In addition, in January 2005, we initiated a Phase 1 dose escalation study of PDX with vitamin B12 and folic acid supplementation in patients with previously treated (Stage IIIB-IV) advanced NSCLC. Recent studies suggest that supplementation with folic acid and vitamin B12 may reduce the incidence of clinically significant stomatitis. This open-label, non-randomized study will seek to enroll one to six patients per treatment level cohort who have received one prior chemotherapy regimen and may or may not have received an EGFR Kinase inhibitor to test the safety, tolerability and pharmacokinetics of escalating doses of PDX. We expect to complete this study in the second half of 2005.

The principal objective of each of these trials is to determine the maximum tolerated dose of PDX. The determination of these doses will be essential for further development of PDX in the treatment of NSCLC.

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 nearly 2% per year. Patients with indolent or low-grade NHL may have survival rates as long as

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 30% to 60% of cases. Standard chemotherapy for NHL involves an initial combination of cyclophosphamide, doxorubicin, vincristine and prednisone. The addition of rituximab to this regimen has increased response rates to nearly 100%. Even so, about 55% of patients eventually relapse and may be candidates for salvage chemotherapy, or chemotherapy given after recurrence of a tumor.

A Phase 1/2 single-agent study of PDX in patients with NHL is currently being conducted at MSKCC. We expect to make a decision on continuing development in this indication during the first half of 2005.

PDX in the treatment of Mesothelioma

Mesothelioma is a chemoresistant tumor whose cause has been linked with exposure to asbestos. Many chemotherapeutic agents alone or in combination have been investigated for the treatment of mesothelioma including platinums, alkylating agents and anthracyclines. The results of these studies have been highly variable although combination approaches have produced higher response rates and longer median survival times than single agent therapies.

Historically, antifolates such as methotrexate have demonstrated the greatest activity in the treatment of mesothelioma with response rates as high as 37%. Newer antifolates, such as pemetrexed, have been combined with platinum based chemotherapy agents to produce response rates over 40%. In February 2004, the FDA granted approval for pemetrexed in combination with cisplatin for the treatment of malignant pleural mesothelioma, the first and only approved regimen for the malignancy. This has validated the role of antifolates in the treatment of mesothelioma and established an antifolate/platinum combination as the new standard of care.

A Phase 2 single-agent study of PDX in patients with unresectable malignant pleural mesothelioma is currently being conducted at MSKCC, although patient enrollment was discontinued in 2004 when it was determined that the results to date fell below the critical threshold for further development in this indication. This study will be terminated once the last patient has completed treatment.

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.

RH1

In December 2004, we acquired an exclusive, worldwide license from the University of Colorado Health Sciences Center, the University of Salford and Cancer Research Technology to certain intellectual property surrounding a proprietary molecule known as RH1. RH1 is a small molecule chemotherapeutic agent that is bioactivated by the enzyme DT-diaphorase, or DTD, which is over-expressed in many tumors relative to normal tissue, including lung, colon, breast and liver tumors. Because RH1 is bioactivated in the presence of DTD, it has the potential to provide targeted drug delivery to these tumor types while limiting the toxicity to normal tissue. RH1 has undergone in vivo efficacy testing by the Developmental Therapeutics Program of the National Cancer Institute and has demonstrated significant activity in both NSCLC and ovarian xenograft models. RH1 was a nominated compound for advancement in the National Cancer Institute's Developmental Therapeutics Program, which provides cancer drug discovery and development resources to the intramural, academic and industrial research communities.

RH1 is currently being evaluated in patients with advanced solid tumors refractory to other chemotherapy regimens in an open label, Phase 1 dose escalation study. Up to 40 patients will be enrolled to test the safety, tolerability and pharmacokinetics of escalating doses of RH1. Patient DTD enzyme levels are being measured to correlate with drug efficacy. Recruitment began in September 2003 and is expected to complete in the second half of 2005. Cancer Research UK will continue to support the ongoing Phase 1 dose escalation study, and we will have the right to obtain an exclusive license to the results of the study, for use in subsequent development and regulatory activities, upon payment of a one-time data option fee. Upon completion of the Phase 1 study, we will assume responsibility for all future development costs and activities.

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 that may be 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.

EFAPROXYN

Under a 1994 agreement with the Center for Innovative Technology, or CIT, we have obtained exclusive worldwide rights to a portfolio of patents related to allosteric hemoglobin modifier compounds, including EFAPROXYN, and their uses. This patent portfolio includes numerous issued patents in the United States, Europe, and Japan and pending patent applications in Canada related to the current EFAPROXYN applications. 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. 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 currently October 2016, but could be later depending on possible patent term extensions.

The licensed patents, which expire at various times between February 2010 and October 2016, contain claims covering methods of allosterically modifying hemoglobin with EFAPROXYN and other compounds, the site within hemoglobin where EFAPROXYN binds, and certain clinical applications of EFAPROXYN 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.

We exclusively own several patent families with pending applications directed to formulations, methods of manufacture, and various additional uses of EFAPROXYN. Issuance of these patent applications may extend the term of patent protection for EFAPROXYN in the United States, Europe and certain other countries.

PDX

Under a December 2002 license agreement with MSKCC, SRI International and Southern Research Institute, we have obtained exclusive worldwide rights to several issued United States patents and equivalent foreign patent applications 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.

RH1

In December 2004, we acquired an exclusive worldwide license from the University of Colorado Health Sciences Center, the University of Salford and Cancer Research Technology to certain intellectual property surrounding a proprietary molecule known as RH1. Under the terms of the license agreement, we will make a series of milestone payments to the licensors based upon the achievement of

specified development, regulatory and commercialization goals. We will also make royalty payments based on product sales, if any, resulting from the collaboration. Cancer Research UK will continue to support the ongoing Phase 1 dose escalation study, and we will have the right to obtain an exclusive license to the results of the study, for use in subsequent development and regulatory activities, upon payment of a one-time data option fee. Upon completion of the Phase 1 study, we will assume responsibility for all future development costs and activities.

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. Additionally, when product candidates can do damage to normal cells, it is not ethical to administer such drugs to healthy patients in a Phase 1 trial.

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.

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 Union, or EU, centralized registration procedures are available to companies wishing to market a product in more than one EU 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, 2005, we had a total of 53 full-time employees and one part-time employee. Of those, 36 are engaged in clinical development, regulatory affairs, biostatistics, manufacturing and preclinical development. The remaining 18 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.

Available Information

We were incorporated under the laws of the Commonwealth of Virginia in September 1992 as HemoTech Sciences, Inc. and changed our name to Allos Therapeutics, Inc. in October 1994. We reincorporated in Delaware 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/SEC Filings. You may also read and copy materials that we file with SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding us and other issuers that file electronically with the SEC at *www.sec.gov*.

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, 2002, 2003 and 2004, we had net losses of $25.8 million, $23.1 million and $21.8 million, respectively. As of December 31, 2004, we had an accumulated deficit of $157.6 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 EFAPROXYN 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. We expect to continue to spend substantial amounts on research and development, including amounts spent on conducting clinical trials for our product candidates. 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.

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 EFAPROXYN. Accordingly, our future prospects are substantially dependent on obtaining regulatory approval in the United States or Europe to market EFAPROXYN as an adjunct to radiation therapy for the treatment of brain metastases originating from breast cancer. EFAPROXYN is not expected to be commercially available for this or any other indication until at least 2007. In addition, PDX and RH1 are in earlier stages of product development relative to EFAPROXYN, and as such, we expect that PDX and RH1 will not be commercially available until after EFAPROXYN is commercially available. 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 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 EFAPROXYN, or we may not obtain regulatory review of such product candidates in a timely manner. For a more complete description of the regulatory approval process and related risks, please refer to the "Government Regulation" section of this Item 1.

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 EFAPROXYN or any other product candidate, it would significantly increase our expenses and delay marketing of our product candidates.

We may experience delays in our clinical trials, including ENRICH, 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 ongoing clinical trials, including ENRICH, 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, including ENRICH, 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 Practices, 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. As a result, there can be no assurance that our ENRICH trial will achieve its primary endpoint. In addition, negative or inconclusive results or adverse medical

events during a clinical trial could cause a clinical trial to be repeated or terminated. Also, 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.

The EMEA may not approve our MAA to market EFAPROXYN in Europe as an adjunct to radiation therapy for the treatment of brain metastases originating from breast cancer.

On April 23, 2003, we announced the results of our pivotal Phase 3 trial of EFAPROXYN 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 June 2004, we submitted our MAA to the EMEA for approval to market EFAPROXYN in Europe as an adjunct to radiation therapy for the treatment of brain metastases originating from breast cancer. In October 2004, we received the EMEA's Day 120 List of Questions relating to the MAA, to which we must respond by April 2005. 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 EMEA 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 EMEA will approve EFAPROXYN for marketing in Europe based on our MAA submission. If the EMEA does not approve EFAPROXYN for marketing, our ability to commercialize EFAPROXYN in Europe would be substantially delayed.

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, among other factors:

- the timing and outcome of our current ENRICH trial;
- costs associated with the commercialization of EFAPROXYN, 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.

We intend to raise additional capital in the future through arrangements with corporate partners, equity or debt financings, or from other sources. 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.

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 infringement 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 patent or other intellectual property infringement claims.

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

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 a contract with Hovione FarmaCiencia SA for the supply of EFAPROXYN bulk drug substance, and a contract with Baxter Healthcare for the supply of EFAPROXYN formulated drug product. These manufacturers are currently our only source for the production and formulation of EFAPROXYN.

Even if we obtain approval to market EFAPROXYN in one or more indications, our current or future manufacturers may be unable to accurately and reliably manufacture commercial quantities of EFAPROXYN 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 EFAPROXYN will be materially and adversely affected.

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

- delays or failure to manufacture sufficient quantities needed for clinical trials in accordance with 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 manufacturers' 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 submissions, 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 timely 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;
- reimbursement and coverage policies of government and private payors such as insurance companies, health maintenance organizations and other plan administrators; and
- the scope and effectiveness of our sales and marketing efforts.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend the use of 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, distribution, and reimbursement management 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 likelihood of commercial success for 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 regulatory approvals to market EFAPROXYN 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, product liability insurance coverage is becoming increasingly expensive, and no assurance can be given that we will be able to maintain product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product 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.

We are currently involved in a securities class action litigation, which could harm our business if management attention is diverted or the claims are decided against us.

We have been named as a defendant in an alleged securities class action lawsuit seeking unspecified damages relating to the issuance of allegedly false and misleading statements regarding EFAPROXYN during the period from May 29, 2003 to April 29, 2004 and subsequent declines in our stock price. We are currently engaged in defending against these claims, which, if decided against us, could have a material adverse effect on our business, financial condition and results of operations. The costs incurred in connection with this lawsuit could be significant and may not be covered by our insurance policies. This lawsuit could also result in continued diversion of our time and attention away from business operations, which could harm our business.

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 54 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 our relationships with academic institutions and scientists. 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, and, if approved, pricing, marketing, 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

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. 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.

If the shares of Exchangeable Preferred that we sold to Warburg Pincus Private Equity VIII, L.P. ("Warburg") in March 2005 are exchanged for shares of common stock, Warburg will control a substantial percentage of the voting power of our outstanding common stock.

On March 2, 2005, we entered into a Securities Purchase Agreement with Warburg and certain other investors pursuant to which we issued and sold an aggregate of 2,352,443 shares of Series A Exchangeable Preferred Stock (the "Exchangeable Preferred") at a price per share of $22.10, of which 2,262,443 shares were issued and sold to Warburg on March 4, 2005. Pursuant to the terms of the Exchangeable Preferred, upon the approval on or prior to June 4, 2006 of holders of our common stock as required by applicable rules of the Nasdaq National Market, each share of Exchangeable Preferred will be automatically exchanged for ten shares of our common stock (subject to appropriate adjustment in the event of any stock split, stock dividend and the like affecting our common stock). We intend to seek stockholder approval of such exchange at our 2005 Annual Meeting of Stockholders, which is currently scheduled for May 18, 2005.

Assuming that the shares of Exchangeable Preferred held by Warburg are exchanged for shares of common stock, Warburg will control approximately 41% of the voting power of our outstanding common stock, based on the number of shares of common stock and Exchangeable Preferred outstanding as of March 4, 2005. Therefore, Warburg would be able to exercise substantial influence over any actions requiring stockholder approval. However, in connection with its purchase of Exchangeable Preferred, Warburg entered into a standstill agreement agreeing not to pursue, for four years, certain activities the purpose or effect of which may be to change or influence the control of Allos.

If our shares of Exchangeable Preferred are not exchanged for common stock and remain outstanding, they will be entitled to accrued dividends and we may be forced to redeem all such shares, which could require substantial cash outlay and would adversely affect our financial position.

Dividends on each share of Exchangeable Preferred will be cumulative and will begin to accrue starting one year from the date of original issuance of such share, at an annual rate of 10% of the purchase price per share, compounded quarterly. If the Exchangeable Preferred remains outstanding as of the later of March 4, 2009 or thirty days after we publicly announce the results of our ENRICH trial, holders of the outstanding Exchangeable Preferred may cause us, at any time thereafter, to redeem all shares of Exchangeable Preferred for cash by paying the original purchase price per share plus all accumulated and unpaid dividends, or if greater, an amount per share equal to ten times the 20-day trailing average closing price of our common stock on Nasdaq preceding the date of the redemption. Such redemption would require us to expend substantial cash resources and could have a material adverse affect on our financial position. In addition, our cash reserves at the time of such redemption may be insufficient to satisfy such redemption, in which case we may not be able to continue as a going concern if we are unable to support our operations or cannot otherwise raise the necessary funds to support our operations.

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. Notwithstanding the foregoing, the three year moratorium imposed on business combinations by Section 203 will not apply to Warburg because, prior to the date on which Warburg became an interested stockholder, our board of directors approved the transaction which resulted in Warburg becoming an interested stockholder. However, in connection with its purchase of Exchangeable Preferred, Warburg entered into a standstill agreement agreeing not to pursue, for four years, certain activities the purpose or effect of which may be to chance or influence the control of Allos.

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.

Because Warburg will, upon exchange of the Exchangeable Preferred for shares of common, if approved by our stockholders, own a substantial percentage of our outstanding common stock, we amended the stockholder rights plan in connection with Warburg's purchase of the Exchangeable Preferred to provide that Warburg and its affiliates will be exempt from the stockholder rights plan, unless Warburg and its affiliates become, without our prior consent, the beneficial owner of more than 44% of our common stock, calculated as if all shares of Exchangeable Preferred (and including any accrued dividends thereon) have been exchanged for common stock as of immediately following the original issuance of the Exchangeable Preferred. Under the stockholder rights plan, our Board of Directors has express authority to amend the rights plan without stockholder approval.

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, including EFAPROXYN, 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.

Substantial sales of shares may impact the market price of our common stock.

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exchange of the Exchangeable Preferred, the market price of our common stock may decline. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we consider appropriate. We are unable to predict the effect that sales may have on the then prevailing market price of our common stock. Pursuant to a Registration Rights Agreement entered into between us and the purchasers of Exchangeable Preferred, beginning on March 4, 2007, the purchasers of Exchangeable Preferred will be entitled to certain registration rights with respect to the shares of common stock, if any, issued upon exchange of the Exchangeable Preferred.

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 on October 31, 2008. In January 2005, we entered into agreements to sublease 9,420 square feet of this space to two other entities.

We believe that our leased facilities are adequate to meet our needs until such time, if any, as we receive regulatory approval to market one or more of our product candidates.

ITEM 3. LEGAL PROCEEDINGS

The Company and one of our officers have been named as defendants in a purported securities class action lawsuit filed in May 2004 in the United States District Court for the District of Colorado. An amended complaint was filed in August 2004. The lawsuit is brought on behalf of a purported class of purchasers of our securities during the period from April 23, 2003 to April 29, 2004, and is seeking unspecified damages relating to the issuance of allegedly false and misleading statements regarding EFAPROXYN during this period and subsequent declines in our stock price. As is typical in this type of litigation, several other purported securities class action lawsuits containing substantially similar allegations were filed against the defendants, but the plaintiffs in all of those cases have subsequently dismissed their actions. Additional lawsuits containing substantially similar allegations may be filed in the future. These lawsuits have been tendered to our insurance carriers.

We believe the claims set forth in the pending lawsuit are without merit, and we intend to vigorously defend against them. On October 12, 2004, we filed a motion to dismiss the case with prejudice. That motion remains pending. As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. If we are not successful in our defense against such claims, we could be forced to make significant payments to the plaintiffs, and such payments could have a material adverse effect on our business, financial condition, results of operations and cash flows to the extent such payments are not covered by our insurance carriers. Even if our defense against such claims is successful, the litigation could result in substantial costs and divert management's attention and resources, which could adversely affect our business.

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 2004.

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, 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

Year Ended December 31, 2004	HIGH	LOW
First Quarter	$5.90	$3.25
Second Quarter	$5.18	$1.54
Third Quarter	$2.45	$1.59
Fourth Quarter	$3.02	$1.73

On March 7, 2005, we had approximately 75 registered holders of record of our common stock.

Dividends

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

On March 2, 2005, we entered into a Securities Purchase Agreement with Warburg Pincus Private Equity VIII, L.P. and certain other investors pursuant to which we issued and sold an aggregate of 2,352,443 shares of our Series A Exchangeable Preferred Stock (the "Exchangeable Preferred") at a price per share of $22.10 (the "Preferred Purchase Price"), for aggregate gross proceeds of approximately $52.0 million. Beginning on March 4, 2006 and for so long as the Exchangeable Preferred remains outstanding, the holders of the Exchangeable Preferred will be entitled to receive, in preference to our common stock and each other class of our equity securities, cumulative dividends at an annual rate of 10% of the Preferred Purchase Price, compounded quarterly beginning with amounts accrued for the quarter ending March 31, 2006. Such dividends will be payable when such shares of Exchangeable Preferred are exchanged for shares of common stock, when such shares of Exchangeable Preferred are redeemed by us, upon a liquidation or change in control or otherwise when and as declared by our board of directors. If paid in connection with the exchange of the Exchangeable Preferred for shares of common stock, we will pay such dividends in shares of our common stock in an amount equal to the dividends that would have been payable through the exchange date had such dividends been paid in cash divided by a price per share of $2.21 for such common stock (subject to appropriate adjustment for stock splits, stock dividends and the like). If paid in connection with a redemption of the Exchangeable Preferred, we will pay such dividends in cash for amounts accrued through the redemption date. If paid in connection with a liquidation or change in control, we will pay such dividends in cash for amounts accrued through the payment date. Otherwise, we may pay such dividends when and as declared by our board of directors, in cash, additional shares of Exchangeable Preferred or a combination thereof, in our sole discretion. For a more complete description of the terms of the Exchangeable Preferred and related matters, please refer to the "Recent Development" section of Item 7 below.

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, 2004, we have used all 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.

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 to be set forth in the section entitled "Securities Authorized for Issuance Under Equity Compensation Plans" in our definitive Proxy Statement for the 2005 Annual Meeting of Stockholders to be filed with the Commission within 120 days after the end of our fiscal year ended December 31, 2004 (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, 2002, 2003, 2004, and cumulative period from September 1, 1992 through December 31, 2004, and the balance sheet data as of December 31, 2003 and 2004, 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, 2000 and 2001, and the balance sheet data as of December 31, 2000, 2001 and 2002, 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,
	2000	2001	2002	2003	2004	2004
	(in thousands, except share and per share data)					
Statement of Operations Data:						
Operating expenses:						
Research and development	$ 10,737	$ 12,660	$ 13,860	$ 11,957	$ 10,158	$ 82,318
Clinical manufacturing	3,200	3,143	3,776	7,252	2,979	25,515
Marketing, general and administrative	13,775	9,277	10,444	9,378	9,194	59,239
Restructuring costs	—	—	—	638	—	638
Total operating expenses	27,712	25,080	28,080	29,225	22,331	167,710
Loss from operations	(27,712)	(25,080)	(28,080)	(29,225)	(22,331)	(167,710)
Gain on settlement claims	—	—	—	5,110	—	5,110
Interest and other income, net	4,351	4,936	2,311	988	494	14,626
Net loss	(23,361)	(20,144)	(25,769)	(23,127)	(21,837)	(147,974)
Dividend related to beneficial conversion feature of preferred stock	—	—	—	—	—	(9,613)
Net loss attributable to common stockholders	$ (23,361)	$ (20,144)	$ (25,769)	$ (23,127)	$ (21,837)	$(157,587)
Net loss per share: basic and diluted	$ (1.29)	$ (0.88)	$ (1.03)	$ (0.87)	$ (0.70)	
Weighted-average shares used in computing basic and diluted net loss per share	18,058,802	22,970,974	24,942,496	26,493,861	31,139,192	

	As of December 31,				
	2000	2001	2002	2003	2004
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and investments in marketable securities	$ 61,777	$ 59,219	$ 54,433	$ 44,897	$ 23,711
Long-term investments in marketable securities	23,906	9,843	5,816	150	138
Working capital	59,170	55,654	48,679	43,806	22,745
Total assets	86,259	72,174	64,401	48,174	26,173
Long-term obligations, less current portion	8	—	—	—	—
Common stock	156,625	156,948	171,046	181,446	181,485
Deficit accumulated during the development stage	(66,710)	(86,854)	(112,623)	(135,750)	(157,587)
Total stockholders' equity	83,411	67,151	57,322	45,411	23,863

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 three product candidates that are currently under development, EFAPROXYN™ (efaproxiral), formerly known as RSR13, PDX (pralatrexate) and RH1. 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, 2002, 2003 and 2004, we had net losses of $25.8 million, $23.1 million and $21.8 million, respectively. As of December 31, 2004, we had an accumulated deficit of $157.6 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 EFAPROXYN 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.

As of December 31, 2004, we had $23.8 million in cash, cash equivalents, and investments in marketable securities. We believe that our existing cash, cash equivalents and investments, along with the $49.0 million of net proceeds from the March 2005 Exchangeable Preferred financing described below, will be adequate to satisfy our capital needs for at least the next twenty-four months.

Recent Development

On March 2, 2005, we entered into a Securities Purchase Agreement with Warburg Pincus Private Equity VIII, L.P. ("Warburg") and certain other investors pursuant to which we issued and sold an aggregate of 2,352,443 shares of Series A Exchangeable Preferred Stock (the "Exchangeable Preferred") at a price per share of $22.10 (the "Preferred Purchase Price"), for aggregate gross proceeds of approximately $52.0 million. We incurred offering expenses of approximately $3.0 million in connection with the sale of the Exchangeable Preferred, resulting in net proceeds to the Company of approximately $49.0 million. The shares were sold under our shelf Registration Statement on Form S-3 (File No. 333-113353) declared effective by the Securities and Exchange Commission on April 21, 2004. The closing of the sale of 2,262,443 shares of Exchangeable Preferred to Warburg occurred on March 4, 2005. The closing of the sale of an additional 90,000 shares of Exchangeable Preferred to certain other investors occurred on March 8, 2005.

The rights, preferences and privileges of the Exchangeable Preferred are set forth in the Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Exchangeable Preferred Stock of Allos Therapeutics, Inc. filed with the Secretary of State of the State of Delaware on March 3, 2005 (the "Certificate of Designations"). Pursuant to the Certificate of Designations, the Exchangeable Preferred ranks senior to our common stock and each other class of our equity securities with respect to dividend rights and rights upon liquidation, winding up or dissolution, and is non-voting stock,

except as otherwise required by Delaware law and subject to a right of its holders to consent to any amendment of its terms.

Beginning on March 4, 2006 and for so long as the Exchangeable Preferred remains outstanding, the holders of the Exchangeable Preferred will be entitled to receive, in preference to our common stock and each other class of our equity securities, cumulative dividends at an annual rate of 10% of the Preferred Purchase Price, compounded quarterly beginning with amounts accrued for the quarter ending March 31, 2006. Except as set forth below, such dividends will be payable when and as declared by our board of directors, in cash, additional shares of Exchangeable Preferred or a combination thereof.

Upon the approval of the holders of our common stock as required by the applicable rules of the Nasdaq National Market, and subject to the receipt of any necessary approval pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Approval"), each share of Exchangeable Preferred will be automatically exchanged for 10 shares of common stock (subject to appropriate adjustments in the event of any stock dividend, stock split, stock distribution or combination, subdivision, reclassification or other corporate action having the similar effect with respect to our common stock); provided that such approvals are obtained by June 4, 2006. Upon any such exchange, all accrued but unpaid dividends (whether or not declared) on the Exchangeable Preferred, if any, will be paid in shares of common stock in an amount equal to the dividends accrued through the exchange date divided by a price per share of $2.21 for such common stock. If the HSR Approval and stockholder approval are not obtained by June 4, 2006, then the Exchangeable Preferred will remain outstanding pursuant to its terms and will not be exchanged for shares of common stock. We intend to seek stockholder approval of the exchange at our 2005 Annual Meeting of Stockholders, to be held on May 18, 2005.

If the Exchangeable Preferred remains outstanding on the later of (i) March 4, 2009 and (ii) thirty days after we publicly announce the results of our ENRICH trial (the "Redemption Eligibility Date"), the holders of a majority of the outstanding shares of Exchangeable Preferred will have the option, at any time thereafter, to cause us to redeem all (but not less than all) of their outstanding shares of Exchangeable Preferred for cash in a per share amount equal to the greater of (a) the Preferred Purchase Price plus all accrued but unpaid dividends (whether or not declared) through the date of such redemption or (b) ten times the average closing price of our common stock on the Nasdaq National Market for the twenty trading days immediately preceding the date of any such redemption (the "Redemption Price"). In addition, if the Exchangeable Preferred remains outstanding on the Redemption Eligibility Date, we will have the option, at any time thereafter, to voluntarily redeem all (but not less than all) of the outstanding shares of Exchangeable Preferred for cash in a per share amount equal to the Redemption Price.

For so long as the Exchangeable Preferred remains outstanding, upon any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of the Exchangeable Preferred will have the right to receive, before any payments are made to the holders of our common stock or any other class of our equity securities, an amount per share equal to the greater of (i) the Preferred Purchase Price plus all accrued but unpaid dividends (whether or not declared) through the date of payment or (ii) ten times the average closing price of our common stock on the Nasdaq National Market for the twenty trading days immediately preceding the date of payment. In addition, for so long as the Exchangeable Preferred remains outstanding, if we consummate a "change in control" (as defined in the Certificate of Designations), the holders of the Exchangeable Preferred will have the right to receive, before any payments are made to the holders of our common stock or any other class of our equity securities, an amount per share equal to the greater of (i) the Preferred Purchase Price plus all accrued and unpaid dividends (whether or not declared) through the date of such change in control or (ii) ten times the fair market value of the consideration per share of common stock received by the holders of our common stock in the change in control transaction. After payment of the full

amount of the distributions to which they are entitled in connection with any liquidation or change in control, the holders of Exchangeable Preferred will have no right or claim to any of our remaining assets.

Pursuant to the Securities Purchase Agreement, for so long as Warburg owns at least two-thirds of the number of shares of Exchangeable Preferred acquired by it under the Securities Purchase Agreement (or two-thirds of the shares of common stock issued upon exchange of such Exchangeable Preferred, if applicable), we will nominate and use our reasonable best efforts to cause to be elected and cause to remain as directors on our board of directors two individuals designated by Warburg (each, an "Investor Designee" and collectively, the "Investor Designees"). If Warburg no longer has the right to designate two members of our board of directors, then, for so long as Warburg owns at least 50% of the number of shares of the Exchangeable Preferred acquired by it under the Securities Purchase Agreement (or 50% of shares of common stock issued upon exchange of such Exchangeable Preferred, if applicable), we will nominate and use our reasonable best efforts to cause to be elected and cause to remain as a director on our board of directors, one Investor Designee. In addition, subject to applicable law and the rules and regulations of the SEC and The Nasdaq Stock Market, we will use our reasonable best efforts to cause one of the Investor Designees to be a member of each principal committee of our board of directors. Effective upon the closing of the sale of Exchangeable Preferred to Warburg on March 4, 2005, Messrs. Stewart Hen and Jonathan Leff, each of whom is a Managing Director of Warburg, were appointed to the board of directors pursuant to Warburg's right to nominate directors.

Pursuant to the Securities Purchase Agreement, for so long as Warburg owns at least two-thirds of the number of shares of Exchangeable Preferred acquired by it under the Securities Purchase Agreement (or two-thirds of the shares of common stock issued upon exchange of such Exchangeable Preferred, if applicable), it will have subscription rights with respect to future issuances of equity securities by the Company, subject to certain standard exceptions. If we determine to issue any equity securities not subject to such exceptions, then we must provide notice to Warburg and offer to sell it a pro rata amount of such securities, based on their percentage ownership of our outstanding common stock, calculated as if all shares of Exchangeable Preferred (including any dividends thereon) have been exchanged for shares of common stock as of immediately following the original issuance of the Exchangeable Preferred, on the same terms as we propose to sell such securities to other investors.

In connection with the sale of Exchangeable Preferred, we entered into a Registration Rights Agreement dated March 4, 2005 pursuant to which we granted Warburg and the other investors certain registration rights with respect to the shares of common stock, if any, issued upon exchange of the Exchangeable Preferred. Pursuant to the Registration Rights Agreement, beginning March 4, 2007, Warburg and the other investors will have one demand registration (which may be initiated only by Warburg), two S-3 shelf registrations (which may be initiated only by Warburg) and unlimited piggyback rights with respect to any shares of our common stock then owned by Warburg or such other investors.

In connection with Warburg's purchase of Exchangeable Preferred, Warburg and certain of its affiliates entered into a letter agreement dated March 4, 2005 pursuant to which they have agreed not to pursue, for four years, certain activities the purpose or effect of which may be to change or influence the control of the Company. In addition, with respect to any vote to elect or remove members of our board of directors, Warburg and its affiliates have agreed to vote any shares of common stock owned by Warburg and such affiliates in excess of 33% of our outstanding common stock either as recommended by our board of directors or in the same proportion as the votes of shares of all other common stock voted in such election, at Warburg's option.

In connection with the sale of Exchangeable Preferred to Warburg, we entered into an Amendment dated March 4, 2005 to our Rights Agreement dated May 6, 2003 with Mellon Investor Services LLC, our transfer agent, providing that Warburg and its affiliates are exempt from the Rights

Agreement, unless Warburg and its affiliates become, without the prior consent of our board of directors, the beneficial owner of more than 44% of our common stock, calculated as if all shares of Exchangeable Preferred (including any dividends thereon) have been exchanged for shares of common stock as of immediately following the original issuance of the Exchangeable Preferred.

Results of Operations

Comparison of Years Ended December 31, 2002, 2003 and 2004

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,		
	2002	2003	2004
	(in millions)		
Research and development expenses, as reported	$13.9	$12.0	$10.2
Stock-based compensation expense (recovery)	(1.0)	—	0.2
	$14.9	$12.0	$10.0

The $2.9 million decrease from 2002 to 2003 was due primarily to: (i) a $3.7 million decrease in costs relating to our Phase 3 REACH trial, for which we completed enrollment in 2002, and (ii) a $2.0 million up-front license fee paid in 2002 for PDX, offset by: (a) a $1.6 million increase in costs relating to our Phase 3 trial of EFAPROXYN in NSCLC, (b) a $1.0 million impairment charge recorded in 2003 relating to our investment in N-Gene Research Laboratories, Inc. ("N-Gene"), and (c) a $331,000 increase in trial costs for PDX.

The $2.0 million decrease from 2003 to 2004 was due primarily to: (i) a $2.4 million decrease resulting from close-out costs recorded in 2003 relating to the termination of our Phase 3 trial of EFAPROXYN in NSCLC, (ii) a $1.0 million decrease in personnel costs due to headcount reductions, and (iii) a $1.0 million impairment charge recorded in 2003 relating to our investment in N-Gene, offset by: (a) a $1.2 million increase in costs relating to our Phase 3 ENRICH trial, (b) a $1.0 million milestone payment paid in 2004 under our license agreement for PDX, and (c) a $277,000 increase in regulatory fees for our MAA filing in 2004.

We expect research and development expenses to increase in 2005, due primarily to costs associated with increasing enrollment in our Phase 3 ENRICH trial and our Phase 1 trial of EFAPROXYN in patients with NSCLC. 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.

We charge direct internal and external research and development expenses to the respective development programs. Since our inception through December 31, 2004, we have incurred direct costs of approximately $28.8 million, $4.6 million and $199,000 associated with the research and development expenses of EFAPROXYN, PDX and RH1 respectively, and an aggregate of approximately $5.5 million associated with our other research and development programs, including programs that have been discontinued. 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. Unallocated costs since inception represent an aggregate of approximately $43.2 million of research and development expenses incurred during such period.

The following table summarizes our research and development expenses for the years ended December 31, 2002, 2003 and 2004:

	Years Ended December 31,		
	2002	2003	2004
	(in millions)		
EFAPROXYN	$ 5.5	$ 2.9	$ 1.9
PDX	2.0	0.6	1.9
RH1	—	—	0.2
Other programs	0.5	1.6	—
Unallocated	5.9	6.9	6.2
Total research and development expenses	$13.9	$12.0	$10.2

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, or if, any net cash inflow from any of our current product candidates will commence.

Clinical Manufacturing. Clinical manufacturing expenses include third party manufacturing costs for EFAPROXYN 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,		
	2002	2003	2004
	(in millions)		
Clinical manufacturing expenses	$3.8	$7.3	$3.0

The $3.5 million increase from 2002 to 2003 was due primarily to: (i) a $3.0 million termination fee paid in 2003 associated with the cancellation of our purchase orders for EFAPROXYN bulk drug substance that were placed in preparation for commercialization and (ii) increased development work performed in 2003 to produce clinical trial drug material for PDX.

The $4.3 million decrease from 2003 to 2004 was due primarily to: (i) the $3.0 million termination fee paid in 2003 associated with the cancellation of our purchase orders for EFAPROXYN bulk drug substance that had been placed in anticipation of commercialization, (ii) a $910,000 decrease in third-party manufacturing costs for EFAPROXYN, PDX and BGP-15, a compound for which the Company discontinued development in 2003, (iii) a $187,000 decrease in personnel costs due to headcount reductions, and (iv) a $157,000 decrease in consulting costs.

We currently have a sufficient supply of EFAPROXYN bulk drug substance and formulated drug product to support our EFAPROXYN clinical trial requirements for 2005. In addition, we currently have a sufficient supply of PDX bulk drug substance to support our PDX clinical trial requirements for 2005, although we may need to purchase additional quantities of PDX formulated drug product. As a result, we expect clinical manufacturing expenses to decrease moderately in 2005 as compared to 2004.

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,		
	2002	2003	2004
	(in millions)		
Marketing, general and administrative, as reported	$10.4	$ 9.4	$ 9.2
Stock-based compensation expense (recovery)	1.4	(0.2)	(0.1)
	$ 9.0	$ 9.6	$ 9.3

The $646,000 increase from 2002 to 2003 was due primarily to fees and expenses of $591,000 incurred in 2003 in connection with our settlement of claims with N-Gene.

The $299,000 decrease from 2003 to 2004 was due primarily to: (i) a $591,000 decrease in fees and expenses relating to the N-Gene settlement, and (ii) decreases in insurance costs and marketing expenses of $170,000 and $191,000, respectively, offset by: (a) a $572,000 increase in expenses incurred in 2004 relating to our compliance efforts with the Sarbanes Oxley Act of 2002 and related regulations.

We expect marketing, general and administrative expenses for 2005 to remain approximately level with 2004.

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 and 2004, 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 a one-time settlement fee from Durus Life Sciences Master Fund, Ltd. relating to short-swing trading liabilities under Section 16(b) of the Securities Exchange Act of 1934, as amended.

Interest and Other Income, Net. Interest income, net of interest expense, for 2002, 2003 and 2004 was $2.3 million, $988,000 and $494,000, respectively. The $1.3 million and $494,000 decrease in 2003 and 2004, 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, 2004, we have approximately $121.8 million of net operating loss ("NOL") carryforwards, approximately $6.2 million of research and development ("R&D") credit carryforwards and a $160,000 orphan drug credit carryforward. These carryforwards will expire beginning in 2009. The utilization of these carryforwards to reduce future income taxes will depend on our ability to generate sufficient taxable income prior to the expiration of these carryforwards. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the NOL, R&D credit, and orphan drug credit carryforwards available for use in any given year upon the occurrence of certain events, including significant changes in ownership interest and are subject to review and possible adjustment by the Internal Revenue Service. 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, R&D credit and orphan drug credit carryforwards from tax periods prior to the ownership change. Our NOL, R&D credit and orphan drug credit carryforwards as of December 31, 2004 will likely be subject to annual limitation due to changes in ownership from the March 2005 Series A Exchangeable Preferred Stock financing and previous financings. The amount of these limitations, if any, is unknown, and our NOL,

R&D credit and orphan drug credit carryforwards may expire unused. Additionally, future ownership changes could further limit the utilization of our NOL, R&D credit and orphan drug credit carryforwards.

Stock-based compensation expense (recovery). 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 2002, we recorded $1.5 million of stock-based compensation expense in marketing, general and administrative expenses, a $1.0 million net recovery of stock-based compensation expense in research and development expenses and $90,000 of stock-based compensation expense in clinical manufacturing expenses. The recovery of stock-based compensation expense recorded in research and development is due to the cancellation of a former employee's unvested options in 2002, resulting in the recovery of $1.2 million of stock-based compensation expense recorded in prior periods. During 2003, we recorded a net recovery of stock-based compensation expense of $210,000 in marketing, general and administrative expenses, and stock-based compensation expense of $17,000 and $50,000 in research and development and clinical manufacturing expenses, respectively. The net recovery of stock-based compensation expense 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, partially offset by $552,000 of other stock-based compensation expense for 2003. During 2004, we recorded $131,000 in stock-based compensation expense. At December 31, 2004, we had $35,000 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 $164.8 million through December 31, 2004. We have used $121.8 million of cash for operating activities through December 31, 2004. Cash, cash equivalents, and short-term investments in marketable securities were $54.4 million, $44.9 million and $23.7 million at December 31, 2002, 2003 and 2004, respectively. Working capital was $43.8 million and $22.7 million at December 31, 2003 and 2004, respectively. Net cash used in operating activities for 2002, 2003 and 2004 was $21.9 million, $26.2 million and $21.1 million, respectively. Cash used in operating activities was primarily to fund net losses, excluding non-cash charges.

Net cash provided by investing activities for 2002, 2003 and 2004 was $7.6 million, $15.7 million and $17.4 million, respectively, and consisted primarily of proceeds from the maturities of investments in marketable securities, partially offset by the purchase of short-term investments in marketable securities, acquisition of property and equipment and the investment in equity of another company in 2002.

Net cash provided by financing activities during 2002, 2003, and 2004 was $15.3 million, $11.4 million, and $158,000 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	$784,351	$1,618,575	$ 772,515	$5,651	$3,181,092
Other long-term obligations	—	1,000,000	1,000,000	—	2,000,000
Total contractual cash obligations	$784,351	$2,618,575	$1,772,515	$5,651	$5,181,092

Other long-term obligations represent future milestone payments under our license agreement for PDX, due upon the passage of certain time periods after the effective date of the agreement, which could be paid earlier depending on the timing of achieving a development milestone.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents, and investments in marketable securities, along with the $49.0 million of net proceeds from the March 2005 Series A Exchangeable Preferred Stock financing, will be adequate to satisfy our capital needs for at least the next twenty-four months. We anticipate continuing our current development programs and/or 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 may 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 may raise additional capital in the future through arrangements with corporate partners, equity or debt financings, or from other sources. 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. If we are unable to generate meaningful amounts of revenue from future product sales, if any, or cannot otherwise raise sufficient additional funds to support our operations, we may 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 costs incurred by 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, 2004. 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 EFAPROXYN. 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 ABOUT 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 13(a)-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 as of December 31, 2004 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.

Management's Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining effective internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or Rule 15d-(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that:

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2004. In making its assessment, management used the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management determined that, as of December 31, 2004, we maintained effective internal control over financial reporting based on those criteria.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report on page F-2 of this Annual Report on Form 10-K.

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 to be 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 to be 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 to be set forth in the section of the Proxy Statement entitled "Compensation of Executive Officers."

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 to be 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 to be set forth in the section of the Proxy Statement entitled "Securities Authorized for Issuance under Equity Compensation Plans."

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 to be set forth in the section of the Proxy Statement entitled "Certain Relationships and Related 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 to be set forth in the section of the Proxy Statement entitled "Principal Accountant Fees and Services."

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.	Note	Description
3.01		Amended and Restated Certificate of Incorporation.
3.02		Certificate of Designation of Series A Junior Participating Preferred Stock.
3.03		Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Exchangeable Preferred Stock.
3.04		Bylaws.
4.01	(1)	Form of Common Stock Certificate.
4.02		Reference is made to Exhibits 3.01, 3.02, 3.03 and 3.04.
4.03	(2)	Rights Agreement dated May 6, 2003 between Allos and Mellon Investor Services LLC.
4.04	(3)	Form of Rights Certificate.
4.05	(4)	Amendment to Rights Agreement dated March 4, 2005 between Allos and Mellon Investor Services LLC.
4.06		Form of Series A Exchangeable Preferred Stock Certificate.
10.01†	(5)	Form of Indemnification Agreement between Allos and each of its directors and officers.
10.02	(6)	Hemotech and CIT Amended and Restated Allosteric Modifiers of Hemoglobin Agreement with Center for Innovative Technology dated January 12, 1994.
10.03	(7)	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	(8)	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	(9)	Assignment and Assumption Agreement with Amendment with Center for Innovative Technology and Virginia Commonwealth University Intellectual Property Foundation dated July 28, 1997.
10.06	(10)	Fourth Amended and Restated Stockholder Rights Agreement dated October 4, 1999 between Allos and the parties listed on Exhibit A thereto.
10.07†	(11)	1995 Stock Option Plan, as amended.
10.08*	(12)	Term Sheet for Contract API Supply dated March 25, 1999 between Allos and Hovione Inter Limited.
10.09	(13)	Confirmatory letter agreement dated January 13, 2000 between Allos and Hovione Inter Limited.
10.10†	(14)	2000 Stock Incentive Compensation Plan.

Exhibit No.	Note	Description
10.10.1†	(15)	Form of Incentive Stock Option Letter Agreement under 2000 Stock Incentive Compensation Plan.
10.10.2†	(16)	Form of Nonstatutory Stock Option Letter Agreement under 2000 Stock Incentive Compensation Plan.
10.11†	(17)	Severance Benefit Plan, effective January 16, 2001, and related benefit schedule thereto.
10.12†	(18)	2001 Employee Stock Purchase Plan and form of Offering.
10.13*	(19)	Office Lease dated April 4, 2001 between Allos and Catellus Development Corporation.
10.13.1*	(20)	Amended and Restated Second Amendment to Lease dated December 9, 2002 between Allos and Catellus Development Corporation.
10.13.2*	(21)	Third Amendment to Lease dated November 28, 2003 between Allos and Catellus Development Corporation.
10.14†	(22)	2002 Broad Based Equity Incentive Plan.
10.14.1†		Form of Stock Option Grant Notice under 2002 Broad Based Equity Incentive Plan.
10.14.2†		Form of Stock Option Agreement under 2002 Broad Based Equity Incentive Plan.
10.15†	(23)	Employment Agreement dated December 17, 2001 between Allos and Michael E. Hart.
10.16	(24)	Securities Purchase Agreement dated April 24, 2002 between Allos and Perseus-Soros BioPharmaceutical Fund, L.P.
10.17	(25)	Registration Rights Agreement dated April 24, 2002 between Allos and Perseus-Soros BioPharmaceutical Fund, L.P.
10.18†	(26)	Employment Agreement, effective August 12, 2002, between Allos and David A. DeLong.
10.19	(27)	Securities Purchase Agreement dated November 20, 2003 between Allos and the Purchasers listed on Exhibit A thereto.
10.20	(28)	Form of Common Stock Purchase Warrant issued pursuant to Securities Purchase Agreement dated November 20, 2003.
10.21*	(29)	Development and Supply Agreement, effective December 19, 2003, between Allos and Baxter Healthcare Corporation.
10.22†	(30)	Separation Agreement effective May 30, 2003, between Allos and Daniel R. Hudspeth.
10.23†	(31)	Employment Agreement dated October 11, 2004 between Allos and Marc H. Graboyes.
10.24	(32)	Securities Purchase Agreement dated March 2, 2005 between Allos and the Investors listed on the signature pages thereto.
10.25	(33)	Registration Rights Agreement dated March 4, 2005 between Allos and the Investors listed on Schedule I thereto.

Exhibit No.	Note	Description
10.26	(34)	Letter Agreement dated March 4, 2005 among Allos, Warburg Pincus Private Equity VIII, L.P., Warburg Pincus & Co. and Warburg Pincus LLC.
23.01		Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.01		Power of Attorney (included on signature page hereto).
31.01		Rule 13a-14(a)/15d-14(a) Certification.
32.01		Section 1350 Certification.

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

* Confidential treatment has been granted with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission ("SEC").

(1) Incorporated by reference to the same numbered exhibit filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(2) Incorporated by reference to Exhibit 99.2 filed with our Current Report on Form 8-K dated May 9, 2003.

(3) Incorporated by reference to Exhibit 99.3 filed with our Current Report on Form 8-K dated May 9, 2003.

(4) Incorporated by reference to Exhibit 4.06 filed with our Current Report on Form 8-K dated March 4, 2005.

(5) Incorporated by reference to the same numbered exhibit filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(6) Incorporated by reference to the same numbered exhibit filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(7) Incorporated by reference to the same numbered exhibit filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(8) Incorporated by reference to the same numbered exhibit filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(9) Incorporated by reference to the same numbered exhibit filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(10) Incorporated by reference to Exhibit 10.10 filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(11) Incorporated by reference to Exhibit 10.11 filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(12) Incorporated by reference to Exhibit 10.18 filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(13) Incorporated by reference to Exhibit 10.19 filed with our Registration Statement on Form S-1 (File No. 333-95439), as amended, declared effective March 27, 2000.

(14) Incorporated by reference to Exhibit 99.2 filed with our Registration Statement on Form S-8 (File No. 333-38696), as filed with the SEC on June 6, 2000.

(15) Incorporated by reference to Exhibit 99.1 filed with our Current Report on Form 8-K dated February 11, 2005.

(16) Incorporated by reference to Exhibit 99.2 filed with our Current Report on Form 8-K dated February 11, 2005.

(17) Incorporated by reference to Exhibit 10.24 filed with our Annual Report on Form 10-K for the year ended December 31, 2000.

(18) Incorporated by reference to Exhibit 10.26 filed with our Annual Report on Form 10-K for the year ended December 31, 2000.

(19) Incorporated by reference to Exhibit 10.27 filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(20) Incorporated by reference to Exhibit 10.27.1 filed with our Annual Report on Form 10-K for the year ended December 31, 2002.

(21) Incorporated by reference to Exhibit 10.27.2 filed with our Annual Report on Form 10-K for the year ended December 31, 2003.

(22) Incorporated by reference to Exhibit 99.1 filed with our Registration Statement on Form S-8 (File No. 333-76804), as filed with the SEC on January 16, 2002.

(23) Incorporated by reference to Exhibit 10.16 filed with our Annual Report on Form 10-K for the year ended December 31, 2001.

(24) Incorporated by reference to Exhibit 10.23 filed with our Current Report on Form 8-K dated April 30, 2002.

(25) Incorporated by reference to Exhibit 10.24 filed with our Current Report on Form 8-K dated April 30, 2002.

(26) Incorporated by reference to Exhibit 10.26 filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(27) Incorporated by reference to Exhibit 99.1 filed with our Current Report on Form 8-K dated November 21, 2003.

(28) Incorporated by reference to Exhibit 99.2 filed with our Current Report on Form 8-K dated November 21, 2003.

(29) Incorporated by reference to Exhibit 10.37 filed with our Annual Report on Form 10-K for the year ended December 31, 2003.

(30) Incorporated by reference to Exhibit 10.38 filed with our Annual Report on Form 10-K for the year ended December 31, 2003.

(31) Incorporated by reference to Exhibit 10.1 filed with our Current Report on Form 8-K dated October 14, 2004.

(32) Incorporated by reference to Exhibit 10.41 filed with our Current Report on Form 8-K/A dated March 10, 2005.

(33) Incorporated by reference to Exhibit 10.42 filed with our Current Report on Form 8-K/A dated March 10, 2005.

(34) Incorporated by reference to Exhibit 10.43 filed with our Current Report on Form 8-K dated March 4, 2005.

(b) Reports on Form 8-K:

On October 4, 2004, we furnished a report on Form 8-K, reporting under Items 8.01 and 9.01 that we had issued a press release announcing the presentation of new findings from a Phase 3 clinical trial of the investigational radiation sensitizer EFAPROXYN in patients with brain metastases.

On October 5, 2004, we furnished a report on Form 8-K, reporting under Items 8.01 and 9.01 that we had issued a press release announcing the presentation of study results from a Phase 3 clinical trial of the investigational radiation sensitizer EFAPROXYN in patients with brain metastases.

On October 13, 2004, we furnished a report on Form 8-K, reporting under Items 1.01, 5.02, 8.01 and 9.01 that we entered into a material definitive agreement with Marc Graboyes in connection with the appointment of Mr. Graboyes as Vice President, General Counsel of Allos.

On November 3, 2004, we furnished a report on Form 8-K, reporting under Items 8.01 and 9.01 that we had issued a press release announcing the presentation of updated results from a Phase 3 clinical trial of the investigational radiation sensitizer EFAPROXYN in patients with brain metastases.

On November 9, 2004, we furnished a report on Form 8-K, reporting under Items 2.02 and 9.01 that we had issued an announcement of our third quarter 2004 financial results.

On December 16, 2004, we furnished a report on Form 8-K, reporting under Items 8.01 and 9.01 that we had issued a press release announcing the acquisition of an exclusive worldwide license from the University of Colorado Health Sciences Center, the University of Salford, and Cancer Research Technology to develop and commercialize a new chemotherapeutic agent known as RH1.

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 14, 2005

By: /s/ MICHAEL E. HART

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

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant on March 14, 2005, and in the capacities indicated:

Name	Title
/s/ STEPHEN J. HOFFMAN Stephen J. Hoffman	Chairman of Board of Directors and Director
/s/ MICHAEL E. HART Michael E. Hart	President, Chief Executive Officer, Chief Financial Officer and Director (Principal Executive Officer and Principal Financial Officer)
/s/ DAVID C. CLARK David C. Clark	Corporate Controller and Treasurer (Principal Accounting Officer)
/s/ MICHAEL D. CASEY Michael D. Casey	Director
/s/ MARK G. EDWARDS Mark G. Edwards	Director
/s/ STEWART HEN Stewart Hen	Director
/s/ MARVIN E. JAFFE Marvin E. Jaffe	Director
/s/ JONATHAN S. LEFF Jonathan S. Leff	Director

Allos Therapeutics, Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

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

We have completed an integrated audit of Allos Therapeutics, Inc.'s 2004 financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Financial statements

In our opinion, the accompanying balance sheets and the related statements of operations, changes in stockholders' equity (deficit), and cash flows present fairly, in all material respects, the financial position of Allos Therapeutics, Inc. (a development stage enterprise) at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 and, cumulatively, for the period from September 1, 1992 (date of inception) to December 31, 2004, 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements 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.

Internal control over financial reporting

Also, in our opinion, management's assessment, Management's Report on Internal Control Over Financial Reporting, appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

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

Denver, Colorado
March 16, 2005

ALLOS THERAPEUTICS, INC.
BALANCE SHEETS

	December 31, 2003	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,642,305	$ 1,108,726
Restricted cash	550,000	550,000
Investments in marketable securities	40,254,935	22,601,805
Prepaid research and development expenses	286,573	272,061
Prepaid expenses and other assets	834,249	522,591
Total current assets	46,568,062	25,055,183
Investments in marketable securities	150,182	138,055
Property and equipment, net	1,455,486	980,242
Total assets	$ 48,173,730	$ 26,173,480
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable—related parties	$ 114,483	$ 47,000
Trade accounts payable and accrued expenses	462,774	601,345
Accrued research and development expenses	1,173,856	894,977
Accrued bonus and employee benefits	1,011,340	767,155
Total current liabilities	2,762,453	2,310,477
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2003 and December 31, 2004; 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 and December 31, 2004; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 75,000,000 shares authorized at December 31, 2003 and December 31, 2004; 31,103,455 and 31,175,783 shares issued and outstanding at December 31, 2003 and December 31, 2004, respectively	31,104	31,176
Additional paid-in capital	181,415,293	181,453,476
Deferred compensation related to stock-based compensation	(285,576)	(34,820)
Deficit accumulated during the development stage	(135,749,544)	(157,586,829)
Total stockholders' equity	45,411,277	23,863,003
Total liabilities and stockholders' equity	$ 48,173,730	$ 26,173,480

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, 2004
	2002	2003	2004	
Operating expenses:				
Research and development	$ 13,860,208	$ 11,957,249	$ 10,158,553	$ 82,317,819
Clinical manufacturing	3,775,921	7,251,807	2,978,684	25,515,125
Marketing, general and administrative	10,443,646	9,378,093	9,193,719	59,238,486
Restructuring costs	—	638,070	—	638,070
Total operating expenses	28,079,775	29,225,219	22,330,956	167,709,500
Loss from operations	(28,079,775)	(29,225,219)	(22,330,956)	(167,709,500)
Gain on settlement claims	—	5,110,083	—	5,110,083
Interest and other income, net	2,310,801	988,511	493,671	14,625,563
Net loss	(25,768,974)	(23,126,625)	(21,837,285)	(147,973,854)
Dividend related to beneficial conversion feature of preferred stock	—	—	—	(9,612,975)
Net loss attributable to common stockholders	$(25,768,974)	$(23,126,625)	$(21,837,285)	$(157,586,829)
Net loss per share: basic and diluted	$ (1.03)	$ (0.87)	$ (0.70)	
Weighted average shares: basic and diluted	24,942,496	26,493,861	31,139,192	

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
Issuance of common stock upon exercise of stock options for cash of $97,794 at $.40 - $4.75 per share	35,935	36	—	—	97,758	—	—	—	97,794
Issuance of common stock upon exercise of purchase rights at an exercise price of $1.85 - $1.91 per share	36,393	36	—	—	68,239	—	—	—	68,275
Stock issuance costs	—	—	—	—	(8,279)	—	—	—	(8,279)
Stock compensation recovery	—	—	—	—	(170,118)	—	—	—	(170,118)
Deferred compensation related to options	—	—	—	—	50,583	—	250,756	—	301,339
Net loss	—	—	—	—	—	—	—	(21,837,285)	(21,837,285)
Balance at December 31, 2004	31,175,783	$31,176	—	$—	$181,453,476	$—	$ (34,820)	$(157,586,829)	$ 23,863,003

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, 2004
	2002	2003	2004	
Cash Flows From Operating Activities:				
Net loss	$(25,768,974)	$(23,126,625)	$(21,837,285)	$(147,973,854)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	489,900	602,354	530,386	2,373,907
Stock-based compensation expense (recovery)	575,925	(143,188)	131,221	21,566,233
Write-off of long-term investment	—	1,000,000	—	1,000,000
Other	21,531	(6,271)	558	98,942
Changes in operating assets and liabilities:				
Prepaids and other assets	133,737	(335,746)	326,170	(784,653)
Interest receivable on investments	545,219	175,258	201,354	(422,552)
Accounts payable—related parties	29,025	2,827	(67,483)	3,405,265
Trade accounts payable and accrued expenses	49,327	53,895	138,571	601,345
Accrued research and development expenses	1,676,505	(3,943,544)	(278,879)	(2,463,287)
Accrued bonus and employee benefits	300,450	(429,385)	(244,185)	767,155
Net cash used in operating activities	(21,947,355)	(26,150,425)	(21,099,572)	(121,831,499)
Cash Flows From Investing Activities:				
Acquisition of property and equipment	(662,589)	(235,292)	(55,700)	(3,099,964)
Purchases of marketable securities	(46,028,561)	(45,204,196)	(39,706,097)	(322,865,160)
Proceeds from sales of marketable securities	55,307,500	61,116,360	57,170,000	300,547,852
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	7,616,350	15,676,872	17,408,203	(26,367,585)
Cash Flows From Financing Activities:				
Principal payments under capital leases	—	—	—	(422,088)
Proceeds from sales leaseback	—	—	—	120,492
Pledging restricted cash	—	—	—	(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	411,032	157,185	166,069	978,985
Proceeds from issuance of common stock, net of issuance costs	14,931,773	11,201,722	(8,279)	108,894,612
Net cash provided by financing activities	15,342,805	11,358,907	157,790	149,307,810
Net increase (decrease) in cash and cash equivalents	1,011,800	885,354	(3,533,579)	1,108,726
Cash and cash equivalents, beginning of period	2,745,151	3,756,951	4,642,305	—
Cash and cash equivalents, end of period	$ 3,756,951	$ 4,642,305	$ 1,108,726	$ 1,108,726
Supplemental Schedule of Cash and Non-cash Operating and Financing Activities:				
Cash paid for interest	$ 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.

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 three product candidates that are currently under development, EFAPROXYN™ (efaproxiral), PDX (pralatrexate) and RH1.

- EFAPROXYN is the first synthetic small molecule designed to sensitize hypoxic, or oxygen-deprived, areas of tumors during 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 EFAPROXYN has the potential to enhance the efficacy of standard radiation therapy.
- PDX is a small molecule chemotherapeutic agent that inhibits dihydrofolate reductase, or DHFR, a folic acid (folate)-dependent enzyme involved in the building of nucleic acid, or DNA, and other processes. Preclinical data suggests that PDX has an enhanced potency and toxicity profile relative to methotrexate and other related DHFR inhibitors. Drugs that inhibit DHFR, such as methotrexate, were among the first antifolate chemotherapeutic agents discovered. Methotrexate remains one of the most widely applied antifolate chemotherapeutics and has been used to treat leukemia, breast, bladder, gastric, esophageal, head, and neck cancers. We believe PDX has the potential to be delivered as a single agent or in combination therapy regimens.
- RH1, acquired in December 2004, is a small molecule chemotherapeutic agent that is bioactivated by the enzyme DT-diaphorase, or DTD, which is over-expressed in many tumors relative to normal tissue, including lung, colon, breast and liver tumors. Because RH1 is bioactivated in the presence of DTD, it has the potential to provide targeted drug delivery to these tumor types while limiting the toxicity to normal tissue. RH1 has undergone in vivo efficacy testing by the Developmental Therapeutics Program of the National Cancer Institute and has demonstrated significant activity in both non-small cell lung cancer and ovarian xenograft models.

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.

We have never generated any revenue from product sales and have experienced significant net losses since our inception in 1992. We have incurred these losses principally from costs incurred in our research and development programs and from our general and administrative expenses. 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 EFAPROXYN as an adjunct to radiation therapy for the treatment of brain metastases originating 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.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and investments in marketable securities, along with the $49.0 million of net proceeds from the March 2005 Series A Exchangeable Preferred Stock financing (See Note 13), will be adequate to satisfy our capital needs for at least the next twenty-four months. We anticipate continuing our current development programs and/or 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 may 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.

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, 2004 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, Cash Equivalents and Investments in 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 investments in 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*. Investments in marketable securities are classified as held to maturity and are carried at cost plus accrued interest. Substantially all of our marketable securities are held in corporate notes with remaining maturities ranging from 1 to 26 months. A reclassification of long-term to short-term investments in marketable securities has been recorded to the December 31, 2003 balance sheet.

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 has been classified as restricted cash on the balance sheet.

Prepaid Research and Development Expenses

In accordance with various research and development agreements, we are obligated to make certain up front payments upon execution of the agreement. 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 $489,900, $602,354 and $530,386 for the years ended 2002, 2003 and 2004, respectively, and $2,373,907 for the cumulative period from inception through December 31, 2004.

The components of property and equipment are as follows:

	December 31,		Estimated Lives
	2003	2004	
Office furniture and equipment	$ 1,209,271	$ 1,207,240	5-7 years
Computer hardware and software	1,199,275	1,155,468	3 years
Lab equipment	103,224	82,689	5 years
Leasehold improvements	394,740	394,740	7 years
	2,906,510	2,840,137	
Less accumulated depreciation and amortization	(1,451,024)	(1,859,895)	
	$ 1,455,486	$ 980,242	

Long-lived Assets

Long-lived assets, consisting primarily of property and equipment, 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.

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.

Accrued Bonus and Employee Benefits

Our Annual Bonus Program (the "Bonus Program") was adopted by the Board of Directors in September 1998 and revised in May 2004. The Bonus Program 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. Bonuses are generally paid in cash in the year following the year in which the bonuses were earned. The components of accrued bonus and employee benefits are as follows:

	December 31,	
	2003	2004
Accrued bonus	$ 787,854	$578,462
Accrued vacation	223,446	175,334
Other	40	13,359
Total	$1,011,340	$767,155

Stock-Based Compensation

We account for grants of stock options according to the intrinsic value method as prescribed by the 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 in accordance with SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. Any deferred stock-based compensation calculated according to APB 25 is amortized over the vesting period of the individual options, generally four years, in accordance with Financial Accounting Standard Board ("FASB") Interpretation No. ("FIN") 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option and Award Plans* ("FIN 28").

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, 2002, 2003 and 2004. 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.

	2002	2003	2004	Cumulative Period from September 1, 1992 (date of inception) through December 31, 2004
Net loss attributable to common stockholders—as reported	$(25,768,974)	$(23,126,625)	$(21,837,285)	$(157,586,829)
Add: Stock-based employee compensation expense included in reported net loss	1,738,079	619,007	301,339	15,953,325
Deduct: Recovery of stock-based compensation expense included in reported net loss	(1,162,154)	(762,195)	(170,118)	(2,094,467)
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards	(2,392,223)	(3,150,362)	(1,618,441)	(24,217,650)
Pro forma net loss attributable to common stockholders	$(27,585,272)	$(26,420,175)	$(23,324,505)	$(167,945,621)
Net loss per share:				
Basic and diluted—as reported	$ (1.03)	$ (0.87)	$ (0.70)	
Basic and diluted—pro forma	$ (1.11)	$ (1.00)	$ (0.75)	

The weighted average estimated grant date fair value, as defined by SFAS 123, for options granted under our stock option plans during fiscal 2002, 2003 and 2004 was $3.43, $2.80 and $2.23 per share, respectively. The weighted average estimated grant date fair value of purchase awards under our Purchase Plan during fiscal 2002, 2003 and 2004 was $1.76, $3.02 and $1.23 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 employee stock purchase awards for the years ended December 31, 2002, 2003 and 2004:

	2002	2003	2004
Stock option plans:			
Expected dividend yield	0%	0%	0%
Expected stock price volatility	33% - 63%	62% - 175%	65% - 126%
Risk free interest rate	3.38% - 7.88%	3.38% - 7.0%	2.14% - 5.5%
Expected life (years)	5.0	2.0 - 5.0	.9 - 5.0
Stock purchase plan:			
Expected dividend yield	0%	0%	0%
Expected stock price volatility	44% - 56%	64% - 131%	64% - 119%
Risk free interest rate	3.49%	0.94% - 3.49%	0.94% - 1.65%
Expected life (years)	1.2	2.0	1.5 - 2.0

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 EFAPROXYN 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. Upon receiving regulatory approval, we will be required to capitalize any future costs of our marketed products at the lower of cost or market and then expense the sold inventory as a component of cost of goods sold.

Income Taxes

Income taxes are accounted for under SFAS No. 109, *Accounting for Income Taxes* ("SFAS 109"). 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 have been established to reduce the Company's deferred tax assets to zero, as we believe that it is more likely than not that such assets will not be realized. Certain prior year amounts have been reclassified to conform to the current year's presentation.

Concentration of Credit

Our cash, cash equivalents and investments in marketable securities at December 31, 2003 and 2004 are maintained in a financial institution in amounts that, at times, may exceed federally insured

limits. We have not experienced any losses in such accounts and believe such accounts are 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* ("SFAS 128"). 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 common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per share for all periods presented 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.

Securities as of December 31, 2002, 2003 and 2004 that are not included in the diluted net loss per share calculations, as the effect of including such securities was anti-dilutive, are as follows:

	December 31,		
	2002	2003	2004
Common stock options	3,023,852	3,539,818	3,873,448
Common stock warrants	—	1,706,893	1,706,893
	3,023,852	5,246,711	5,580,341

Fair Value of Financial Instruments

Our financial instruments include cash and cash equivalents, investments in marketable securities, 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 investments in marketable securities approximates $150,000 and $138,000 at December 31, 2003 and 2004, respectively.

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs-an amendment of ARB No. 43" ("SFAS 151"), which is the result of its efforts to converge U.S. accounting standards for inventories with International Accounting Standards. SFAS 151 requires idle facility expenses, freight, handling costs, and wasted material (spoilage) costs to be recognized as current-period charges. It also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS 151 will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on our financial position and results of operations.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which replaces SFAS No. 123, "Accounting for Stock-Based Compensation," ("SFAS 123") and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim or annual period after June 15, 2005. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. We are required to adopt SFAS 123R in the third quarter of fiscal 2005, beginning July 1, 2005. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive

option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are evaluating the requirements of SFAS 123R and expect that the adoption of SFAS 123R will have a material impact on our results of operations and earnings per share. We have not yet determined the method of adoption or the effect of adopting SFAS 123R, and have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123.

3. 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. ("N-Gene"), 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.

4. 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. 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.

On March 27, 2000, the Securities and Exchange Commission ("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.

Concurrent with the close of our IPO, our Certificate of Incorporation was amended to authorize 10,000,000 shares of undesignated preferred stock, none of which were issued or outstanding at December 31, 2004. 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.

At December 31, 2004, we have reserved shares of common stock for future issuance as follows:

1995 Stock Option Plan	1,151,153
2000 Stock Option Plan	2,571,459
2001 Employee Stock Purchase Plan	2,394,747
2002 Broad Based Equity Incentive Plan	991,968
Total	7,109,327

Stock Warrants

On November 20, 2003, in conjunction with the private placement completed on this date, we issued warrants to purchase 1,706,893 shares of common stock at an exercise price of $3.14 per share with a life of four years. As of December 31, 2004, these warrants were outstanding.

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.

In connection with the sale of shares of Series A Exchangeable Preferred Stock ("Exchangeable Preferred") to Warburg Pincus Private Equity VIII, L.P. ("Warburg") on March 4, 2005 (see Note 13), we amended the Stockholder Rights Plan to provide that Warburg and its affiliates will be exempt from the Stockholder Rights Plan, unless Warburg and its affiliates become, without the prior consent of our Board of Directors, the beneficial owner of more than 44% of our common stock, calculated as if all shares of Exchangeable Preferred (including any accrued dividends thereon) have been exchanged for common stock as of immediately following the original issuance of the Exchangeable Preferred. Under the Stockholder Rights Plan, our Board of Directors has express authority to amend the rights plan without stockholder approval.

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, 2004, 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 could grant fixed and performance-based stock options and stock appreciation rights to officers, employees, consultants and directors. The stock options were 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 of Directors suspended the 1995 Plan and adopted the Allos Therapeutics, Inc. 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 the 1995 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 of Directors.

In January 2002, the Board of Directors approved the Allos Therapeutics, Inc. 2002 Broad Based Equity Incentive Plan (the "2002 Plan"). Under the 2002 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 2002 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. The 2002 Plan will terminate on January 7, 2012.

As of December 31, 2004, we had 653,834 and 187,298 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, 2002, 2003 and 2004, we recorded stock-based compensation expense of $576,000, a net recovery of stock-based compensation expense of $143,000, and stock-based compensation expense of $131,000, respectively. Of the net recovery of stock-based compensation expense of $143,000 recorded for the year ended December 31, 2003, we recorded a net recovery of $210,000 in marketing, general and administrative expenses, and stock-based compensation expense of $17,000 and $50,000 in research and development and in clinical manufacturing, respectively. The net recovery of stock-based compensation expense 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, partially offset by $552,000 of other stock-based compensation expense for 2003.

Deferred stock-based 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, 2004, we had $35,000 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
Granted	1,018,310	3.29		
Exercised	(35,935)	2.72		
Canceled	(648,745)	4.66		
Outstanding at December 31, 2004	3,873,448	$3.84	2,537,256	$3.76

The following table summarizes information about options outstanding as of December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Outstanding as of December 31, 2004	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable as of December 31, 2004	Weighted Average Exercise Price
$ 0.00 - $ 1.38	595,292	3.6	$ 0.50	595,292	$ 0.50
$ 1.39 - $ 2.75	995,780	7.3	2.29	522,921	2.40
$ 2.76 - $ 4.13	574,090	8.5	3.18	327,908	3.20
$ 4.14 - $ 5.50	872,798	7.7	4.99	435,359	4.88
$ 5.51 - $ 6.88	466,383	6.3	6.18	390,025	6.21
$ 6.89 - $ 8.25	105,000	7.7	7.28	66,144	7.30
$ 8.26 - $ 9.63	218,805	6.5	8.85	154,307	8.90
$ 9.64 - $11.00	28,500	5.5	10.95	28,500	10.95
$11.01 - $12.38	2,000	5.7	11.13	2,000	11.13
$12.39 - $13.75	14,800	5.5	13.75	14,800	13.75
	3,873,448	6.8	$ 3.84	2,537,256	$ 3.76

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 32,189 and 36,393 shares to employees in 2003 and 2004, respectively. There are 2,394,747 shares available for sale at December 31, 2004. The Purchase Plan will terminate on February 27, 2011.

5. 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 and paid $638,070 in restructuring costs, which consisted of $633,799 in severance, payroll taxes and employee benefits and $4,271 in legal costs. The restructuring costs were recorded to expense as follows:

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

6. 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, 2002, 2003 and 2004:

	2002	2003	2004
Federal income tax benefit at 35%	$(9,019,100)	$(8,094,300)	$(7,643,000)
State income tax, net of federal benefit	(756,700)	(677,500)	(626,400)
Stock-based compensation	(325,769)	(25,259)	47,500
Research and development and orphan drug credits	(784,900)	(542,200)	(721,126)
Change in valuation allowance	10,865,200	9,266,199	8,931,326
Other	21,269	73,060	11,700
Benefit for income taxes	$ —	$ —	$ —

The components of our deferred tax assets under SFAS 109 as of December 31, 2003 and 2004 are as follows:

	2003	2004
Deferred tax assets:		
Temporary differences	$ 452,200	$ 449,200
Research and development and orphan drug credit carryforwards	5,339,100	6,362,126
Net operating loss carryforwards	38,376,100	46,287,500
Total deferred tax assets	44,167,400	53,098,826
Valuation allowance	(44,167,400)	(53,098,826)
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, 2004, we have approximately $121.8 million of net operating loss ("NOL") carryforwards, approximately $6.2 million of research and development ("R&D") credit carryforwards and a $160,000 orphan drug credit carryforward. These carryforwards will expire beginning in 2009. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the NOL, R&D credit, and orphan drug credit carryforwards available for use in any given year upon the occurrence of certain events, including significant changes in ownership interest and are subject to review and possible adjustment by the Internal Revenue Service. 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, R&D credit and orphan drug credit carryforwards from tax periods prior to the ownership change. Our NOL, R&D credit and orphan drug credit carryforwards as of December 31, 2004 will likely be subject to annual limitation due to changes in ownership from the March 2005 Series A Exchangeable Preferred Stock financing (see Note 13) and previous financings. The amount of these limitations, if any, is unknown, and our NOL, R&D credit and orphan drug credit carryforwards may expire unused. Additionally, future ownership changes could further limit the utilization of our NOL, R&D credit and orphan drug credit carryforwards.

7. 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 $118,383, $130,731 and $108,048 in 2002, 2003 and 2004, respectively.

8. 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 2010. Total rent expense in 2002, 2003 and 2004 and the cumulative period from inception through December 31, 2004 was $629,793, $697,930, $735,409 and $3,171,586, respectively.

The aggregate future minimum rental commitments as of December 31, 2004, for noncancelable operating leases with initial or remaining terms in excess of one year are as follows:

	Operating Leases
Year Ending December 31:	
2005	$ 784,351
2006	787,774
2007	830,801
2008	704,873
2009	67,642
2010	5,651
Total minimum lease payments	$3,181,092

Contingencies

In 2002, we signed two purchase orders to purchase approximately $8.0 million of commercial grade EFAPROXYN 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 for the year ended December 31, 2003.

In December 2003, we entered into an agreement with Baxter Healthcare Corporation ("Baxter") for certain development and manufacturing services for the clinical and commercial production of EFAPROXYN formulated drug product. The agreement requires minimum purchase obligations by us, subject to FDA approval of EFAPROXYN. We currently have no commitments to Baxter under this agreement.

The Company and one of our officers have been named as defendants in a purported securities class action lawsuit filed in May 2004 in the United States District Court for the District of Colorado. An amended complaint was filed in August 2004. The lawsuit is brought on behalf of a purported class of purchasers of our securities during the period from April 23, 2003 to April 29, 2004, and is seeking unspecified damages relating to the issuance of allegedly false and misleading statements regarding EFAPROXYN during this period and subsequent declines in our stock price. As is typical in this type of litigation, several other purported securities class action lawsuits containing substantially similar allegations were filed against the defendants, but the plaintiffs in all of those cases have subsequently dismissed their actions. Additional lawsuits containing substantially similar allegations may be filed in the future. These lawsuits have been tendered to our insurance carriers.

We believe the claims set forth in the pending lawsuit are without merit, and we intend to vigorously defend against them. On October 12, 2004, we filed a motion to dismiss the case with prejudice. That motion remains pending. As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. If we are not successful in our defense against such claims, we could be forced to make significant payments to the plaintiffs, and such payments could have a material adverse effect on our business, financial condition, results of operations and cash flows to the extent such payments are not covered by our insurance carriers. Even if our defense against such claims is successful, the litigation could result in substantial costs and divert management's attention and resources, which could adversely affect our business.

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, 2004.

9. Royalty and License Fee Commitments

On January 14, 1994, we entered into a license agreement with the Center for Innovative Technology ("CIT"), under which we obtained exclusive worldwide rights to a portfolio of patents related to allosteric hemoglobin modifier compounds, including EFAPROXYN, and their uses. 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 July 28, 1997. Under the terms of the agreement, we have the right to grant sublicenses, for which we must also pay royalties to VCUIPF for products produced by the sublicensees. 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 currently October 2016, but could be later depending on possible patent term extensions. Quarterly royalty payments are due within 60 days from the end of each calendar quarter. As of December 31, 2004, no royalty payments have been incurred.

In March 2002, we entered into an agreement with N-Gene, under which we obtained an exclusive United States license to intellectual property surrounding BGP-15, an investigational compound. 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, 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 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 a license agreement with Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute, under which we obtained exclusive worldwide rights to several patents and equivalent foreign patent applications to develop and market any product derived from PDX in connection with all diagnostic and therapeutic uses, including human and veterinary diseases. Under the terms of the agreement, we made an up-front payment and will also make certain cash payments to the licensor upon the earlier of 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 arising from sales of the product or sublicense revenues arising from sublicensing the product, if and when such sales or sublicenses occur. As of December 31, 2004, no royalty payments have been made.

In December 2004, we entered into an agreement with the University of Colorado Health Sciences Center, the University of Salford and Cancer Research Technology, under which we obtained exclusive worldwide rights to certain intellectual property surrounding a proprietary molecule known as RH1. Under the terms of the agreement, we made up-front payments in 2004, which we recorded as research and development expense, and will also make a series of milestone payments to the licensors based upon the achievement of specified development, regulatory and commercialization goals. Such subsequent payments will be expensed as incurred. Cancer Research UK will continue to support an ongoing Phase 1 dose escalation study, and we will have the right to obtain an exclusive license to the results of the study, for use in subsequent development and regulatory activities, upon payment of a one-time data option fee. Upon completion of the Phase 1 study, we will assume responsibility for all future development costs and activities. In addition, we will pay the licensor a royalty based on a percentage of net revenues from product sales, if and when such sales occur. As of December 31, 2004, no royalty payments have been made.

10. 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 2002 and the cumulative period from inception, we paid Dr. Jaffe consulting fees of $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 and 2004 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 from 1994 through May 10, 2004. 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. Effective July 1, 2003, we entered into

another one-year consulting agreement, under which we paid Dr. Abraham consulting fees of $5,000 per month. In June 2004, this agreement was renewed through June 30, 2005. For 2002, 2003, 2004, and the cumulative period from inception, we paid Dr. Abraham consulting fees of $6,000, $0, $90,000, and $138,000, 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 Virginia Commonwealth University. During 2002 and 2003, services provided under these contracts totaled $412,921 and $200,116, respectively, all of which was paid prior to December 31, 2003. There were no such payments in 2004.

Effective February 28 2003, we entered into a consulting agreement with Dr. Stephen Hoffman and terminated his employment agreement. This consulting agreement expired on February 28, 2005. Pursuant to the consulting agreement, Dr. Hoffman served us as non-executive Chairman of the Board and was required to provide consulting services as requested by us from time to time. The consulting agreement provided for an annual consulting fee of $150,000, paid monthly, so long as Dr. Hoffman provided consulting services in accordance with the agreement. The consulting agreement also provided 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. For 2003 and 2004, we paid Dr. Hoffman consulting fees of $125,000 and $127,150, respectively. We also paid $45,000 in 2004 relating to incentive compensation for 2003 and we have accrued $45,000 of incentive compensation as of December 31, 2004 relating to 2004. According to the consulting agreement, Dr. Hoffman's options continued to vest through the end of the term of the agreement, or February 28, 2005. We have accounted for these stock options using variable accounting as prescribed by FIN 44, *Accounting for Certain Transactions Involving Stock Compensation*. We have recorded non-cash stock-based compensation of $173,963 and a recovery of stock-based compensation of $170,118 for the years ended 2003 and 2004, respectively. Stock options granted in 2003 and 2004 related to Board of Director services.

11. 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 as a gain in our Statement of Operations during the fourth quarter of 2003.

12. Quarterly Information (Unaudited)

The results of operations on a quarterly basis for the years ended December 31, 2003 and 2004 were as follows:

	March 31, 2003	June 30, 2003	Sept. 30, 2003	Dec. 31, 2003	March 31, 2004	June 30, 2004	Sept. 30, 2004	Dec. 31, 2004
Operating expenses:								
Research and development	$ 3,405,572	$ 5,081,232	$ 1,629,139	$ 1,841,306	$ 1,988,567	$ 3,446,545	$ 2,202,790	$ 2,520,651
Clinical manufacturing	2,080,207	3,865,872	707,431	598,297	782,571	1,373,815	432,421	389,877
Marketing, general and administrative	2,019,254	2,522,994	2,796,971	2,038,874	2,513,002	2,441,511	2,034,721	2,204,485
Restructuring costs	—	577,665	59,934	471	—	—	—	—
Total operating expenses	7,505,033	12,047,763	5,193,475	4,478,948	5,284,140	7,261,871	4,669,932	5,115,013
Loss from operations	(7,505,033)	(12,047,763)	(5,193,475)	(4,478,948)	(5,284,140)	(7,261,871)	(4,669,932)	(5,115,013)
Gain on settlement claims	—	—	—	5,110,083	—	—	—	
Interest and other income, net	371,684	276,983	179,828	160,016	137,615	111,284	115,989	128,783
Net income (loss) attributable to common stockholders	$(7,133,349)	$(11,770,780)	$(5,013,647)	$ 791,151	$(5,146,525)	$(7,150,587)	$(4,553,943)	$(4,986,230)
Net income (loss) per share: Basic and diluted	$ (0.28)	$ (0.45)	$ (0.19)	$ 0.03	$ (0.17)	$ (0.23)	$ (0.15)	$ (0.16)
Weighted average shares: basic	25,880,216	25,888,500	25,911,309	28,275,497	31,109,944	31,139,289	31,153,489	31,153,731
Weighted average shares: diluted	25,880,216	25,888,500	25,911,309	28,807,281	31,109,944	31,139,289	31,153,489	31,153,731

13. Subsequent Events

Sub-leases

In January 2005, we signed agreements to sub-lease excess space in our corporate offices located in Westminster, Colorado. The term of each sub-lease agreement is through the term of our office lease, or October 31, 2008. As the payments to us under the subleases of approximately $230,000 are less than our obligations under our primary lease, we will record a loss in the first quarter of 2005 of approximately $450,000.

Series A Exchangeable Preferred Stock Financing

On March 2, 2005, we entered into a Securities Purchase Agreement with Warburg Pincus Private Equity VIII, L.P. ("Warburg") and certain other investors pursuant to which we issued and sold an aggregate of 2,352,443 shares of Series A Exchangeable Preferred Stock (the "Exchangeable Preferred") at a price per share of $22.10 (the "Preferred Purchase Price"), for aggregate gross proceeds of approximately $52.0 million. We incurred offering expenses of approximately $3.0 million in connection with the sale of the Exchangeable Preferred, resulting in net proceeds to the Company of approximately $49.0 million. The shares were sold under our shelf Registration Statement on Form S-3 (File No. 333-113353) declared effective by the Securities and Exchange Commission on April 21, 2004. The closing of the sale of 2,262,443 shares of Exchangeable Preferred to Warburg occurred on March 4, 2005. The closing of the sale of an additional 90,000 shares of Exchangeable Preferred to certain other investors occurred on March 8, 2005.

The rights, preferences and privileges of the Exchangeable Preferred are set forth in the Certificate of Designations, Number, Voting Powers, Preferences and Rights of Series A Exchangeable Preferred Stock of Allos Therapeutics, Inc. filed with the Secretary of State of the State of Delaware on March 3, 2005 (the "Certificate of Designations"). Pursuant to Certificate of Designations, the Exchangeable Preferred ranks senior to our common stock and each other class of our equity securities with respect to dividend rights and rights upon liquidation, winding up or dissolution, and is non-voting stock, except as otherwise required by Delaware law and subject to a right of its holders to consent to any amendment of its terms.

Beginning on March 4, 2006 and for so long as the Exchangeable Preferred remains outstanding, the holders of the Exchangeable Preferred will be entitled to receive, in preference to our common stock and each other class of our equity securities, cumulative dividends at an annual rate of 10% of the Preferred Purchase Price, compounded quarterly beginning with amounts accrued for the quarter ending March 31, 2006. Except as set forth below, such dividends will be payable when and as declared by our board of directors, in cash, additional shares of Exchangeable Preferred or a combination thereof.

Upon the approval of the holders of our common stock as required by the applicable rules of the Nasdaq National Market, and subject to the receipt of any necessary approval pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Approval"), each share of Exchangeable Preferred will be automatically exchanged for 10 shares of common stock (subject to appropriate adjustments in the event of any stock dividend, stock split, stock distribution or combination, subdivision, reclassification or other corporate action having the similar effect with respect to our common stock); provided that such approvals are obtained by June 4, 2006. Upon any such exchange, all accrued but unpaid dividends (whether or not declared) on the Exchangeable Preferred, if any, will be paid in shares of common stock in an amount equal to the dividends accrued through the exchange date divided by a price per share of $2.21 for such common stock. If the HSR Approval and stockholder approval are not obtained by June 4, 2006, then the Exchangeable Preferred will remain outstanding pursuant to its terms and will not be exchanged for shares of common stock.

If the Exchangeable Preferred remains outstanding on the later of (i) March 4, 2009 or (ii) thirty days after we publicly announce the results of our ENRICH trial (the "Redemption Eligibility Date"), the holders of a majority of the outstanding shares of Exchangeable Preferred will have the option, at any time thereafter, to cause us to redeem all (but not less than all) of their outstanding shares of Exchangeable Preferred for cash in a per share amount equal to the greater of (a) the Preferred Purchase Price plus all accrued but unpaid dividends (whether or not declared) through the date of such redemption or (b) ten times the average closing price of our common stock on the Nasdaq National Market for the twenty trading days immediately preceding the date of any such redemption (the "Redemption Price"). In addition, if the Exchangeable Preferred remains outstanding on the Redemption Eligibility Date, we will have the option, at any time thereafter, to voluntarily redeem all (but not less than all) of the outstanding shares of Exchangeable Preferred for cash in a per share amount equal to the Redemption Price.

For so long as the Exchangeable Preferred remains outstanding, upon any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of the Exchangeable Preferred will have the right to receive, before any payments are made to the holders of our common stock or any other class of our equity securities, an amount per share equal to the greater of (i) the Preferred Purchase Price plus all accrued but unpaid dividends (whether or not declared) through the date of payment or (ii) ten times the average closing price of our common stock on the Nasdaq National Market for the twenty trading days immediately preceding the date of payment. In addition, for so long as the Exchangeable Preferred remains outstanding, if we consummate a "change in control" (as defined in the Certificate of Designations), the holders of the Exchangeable Preferred will have the right to receive, before any payments are made to the holders of our common stock or any other class

of our equity securities, an amount per share equal to the greater of (i) the Preferred Purchase Price plus all accrued and unpaid dividends (whether or not declared) through the date of such change in control or (ii) ten times the fair market value of the consideration per share of common stock received by the holders of our common stock in the change in control transaction. After payment of the full amount of the distributions to which they are entitled in connection with any liquidation or change in control, the holders of Exchangeable Preferred will have no right or claim to any of our remaining assets.

In connection with the sale of Exchangeable Preferred, we entered into a Registration Rights Agreement dated March 4, 2004 pursuant to which we granted certain registration rights with respect to the shares of common stock, if any, issued upon exchange of the Exchangeable Preferred.

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Corporate Information

BOARD OF DIRECTORS

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

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

Michael D. Casey
Pharmaceutical Industry Consultant

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

Stewart Hen
Managing Director,
Warburg Pincus LLC

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

Jonathan S. Leff
Managing Director,
Warburg Pincus LLC

CORPORATE HEADQUARTERS

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Fax: 303-426-4731

INDEPENDENT AUDITORS

PricewaterhouseCoopers LLP
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Denver, CO 80202

GENERAL COUNSEL

Cooley Godward, LLP
380 Interlocken Crescent
Suite 900
Broomfield, Colorado 80021

STOCK LISTING

Our common stock is listed on the Nasdaq National Market under the symbol ALTH.

WEBSITE

www.allos.com

ANNUAL MEETING

The 2005 annual meeting of stockholders will be held on Wednesday, May 18, 2005, at 8:30 AM at our corporate headquarters.

STOCKHOLDER INQUIRIES

Inquiries from stockholders and potential investors regarding our company are always welcome. Please direct your requests for information to:

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