2008

ANNUAL REPORT

ALLOS THERAPEUTICS, INC.

OUR TEAM OF DEDICATED EMPLOYEES IS COMMITTED TO DEVELOPING AND DELIVERING NEW THERAPIES FOR PEOPLE WITH CANCER.

PRALATREXATE IS A TARGETED ANTIFOLATE WITH POTENTIAL IN BOTH HEMATOLOGICAL MALIGNANCIES AND SOLID TUMORS. IF APPROVED, PRALATREXATE REPRESENTS A FIRST-TO-MARKET OPPORTUNITY FOR ALLOS AND COULD BE THE FIRST AGENT APPROVED BY THE FDA FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY PTCL.

In addition to the PROPEL trial, we are committed to evaluating pralatrexate both as a monotherapy and in combination with other anticancer agents in a variety of hematologic malignancies and solid tumor indications. Beyond PTCL, pralatrexate has demonstrated encouraging clinical activity in patients with relapsed or refractory cutaneous T-cell lymphoma, non-Hodgkin's lymphoma, Hodgkin's lymphoma and non-small cell lung cancer. We are currently conducting clinical trials to assess the safety and efficacy of pralatrexate in several other types of cancer, for which new treatment options are needed. These include:

- Non-small cell lung cancer (NSCLC): A Phase 2b randomized trial comparing pralatrexate and erlotinib in patients with previously treated Stage IIIB/IV NSCLC who are, or have been, cigarette smokers. The objective of the study is to assess the treatment effect in patient subsets where we feel pralatrexate has the potential for benefit relative to erlotinib. Once the study is complete, we will evaluate the results according to the analysis plan. Future development of pralatrexate in this indication will be based on observing a clinically significant treatment effect.
- Carcinoma of the urinary bladder: A Phase 2 open-label single-arm multicenter study investigating pralatrexate in patients with advanced or metastatic relapsed transitional cell carcinoma or TCC of the urinary bladder.
- Non-Hodgkin's lymphoma (NHL) or Hodgkin's disease: A Phase 1/2a combination trial of pralatrexate and gemcitabine in patients with relapsed or refractory NHL.
- Cutaneous T-cell lymphoma (CTCL): A Phase 1 open label, multi-center single-agent trial in patients with relapsed or refractory CTCL.

As we look ahead, 2009 promises to be an exciting year for Allos, as we continue to execute on our prioritized product development and commercialization plan for pralatrexate. We also have a solid cash position, no debt and a team of dedicated employees focused on delivering new cancer therapies to patients. We are enthusiastic about our prospects for a first-to-market opportunity with pralatrexate and the potential to make a difference for patients with PTCL and their families. We believe we have established a strong foundation for continued progress and look forward to providing future updates.

On behalf of the Board of Directors and executive management team, we would like to express our thanks to all of our employees for their unwavering dedication and commitment, our clinical collaborators and their patients who have participated in our studies and you, our stockholders, for your continued support.

Paul L. Berns

President and Chief Executive Officer
May 15, 2009

2009 MILESTONES

3/24 Submitted New Drug Application (NDA) for pralatrexate for patients with relapsed or refractory PTCL

- Present final results from PROPEL at an upcoming scientific meeting
- Prepare for potential commercialization of pralatrexate in PTCL
- Continue to advance patient enrollment in ongoing clinical trials evaluating pralatrexate in hematologic malignancies and solid tumor indications
- Complete patient accrual in Phase 2b clinical trial comparing pralatrexate and erlotinib in patients with advanced NSCLC in Q3 2009

DEAR STOCKHOLDERS,

It is my pleasure to update you on our recent accomplishments and to share our outlook for the remainder of 2009, which we believe will be a transformational year for Allos. Throughout the past year, we made significant progress advancing our product development and commercialization plan for pralatrexate, a targeted antifolate designed to accumulate preferentially in cancer cells. We believe pralatrexate has potential utility in both hematologic malignancies and solid tumors.

In March 2009, we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the use of pralatrexate for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). The NDA submission is based on the encouraging efficacy and safety data from our pivotal Phase 2 PROPEL trial that were reported earlier in the year. As part of the submission, we requested a priority review of the application, which, if granted, would give the FDA six months from receipt of the submission to take action on the NDA. There are currently no FDA-approved agents for PTCL, either in the first-line or relapsed or refractory setting, which demonstrates the high unmet need for new therapies to treat patients with this devastating disease. If approved, pralatrexate represents a potential first-to-market opportunity for Allos and could be the first agent approved by the FDA for the treatment of patients with this challenging disease.

PTCL comprises a biologically diverse group of hematological malignancies that typically has a worse prognosis than other types of lymphoma. According to the clinical literature, patients with aggressive PTCL only have a five-year overall survival rate of approximately 25 percent after first-line therapy. PTCL accounts for approximately 10 to 15 percent of all cases of non-Hodgkin's lymphoma diagnosed each year in the U.S. We estimate the 2009 U.S. incidence of PTCL to be approximately 5,600 patients based on our analysis of the clinical literature, epidemiological data in the public domain and our own market research and third-party assessment. In addition, we estimate the annual U.S. prevalence to be approximately 9,500 patients.

The PROPEL trial was conducted under an agreement reached with the FDA under its Special Protocol Assessment process. This process allows for the FDA evaluation of the clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application and provides an agreement that the trial design, including trial size, clinical endpoints and data analysis are acceptable to the FDA. Pralatrexate has orphan drug designation and fast track designation in the United States for the treatment of patients with T-cell lymphoma and orphan medicinal product designation in Europe for the treatment of PTCL.

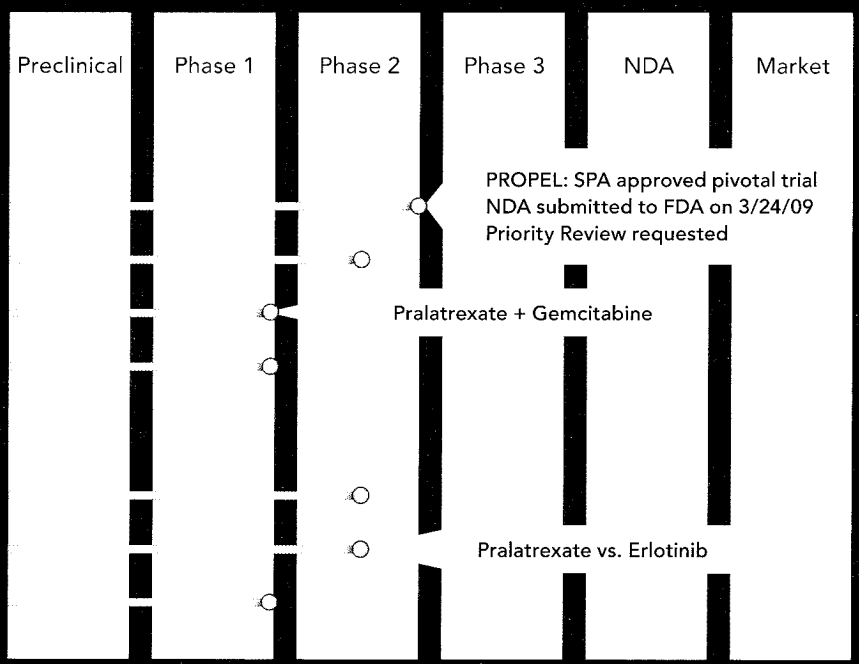
There were a total of 115 patients enrolled in the PROPEL trial. We believe this makes PROPEL the largest prospectively designed single-agent trial conducted to date in patients with relapsed or refractory PTCL. The diagnosis of peripheral T-cell lymphoma was confirmed by independent pathology review and patient responses were determined by central independent oncology review, which demonstrates the rigor of the trial design.

We are encouraged by the results of the PROPEL trial, which demonstrate that:

- 29 of 109 evaluable patients, or 27 percent, achieved a response as assessed by central independent oncology review. 42 of 109 evaluable patients, or 39 percent, achieved a response, as assessed by PROPEL investigators.
- The Kaplan-Meier estimate for the median duration of response was 287 days, or 9.4 months. Importantly, duration of response is measured from the first day of documented response to progression of disease or death.
- The most common grade 3/4 adverse events were thrombocytopenia, mucosal inflammation, neutropenia and anemia.

We believe the U.S. market for relapsed or refractory PTCL is scalable with a significant number of patients treated at large cancer centers and institutions. If pralatrexate is approved for marketing, we intend to commercialize pralatrexate by building a targeted U.S. sales and marketing organization. In addition, we are also reviewing our strategic partnering opportunities for pralatrexate. Our intent is to selectively pursue those partnerships that we believe are in the best interest of the company, customers and our shareholders.

PRALATREXATE A PIPELINE WITHIN A PRODUCT



HEMATOLOGIC MALIGNANCIES

Peripheral T-cell Lymphoma

B-cell Non-Hodgkin's Lymphoma

Non-Hodgkin's Lymphoma

Cutaneous T-cell Lymphoma

SOLID TUMORS

Bladder Cancer

Non-small Cell Lung Cancer

Non-small Cell Lung Cancer

2008 ACHIEVEMENTS

1/08 Initiated Phase 2b study comparing pralatrexate and erlotinib in patients with advanced non-small cell lung cancer

4/08 Completed patient enrollment in pivotal Phase 2 PROPEL trial of pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL)

5/08 Reported interim response and safety data from pivotal Phase 2 PROPEL trial

5/08 Completed public common stock offering and received net proceeds of approximately $65.2 million

6/08 Announced interim data from Phase 1 study of pralatrexate in patients with relapsed or refractory cutaneous T-cell lymphoma (CTCL)

7/08 Initiated Phase 2 study of pralatrexate in patients with advanced or metastatic relapsed transitional cell carcinoma of the urinary bladder

11/08 Received orphan drug designation from U.S. FDA for pralatrexate for the treatment of patients with diffuse large B-cell lymphoma

12/08 Received orphan drug designation from U.S. FDA for pralatrexate for the treatment of patients with follicular lymphoma

12/08 Presented interim data from CTCL and pralatrexate + gemcitabine studies at the American Society of Hematology (ASH)

12/08 Announced preliminary top line results from pivotal Phase 2 PROPEL trial of pralatrexate in patients with relapsed or refractory PTCL at ASH

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

Amendment No. 1

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

For the fiscal year ended December 31, 2008.

☐ **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:

Common Stock $.001 Par Value	**NASDAQ Stock Market LLC (NASDAQ Global Market)**
(Title of class)	(Name of each exchange on which registered)

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

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

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

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

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

The aggregate market value of common stock held by nonaffiliates of the registrant (based upon the closing sale price of such shares on the NASDAQ Global Market on June 30, 2008) was $293,509,927. Shares of the registrant's common stock held by each current executive officer and director and by each stockholder 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 Schedules 13D and 13G, if any, filed with the Commission. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of April 15, 2009, there were 89,360,666 shares of the registrant's common stock outstanding.

EXPLANATORY NOTE: This Amendment No. 1 on Form 10-K/A ("Amendment No. 1") amends the registrant's Annual Report on Form 10-K for the year ended December 31, 2008, as filed by the registrant on March 3, 2009 (the "Report"), and is being filed solely to replace Part III, Item 10 through Item 14. The reference on the cover of the Report to the incorporation by reference of the registrant's definitive proxy statement into Part III of the Report is hereby amended to delete that reference. In addition, we are also including Exhibits 31.1 and 31.2 required by the filing of this Amendment No. 1. Except as otherwise stated herein, no other information contained in the Report has been updated by this Amendment No. 1. Unless the context requires otherwise, references in this Amendment No. 1 to "Allos," the "Company," "we," "us," and "our" refer to Allos Therapeutics, Inc.

ALLOS THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K/A
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008
Amendment No. 1

TABLE OF CONTENTS

		Page
PART III		
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE . .	1
ITEM 11.	EXECUTIVE COMPENSATION	6
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	42
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	45
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	46
	SIGNATURES	48

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information about our directors and executive officers, as of April 15, 2009:

Name	Age	Position
Paul L. Berns	42	President, Chief Executive Officer and Director
Bruce K. Bennett, Jr.	58	Vice President, Pharmaceutical Operations
Pablo J. Cagnoni, M.D.	46	Senior Vice President, Chief Medical Officer
James V. Caruso	50	Executive Vice President, Chief Commercial Officer
Michael D. Casey	63	Director
David C. Clark	40	Vice President, Finance, Treasurer and Assistant Secretary
Marc H. Graboyes	39	Senior Vice President, General Counsel and Secretary
Stewart Hen	42	Director
Stephen J. Hoffman, Ph.D., M.D.	55	Chairman of the Board
Jeffrey R. Latts, M.D.	61	Director
Jonathan S. Leff	40	Director
Timothy P. Lynch	39	Director
David M. Stout	54	Director

Paul L. Berns has served as the Company's President and Chief Executive Officer, and as a member of the Board of Directors, since March 2006. Prior to joining the Company, Mr. Berns was a self-employed consultant to the pharmaceutical industry from July 2005 to March 2006. From June 2002 to July 2005, Mr. Berns was President, Chief Executive Officer and a director of Bone Care International, Inc., a specialty pharmaceutical company that was acquired by Genzyme Corporation in 2005. Prior to that, from 2001 to 2002, Mr. Berns served as Vice President and General Manager of the Immunology, Oncology and Pain Therapeutics business unit of Abbott Laboratories, a pharmaceutical company. From 2000 to 2001, he served as Vice President, Marketing of BASF Pharmaceuticals-Knoll, a pharmaceutical company, and from 1990 to 2000, Mr. Berns held various positions, including senior management roles, at Bristol-Myers Squibb Company, a pharmaceutical company. Mr. Berns is a director of XenoPort, Inc. Mr. Berns received a B.S. in Economics from the University of Wisconsin.

Bruce K. Bennett, Jr. has served as the Company's Vice President, Pharmaceutical Operations since January 2008. Prior to joining the Company, Mr. Bennett was a self-employed consultant to the biotechnology and pharmaceutical industries from 2006 to January 2008. From 2002 to 2006, Mr. Bennett served as Vice President, Manufacturing at La Jolla Pharmaceuticals. Prior to La Jolla, Mr. Bennett served as Vice President, Operations at Provasis Therapeutics from 2000 to 2002, and as Vice President, Operations, RA/QA/QC and Commercial Development at Via Medical Corporation from 1997 to 2000. From 1987 to 1997, Mr. Bennett served as a senior operations executive of various pharmaceutical, biotechnology and other companies. Mr. Bennett earned his M.B.A. from Pepperdine University and his B.S. in Industrial Technology from California State University, Long Beach.

Pablo J. Cagnoni, M.D. has served as the Company's Senior Vice President, Chief Medical Officer since March 2007. From August 2004 to March 2007, Dr. Cagnoni held several key management positions with OSI Pharmaceuticals, Inc., serving most recently as Chief Medical Officer and Vice President, Clinical Research and Medical Affairs. During his tenure, among other responsibilities, Dr. Cagnoni oversaw all of OSI's clinical development and medical affairs activities relating to Tarceva®. From July 2001 to July 2004, Dr. Cagnoni held key roles in clinical development with Allos, serving most recently as Vice President, Clinical Development. Prior to that, Dr. Cagnoni was Assistant Professor of Medicine in the Division of Oncology at the University of Colorado, where he also served

as Assistant Director of the Pharmacology Laboratory and member of the Bone Marrow Transplant Program. Dr. Cagnoni received his M.D. from the University of Buenos Aires Medical School.

James V. Caruso has served as the Company's Executive Vice President, Chief Commercial Officer since June 2006. Prior to joining the Company, Mr. Caruso was a self-employed consultant to the pharmaceutical industry from July 2005 to June 2006. From June 2002 to July 2005, Mr. Caruso was Senior Vice President, Sales and Marketing at Bone Care International, Inc., a specialty pharmaceutical company that was acquired by Genzyme Corporation in 2005. Prior to that, from June 2001 to June 2002, Mr. Caruso was a Vice President of Specialty Sales at Novartis, a pharmaceutical company. From 2000 to 2001, he served as Vice President, Sales of BASF Pharmaceuticals-Knoll, a pharmaceutical company, and from 1988 to 2000, Mr. Caruso held various positions, including senior management roles, at Bristol-Myers Squibb Company, a pharmaceutical company. Mr. Caruso earned his B.S. in Finance from the University of Nevada.

Michael D. Casey has served as a member of the Board of Directors since June 2002. Since February 2002, Mr. Casey has been a self-employed consultant to the pharmaceutical industry. Previously, Mr. Casey served four years as President, Chief Executive Officer and Chairman of Matrix Pharmaceuticals, Inc., a biopharmaceutical company, until Chiron Corporation acquired the company in February 2002. Prior to joining Matrix, Mr. Casey was President of two divisions of Schein Pharmaceutical, Inc. from 1995 to 1997, and President and Chief Operating Officer of Genetic Therapy, Inc. from 1993 to 1995 when it was sold to Sandoz (Novartis). Mr. Casey also spent 25 years with Johnson & Johnson, including as Vice President of Sales and Marketing of Ortho Pharmaceutical Corporation and President of McNeil Pharmaceuticals. Mr. Casey is a director of AVI Biopharma, Inc., Celgene Corp. and Durect Corporation.

David C. Clark has served as the Company's Vice President, Finance since February 2007, as Principal Financial Officer since March 2006 and as the Company's Treasurer since May 2004. Mr. Clark also served as the Company's Corporate Controller from May 2004 to April 2007. He has served as the Company's Assistant Secretary since October 2004 and served as Secretary from May 2004 to October 2004. From March 2000 to October 2003, Mr. Clark held several positions at Seurat Company (formerly XOR Inc.), a technology company, serving most recently as Vice President of Finance and Chief Financial Officer. From 1992 to March 2000, Mr. Clark worked in the audit practice of PricewaterhouseCoopers LLP. Mr. Clark is a Certified Public Accountant and received a Masters of Accountancy and a B.S. in Accounting from the University of Denver.

Marc H. Graboyes has served as the Company's Senior Vice President, General Counsel and Secretary since February 2008, and served as the Company's Vice President, General Counsel and Secretary from October 2004 to January 2008. From 2000 to October 2004, Mr. Graboyes was an attorney with Cooley Godward LLP, where he practiced corporate and securities law and served as outside counsel to the Company for nearly five years. Prior to joining Cooley Godward, Mr. Graboyes practiced corporate and securities law with several other national law firms. Mr. Graboyes earned his J.D. from the University of Colorado School of Law and received his B.S. in Entrepreneurship & Small Business Management from the University of Colorado at Boulder.

Stewart Hen has served as a member of the Board of Directors since March 2005. Mr. Hen serves as a General Partner of Warburg Pincus & Co. and as a Managing Director and Member of Warburg Pincus LLC. Mr. Hen joined Warburg Pincus in 2000 and focuses on investments in biotechnology and pharmaceuticals. Prior to joining Warburg Pincus, he served as a management consultant at McKinsey & Company. Prior to joining McKinsey, Mr. Hen held positions at Merck in both Research & Development and Manufacturing. Mr. Hen is currently a director of Neurogen Corporation, WuXi PharmaTech (Cayman) Inc. and several private companies. Mr. Hen holds an M.B.A. from The Wharton School, an M.S. in chemical engineering from the Massachusetts Institute of Technology and a B.S. in chemical engineering from the University of Delaware.

Stephen J. Hoffman, Ph.D., M.D. is the Company's Chairman of the Board. Dr. Hoffman has served as a Managing Director of Skyline Ventures, a venture capital firm, since May 2007. From January 2003 to March 2007, Dr. Hoffman was a General Partner of TechnoVenture Management, a venture capital firm. He has served as a member of the Board of Directors since 1994 and as the Company's Chairman of the Board since December 2001. From July 1994 to December 2001, Dr. Hoffman served as the Company's President and Chief Executive Officer. Prior to that, from inception to 1994, Dr. Hoffman served as a consultant to the Company's investor group. From 1990 to 1994, he completed a fellowship in clinical oncology and a residency/fellowship in dermatology, both at the University of Colorado. Dr. Hoffman was the scientific founder of Somatogen Inc., a biopharmaceutical company, where he held the position of Director of Corporate Research and Vice President of Science and Technology from 1987 to 1990. Dr. Hoffman received his Ph.D. in bio-organic chemistry from Northwestern University and his M.D. from the University of Colorado School of Medicine.

Jeffrey R. Latts, M.D. has served as a member of the Board of Directors since April 2007. Since January 2007, Dr. Latts has been a self-employed consultant to the pharmaceutical industry. Previously, Dr. Latts served as Executive Vice President of Exelixis, Inc., a biotechnology company, from January 2006 to January 2007, and as Senior Vice President of Exelixis, Inc. from July 2001 to December 2005. He also served as Chief Medical Officer of Exelixis, Inc. from July 2001 to September 2006. Prior to that, Dr. Latts held key management positions with Berlex Laboratories, a pharmaceutical healthcare company, where he served as Chief Medical Officer from 1995 to 2001, and Vice President, Clinical Research and Development from 1990 to 2001. Prior to that, Dr. Latts served as Vice President of Clinical Research at Wyeth Ayerst Research, a division of Wyeth Laboratories. He began his career in the pharmaceutical industry with the Parke-Davis Pharmaceutical Division of Warner Lambert. In over 25 years in the pharmaceutical industry, Dr. Latts has been involved in numerous investigational new drug application submissions and has successfully initiated early to late stage clinical trials for multiple disease areas, including cancer, immunology, central nervous system and metabolic diseases. Dr. Latts received a B.S. in medicine and an M.D. from the University of Minnesota.

Jonathan S. Leff has served as a member of the Board of Directors since March 2005. Mr. Leff serves as a General Partner of Warburg Pincus & Co. and as a Managing Director and Member of Warburg Pincus LLC. Mr. Leff joined Warburg Pincus in 1996 and is responsible for the firm's investment efforts in biotechnology and pharmaceuticals. Prior to joining Warburg Pincus, he was a consultant at Oliver, Wyman & Co. Mr. Leff is currently a director of Inspire Pharmaceuticals, Inc., InterMune, Inc., ZymoGenetics, Inc. and several private companies. Mr. Leff received his A.B. in Government from Harvard College and his M.B.A. from Stanford University Graduate School of Business.

Timothy P. Lynch has served as a member of the Board of Directors since November 2005. Mr. Lynch is a General Partner of Stonepine Capital, L.P., a life-science focused investment fund. From October 2005 through June 2008, Mr. Lynch was the President and Chief Executive Officer of NeuroStat Pharmaceuticals, a start-up specialty pharmaceutical company. From June 2005 through September 2005, Mr. Lynch was President and Chief Executive Officer of Vivo Therapeutics, Inc., a venture-backed specialty pharmaceuticals start-up. From October 2002 through June 2005, Mr. Lynch served as Chief Financial Officer of Tercica, Inc. From 1999 to June 2002, Mr. Lynch served as Chief Financial Officer of InterMune, Inc. He was involved with the initial public offerings of both biopharmaceutical companies. Previously, Mr. Lynch served as Director of Strategic Planning and as a pharmaceutical sales representative at Elan Corporation, plc, a pharmaceutical company. He started his career as an investment banker at Goldman, Sachs & Co. and Chase Securities, Inc. Mr. Lynch is a director of BioForm Medical, Inc., Insite Vision, Inc., and Nabi Biopharmaceuticals. Mr. Lynch received his B.A. in economics from Colgate University and his M.B.A. from the Harvard Graduate School of Business.

David M. Stout has served as a member of the Board of Directors since March 2009. Mr. Stout most recently served as President, Pharmaceuticals at GlaxoSmithKline, where he was responsible for the company's global pharmaceutical operations, from January 2003 to February 2008. From 1999 to January 2003, Mr. Stout served as President, U.S. Pharmaceuticals at GlaxoSmithKline. From 1996 to 1998, Mr. Stout served as President and Director, Sales and Marketing-U.S. for SmithKline Beecham. Prior to that, Mr. Stout was President of Schering Laboratories, a division of Schering-Plough Corporation from 1994 to 1996. Mr. Stout also held various executive and sales and marketing positions with Schering-Plough Corporation from 1979, when he joined the company, until 1994. Mr. Stout is a director of Airgas, Inc. Mr. Stout received his B.A. in biology from McDaniel College.

The term of each of our directors currently runs through the date of our 2009 Annual Meeting of Stockholders. Pursuant to a Securities Purchase Agreement (the "Securities Purchase Agreement") dated March 2, 2005 between the Company and Warburg Pincus Private Equity VIII, L.P. ("Warburg"), for so long as Warburg owns at least two-thirds of the number of shares of common stock issued upon exchange of the Series A Exchangeable Preferred Stock (the "Exchangeable Preferred") acquired by it under the Securities Purchase Agreement, the Company is required to nominate and use its reasonable best efforts to cause to be elected and cause to remain as directors on its 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 the Board of Directors, then, for so long as Warburg owns at least 50% of the number of shares of common stock issued upon exchange of the Exchangeable Preferred acquired by it under the Securities Purchase Agreement, the Company is required to nominate and use its reasonable best efforts to cause to be elected and cause to remain as a director on the Board of Directors, one Investor Designee. Effective March 4, 2005, Stewart Hen and Jonathan S. Leff, each of whom is a Managing Director of Warburg, were elected to the Company's Board of Directors. In addition, subject to applicable law and the rules and regulations of the Securities and Exchange Commission ("SEC") and The Nasdaq Stock Market ("Nasdaq"), the Company is required to use its reasonable best efforts to cause one of the Investor Designees to be a member of each principal committee of the Board of Directors. However, the Board of Directors has determined, based on its analysis of Rule 10A-3 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that the Investor Designees are not eligible to serve as members of the Audit Committee of the Board of Directors due to the size of Warburg's ownership interest.

Audit Committee

The Audit Committee of the Board of Directors was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act to oversee the Company's corporate accounting and financial reporting processes, the Company's systems of internal accounting and financial controls, and audits of the Company's financial statements. The Board has adopted a written charter for the Audit Committee that is available to stockholders on the Company's website at http://www.allos.com. The written charter describes the full power and authority of the Audit Committee and delegates responsibility to the Audit Committee to perform the following principal functions:

- evaluate the performance of and assess the qualifications of the Company's independent registered public accountants;
- determine and approve the engagement of the Company's independent registered public accountants;
- determine whether to retain or terminate the Company's existing independent registered public accountants or to appoint and engage new independent registered public accountants;
- review and approve the retention of the Company's independent registered public accountants to perform any proposed permissible non-audit services;

- monitor the rotation of partners of the Company's independent registered public accountants on the Company's audit engagement team as required by law;
- confer with management and the Company's independent registered public accountants regarding the effectiveness of the Company's internal controls over financial reporting;
- establish procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; and
- meet to review the Company's annual audited financial statements and quarterly financial statements with management and the Company's independent registered public accountants, including reviewing the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The Audit Committee is composed of three directors: Messrs. Casey, Lynch and Hoffman. The Board of Directors reviews the Nasdaq listing rules definition of independence for Audit Committee members on an annual basis and has determined that all members of the Audit Committee are independent (as independence is currently defined in the Nasdaq listing rules). Further, the Board of Directors determined that William R. Ringo, who resigned as a director of the Company effective June 24, 2008, the date of the Company's 2008 Annual Meeting of Stockholders, was independent (as defined above) while he served as a member of the Audit Committee during 2008. The Board of Directors has also determined that Mr. Lynch, the Chairman of the Audit Committee, qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of the level of knowledge and experience of Mr. Lynch based on a number of factors, including his formal education, experience and business acumen. The Board of Directors periodically reviews and approves the chairmanship and membership of the Audit Committee, based in part upon the recommendations of the Nominating and Corporate Governance Committee.

Section 16(a) Beneficial Ownership Reporting Compliance

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

To the Company's knowledge, based solely on a review of the copies of such reports furnished to the Company and written representations that no other reports were required, during the fiscal year ended December 31, 2008, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent beneficial owners were complied with.

Code of Ethics

Our Board of Directors has adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees. Stockholders may locate a copy of our Code of Business Conduct and Ethics on our website at http://www.allos.com or request a free copy from:

Allos Therapeutics, Inc.
Attention: Investor Relations
11080 CirclePoint Road, Suite 200
Westminster, CO 80020
Telephone: 303-426-6262

To date, there have been no waivers under our Code of Business Conduct and Ethics. We will post any waivers, if and when granted, of our Code of Business Conduct and Ethics on our website.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion & Analysis

This compensation discussion and analysis provides information regarding the compensation program in place for the executive officers named in the Summary Compensation Table on page 21 of this Amendment No. 1 (collectively, the "named executive officers"). It includes information regarding the objectives of our compensation program, our compensation processes and procedures, each element of compensation that we provide, why we choose these elements, how we determine the amount of each component to pay, and our compensation decisions for 2008 and the first quarter of 2009. This compensation discussion and analysis should be read in conjunction with the tables and related discussion beginning on page 21 of this Amendment No. 1.

Objectives of our Executive Compensation Program

Our executive compensation program is designed to attract, retain and motivate talented executives capable of providing the leadership, vision and execution necessary to achieve our business objectives and create long-term stockholder value. We believe there is a direct correlation between company performance and leadership talent, and that executive officers with the requisite experience, qualifications and values are essential to our success and the success of our stockholders. We also believe the successful execution of our strategic business objectives necessitates the retention of our management team and keeping management focused on business goals. We actively seek to foster a pay-for-performance environment that aligns the interests of our executive officers with the creation of stockholder value. To this end, our executive compensation program is strongly linked to the delivery of long-term returns to our stockholders, the achievement of short- and long-term strategic business objectives, individual performance, and the demonstration of competencies that are aligned with our culture and values and that will contribute to our long-term success.

Role of our Compensation Committee

The Compensation Committee is responsible for overseeing our compensation policies, plans and programs, and reviewing and determining the salary, bonuses, equity incentives, perquisites, severance arrangements and other related benefits paid to our directors and executive officers. The Compensation Committee also oversees the administration of our employee benefit plans. The Compensation Committee's charter reflects these various responsibilities, and the Compensation Committee reviews the charter annually and recommends any appropriate changes or revisions to the Board for its consideration.

The Compensation Committee, with the input of management and its outside advisors, develops our compensation policies, plans and programs by utilizing publicly available compensation data and subscription compensation survey data for national and regional companies in the biopharmaceutical industry, with a particular focus on companies of comparable sizes and stages of development as Allos. The Compensation Committee believes these companies provide appropriate benchmarks for our executive compensation program because they have similar organizational structures and tend to compete with us for executives and other employees.

Based on these data, the Compensation Committee has implemented a pay-for-performance compensation program, which ties a substantial portion of executives' overall compensation, in the form of short- and long-term cash and equity incentives, to the achievement of measurable corporate and

individual performance objectives and the creation of stockholder value. As described in more detail below, our executive compensation program consists of the following key components:

- Base salary;
- Performance-based cash bonuses;
- Equity incentives; and
- Severance and change-in-control benefits.

The Compensation Committee has not established any formal policies or guidelines for allocating compensation between current and long-term incentive compensation, or between cash and non-cash compensation. However, commensurate with the Company's philosophy of establishing a link between compensation and corporate performance, the Compensation Committee believes that a significant portion of each executive officer's total compensation opportunity should be performance-based, reflecting both upside potential and down-side risk.

Compensation Committee Processes and Procedures

Typically, the Compensation Committee meets at least four times a year, and it also considers and takes action by written consent. The Compensation Committee meets regularly in executive session. The agenda for each meeting is usually developed by our Chief Executive Officer, in consultation with the Chair of the Compensation Committee. From time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, provide financial or other background information or advice or otherwise participate in Compensation Committee meetings. The Chair of the Compensation Committee reports on committee actions and recommendations at each regularly scheduled meeting of the Board.

Historically, the Compensation Committee has reviewed and determined any base salary increases, cash bonuses and equity incentives to be awarded to the Company's executive officers, and established annual corporate and individual performance objectives, at one or more meetings held during the first quarter of the year. However, the Compensation Committee also considers matters related to individual compensation from time-to-time upon an executive's promotion or other change in job responsibility that occurs outside the Company's annual performance review and appraisal process, as well as in connection with the hiring of a new executive officer.

Generally, the Compensation Committee's executive compensation process comprises two related elements: the establishment of performance objectives and the determination of executive compensation levels. At the beginning of each year, the Compensation Committee approves annual performance objectives for the corporation as a whole and for each individual executive officer (other than the Chief Executive Officer, whose bonus is tied entirely to the achievement of corporate objectives). The corporate objectives generally target the achievement of specific product development, corporate development, financial and operational milestones. The individual objectives focus on contributions that are consistent with and support the corporate objectives or are otherwise intended to contribute to the success of the Company. The annual corporate and individual performance objectives are proposed by management and reviewed and approved by the Compensation Committee, usually during the first quarter of the year. The corporate objectives are also subject to review and approval by the full Board. The Compensation Committee typically performs an interim assessment of the annual performance objectives in the middle of each year to review corporate and individual progress, and may, on occasion, make certain adjustments to the objectives that the committee deems appropriate based on changing circumstances.

At the conclusion of each year, the Chief Executive Officer prepares a written performance appraisal and assigns each executive officer (other than himself) a performance rating for the year. The performance appraisal evaluates each executive officer's level of performance of his or her core job responsibilities, as well as various skills, behaviors and competencies that are viewed as important to our ability to build and maintain a high performance operating culture. The Chief Executive Officer also evaluates the degree of achievement of the annual corporate and individual performance objectives and submits his recommendations to the Compensation Committee for any base salary increases, cash bonuses and/or equity incentive awards for each executive officer (other than himself). The Chief Executive Officer's recommendations and Compensation Committee's determinations are generally based upon a mix of the following factors:

- The executive's individual performance for the year;
- The degree of achievement of annual corporate and individual performance objectives, as well as any contributions made with regard to objectives or strategic initiatives not covered by the formal goal-setting process;
- Comparisons with market data for compensation paid to comparable executives of other biopharmaceutical or biotechnology companies, with a particular focus on companies of similar sizes and stages of development and/or with which we compete for talented executives;
- The executive's compensation relative to other executive officers at Allos; and
- The importance of the executive's continued service with the Company.

In the case of the Chief Executive Officer, his individual performance appraisal is conducted by the Compensation Committee, which determines his compensation adjustments and awards, if any, based on these same factors. The Chief Executive Officer may not participate in or be present during any deliberations or determinations of the Compensation Committee regarding his compensation. To the extent approved, any base salary increases, cash bonuses and/or equity incentive awards for the executives, including the Chief Executive Officer, are implemented during the first calendar quarter of the year.

With respect to newly hired executive officers, the Compensation Committee, in consultation with the Chief Executive Officer, determines the executive's compensation package, including the terms of any employment agreement, relocation arrangements, severance arrangements or change-in-control protections, based on a variety of subjective and objective factors, including:

- The executive's particular qualifications and experience;
- The competitive recruiting environment for the executive's services;
- Comparisons to market data regarding compensation levels for comparable executives of other biopharmaceutical or biotechnology companies of similar sizes and stages of development and/or with which we compete for talented executives;
- The executive's anticipated role and responsibilities with the Company; and
- The executive's past compensation history.

For all executives, as part of its deliberations, the Compensation Committee reviews a tally sheet setting forth each component of the executive's proposed compensation package, including base salary, bonus potential, the value to the executive and cost to the Company of all equity incentives, perquisites and other personal benefits, the executive's realized and unrealized equity gains, and the Company's projected payout obligations under several severance and change-in-control scenarios, to ensure that each executive's total compensation remains in line with the Company's overall compensation philosophy. The Compensation Committee may also review and consider, as appropriate, materials such

as financial reports and projections, operational data, tax and accounting information, company stock performance data, analyses of historical executive compensation levels and current company-wide compensation levels, and recommendations of the Compensation Committee's compensation consultant.

Under its charter, the Compensation Committee may form and delegate authority to subcommittees, as appropriate, including, but not limited to, a subcommittee composed of one or more members of the Board, to grant stock awards under the Company's equity incentive plans to persons who are not executive officers of the Company. In February 2007, the Compensation Committee adopted an Equity Compensation Awards Policy to define the specific practices and procedures to be followed in connection with the granting of equity awards. Pursuant to the Equity Compensation Awards Policy, as amended in February 2009, the Compensation Committee delegated authority to the Chief Executive Officer to grant stock options and restricted stock units to newly hired employees who are not executive officers in connection with such employee's commencement of employment, within specific guidelines and limitations approved by the Compensation Committee. The authority to approve all other stock awards, including all stock options or other equity grants to the Company's executive officers, and all annual or promotional grants to the Company's other employees, remains vested in the Compensation Committee.

Role of our Compensation Consultants

The Compensation Committee believes that it is important when making compensation decisions to be informed as to the compensation practices of comparable publicly-held companies. To this end, during 2006, the Compensation Committee approved the engagement of Pearl Meyer & Partners ("PM&P"), an independent compensation consulting firm, to conduct reviews of the overall structure and competitiveness of our executive and director compensation programs. The purpose of these reviews was to ensure that our executive and director compensation programs remained competitive, but were also flexible enough to meet our needs as we move to our anticipated next stage of development.

Initially, PM&P was instructed to compare all elements of total direct compensation (i.e., base salary, annual bonus and equity incentives) for our executive officers to compensation data compiled from the most recent proxy statements for two distinct peer groups, both of which were reviewed and approved in advance by the Compensation Committee. The first peer group was comprised of 11 development-stage companies of similar size and scope to Allos, and was intended to serve as a point of reference for compensation practices based on our current stage of development. The second peer group was comprised of 14 "next-stage" companies that had brought at least one product to market and were generating revenue based on the sale of that product, and was intended to serve as a point of reference for compensation practices for our anticipated next stage of development. The Compensation Committee felt this was important because we had two product candidates in late-stage development at that time, and because the competitive recruiting environment for Messrs. Berns and Caruso, who were hired during 2006 to lead our future growth efforts and the potential commercialization of our product candidates, is composed largely of next-stage companies. PM&P was also requested to review and provide recommendations regarding our executive compensation strategy, including the structure and effectiveness of our base salary, annual bonus, equity incentive and change-in-control programs. Separately, PM&P was instructed to compare our director compensation program to the director compensation practices for the two peer groups used in the executive compensation analysis, and to review and provide recommendations regarding the structure of our director compensation program and current trends in director retirement programs.

PM&P presented its findings, observations and recommendations regarding our executive and director compensation programs to the Compensation Committee in September 2006. The Compensation Committee determined at that time that it would be preferable to benchmark the Company's executive compensation program against a single peer group rather than two separate peer

groups. As a result, PM&P, in consultation with the Compensation Committee and our Chief Executive Officer, developed a "blended" peer group comprised of 10 development-stage companies and five next-stage companies. This peer group was intended to allow PM&P to benchmark our executive compensation practices against a broader spectrum of the competitive markets for executive talent, and included the following companies:

- Ariad Pharmaceuticals, Inc.
- Array BioPharma Inc.
- AVI BioPharma, Inc.
- Biocryst Pharmaceuticals, Inc.
- Bioenvision, Inc.
- Coley Pharmaceutical, Inc.
- CV Therapeutics, Inc.
- Dendreon Corporation
- Geron Corporation
- Incyte Corporation
- Isis Pharmaceuticals, Inc.
- Keryx Biopharmaceuticals, Inc.
- Onyx Pharmaceuticals, Inc.
- Pharmion Corporation
- Seattle Genetics, Inc.

PM&P then compared all elements of total direct compensation (i.e., base salary, annual bonus and equity incentives) for our executive officers to compensation data compiled from the most recent proxy statements for the blended peer group. PM&P presented its updated findings, observations and recommendations regarding our executive compensation program to the Compensation Committee in December 2006, which the Compensation Committee considered, among other factors, in setting 2007 executive compensation.

Our relationship with PM&P continued in 2007, as the Compensation Committee retained PM&P to conduct a review of the structure and competitiveness of our executive severance and change-in-control arrangements. As discussed below under the heading "Severance and Change-in-Control Benefits," in our experience, post-termination protection for executive officers is common among our peer group, and the Compensation Committee believes that providing this protection is essential to our ability to attract and retain talented executives capable of providing the leadership, vision and execution necessary to achieve our business objectives. As a result, the Compensation Committee requested that PM&P review and provide recommendations regarding the structure and competitiveness of our executive severance and change-in-control arrangements based on an analysis of practices at our blended peer group of companies, certain specialized studies in severance and change-in-control, as well as information in PM&P's proprietary database. PM&P's findings, observations and recommendations regarding our executive severance and change-in-control programs were presented to the Compensation Committee in September 2007 and relied upon by the Compensation Committee, among other factors, in approving amended and restated employment agreements for Messrs. Caruso and Graboyes and Dr. Cagnoni in December 2007.

In January 2008, the Compensation Committee engaged Mercer, an independent compensation consulting firm, to update our "blended" peer group and provide an assessment of the competitiveness of our 2007 executive compensation program. Mercer compared all elements of total direct compensation (i.e., base salary, annual bonus and equity incentives) for our executive officers to compensation data compiled from the most recent proxy statements for the updated peer group, which was reviewed and approved in advance by the Compensation Committee. As in 2006, the Compensation Committee felt that the use of a blended peer group was appropriate because of the late-stage development status of pralatrexate, our lead product candidate, and because the competitive recruiting environment for Messrs. Berns and Caruso and Dr. Cagnoni, who was hired during 2007 to lead our clinical development organization, is composed largely of next-stage companies. The updated peer group was comprised of 10 development-stage companies and five next-stage companies, and was intended to allow Mercer to benchmark our executive compensation practices against a broad spectrum of the competitive markets for executive talent.

The updated peer group for 2008 included the following companies:

- Ariad Pharmaceuticals, Inc.
- Array BioPharma Inc.
- Biocryst Pharmaceuticals, Inc.
- Coley Pharmaceutical, Inc.
- CV Therapeutics, Inc.
- Dendreon Corporation
- Geron Corporation
- Incyte Corporation
- Isis Pharmaceuticals, Inc.
- Keryx Biopharmaceuticals, Inc.
- Onyx Pharmaceuticals, Inc.
- OSI Pharmaceuticals, Inc.
- Pharmion Corporation
- Progenics Pharmaceuticals, Inc.
- Seattle Genetics, Inc.

Mercer's findings, observations and recommendations were presented to the Compensation Committee in February 2008 and considered by the Compensation Committee, among other factors, in setting 2008 executive compensation.

In October 2008, the Compensation Committee engaged Compensia, an independent compensation consulting firm, to update our "blended" peer group and provide an assessment of the competitiveness of our 2008 executive compensation program. Compensia compared all elements of total direct compensation (i.e., base salary, annual bonus and equity incentives) for our executive officers to compensation data compiled from the most recent proxy statements for the updated peer group, which was reviewed and approved in advance by the Compensation Committee. The updated peer group was comprised of eight development-stage companies and eight next-stage companies, and was intended to allow Compensia to benchmark our executive compensation practices against a broad spectrum of the competitive markets for executive talent. The Compensation Committee felt that the use of a blended peer group that was comprised of one-half development-stage companies and one-half next-stage companies was appropriate given the further progress in the development status of pralatrexate and because the competitive recruiting environment for Messrs. Berns and Caruso and Dr. Cagnoni is composed largely of next-stage companies. Separately, Compensia was requested to review and provide recommendations regarding the Company's equity compensation strategy, including the potential award of restricted stock units and the Company's non-executive equity grant guidelines.

The updated peer group for 2009 included the following companies:

- Ariad Pharmaceuticals, Inc.
- Array BioPharma Inc.
- Alexion Pharmaceuticals, Inc.
- BioMarin Pharmaceutical Inc.
- Cubist Pharmaceuticals, Inc.
- CV Therapeutics, Inc.
- Dendreon Corporation
- Geron Corporation
- Incyte Corporation
- Maxygen, Inc.
- Onyx Pharmaceuticals, Inc.
- OSI Pharmaceuticals, Inc.
- Regeneron Pharmaceuticals, Inc.
- Rigel Pharmaceuticals, Inc.
- Seattle Genetics, Inc.
- ZymoGenetics, Inc.

Compensia's findings, observations and recommendations were presented to the Compensation Committee in December 2008 and February 2009 and were considered by the Compensation Committee, among other factors, in setting 2009 executive compensation.

Compensation Benchmarking

The Compensation Committee recognizes that development-stage companies, such as Allos, often have senior management teams that are differentiated significantly by industry experience, leadership skills and performance. This is because some members of the executive team may have been hired to run the company as a development-stage entity. However, as these companies plan for the potential commercialization of their product candidates, they will often hire senior executives with a proven track record of performance and success in commercial organizations. As a result, the point of reference for market practices can vary for individual members of the executive team within the same company. The Compensation Committee believes that the use of a blended peer group as described above allows us to benchmark our executive officers against appropriate reference points in the market.

For each element of compensation, our strategy has been to examine peer group compensation practices and target our executive compensation between the 50th and 75th percentile of the relevant blended peer group. The Compensation Committee believes these are the appropriate reference points based on the industry experience, leadership skills and performance of our executive officers. However, the Compensation Committee has historically approved actual compensation levels for executive officers above and below these targets based on individual and corporate performance to ensure an appropriate pay-for-performance environment. Moreover, the Compensation Committee believes that the emphasis on variable, or at-risk compensation, helps calibrate actual compensation to performance since executives do not receive value if the Company is not performing well.

The Compensation Committee realizes that benchmarking our executive compensation program against compensation earned at comparable companies may not always be appropriate as a stand-alone tool for setting compensation due to some aspects of our business and objectives that may be unique to Allos. However, the Compensation Committee generally believes that gathering this information is an important part of its decision-making process with respect to our executive compensation program. In addition to the compensation benchmarking data provided by its consultants, the Compensation Committee has historically taken into account input from other sources, including input from other members of the Board of Directors and commercially available survey data relating to compensation practices for the pharmaceutical and biotechnology sectors.

Elements of Executive Compensation Program

Our executive compensation program consists of the following key components:

- Base salary;
- Performance-based cash bonuses;
- Equity incentives; and
- Severance and change-in-control benefits.

The Compensation Committee believes that these four components are the most effective combination in motivating and retaining talented executive officers at this stage in our development. The Compensation Committee does not have any specific targets for the percentage of compensation represented by each component, although a significant percentage of total compensation is allocated to long-term equity incentives as a result of the compensation philosophy discussed above. For example, in fiscal 2008, base salary, performance-based cash bonuses and long-term equity incentives represented an average of approximately 30%, 13% and 57%, respectively, of the named executive officers' total compensation. As a general matter, subject only to limited exceptions relating to the relocation of executive officers, we do not provide perquisites or benefits for our named executive officers on a basis that is different from other eligible employees.

Base Salary

Base salary is the primary fixed component of our executive compensation program. We use base salary to compensate executives for services rendered during the fiscal year, and to ensure that we remain competitive in attracting and retaining executive talent. Base salaries are generally set within a range of salaries paid to industry peers with comparable qualifications, experience, responsibilities and performance at similar companies.

For newly hired executives, the Compensation Committee determines base salary on a case-by-case basis by evaluating a number of factors, including the executive's qualifications and experience, the competitive recruiting environment for his or her services, the executive's anticipated role and responsibilities with the Company, the executive's past compensation history, and comparisons to

market data regarding compensation levels for comparable executives of other biotechnology companies of similar sizes and stages of development or with which we compete for talented executives.

For continuing executives, the Compensation Committee reviews base salaries annually as part of our performance review and appraisal process. Base salary increases, if any, are based primarily on each executive's job performance for the prior year, as well as a review of competitive market data, the executive's compensation relative to other executive officers, and the importance of the executive's continued service with the Company. Annual salary adjustments are effective March 1 of each year. The Compensation Committee may also review an executive's base salary from time-to-time upon a promotion or other change in job responsibility that occurs outside of our annual performance review and appraisal process.

Performance-Based Cash Bonuses

Our performance-based cash bonus program is designed to promote the interests of the Company and its stockholders by providing executive officers with the opportunity to earn annual cash bonuses based upon the achievement of pre-specified corporate and individual performance objectives, and to assist the Company in attracting and retaining executive talent.

At the beginning of each year, we establish annual performance objectives for the corporation as a whole and for each executive officer (other than our Chief Executive Officer, whose bonus is tied entirely to the achievement of corporate objectives). Because we are a development-stage company, the corporate objectives generally target the achievement of specific product development, corporate development, financial and operational milestones that are considered to be critical to the achievement of our long-term strategic goals. The individual objectives focus on contributions that are consistent with and support the corporate objectives or are otherwise intended to contribute to the success of the Company. The annual corporate and individual performance objectives are proposed by management and reviewed and approved by the Compensation Committee, typically during the first quarter of the year. The corporate objectives are also subject to review and approval by the full Board. At this time, the Compensation Committee also approves each executive officer's bonus target for the year based on its analysis of relevant market data, and determines the relative weighting of each executive's bonus between corporate and individual objectives.

The Compensation Committee typically performs an interim assessment of the annual performance objectives in the middle of each year to review corporate and individual progress, and may, on occasion, make certain adjustments to the objectives that the committee deems appropriate based on changing circumstances. At the conclusion of each year, the Chief Executive Officer evaluates the degree of achievement of the annual corporate and individual performance objectives, and submits his bonus recommendations to the Compensation Committee, which determines the final bonus amount, if any, for each executive officer. The Company must generally achieve at least 75% of its weighed corporate objectives for the year in order for any bonuses to be paid, although the Compensation Committee may determine to grant a bonus even though certain corporate or individual performance objectives are not met. If the Compensation Committee determines that corporate or individual performance for the year exceeded objectives or was excellent in view of prevailing conditions, the Compensation Committee may approve corporate or individual performance multipliers, as the case may be, up to 150% of bonus targets. The Compensation Committee also retains the authority, in its discretion, to identify any unplanned achievements that have been accomplished and to approve adjustments to an executive officer's bonus award. Bonuses are generally paid in March of each year for services rendered during the prior fiscal year.

Equity Incentives

Equity incentives represent the largest at-risk component of our executive compensation program. Our equity incentives are designed to align the interests of our executive officers with those of our stockholders by creating an incentive for our executive officers to maximize stockholder value. The equity compensation program is also designed to encourage our executive officers to remain employed with us despite a competitive labor market.

Historically, we have granted stock options and shares of restricted stock to newly-hired executive officers on their first day of employment with us. We have also granted stock options and, beginning in 2009, restricted stock units to continuing executive officers once a year as part of our annual performance review and appraisal process. The annual stock options and restricted stock unit awards are granted as a reward for past individual and corporate performance and as an incentive for future performance. The restricted stock units are also intended to promote employee retention as the Compensation Committee believes that the successful execution of our business strategy necessitates keeping our management team in place and focused on business goals. In addition, there is a trend among our peer group and the biopharmaceutical industry in general toward the use of full value shares, and the Compensation Committee believes the use of restricted stock units are appropriate to maintain a competitive compensation program.

All stock options are granted with a 10-year term and an exercise price equal to 100% of the fair market value of our common stock on the date of grant. The stock options generally vest over a four-year period, with 25% of the options vesting one year after the date of grant, and the remaining 75% of the options vesting in equal monthly installments thereafter over the next three years, subject to the executive's continued employment with us through such vesting dates. The shares of restricted stock and restricted stock units vest in equal installments on each of the first four anniversaries of the date of grant, subject to the executive's continued employment with us through such vesting dates.

The Compensation Committee approves all equity incentive awards for our executive officers. New-hire equity awards are either approved by the Compensation Committee, at regularly scheduled meetings or by unanimous written consent, or by our Chief Executive Officer in accordance with our Equity Compensation Awards Policy. The Compensation Committee approves annual equity grants at its February meeting, the date of which is generally set approximately one year in advance. The Compensation Committee selected the February meeting as the date to approve annual equity grants because it coincides with the Compensation Committee's review of prior year corporate and individual performance and the approval of other executive compensation decisions (e.g., base salary increases and bonus determinations). Grants approved during scheduled meetings become effective and are priced as of the date of approval or a predetermined future date (for example, new hire grants are effective as of the later of the date of approval or the newly-hired executive's start date). Grants approved by unanimous written consent become effective and are priced as of the date the last signature is obtained or as of a predetermined future date. The Compensation Committee has not granted, nor does it intend to grant, equity compensation awards to executive officers in anticipation of the release of material nonpublic information that is likely to result in changes to the price of our common stock, such as a significant positive or negative clinical trial result. Similarly, the Compensation Committee has not timed, nor does it intend in the future to time, the release of material nonpublic information based on equity award grant dates. Also, because equity compensation awards typically vest over a four-year period (and, with respect to options, with a one-year "cliff" followed by monthly vesting thereafter), the value to recipients of any immediate increase in the price of our common stock following a grant will be attenuated.

The Compensation Committee determines the number of stock options, shares or restricted stock and/or restricted stock units to award to a newly-hired executive officer using the same factors described above that are considered in determining the base salaries of newly-hired executive officers.

The Compensation Committee determines the number of stock options and restricted stock units to be awarded to continuing executives based on a variety of factors, including its review of competitive market data, its assessment of each executive officer's individual performance and expected future contribution, a review of each executive's existing equity incentive awards, and the importance of the executive's continued service with the Company.

Severance and Change-in-Control Benefits

We enter into employment agreements with our executives in select cases, generally when it is necessary to secure the services of a newly hired executive. We have entered into employment agreements with each of Messrs. Berns, Caruso and Graboyes and Dr. Cagnoni, each of which were amended and restated in December of 2007, as well as certain other officers, in connection with their commencement of employment with the Company. These agreements provide for severance compensation to be paid if the officers are terminated under certain conditions, such as in connection with a change-in-control of the Company or a termination without cause by us, each as defined in the agreements. In addition, the employment agreements with each of Messrs. Berns and Caruso and Dr. Cagnoni provide that if it is determined that any payment or distribution by the Company to such person to be made in connection with a change-in-control of the Company would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), such person will be entitled to receive an additional payment or "gross up" to offset the economic impact of such excise tax. The terms of such employment agreements, including the severance compensation payable thereunder, are described in more detail beginning on page 26 of this Amendment No. 1 under the heading "Employment, Severance and Change-in-Control Agreements."

In our experience, post-termination protection for executive officers is common among our peer group, and the Compensation Committee believes that providing this protection is essential to our ability to attract and retain talented executives capable of providing the leadership, vision and execution necessary to achieve our business objectives. In addition, the employment agreements and the related post-termination compensation provisions are designed to meet the following objectives:

- *Change-in-control:* As part of our normal course of business, we engage in discussions with other pharmaceutical companies about possible collaborations, licensing and/or other ways in which the companies may work together to further our respective long-term objectives. In addition, many larger established pharmaceutical companies consider companies at similar stages of development to ours as potential acquisition targets. In certain scenarios, the potential for a merger or being acquired may be in the best interests of our stockholders. We provide post-termination compensation if an officer is terminated as a result of a change-in-control transaction to promote the ability of our officers to act in the best interests of our stockholders even though they could be terminated as a result of the transaction. This is particularly important for a company such as Allos, where a majority of our executive officers are relatively new to the company and have not had the opportunity to realize a substantial portion of the value of their equity compensation.
- *Termination without Cause:* In certain instances, if we terminate the employment of an officer "without cause" or the officer resigns for "good reason", each as defined in the applicable agreement, we are obligated to pay the officers certain severance benefits under their employment agreements. We believe this is appropriate because the terminated officer is bound by confidentiality and non-competition provisions covering one year after termination and because we and the officer have a mutually agreed-to severance package that is in place prior to any termination event. This provides us with more flexibility to make a change in senior management if such a change is in our and our stockholders' best interest.

We have also adopted a broad-based Severance Benefit Plan and related Change of Control Severance Benefit Schedule that provides for severance compensation to all officers and employees of the Company with whom we do not have employment agreements in the event such individuals are terminated in connection with a change-in-control. The Severance Benefit Plan and related Change of Control Severance Benefit Schedule is designed to meet the same objectives discussed above with respect to the change-in-control protection provided to Messrs. Berns, Caruso and Graboyes and Dr. Cagnoni under their employment agreements with the Company. The Severance Benefit Plan and related Change of Control Severance Benefit Schedule is described in more detail on page 29 of this Amendment No. 1 under the heading "Severance and Change-in-Control Arrangements."

In addition, our equity incentive plans have provisions regarding vesting following a change-in-control, as defined in those plans.

Perquisites

Perquisites and other personal benefits are not factored into our executive compensation program. We prefer to compensate executive officers using a mix of current, short- and long-term compensation with an emphasis on performance and do not believe that providing an executive perquisite program is consistent with our overall compensation philosophy. We typically provide perquisites and other personal benefits to executive officers on an exception-only basis, and they are generally limited to executive relocation assistance and temporary commuting and living expenses.

Employee Stock Purchase Plan

We have an Employee Stock Purchase Plan, or ESPP, in which all eligible employees, including our executive officers, may elect to participate. Under the ESPP, eligible employees can choose to have up to 10% of their annual base earnings withheld to purchase shares of our common stock during each offering period. The purchase price of the common 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 offering period. Each offering is for a period of six months beginning on January 1 and July 1 of each year.

Indemnification Agreements

We enter into indemnification agreements with each of our directors and executive officers. These indemnification agreements provide, among other things, that we will indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts, incurred by any such person in any action or proceeding by reason of their position as a director, officer, employee, agent or fiduciary of the Company, any subsidiary of the Company or any other company or enterprise that such executive officer or director serves at the Company's request. We believe that indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Other Benefits

We maintain health, dental and vision insurance plans for the benefit of all eligible employees, including our executive officers. Each of these benefit plans requires the employee to pay a portion of the premium, and we pay the remainder of the premiums. These benefits are offered on the same basis to all employees. We also maintain a 401(k) retirement savings plan that is available to all eligible employees. Under the 401(k) plan, we match 50% of each employee's contribution up to a maximum of $5,000 per year. Executives are eligible to participate in the 401(k) plan up to ERISA limits. No supplementary participation is available to the executives. Life, accidental death and dismemberment, short- and long-term disability insurance coverage, and wellness programs are also offered to all eligible

employees and premiums are paid in full by the Company. Other voluntary benefits, such as supplemental long-term disability insurance coverage, are also made available and paid for by the employees. The above benefits are available to our executive officers on the same basis as all other eligible employees.

2008 and 2009 Executive Compensation Determinations

The key compensation determinations for Mr. Berns and the other named executive officers during 2008 and the first quarter of 2009 were as follows:

Paul L. Berns—President and Chief Executive Officer

For fiscal 2008, Mr. Berns' base salary was set at $500,800, representing a 5% increase from his 2007 base salary of $477,000. Mr. Berns' 2008 bonus target was set at 60% of base salary, weighted 100% to the achievement of corporate objectives. For 2008, the Compensation Committee approved a corporate bonus percentage of 100% of target based on our achievement of certain product development, corporate development, financial and operating milestones. As a result, Mr. Berns was awarded a cash bonus of $298,300 (which was determined and paid in 2009), or 100% of his target bonus. Some highlights of our 2008 corporate achievements approved by the Compensation Committee include the following:

- the completion of patient enrollment and the announcement of top-line data relating to our pivotal Phase 2 PROPEL trial of pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma;
- the advancement of our product development program for pralatrexate in lymphoma and solid tumors, including the completion of certain patient enrollment and study conduct objectives relating to our Phase 1 study of pralatrexate in patients with cutaneous T-cell lymphoma, our Phase 1/2a study of pralatrexate plus gemcitabine in patients with non-Hodgkin's lymphoma, our Phase 2b study of pralatrexate in patients with non-small cell lung cancer, and our Phase 2 study in patients with advanced or metastatic relapsed transitional cell carcinoma of the urinary bladder;
- the completion of certain objectives relating to the potential future commercial launch of pralatrexate for patients with relapsed or refractory peripheral T-cell lymphoma, including activities relating to the preparation of the Company's New Drug Application for filing with the U.S. Food and Drug Administration, the development and execution of the Company's strategic launch plan and priority market research activities, and the execution of the Company's manufacturing process validation activities;
- the closing of our $70 million underwritten offering of common stock in May 2008; and
- the completion of various objectives relating to the development, implementation and execution of our ex-U.S. partnering strategy for pralatrexate and our corporate growth strategy.

In February 2008, Mr. Berns was awarded a stock option to purchase 275,000 shares of common stock at an exercise price of $6.12 per share, the fair market value of our common stock on the date of grant. As was the case for all named executive officers, the 2008 option grant was awarded both as a reward for 2007 individual and corporate performance and as an incentive for future performance.

For fiscal 2009, Mr. Berns volunteered to forego any increases to his base salary or bonus target as a result of the challenging economic environment. As a result, his 2009 base salary remained at $500,800 and his 2009 bonus target remained at 60% of base salary, weighted 100% to the achievement of corporate objectives. In February 2009, Mr. Berns was awarded a stock option to purchase 280,000 shares of common stock at an exercise price of $6.40 per share, the fair market value of our common

stock on the date of grant, and 46,667 restricted stock units. As was the case for all named executive officers, the 2009 stock option and restricted stock unit grants were awarded both as a reward for 2008 individual and corporate performance and as an incentive for future performance. Additionally, the restricted stock units were intended to promote employee retention in light of the current macroeconomic environment, where successful Company performance may not necessarily be reflected in the Company's stock price.

Mr. Berns does not receive separate compensation for serving as a member of the Board.

Pablo J. Cagnoni, M.D.—Senior Vice President, Chief Medical Officer

For fiscal 2008, Dr. Cagnoni's base salary was set at $404,200, representing a 5% increase from his 2007 base salary of $385,000. Dr. Cagnoni's 2008 bonus target was set at 40% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. For 2008, Dr. Cagnoni was awarded a cash bonus of $170,100 (which was determined and paid in 2009), or approximately 106% of his target bonus, which reflected a corporate bonus component of 100% and an individual bonus component of approximately 115% of target. In February 2008, Dr. Cagnoni was awarded a stock option to purchase 150,000 shares of common stock at an exercise price of $6.12 per share, the fair market value of our common stock on the date of grant.

For fiscal 2009, as was the case for all named executive officers (other than Mr. Berns), the Compensation Committee approved a base salary increase of 2.5% for Dr. Cagnoni, resulting in a 2009 base salary of $414,400. Dr. Cagnoni's 2009 bonus target remained at 40% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. In addition, Dr. Cagnoni was awarded a stock option to purchase 143,452 shares of common stock at an exercise price of $6.40 per share, the fair market value of our common stock on the date of grant, and 23,873 restricted stock units.

James V. Caruso—Executive Vice President, Chief Commercial Officer

For fiscal 2008, Mr. Caruso's base salary was set at $398,600, representing a 5% increase from his 2007 base salary of $379,600. Mr. Caruso's 2008 bonus target was set at 40% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. For 2008, Mr. Caruso was awarded a cash bonus of $168,900 (which was determined and paid in 2009), or approximately 107% of his target bonus, which reflected a corporate bonus component of 100% of target and an individual bonus component of approximately 117% of target. In February 2008, Mr. Caruso was awarded a stock option to purchase 150,000 shares of common stock at an exercise price of $6.12 per share, the fair market value of our common stock on the date of grant.

For fiscal 2009, Mr. Caruso's base salary was set at $408,500, representing a 2.5% increase from his 2008 base salary. Mr. Caruso's 2009 bonus target remained at 40% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. In addition, Mr. Caruso was awarded a stock option to purchase 143,452 shares of common stock at an exercise price of $6.40 per share, the fair market value of our common stock on the date of grant, and 23,873 restricted stock units.

David C. Clark—Vice President, Finance, Treasurer and Assistant Secretary

For fiscal 2008, Mr. Clark's base salary was set at $210,000, representing a 13.2% increase from his 2007 base salary of $185,500. This included a 4% merit increase and a 9.2% market adjustment based on the Compensation Committee's review of competitive market data. Mr. Clark's 2008 bonus target was set at 25% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. For 2008, Mr. Clark was awarded a cash bonus of $53,600 (which was determined and paid in 2009), or approximately 104% of his target bonus, which reflected a

corporate bonus component of 100% of target and an individual bonus component of 110% of target. In February 2008, Mr. Clark was awarded a stock option to purchase 57,500 shares of common stock at an exercise price of $6.12 per share, the fair market value of our common stock on the date of grant.

For fiscal 2009, Mr. Clark's base salary was set at $215,500, representing a 2.5% increase from his 2008 base salary. Mr. Clark's 2009 bonus target remained at 25% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. In addition, Mr. Clark was awarded a stock option to purchase 35,000 shares of common stock at an exercise price of $6.40 per share, the fair market value of our common stock on the date of grant, and 5,875 restricted stock units.

Marc H. Graboyes—Senior Vice President, General Counsel and Secretary

For fiscal 2008, Mr. Graboyes' base salary was set at $300,600, representing a 17.6% increase from his 2007 base salary of $255,500. This included a 5% merit increase and a 12.6% promotional adjustment in connection with Mr. Graboyes' appointment as Senior Vice President, General Counsel and Secretary. Mr. Graboyes' 2008 bonus target was set at 30% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. For 2008, Mr. Graboyes was awarded a cash bonus of $91,600 (which was determined and paid in 2009), or approximately 104% of his target bonus, which reflected a corporate bonus component of 100% of target and an individual bonus component of 110% of target. In February 2008, Mr. Graboyes was awarded a stock option to purchase 100,000 shares of common stock at an exercise price of $6.12 per share, the fair market value of our common stock on the date of grant.

For fiscal 2009, Mr. Graboyes' base salary was set at $308,100, representing a 2.5% increase from his 2008 base salary. Mr. Graboyes' 2008 bonus target was set at 40% of base salary, weighted 60% to the achievement of corporate objectives and 40% to the achievement of individual objectives. In addition, Mr. Graboyes was awarded a stock option to purchase 90,496 shares of common stock at an exercise price of $6.40 per share, the fair market value of our common stock on the date of grant, and 15,060 restricted stock units.

Accounting and Tax Considerations

Effective January 1, 2006, we adopted the fair value recognition provisions of Financial Accounting Standards Board, or FASB, Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R. Under SFAS 123R, we are required to estimate and record an expense for each award of equity compensation over the vesting period of the award. Until we achieve sustained profitability, the availability to us of a tax deduction for compensation expense is not material to our financial position. We structure cash incentive bonus compensation so that it is taxable to our employees at the time it becomes available to them.

Section 162(m) of the Code limits us to a deduction for federal income tax purposes of up to $1 million of compensation paid to certain named executive officers in a taxable year. It is possible that compensation attributable to awards, when combined with all other types of compensation received by a covered employee from us, may cause this limitation to be exceeded in any particular year. Certain kinds of compensation, including qualified "performance-based compensation," are disregarded for purposes of the deduction limitation. In accordance with Treasury Regulations issued under Section 162(m) of the Code, compensation attributable to stock options and stock appreciation rights will qualify as performance-based compensation if (a) such awards are granted by a compensation committee comprised solely of "outside directors," (b) the plan contains a per-employee limitation on the number of shares for which such awards may be granted during a specified period, (c) the per-employee limitation is approved by the stockholders, and (d) the exercise or strike price of the award is no less than the fair market value of the stock on the date of grant. Compensation attributable

to stock purchase awards, stock bonus awards, stock unit awards, performance stock awards, and performance cash awards will qualify as performance-based compensation, provided that: (i) the award is granted by a compensation committee comprised solely of "outside directors"; (ii) the award is granted (or exercisable) only upon the achievement of an objective performance goal established in writing by the compensation committee while the outcome is substantially uncertain; (iii) the compensation committee certifies in writing prior to the grant, vesting or exercise of the award that the performance goal has been satisfied; and (iv) prior to the grant of the award, stockholders have approved the material terms of the award (including the class of employees eligible for such award, the business criteria on which the performance goal is based, and the maximum amount, or formula used to calculate the amount, payable upon attainment of the performance goal).

Our Compensation Committee intends for all stock options and stock appreciation rights granted under our 2008 Equity Incentive Plan to qualify as performance-based compensation within the meaning of Section 162(m) of the Code. In addition, under our 2008 Equity Incentive Plan our Compensation Committee has the discretion to grant other types of awards that may qualify as performance-based compensation within the meaning of Section 162(m) of the Code. Stock options granted under our 2000 Stock Incentive Compensation Plan are performance-based compensation within the meaning of Section 162(m) of the Code and, as such, are fully deductible as long as our Board of Directors or the committee of our Board of Directors granting such stock options is composed solely of "outside directors." However, stock options granted under our 2002 Broad Based Equity Incentive Plan and our 2006 Inducement Award Plan are not considered performance-based compensation within the meaning of Section 162(m) of the Code. Accordingly, our compensation deduction, if any, resulting from the exercise of such options may not be fully deductible, depending on whether the optionee is a named executive officer at the time of exercise and on whether the total non-exempt compensation paid to such optionee exceeds $1 million in the year of such option exercise. To maintain flexibility in compensating executive officers in a manner designed to promote varying corporate goals, our Compensation Committee has not adopted a policy requiring all compensation to be deductible. Our Compensation Committee intends to continue to evaluate the effects of the compensation limits of Section 162(m) of the Code and to grant compensation awards in the future in a manner consistent with the best interests of the Company and our stockholders.

Summary Compensation Table

The following table shows for the fiscal years ended December 31, 2008, 2007 and 2006, compensation awarded or paid to, or earned by, the Company's President and Chief Executive Officer (Principal Executive Officer), Vice President, Finance and Treasurer (Principal Financial Officer) and our three other most highly compensated executive officers at December 31, 2008 (as previously defined, the "named executive officers").

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)(4)	Total ($)
Paul L. Berns	2008	497,200	—	159,700	1,123,600	298,300	12,800(5)	2,091,600
President and Chief	2007	472,800	—	298,300	1,109,200	280,800	156,100(6)	2,317,200
Executive Officer	2006	366,900	184,900(7)	399,600	659,900	—	106,500(8)	1,717,800
David C. Clark	2008	206,200	—	—	201,800	53,600	5,000	466,600
Vice President, Finance	2007	183,900	5,600(9)	—	166,800	53,200	5,000	414,500
and Treasurer	2006	168,100	—	—	74,300	33,600	2,000	278,000
James V. Caruso	2008	395,600	—	68,700	621,500	168,900	5,000	1,259,700
Executive Vice President,	2007	377,400	—	129,700	641,800	154,900	3,700(10)	1,307,500
Chief Commercial Officer	2006	210,600	—	102,900	229,200	73,700	93,700(11)	710,100
Pablo J. Cagnoni	2008	401,300	—	150,300	682,000	170,100	5,000	1,408,700
Senior Vice President,	2007	303,600	50,000(12)	189,500	531,700	175,000(13)	4,700	1,254,500
Chief Medical Officer								
Marc H. Graboyes	2008	293,600	—	—	328,800	91,600	5,000	719,000
Senior Vice President,	2007	252,600	—	—	246,600	73,200	5,000	577,400
General Counsel and	2006	232,000	15,000(14)	—	125,000	61,600	2,000	435,600
Secretary								

(1) The amounts shown in this column represent the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year for restricted stock awards granted to the named executive officers, as determined in accordance with Financial Accounting Standards Board Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (which we refer to as SFAS 123R). Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For additional information, see Note 4 to the Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008. These amounts reflect the Company's accounting expense for these awards, and do not correspond to the actual value that will be recognized by the named executive officers.

(2) The amounts shown in this column represent the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year for stock options granted to the named executive officers, as determined in accordance with SFAS 123R. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For additional information on the valuation assumptions used to calculate these amounts, see Note 4 to the Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008. These amounts reflect the Company's accounting expense for these awards, and do not correspond to the actual value that will be recognized by the named executive officers.

(3) The amounts shown in this column represent the cash bonuses earned by the named executive officers with respect to the fiscal year under the Company's performance-based cash bonus program. Amounts earned with respect to the fiscal year are generally paid in March of the following year. For example, the amounts shown for 2008 were paid in March 2009. For additional information, see the Compensation Discussion and Analysis beginning on page 6 of this Amendment No. 1.

(4) Unless otherwise indicated, the amounts shown in this column represent Company contributions under the Company's 401(k) plan.

(5) This amount for Mr. Berns consists of the following: (i) $7,800 in supplemental disability insurance premiums and (ii) $5,000 Company contribution under the Company's 401(k) plan.

(6) This amount for Mr. Berns consists of the following: (i) executive relocation expenses totaling $96,200, which total includes closing costs on the sale of his residence of $64,000, temporary living expenses of $18,900, travel between home and office of $7,600 and car rental costs; (ii) $5,000 Company contribution under the Company's 401(k) plan; (iii) $7,700 in supplemental disability insurance premiums; and (iv) $47,200 in tax reimbursement in connection with the relocation expenses and supplemental disability insurance premiums described in (i) and (iii) above.

(7) This amount for Mr. Berns represents a guaranteed bonus paid in accordance with the terms of his employment agreement with the Company, as in effect for 2006.

(8) This amount for Mr. Berns consists of the following: (i) executive relocation expenses totaling $72,000, which total includes temporary living expenses of $40,400, travel between home and office, car rental costs and house-hunting costs; (ii) $32,500 in tax reimbursement in connection with the relocation expenses described in (i) above; and (iii) $2,000 Company contribution under the Company's 401(k) plan.

(9) This amount for Mr. Clark represents a cash payment made in connection with the increase in the exercise price of an option granted to Mr. Clark in April 2004 in order to avoid the adverse tax consequences of Section 409A of the Code. During 2007, the Company determined that the actual date on which the option was granted to Mr. Clark was April 28, 2004, when the closing market price of the Company's common stock was $4.78, rather than April 19, 2004, when the closing market price of the Company's common stock was $4.50. In order to avoid the adverse tax consequences of Section 409A of the Code resulting from the vesting of a "discounted option" after December 31, 2004, Mr. Clark and the Company agreed to amend the option to provide that, with respect to the portion of the option vesting after December 31, 2004 (20,000 shares), the option will have an exercise price of $4.78 per share. In connection with such amendment, in January 2008, the Company awarded Mr. Clark a cash payment of $5,600, which is equal to the aggregate increase in the exercise price of the option.

(10) This amount for Mr. Caruso consists of a $5,000 Company contribution under the Company's 401(k) plan, offset by $1,300 in payments received from Mr. Caruso as reimbursement for certain benefits provided by the Company during 2006.

(11) This amount for Mr. Caruso consists of the following: (i) executive relocation expenses totaling $65,000, which total includes temporary living expenses of $28,000, travel between home and office of $33,000 and car rental costs; (ii) $26,700 in tax reimbursement in connection with the relocation expenses described in (i) above; and (iii) $2,000 Company contribution under the Company's 401(k) plan.

(12) This amount for Dr. Cagnoni represents a signing bonus paid in connection with his commencement of employment with the Company in March 2007.

(13) This amount for Dr. Cagnoni consists of the following: (i) a $125,000 cash bonus earned under the Company's performance-based cash bonus program (which was determined and paid in 2008); and (ii) an additional $50,000 bonus paid in January 2008 under the terms of his employment agreement with the Company based on his achievement of certain clinical development milestones.

(14) This amount for Mr. Graboyes represents a discretionary bonus paid in addition to Mr. Graboyes' cash bonus earned under the Company's performance-based cash bonus program. The discretionary bonus was awarded by the Compensation Committee in recognition of certain additional achievements by Mr. Graboyes during 2006.

Grants of Plan-Based Awards

The following table sets forth certain information regarding grants of plan-based awards to the named executive officers during the year ended December 31, 2008:

Name	Grant Date	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards(1)			All Other Option Awards: Number of Securities Underlying Options (#)(2)	Exercise or Base Price of Option Awards ($/Sh)(3)	Grant Date Fair Value of Stock and Option Awards ($)(4)
		Threshold ($)	Target ($)	Maximum ($)			
Paul L. Berns	1/1/2008	223,700	298,300	447,500	—	—	—
	2/25/2008	—	—	—	275,000	6.12	1,073,700
David C. Clark	1/1/2008	38,700	51,600	77,300	—	—	—
	2/25/2008	—	—	—	57,500	6.12	174,900
James V. Caruso	1/1/2008	118,700	158,300	237,400	—	—	—
	2/25/2008	—	—	—	150,000	6.12	585,700
Pablo J. Cagnoni	1/1/2008	120,400	160,500	240,800			
	2/25/2008	—	—	—	150,000	6.12	585,700
Marc H. Graboyes	1/1/2008	66,100	88,100	132,100	—	—	—
	2/25/2008	—	—	—	100,000	6.12	304,200

(1) These columns show the possible threshold, target and maximum cash bonus payments to the named executive officers for the year ended December 31, 2008 under the Company's performance-based cash bonus program, which is described in more detail in the Compensation Discussion and Analysis beginning on page 6 of this Amendment No. 1. The actual cash bonus awards earned by the named executive officers for the year ended December 31, 2008 are set forth in the Summary Compensation Table above under the column entitled "Non-Equity Incentive Plan Compensation," and the amounts set forth in these columns do not represent additional compensation paid to or earned by the named executive officers for the year ended December 31, 2008. The Company's performance-based cash bonus program provides that the Company must generally achieve at least 75% of its weighted corporate objectives for the year in order for any bonuses to be paid, although the Compensation Committee may determine to grant a bonus even though certain corporate or individual performance objectives are not met. If the Compensation Committee determines that corporate or individual performance for the year exceeded objectives or was excellent in view of prevailing conditions, the Compensation Committee may approve corporate or individual multipliers, as the case may be, up to 150% of target. The possible threshold, target and maximum cash bonus payments for the named executive officers for the year ended December 31, 2008 under the Company's performance-based cash bonus program are calculated as follows:

Name	Actual Base Salary Earned ($)	Bonus Target as % of Base Salary	Threshold ($)	Target ($)	Maximum ($)
Paul L. Berns	497,200	60%	223,700	298,300	447,500
David C. Clark	206,200	25%	38,700	51,600	77,300
James V. Caruso	395,600	40%	118,700	158,300	237,400
Pablo J. Cagnoni	401,300	40%	120,400	160,500	240,800
Marc H. Graboyes	293,600	30%	66,100	88,100	132,100

(2) This column shows the number of shares of common stock underlying stock options granted to the named executive officers during the year ended December 31, 2008. The stock options have a 10-year term and vest over a four-year period, with 25% of the options vesting on the first

anniversary of the date of grant and the remaining 75% of the options vesting in equal monthly installments thereafter over the next three years, subject to the recipient's continued employment with the Company through such vesting dates.

(3) This column shows the exercise price for the stock options granted to the named executive officers during the year ended December 31, 2008, which equals the fair market value of the Company's common stock on the date of grant.

(4) This column shows the full grant date fair value of the stock options granted to the named executive officers during the year ended December 31, 2008, as determined in accordance with SFAS 123R. The full grant date fair value is the amount that the Company recognizes as stock-based compensation expense in its financial statements over the required service period of the award. For additional information, see Note 4 to the Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth certain information regarding equity awards granted to the named executive officers that were outstanding as of December 31, 2008:

	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options(1)		Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(2)
Name	Exercisable (#)	Unexercisable (#)				
Paul L. Berns	481,245	218,755	3.14	3/9/2016	—	—
	—	—	—	—	150,000(3)	918,000
	126,040	148,960	7.47	2/16/2017	—	—
	—	275,000	6.12	2/25/2018	—	—
David C. Clark	20,000	—	4.78(4)	4/19/2014	—	—
	10,000	—	2.28(5)	9/8/2014	—	—
	14,062	938	2.46	3/4/2015	—	—
	28,333	11,667	2.70	2/10/2016	—	—
	17,437	9,563	2.93	5/9/2016	—	—
	22,916	27,084	7.47	2/16/2017	—	—
	—	57,500	6.12	2/25/2018	—	—
James V. Caruso	218,747	131,253	3.13	6/5/2016	—	—
	—	—	—	—	55,000(6)	336,600
	68,749	81,251	7.47	2/16/2017	—	—
	—	150,000	6.12	2/25/2018	—	—
Pablo J. Cagnoni	131,249	168,751	6.17	3/19/2017	—	—
	—	—	—	—	56,250(7)	344,300
	—	150,000	6.12	2/25/2018	—	—
Marc H. Graboyes	80,000	—	2.00	10/11/2014	—	—
	18,749	1,251	2.46	3/4/2015	—	—
	70,832	29,168	2.70	2/10/2016	—	—
	34,374	40,626	7.47	2/16/2017	—	—
	—	100,000	6.12	2/25/2018	—	—

(1) Unless otherwise indicated, these options have a 10-year term and vest over a four-year period, with 25% of the options vesting on the first anniversary of the date of grant and the remaining 75% of the options vesting in equal monthly installments thereafter over the next three years, subject to the recipient's continued employment with the Company through such vesting dates.

(2) The market value of the shares of restricted stock that have not vested as of December 31, 2008 is based on $6.12 per share, which equaled the closing price of the Company's common stock on December 31, 2008, the last business day of the 2008 fiscal year.

(3) Three hundred thousand shares of restricted stock were granted to Mr. Berns on March 9, 2006 in connection with his commencement of employment with the Company. Twenty-five percent of the shares (75,000 shares) vested on each of March 9, 2007 and 2008 and the remaining 50% of the shares (150,000 shares) will vest in two equal installments on each of March 9, 2009 and 2010, subject to Mr. Berns' continued employment with the Company through such vesting dates.

(4) The exercise price of this option was previously reported as $4.50 per share, which equaled the closing price of the Company's common stock on April 19, 2004. During 2007, the Company determined that the actual date on which the option was granted to Mr. Clark was April 28, 2004, when the closing price of the Company's common stock was $4.78, rather than April 19, 2004. In order to avoid the adverse tax consequences of Section 409A of the Code resulting from the vesting of a "discounted option" after December 31, 2004, Mr. Clark and the Company agreed to amend the option to provide that, with respect to the portion of the option vesting after December 31, 2004 (20,000 shares), the option will have an exercise price of $4.78 per share.

(5) These options have a 10-year term and vested over a two-year period, with 25% of the options vesting on the six month anniversary of the date of grant and the remaining 75% of the options vesting in equal monthly installments thereafter over the next 18 months.

(6) One hundred and ten thousand shares of restricted stock were granted to Mr. Caruso on June 5, 2006 in connection with his commencement of employment with the Company. Twenty-five percent of the shares (27,500 shares) vested on each of June 5, 2007 and 2008 and the remaining 50% of the shares (55,000 shares) will vest in two equal installments on each of June 5, 2009 and 2010, subject to Mr. Caruso's continued employment with the Company through such vesting dates.

(7) Seventy-five thousand shares of restricted stock were granted to Dr. Cagnoni on March 19, 2007 in connection with his commencement of employment with the Company. Twenty-five percent of the shares (18,750 shares) vested on March 19, 2008 and the remaining 75% of the shares (56,250 shares) will vest in three equal installments on each of March 19, 2009, 2010 and 2011, subject to Dr. Cagnoni's continued employment with the Company through such vesting dates.

Option Exercises And Stock Vested

The following table sets forth certain information regarding option exercises and shares of restricted stock that vested during the year ended December 31, 2008 with respect to the named executive officers:

	Option Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)(1)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)(2)
Paul L. Berns	—	—	75,000	417,800
David C. Clark	—	—	—	—
James V. Caruso	—	—	27,500	184,800
Pablo J. Cagnoni	—	—	18,750	101,600
Marc H. Graboyes	—	—	—	—

(1) There were no stock option exercises by the named executive officers during the year ended December 31, 2008.

(2) The value realized on vesting of shares of restricted stock equals the market value of the Company's common stock on the vesting date, multiplied by the number of shares that vested.

Retirement Payments and Benefits

None of the named executive officers participate in or have account balances in qualified or non-qualified deferred benefit plans sponsored by the Company.

Nonqualified Deferred Compensation

None of the named executive officers participate in or have account balances in non-qualified defined contribution plans or other deferred compensation plans maintained by the Company. In the future, the Compensation Committee may elect to provide the named executive officers and other employees with non-qualified defined contribution or deferred compensation benefits if the Compensation Committee determines that doing so is in the Company's best interests.

Employment, Severance and Change-in-Control Agreements

The Company has entered into employment agreements with each of the named executive officers other than Mr. Clark. The material terms of such agreements are summarized below.

Employment Agreement with Mr. Berns

On March 9, 2006, the Company entered into an employment agreement with Mr. Berns in connection with his appointment to serve as the Company's President and Chief Executive Officer. On December 12, 2006, the Company and Mr. Berns amended and restated the employment agreement to extend the time during which the Company was obligated to reimburse certain commuting and temporary living expenses to June 30, 2007. On December 13, 2007, the Company and Mr. Berns entered into a second amended and restated employment agreement to, among other things, bring the employment agreement into compliance with Section 409A of the Code and clarify Mr. Berns' change-in-control termination benefits regarding the acceleration of stock options and restricted stock upon a change-in-control termination.

Pursuant to the second amended and restated employment agreement, Mr. Berns earns an annual base salary, which amount may be increased annually at the discretion of the Board. Currently, Mr. Berns earns an annual base salary of $500,800. Mr. Berns is also eligible to participate in the Company's performance-based cash bonus plan, pursuant to which he is eligible for an annual bonus award determined in accordance with the terms of the plan. Currently, Mr. Berns' target bonus is set at 60% of his annual base salary.

The second amended and restated employment agreement with Mr. Berns also provides that his employment with the Company is at-will and may be terminated by either Mr. Berns or the Company at any time. However, if the Company terminates Mr. Berns' employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), provided that Mr. Berns executes a general release in favor of the Company at the election of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

The second amended and restated employment agreement with Mr. Berns further provides that if the Company (or any surviving or acquiring corporation) terminates Mr. Berns' employment without cause or if he resigns for good reason within one month prior to or two years following the effective date of a change-in-control of the Company, provided that Mr. Berns executes a general release in favor of the Company (or any surviving or acquiring corporation) at the election thereof, he will be

entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

The second amended and restated employment agreement also imposes on Mr. Berns certain confidentiality, non-compete and non-solicitation obligations. The non-compete and non-solicit obligations are in effect for the term of his employment and will continue for 12 months after termination of his employment for any reason, provided that such non-compete obligations will terminate upon a change-in-control of the Company. In the event that Mr. Berns violates his confidentiality, non-compete or non-solicitation obligations or the terms of his confidentiality and inventions assignment agreement with the Company, his right to most of the severance benefits that he would have otherwise been entitled to pursuant to the second amended and restated employment agreement (other than in connection with a change-in-control of the Company) will cease on the date of such violation.

Employment Agreement with Dr. Cagnoni

On March 19, 2007, the Company entered into an employment agreement with Dr. Cagnoni in connection with his appointment to serve as the Company's Senior Vice President, Chief Medical Officer. On December 13, 2007, the Company and Dr. Cagnoni entered into an amended and restated employment agreement to, among other things, bring the employment agreement into compliance with Section 409A of the Code and implement certain changes recommended by the Company's outside compensation consultant regarding Dr. Cagnoni's change-in-control severance benefits.

Pursuant to the amended and restated employment agreement, Dr. Cagnoni earns an annual base salary, which is subject to annual review and adjustment by the Compensation Committee. Currently, Dr. Cagnoni earns an annual base salary of $414,400. Dr. Cagnoni is also eligible to participate in the Company's performance-based cash bonus plan, pursuant to which he is eligible for an annual bonus award determined in accordance with the terms of the plan. Currently, Dr. Cagnoni's target bonus is set at 40% of his annual base salary.

Pursuant to the amended and restated employment agreement, on the date Dr. Cagnoni started employment with the Company, he received a signing bonus of $50,000 less applicable employment tax withholdings and deductions. Upon satisfaction of certain milestones and pursuant to the amended and restated employment agreement, Dr. Cagnoni received an additional bonus of $50,000 less applicable employment tax withholdings and deductions on January 11, 2008.

The amended and restated employment agreement with Dr. Cagnoni also provides that his employment with the Company is at-will and may be altered or terminated by either Dr. Cagnoni or the Company at any time. However, if the Company terminates Dr. Cagnoni's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), provided that Dr. Cagnoni executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

The amended and restated employment agreement with Dr. Cagnoni further provides that if the Company (or any surviving or acquiring corporation) terminates Dr. Cagnoni's employment without just cause or if he resigns for good reason within one month prior to or 12 months following the effective date of a change-in-control of the Company, provided that Dr. Cagnoni executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

Employment Agreement with Mr. Caruso

On June 5, 2006, the Company entered into an employment agreement with Mr. Caruso in connection with his appointment to serve as the Company's Executive Vice President, Chief Commercial Officer. On December 13, 2007, the Company and Mr. Caruso entered into an amended and restated employment agreement to, among other things, bring the employment agreement into compliance with Section 409A of the Code and implement certain changes recommended by the Company's outside compensation consultant regarding Mr. Caruso's change-in-control severance benefits.

Pursuant to the amended and restated employment agreement, Mr. Caruso earns an annual base salary, which is subject to annual review and adjustment by the Compensation Committee. Currently, Mr. Caruso earns an annual base salary of $408,500. Mr. Caruso is also eligible to participate in the Company's performance-based cash bonus plan, pursuant to which he is eligible for an annual bonus award determined in accordance with the terms of the plan. Currently, Mr. Caruso's target bonus is set at 40% of his annual base salary.

The amended and restated employment agreement with Mr. Caruso also provides that his employment with the Company is at-will and may be altered or terminated by either Mr. Caruso or the Company at any time. However, if the Company terminates Mr. Caruso's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), provided that Mr. Caruso executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

The amended and restated employment agreement with Mr. Caruso further provides that if the Company (or any surviving or acquiring corporation) terminates Mr. Caruso's employment without just cause or if he resigns for good reason within one month prior to or 12 months following the effective date of a change-in-control of the Company, provided that Mr. Caruso executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

Employment Agreement with Mr. Graboyes

On October 11, 2004, the Company entered into an employment agreement with Mr. Graboyes in connection with his appointment as Vice President, General Counsel. On December 13, 2007, the Company and Mr. Graboyes entered into an amended and restated employment agreement to, among other things, bring the employment agreement into compliance with Section 409A of the Code and implement certain changes recommended by the Company's outside compensation consultant regarding Mr. Graboyes' change-in-control severance benefits.

Pursuant to the amended and restated employment agreement, Mr. Graboyes earns an annual base salary, which is subject to annual review and adjustment by the Compensation Committee. Currently, Mr. Graboyes earns an annual base salary of $308,100. Mr. Graboyes is also eligible to participate in the Company's performance-based cash bonus plan, pursuant to which he is eligible for an annual bonus award determined in accordance with the terms of the plan. Currently, Mr. Graboyes' target bonus is set at 40% of his annual base salary.

The amended and restated employment agreement with Mr. Graboyes also provides that his employment with the Company is at-will and may be altered or terminated by either Mr. Graboyes or the Company at any time. However, if the Company terminates Mr. Graboyes' employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the

Company), provided that Mr. Graboyes executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

The amended and restated employment agreement with Mr. Graboyes further provides that if the Company (or any surviving or acquiring corporation) terminates Mr. Graboyes' employment without just cause or if he resigns for good reason within one month prior to or 12 months following the effective date of a change-in-control, provided that Mr. Graboyes executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change-in-Control" beginning on page 30 of this Amendment No. 1.

Severance and Change-in-Control Arrangements

The Company has established a Severance Benefit Plan to provide for the payment of severance benefits to all full-time employees, including the named executive officers, who do not otherwise have separate employment agreements with the Company and whose employment is involuntarily terminated due to a change-in-control of the Company.

The Change of Control Severance Benefit Schedule under the Severance Benefit Plan provides that if the Company terminates an eligible employee's employment without just cause or if the eligible employee resigns for good reason within two months prior to or six months following the effective date of a change-in-control of the Company, and upon the eligible employee's execution of a general release releasing the Company from all claims known or unknown that the eligible employee may have against the Company, the eligible employee will be entitled to receive the following severance benefits:

- If the eligible employee holds a position with the Company of director or above, the Company will pay the employee a lump-sum cash payment equal to (i) six months of the employee's base salary then in effect plus an additional two weeks base salary for each 12 months of continuous service with the Company, up to a maximum of 52 weeks, plus (ii) the employee's target bonus award for the year in which the employee's employment terminates, prorated through the date of termination. Eligible employees who are entitled to severance under this paragraph with more than five but fewer than 12 full months of continuous service with the Company will be deemed to be in continuous service with the Company for 12 full months.
- If the eligible employee holds a position with the Company below director, the Company will pay the employee a lump-sum cash payment equal to (i) three months of the employee's base salary then in effect plus an additional two weeks base salary for each 12 months of continuous service with the Company, up to a maximum of 52 weeks, plus (ii) the employee's target bonus award for the year in which the employee's employment terminates, prorated through the date of termination. Eligible employees who are entitled to severance under this paragraph with more than five but fewer than 12 full months of continuous service with the Company will be deemed to be in continuous service with the Company for 12 full months.
- Full acceleration of vesting of any outstanding stock options and restricted stock issued to the eligible employee.
- Payment of premiums for the eligible employee's group health insurance COBRA continuation coverage after the date of termination for the number of weeks that are used to determine the amount of the eligible employee's cash severance as described above.
- Outplacement assistance through an outside organization as a resource to aid in the eligible employee's career transition.

Potential Payments Upon Termination or Change-in-Control

The following tables reflect the estimated potential payments upon termination or change-in-control of the Company that would be payable to each of the named executive officers. For purposes of calculating the potential payments set forth in the tables below, we have assumed that (i) the date of termination was December 31, 2008 and (ii) the stock price was $6.12, the closing market price of the Company's common stock on December 31, 2008, the last business day of the 2008 fiscal year.

Paul L. Berns—President and Chief Executive Officer

Under the terms of Mr. Berns' second amended and restated employment agreement, if the Company terminates Mr. Berns' employment for just cause or Mr. Berns resigns without good reason, Mr. Berns is entitled to the following: (i) any base salary and annual bonus earned but unpaid prior to the date of termination; (ii) all accrued but unused personal time; and (iii) any unreimbursed business expenses (collectively, the "Accrued Obligations"). Such amounts are to be paid within 30 days after the date of termination. Following such termination, Mr. Berns' then outstanding stock options and restricted stock will remain subject to the terms of their respective governing documents.

Under the terms of Mr. Berns' second amended and restated employment agreement, if the Company terminates Mr. Berns' employment without just cause or Mr. Berns resigns with good reason (other than in connection with a change-in-control of the Company), provided that Mr. Berns executes a general release in favor of the Company at the election of the Company, Mr. Berns is entitled to the following: (i) payment of the Accrued Obligations within 30 days after the date of termination; (ii) an amount equal to his target bonus for the year in which the termination occurs, pro rated through the date of termination; (iii) an amount equal to 1.5 times his base salary then in effect, payable in monthly installments over the 18-month period following the date of termination; (iv) an amount equal to 1.5 times his annual bonus for the year preceding the year in which the termination occurs, payable in a lump sum within 30 days after the date of termination; (v) treatment of his then outstanding stock options and restricted stock in accordance with the terms of their respective governing documents; (vi) payment of premiums for his group health insurance COBRA continuation coverage for up to 12 months following the date of termination; and (vii) outplacement assistance for up to 12 months following the date of termination with an aggregate cost of up to $15,000. Except for the Accrued Obligations, the payments described above shall cease, and the Company shall have no further obligations to Mr. Berns with respect thereto, in the event that Mr. Berns breaches his confidentiality, non-compete or non-solicitation obligations under the second amended and restated employment agreement or the terms of his confidentiality and inventions assignment agreement with the Company. The Company's obligation to pay Mr. Berns' COBRA premiums ceases upon Mr. Berns' eligibility for comparable coverage provided by a new employer.

Under the terms of Mr. Berns' second amended and restated employment agreement, if the Company (or any surviving or acquiring corporation) terminates Mr. Berns' employment without just cause or Mr. Berns resigns with good reason within one month prior to or two years following the effective date of a change-in-control of the Company, provided that Mr. Berns executes a general release in favor of the Company (or any surviving or acquiring corporation) at the election thereof, Mr. Berns is entitled to the following: (i) payment of the Accrued Obligations within 30 days after the date of termination; (ii) an amount equal to his target bonus for the year in which the termination occurs, pro rated through the date of termination; (iii) a lump-sum cash payment in an amount equal to (x) two times his highest annual base salary in effect during the 12 months prior to such termination, plus (y) two times his highest annualized bonus paid or payable in respect of the five years preceding the year in which the change-in-control occurs; (iv) immediate vesting of all outstanding stock options and restricted stock granted to Mr. Berns and the extension of the option exercise period for 24 months after the date of termination; (v) continued coverage for 18 months under all policies of

medical, accident, disability and life insurance for Mr. Berns and his dependents; and (vi) outplacement assistance for up to 12 months following the date of termination with an aggregate cost of up to $15,000. In addition, Mr. Berns' second amended and restated employment agreement provides that, in certain circumstances, he will be entitled to a gross-up payment for payments that result in an excise tax imposed by Section 4999 of the Code.

The following table reflects the estimated potential payments that would be payable to Mr. Berns upon a termination or change-in-control of the Company under the terms of his second amended and restated employment agreement. The amounts shown reflect only the additional payments or benefits that Mr. Berns would have received upon the occurrence of the respective triggering events listed below; they do not include the value of payments or benefits that would have been earned, or any amounts associated with equity awards that would have vested, absent the triggering event.

	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change-in-Control)
Paul L. Berns			
Cash Payments			
Cash Severance	$ —	$1,172,400(1)	$1,563,200(2)
Target Bonus for Year of Separation	$ —	$ 298,300	$ 298,300
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 651,900(3)
Restricted Stock (Unvested and Accelerated)	$ —	$ —	$ 918,000(4)
Benefits and Perquisites			
Accrued Sick Leave	$30,800	$ 30,800	$ 30,800
Benefits Continuation	$ —	$ 16,900	$ 27,900
Outplacement Assistance	$ —	$ 15,000	$ 15,000
Excise Tax Gross-Up (Estimated)	$ —	$ —	$ —
Total Payments Upon Termination	***$30,800***	***$1,533,400***	***$3,505,100***

(1) Amount represents (i) 1.5 times base salary then in effect, payable in monthly installments over the 18-month period following the date of termination, plus (ii) 1.5 times the annual bonus for the year preceding the year in which the termination occurs, payable in a lump sum within 30 days after the date of termination.

(2) Amount represents a lump sum payment equal to (i) two times base salary, plus (ii) two times highest annualized bonus, paid or payable, in respect of the five fiscal years preceding the year of termination.

(3) Amount represents the in-the-money value of unvested stock options as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Securities Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

(4) Amount represents the in-the-money value of unvested restricted stock as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares of restricted stock are reflected in the column entitled "Number of Shares or

Units of Stock that Have Not Vested" in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

Pablo J. Cagnoni—Senior Vice President, Chief Medical Officer

Under the terms of Dr. Cagnoni's amended and restated employment agreement, if the Company terminates Dr. Cagnoni's employment for just cause or Dr. Cagnoni resigns without good reason, Dr. Cagnoni is entitled to the following: (i) any salary earned but unpaid prior to the date of termination; (ii) all accrued but unused vacation; and (iii) any unreimbursed business expenses.

Under the terms of Dr. Cagnoni's amended and restated employment agreement, if the Company terminates Dr. Cagnoni's employment without just cause or Dr. Cagnoni resigns with good reason (other than in connection with a change-in-control of the Company), provided that Dr. Cagnoni executes a general release in favor of the Company, Dr. Cagnoni is entitled to the following: (i) continuation of Dr. Cagnoni's then current base salary for a period of 12 months following the date of termination, paid on the same basis and at the same time as previously paid; (ii) payment of any accrued but unused vacation and sick leave; and (iii) payment of premiums for his group health insurance COBRA continuation coverage for up to 12 months following the date of termination. The Company's obligation to pay Dr. Cagnoni's COBRA premiums ceases upon Dr. Cagnoni's eligibility for comparable coverage provided by a new employer. Except for the payment of any accrued but unused vacation and sick leave, the payments described above shall cease, and the Company shall have no further obligations to Dr. Cagnoni with respect thereto, in the event that Dr. Cagnoni breaches the confidentiality, non-compete or non-solicitation provisions under his confidentiality and inventions assignment agreement with the Company.

Under the terms of Dr. Cagnoni's amended and restated employment agreement, if the Company (or any surviving or acquiring corporation) terminates Dr. Cagnoni's employment without just cause or Dr. Cagnoni resigns with good reason within one month prior to or 12 months following the effective date of a change-in-control of the Company, provided that Dr. Cagnoni executes a general release in favor of the Company, Dr. Cagnoni is entitled to the following: (i) a lump-sum cash payment in an amount equal to (A) 1.5 times Dr. Cagnoni's annual base salary then in effect, plus (B) 1.5 times the greater of (1) Dr. Cagnoni's annualized target bonus award for the year in which Dr. Cagnoni's employment terminates or (2) the annual bonus amount paid to Dr. Cagnoni in the immediately prior year; (ii) payment of any accrued but unused vacation and sick leave; (iii) payment of Dr. Cagnoni's target bonus award for the year in which Dr. Cagnoni's employment terminates, prorated through the date of termination; (iv) payment of premiums for his group health insurance COBRA continuation coverage for up to 18 months following the date of termination; (v) outplacement assistance for up to nine months following the date of termination with an aggregate cost of up to $11,250; and (vi) immediate vesting of all outstanding stock options and restricted stock granted to Dr. Cagnoni and the extension of the option exercise period for 12 months after the date of termination. The Company's obligation to pay Dr. Cagnoni's COBRA premiums ceases upon Dr. Cagnoni's eligibility for comparable coverage provided by a new employer. Certain of the payments described above shall cease, and the Company shall have no further obligations to Dr. Cagnoni with respect thereto, in the event that Dr. Cagnoni breaches the confidentiality, non-compete or non-solicitation provisions under his confidentiality and inventions assignment agreement with the Company. In addition, Dr. Cagnoni's amended and restated employment agreement provides that, in certain circumstances, he will be entitled to a gross-up payment for payments that result in an excise tax imposed by Section 4999 of the Code.

The following table reflects the estimated potential payments that would be payable to Dr. Cagnoni upon a termination or change-in-control of the Company under the terms of his amended and restated employment agreement. The amounts shown reflect only the additional payments or benefits that Dr. Cagnoni would have received upon the occurrence of the respective triggering events

listed below; they do not include the value of payments or benefits that would have been earned, or any amounts associated with equity awards that would have vested, absent the triggering event.

	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change-in-Control)
Pablo J. Cagnoni			
Cash Payments			
Cash Severance	$ —	$ 404,200(1)	$ 848,900(2)
Target Bonus for Year of Separation	$ —	$ —	$ 161,700
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ —(3)
Restricted Stock (Unvested and Accelerated)	$ —	$ —	$ 344,300(4)
Benefits and Perquisites			
Accrued Sick Leave	$ —	$ 24,900	$ 24,900
Benefits Continuation	$ —	$ 11,400	$ 17,100
Outplacement Assistance	$ —	$ —	$ 11,250
Excise Tax Gross-Up (Estimated)	$ —	$ —	$ —
Total Payments Upon Termination	***$ —***	***$ 440,500***	***$1,408,150***

(1) Amount represents 1.0 times base salary then in effect, payable on the same basis and at the same time as paid at the time of termination.

(2) Amount represents a lump sum payment equal to (i) 1.5 times base salary then in effect, plus (ii) 1.5 times annualized target bonus award for the year of termination.

(3) Amount represents the in-the-money value of unvested stock options as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Securities Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

(4) Amount represents the in-the-money value of unvested restricted stock as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares of restricted stock are reflected in the column entitled "Number of Shares or Units of Stock that Have Not Vested" in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

James V. Caruso—Executive Vice President, Chief Commercial Officer

Under the terms of Mr. Caruso's amended and restated employment agreement, if the Company terminates Mr. Caruso's employment for just cause or Mr. Caruso resigns without good reason, Mr. Caruso is entitled to the following: (i) any salary earned but unpaid prior to the date of termination; (ii) all accrued but unused vacation; and (iii) any unreimbursed business expenses.

Under the terms of Mr. Caruso's amended and restated employment agreement, if the Company terminates Mr. Caruso's employment without just cause or Mr. Caruso resigns with good reason (other than in connection with a change-in-control of the Company), provided that Mr. Caruso executes a general release in favor of the Company, Mr. Caruso is entitled to the following: (i) continuation of Mr. Caruso's then current base salary for a period of 12 months following the date of termination, paid

on the same basis and at the same time as previously paid; (ii) payment of any accrued but unused vacation and sick leave; and (iii) payment of premiums for his group health insurance COBRA continuation coverage for up to 12 months following the date of termination. The Company's obligation to pay Mr. Caruso's COBRA premiums ceases upon Mr. Caruso's eligibility for comparable coverage provided by a new employer. Except for the payment of any accrued but unused vacation and sick leave, the payments described above shall cease, and the Company shall have no further obligations to Mr. Caruso with respect thereto, in the event that Mr. Caruso breaches the confidentiality, non-compete or non-solicitation provisions under his confidentiality and inventions assignment agreement with the Company.

Under the terms of Mr. Caruso's amended and restated employment agreement, if the Company (or any surviving or acquiring corporation) terminates Mr. Caruso's employment without just cause or Mr. Caruso resigns with good reason within one month prior to or 12 months following the effective date of a change-in-control of the Company, provided that Mr. Caruso executes a general release in favor of the Company, Mr. Caruso is entitled to the following: (i) a lump-sum cash payment in an amount equal to (A) 1.5 times Mr. Caruso's annual base salary then in effect, plus (B) 1.5 times the greater of (1) Mr. Caruso's annualized target bonus award for the year in which Mr. Caruso's employment terminates or (2) the annual bonus amount paid to Mr. Caruso in the immediately prior year; (ii) payment of any accrued but unused vacation and sick leave; (iii) payment of Mr. Caruso's target bonus award for the year in which Mr. Caruso's employment terminates, prorated through the date of termination; (iv) payment of premiums for his group health insurance COBRA continuation coverage for up to 18 months following the date of termination; (v) outplacement assistance for up to nine months following the date of termination with an aggregate cost of up to $11,250; and (vi) immediate vesting of all outstanding stock options and restricted stock granted to Mr. Caruso and the extension of the option exercise period for 12 months after the date of termination. The Company's obligation to pay Mr. Caruso's COBRA premiums ceases upon Mr. Caruso's eligibility for comparable coverage provided by a new employer. Certain of the payments described above shall cease, and the Company shall have no further obligations to Mr. Caruso with respect thereto, in the event that Mr. Caruso breaches the confidentiality, non-compete or non-solicitation provisions under his confidentiality and inventions assignment agreement with the Company. In addition, Mr. Caruso's amended and restated employment agreement provides that, in certain circumstances, he will be entitled to a gross-up payment for payments that result in an excise tax imposed by Section 4999 of the Code.

The following table reflects the estimated potential payments that would be payable to Mr. Caruso upon a termination or change-in-control of the Company under the terms of his amended and restated employment agreement. The amounts shown reflect only the additional payments or benefits that Mr. Caruso would have received upon the occurrence of the respective triggering events listed below;

they do not include the value of payments or benefits that would have been earned, or any amounts associated with equity awards that would have vested, absent the triggering event.

	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change-in-Control)
James V. Caruso			
Cash Payments			
Cash Severance	$ —	$ 398,600(1)	$ 837,000(2)
Target Bonus for Year of Separation	$ —	$ —	$ 159,400
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 392,400(3)
Restricted Stock (Unvested and Accelerated)	$ —	$ —	$ 336,600(4)
Benefits and Perquisites			
Accrued Sick Leave	$ —	$ 24,500	$ 24,500
Benefits Continuation	$ —	$ 16,900	$ 25,300
Outplacement Assistance	$ —	$ —	$ 11,250
Excise Tax Gross-Up (Estimated)	$ —	$ —	$ —
Total Payments Upon Termination	***$ —***	***$ 440,000***	***$1,786,450***

(1) Amount represents 1.0 times base salary then in effect, payable on the same basis and at the same time as paid at the time of termination.

(2) Amount represents a lump sum payment equal to (i) 1.5 times base salary then in effect, plus (ii) 1.5 times annualized target bonus award for the year of termination.

(3) Amount represents the in-the-money value of unvested stock options as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Securities Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

(4) Amount represents the in-the-money value of unvested restricted stock as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares of restricted stock are reflected in the column entitled "Number of Shares or Units of Stock that Have Not Vested" in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

Marc H. Graboyes—Senior Vice President, General Counsel and Secretary

Under the terms of Mr. Graboyes' amended and restated employment agreement, if the Company terminates Mr. Graboyes' employment for just cause or Mr. Graboyes resigns without good reason, Mr. Graboyes is entitled to the following: (i) any base salary earned but unpaid prior to the date of termination; (ii) all accrued but unused vacation; and (iii) any unreimbursed business expenses.

Under the terms of Mr. Graboyes' amended and restated employment agreement, if the Company terminates Mr. Graboyes' employment without just cause or Mr. Graboyes resigns with good reason (other than in connection with a change-in-control of the Company), provided that Mr. Graboyes executes a general release in favor of the Company, Mr. Graboyes is entitled to the following: (i) continuation of Mr. Graboyes' then current base salary for a period of six months following the date

of termination, paid on the same basis and at the same time as previously paid; (ii) payment of any accrued but unused vacation and sick leave; and (iii) payment of premiums for his group health insurance COBRA continuation coverage for up to six months following the date of termination. The Company's obligation to pay Mr. Graboyes' COBRA premiums ceases upon Mr. Graboyes' eligibility for comparable coverage provided by a new employer. Except for the payment of any accrued but unused vacation and sick leave, the payments described above shall cease, and the Company shall have no further obligations to Mr. Graboyes with respect thereto, in the event that Mr. Graboyes breaches the confidentiality, non-compete or non-solicitation provisions under his confidentiality and inventions assignment agreement with the Company.

Under the terms of Mr. Graboyes' amended and restated employment agreement, if the Company (or any surviving or acquiring corporation) terminates Mr. Graboyes' employment without just cause or Mr. Graboyes resigns with good reason within one month prior to or 12 months following the effective date of a change-in-control of the Company, provided that Mr. Graboyes executes a general release in favor of the Company, Mr. Graboyes is entitled to the following: (i) a lump-sum cash payment in an amount equal to (A) Mr. Graboyes' annual base salary then in effect, plus (B) the greater of (1) Mr. Graboyes' annualized target bonus award for the year in which Mr. Graboyes' employment terminates or (2) the annual bonus amount paid to Mr. Graboyes in the immediately prior year; (ii) payment of any accrued but unused vacation and sick leave; (iii) payment of Mr. Graboyes' target bonus award for the year in which Mr. Graboyes' employment terminates, prorated through the date of termination; (iv) payment of premiums for his group health insurance COBRA continuation coverage for up to 12 months following the date of termination; (v) outplacement assistance for up to six months following the date of termination with an aggregate cost of up to $7,500; and (vi) immediate vesting of all outstanding stock options and restricted stock granted to Mr. Graboyes and the extension of the option exercise period for 12 months after the date of termination. The Company's obligation to pay Mr. Graboyes' COBRA premiums ceases upon Mr. Graboyes' eligibility for comparable coverage provided by a new employer. Certain of the payments described above shall cease, and the Company shall have no further obligations to Mr. Graboyes with respect thereto, in the event that Mr. Graboyes breaches the confidentiality, non-compete or non-solicitation provisions under his confidentiality and inventions assignment agreement with the Company.

The following table reflects the estimated potential payments that would be payable to Mr. Graboyes upon a termination or change-in-control of the Company under the terms of his amended and restated employment agreement. The amounts shown reflect only the additional payments or benefits that Mr. Graboyes would have received upon the occurrence of the respective triggering events listed below; they do not include the value of payments or benefits that would have

been earned, or any amounts associated with equity awards that would have vested absent the triggering event.

	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change-in-Control)
Marc H. Graboyes			
Cash Payments			
Cash Severance	$ —	$ 150,300(1)	$ 390,800(2)
Target Bonus for Year of Separation	$ —	$ —	$ 90,200
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 104,300(3)
Restricted Stock (Unvested and Accelerated)	$ —	$ —	$ —
Benefits and Perquisites			
Accrued Sick Leave	$ —	$ 18,500	$ 18,500
Benefits Continuation	$ —	$ 8,400	$ 16,900
Outplacement Assistance	$ —	$ —	$ 7,500
Total Payments Upon Termination	***$ —***	***$ 177,200***	***$ 628,200***

(1) Amount represents 0.5 times base salary then in effect, payable on the same basis and at the same time as paid at the time of termination.

(2) Amount represents a lump sum payment equal to (i) 1.0 times base salary then in effect, plus (ii) 1.0 times annualized target bonus award for the year of termination.

(3) Amount represents the in-the-money value of unvested stock options as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Securities Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

David C. Clark, Vice President, Finance

Mr. Clark is not party to an employment agreement with the Company. Accordingly, his entitlement to any termination payment or payments upon a change-in-control of the Company is subject to and pursuant to the Company's Severance Benefit Plan and the Change of Control Severance Benefit Schedule thereto.

Under the terms of the Change of Control Severance Benefit Schedule, if the Company terminates Mr. Clark's employment without just cause or Mr. Clark resigns for good reason within two months prior to or six months following the effective date of a change-in-control of the Company, provided that Mr. Clark executes a general release in favor of the Company, Mr. Clark is entitled to receive the following: (i) any base salary earned but unpaid prior to the date of termination; (ii) all accrued but unused vacation; (iii) any unreimbursed business expenses; (iv) six months base pay plus an additional two weeks base pay for each 12 months of continuous service, up to a maximum of 52 weeks base pay; (v) payment of Mr. Clark's target bonus award for the year in which Mr. Clark's employment terminates, prorated through the date of termination; (vi) payment of premiums for his group health insurance COBRA continuation coverage for the same duration as to which he is entitled to base pay; and (vii) immediate vesting of all outstanding options and restricted stock granted to him. In addition,

Mr. Clark is eligible to participate in an outplacement assistance program to be selected by the Company. The Company's obligation to pay Mr. Clark's COBRA premiums ceases upon Mr. Clark's eligibility for comparable coverage provided by a new employer. The amount of the foregoing benefits are capped at two times Mr. Clark's annual compensation earned during the calendar year immediately preceding his termination of employment (calculated on an annualized basis).

The following table reflects the estimated potential payments that would be payable to Mr. Clark upon a termination or change-in-control of the Company under the Company's Severance Benefit Plan and the Change of Control Severance Benefit Schedule thereto. The amounts shown reflect only the additional payments or benefits that Mr. Clark would have received upon the occurrence of the respective triggering events listed below; they do not include the value of payments or benefits that would have been earned, or any amounts associated with equity awards that would have vested absent the triggering event.

	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change-in-Control)
David C. Clark			
Cash Payments			
Cash Severance	$ —	$ —	$ 137,300
Target Bonus for Year of Separation	$ —	$ —	$ 51,600
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 73,800(1)
Restricted Stock (Unvested and Accelerated)	$ —	$ —	$ —
Benefits and Perquisites			
Accrued Sick Leave	$ —	$ —	$ —
Benefits Continuation	$ —	$ —	$ 16,900
Outplacement Assistance	$ —		$ —
Total Payments Upon Termination	***$ —***	***$ —***	***$ 279,600***

(1) Amount represents the in-the-money value of unvested stock options as of December 31, 2008, using the closing market price of the Company's common stock on December 31, 2008. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Securities Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the Outstanding Equity Awards at Fiscal Year End table set forth on page 24 of this Amendment No. 1.

Director Compensation

The following table shows certain information with respect to the compensation of all non-employee directors of the Company for the fiscal year ended December 31, 2008:

Director Compensation for Fiscal 2008

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Stephen J. Hoffman(2)	82,500	184,500	267,000
Michael D. Casey(3)	62,500	73,800	136,300
Stewart Hen(4)	46,300	74,400	120,700
Jonathan Leff(5)	45,000	74,400	119,400
Timothy Lynch(6)	57,500	76,800	134,300
Jeffrey Latts(7)	45,000	79,500	124,500
William Ringo(8)	26,300	9,600	35,900

(1) The amounts shown in this column represent the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year for stock options granted to the non-employee directors, as determined in accordance with SFAS 123R. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For additional information on the valuation assumptions used to calculate these amounts, see Note 4 to the Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008. These amounts reflect the Company's accounting expense for these awards, and do not correspond to the actual value that will be recognized by the non-employee directors.

(2) Grant date fair value of 50,000 options granted in 2008: $145,900. Total number of shares subject to stock options outstanding at December 31, 2008: 583,971.

(3) Grant date fair value of 20,000 options granted in 2008: $58,400. Total number of shares subject to stock options outstanding at December 31, 2008: 120,000.

(4) Grant date fair value of 20,000 options granted in 2008: $58,400. Total number of shares subject to stock options outstanding at December 31, 2008: 80,000.

(5) Grant date fair value of 20,000 options granted in 2008: $58,400. Total number of shares subject to stock options outstanding at December 31, 2008: 80,000.

(6) Grant date fair value of 20,000 options granted in 2008: $58,400. Total number of shares subject to stock options outstanding at December 31, 2008: 85,000.

(7) Grant date fair value of 20,000 options granted in 2008: $58,400. Total number of shares subject to stock options outstanding at December 31, 2008: 45,000.

(8) There were no options granted in 2008. There were no stock options outstanding at December 31, 2008.

Cash Compensation

Effective as of the Company's 2007 Annual Meeting of Stockholders, the Board of Directors approved the following compensation arrangements for the Company's non-employee directors. Each non-employee director of the Company receives an annual retainer of $40,000, except that the Chairman of the Board receives an annual retainer of $80,000. Each non-employee director that serves as Chairman of the Audit Committee, Chairman of the Compensation Committee or Chairman of the

Nominating and Corporate Governance Committee also receives an additional annual retainer of $12,500, $12,500 and $7,500, respectively. Each non-employee director who serves on a committee of the Board receives an additional retainer of $5,000. Annual retainers are paid in equal quarterly installments on the first day of each calendar quarter.

In addition, each non-employee director, including the Chairman of the Board, is reimbursed for all reasonable out-of-pocket expenses incurred by such director in connection with attending any regular or special meeting of the Board or any regular or special meeting of any committee of the Board.

Stock Options

The Company grants stock options to its non-employee directors under a stock option grant program for non-employee directors (the "Directors' Program") administered under our 2008 Equity Incentive Plan.

Under the Directors' Program, each person who becomes a non-employee director of the Company is automatically granted a non-qualified stock option to purchase 25,000 shares of common stock on the date of his or her initial election, except that any person who becomes the Company's Chairman of the Board (other than an employee of the Company) is automatically granted a nonqualified stock option to purchase 50,000 shares of common stock on the date of his or her initial election (each, an "Initial Grant"). Initial Grants vest in equal installments on each of the first, second and third anniversaries of the date of grant, assuming continued service as a director during such period.

In addition, under the Directors' Program, each non-employee director is automatically granted a non-qualified stock option to purchase 20,000 shares of common stock immediately following each year's annual meeting of stockholders, except that the Chairman of the Board is automatically granted a non-qualified stock option to purchase 50,000 shares of common stock immediately following each year's annual meeting of stockholders (each, an "Annual Grant"). Annual Grants fully vest on the date of the next year's annual meeting of stockholders, assuming continued service as a director during such period. However, any non-employee director who received an Initial Grant within three months prior to an annual meeting is not eligible to receive an Annual Grant until the second annual meeting after his or her Initial Grant.

All stock options granted under the Directors' Program have a term of 10 years and an exercise price equal to the closing price of a share of the Company's common stock on the date of grant. During the fiscal year ended December 31, 2008, Mr. Ringo, who resigned as a director of the Company effective June 24, 2008, exercised options awarded under the Directors' Program to purchase 28,333 shares of the Company's common stock and Dr. Hoffman exercised options under the Directors' Program to purchase 40,000 shares of the Company's common stock. As of April 15, 2009, Dr. Hoffman has exercised options under the Directors' Program to purchase an additional 36,400 shares of the Company's common stock. As of April 15, 2009, no other stock options had been exercised under the Directors' Plan during the fiscal year ending December 31, 2009.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee of the Board of Directors consists of Messrs. Casey and Leff and Dr. Latts. During a portion of the fiscal year ended December 31, 2008, Mr. Lynch also served as a member of the Compensation Committee. None of the Company's executive officers serve as a member of the board of directors or compensation committee of any entity that has one or more executive officers who serve on the Company's Board of Directors or Compensation Committee.

Compensation Committee Report(1)

The Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis contained in this Amendment No. 1. Based on this review and discussion, the Compensation Committee has recommended to the Board of Directors that such Compensation Discussion and Analysis be included in this Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

Mr. Michael D. Casey
Dr. Jeffrey R. Latts
Mr. Jonathan S. Leff

(1) The material in this report is not "soliciting material," is not deemed "filed" with the SEC, and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

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

The following table sets forth certain information regarding the ownership of the Company's common stock as of April 15, 2009 by: (i) each director; (ii) each of the executive officers named in the summary compensation table on page 21 of this Amendment No. 1; (iii) all executive officers and directors of the Company as a group; and (iv) all those known by the Company to be beneficial owners of more than five percent of the Company's common stock.

	Beneficial Ownership(1)	
Beneficial Owner(2)	Number of Shares	Percent of Total
Warburg Pincus Private Equity VIII, L.P.(3) 466 Lexington Avenue New York, New York 10017	26,124,430	29.2%
Entities affiliated with Felix J. Baker and Julian C. Baker(4) 667 Madison Avenue New York, New York 10021	8,064,252	9.0
Entities affiliated with Samuel D. Isaly(5) 767 Third Avenue, 30th Floor New York, New York 10017	7,518,800	8.4
Stephen J. Hoffman, Ph.D., M.D.(6)	973,241	1.1
Paul L. Berns(7)	994,606	1.1
Bruce K. Bennett, Jr.(8)	33,554	*
Pablo J. Cagnoni, M.D.(9)	272,072	*
James V. Caruso(10)	386,245	*
Michael D. Casey(11)	100,000	*
David C. Clark(12)	76,493	*
Marc H. Graboyes(13)	186,768	*
Stewart Hen(3)(14)	26,184,430	29.3
Jeffrey R. Latts, M.D.(15)	16,666	*
Jonathan S. Leff(3)(16)	26,184,430	29.3
Timothy P. Lynch(17)	65,000	*
David M. Stout	—	*
All executive officers and directors as a group (13 persons)(18)	29,349,075	32.0%

* Less than one percent.

(1) This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 89,360,666 shares outstanding on April 15, 2009, adjusted as required by rules promulgated by the SEC.

(2) The address for each director, nominee and executive officer is c/o Allos Therapeutics, Inc., 11080 CirclePoint Road, Suite 200, Westminster, Colorado 80020.

(3) Stewart Hen and Jonathan S. Leff, directors of the Company, are partners of Warburg Pincus & Co. ("WP"), which is the sole managing member of Warburg Pincus Partners LLC ("WP Partners"), which is the sole general partner of Warburg Pincus Private Equity VIII, L.P. ("WP VIII"). Messrs Hen and Leff are also managing directors and members of Warburg Pincus LLC ("WP LLC"), which manages WP VIII. WP, WP Partners, WP VIII and WP LLC are collectively referred to as the "Warburg Pincus Entities." Messrs. Hen and Leff, along with Charles R. Kaye and Joseph P. Landy, who are managing general partners of WP and managing members and co-presidents of WP LLC, may be deemed to indirectly beneficially own the shares held by WP VIII because of their affiliation with the Warburg Pincus Entities. Messrs. Hen, Leff, Kaye and Landy disclaim beneficial ownership of the shares held by the Warburg Pincus Entities except to the extent of their pecuniary interests therein. None of WP, WP VIII and WP LLC has sole voting power or sole dispositive power over any of the listed shares.

(4) Based solely upon a Schedule 13G filed with the SEC on February 17, 2009. Includes: 1,629 shares owned by Baker Bros. Investments II, L.P.; 2,022,293 shares owned by Baker Biotech Fund I, L.P.; 5,771,961 shares owned by Baker Brothers Life Sciences, L.P.; 190,917 shares owned by 14159, L.P.; 72,035 shares owned by Baker/Tisch Investments, L.P.; and 5,417 shares owned by FBB Associates. By virtue of their ownership of entities that have the power to control the investment decisions of the limited partnerships listed above, Felix J. Baker and Julian C. Baker may each be deemed to be beneficial owners of shares owned by such entities and may be deemed to have shared power to vote or direct the vote of and shared power to dispose or direct the disposition of such securities.

(5) Includes 3,643,900 shares held by OrbiMed Advisors LLC and 3,874,900 shares held by OrbiMed Capital LLC. None of Samuel D. Isaly, OrbiMed Advisors LLC and OrbiMed Capital LLC has sole voting power or sole dispositive power over the shares.

(6) Includes 800 shares held as custodian for Dr. Hoffman's children and 497,571 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(7) Includes 75,000 shares of restricted stock, which vest on March 9, 2010, subject to Mr. Berns' continued employment with the Company through such vesting date, and 809,366 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(8) Includes 33,333 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(9) Includes 37,500 shares of restricted stock, which vest in equal annual installments on each of March 19, 2010 and 2011, subject to Dr. Cagnoni's continued employment with the Company through such vesting dates, and 209,372 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(10) Includes 55,000 shares of restricted stock, which vest in equal annual installments on each of June 5, 2009, and 2010, subject to Mr. Caruso's continued employment with the Company through such vesting dates, and 293,745 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(11) Includes 100,000 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(12) Includes 75,236 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(13) Includes 181,768 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(14) Includes 26,124,430 shares held by WP VIII and 60,000 shares issuable upon exercise of options held by Mr. Hen exercisable within 60 days of April 15, 2009. Mr. Hen may be deemed to be the indirect beneficial owner of the shares held by WP VIII because of his affiliation with the Warburg Pincus Entities. Mr. Hen disclaims beneficial ownership of the shares held by the Warburg Pincus Entities except to the extent of his pecuniary interests therein.

(15) Includes 16,666 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(16) Includes 26,124,430 shares held by WP VIII and 60,000 shares issuable upon exercise of options held by Mr. Leff exercisable within 60 days of April 15, 2009. Mr. Leff may be deemed to be the indirect beneficial owner of the shares held by WP VIII because of his affiliation with the Warburg Pincus Entities. Mr. Leff disclaims beneficial ownership of the shares held by the Warburg Pincus Entities except to the extent of his pecuniary interests therein.

(17) Includes 65,000 shares issuable upon exercise of options exercisable within 60 days of April 15, 2009.

(18) Includes 167,500 shares of restricted stock and 2,402,057 shares issuable upon exercise of options held by all executive officers and directors as a group exercisable within 60 days of April 15, 2009. See footnotes (6) through (17).

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2008:

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted-average exercise price of outstanding options and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	7,236,512	$5.14	7,406,478(1)(2)
Equity compensation plans not approved by security holders	—	—	—
Total	7,236,512	$5.14	7,406,478(1)(2)

(1) Includes 5,146,701 shares of common stock available for future issuance under our 2008 Equity Incentive Plan. All stock awards granted under our 2008 Equity Incentive Plan after the June 24, 2008 effective date thereof, other than stock options and stock appreciation rights granted with an exercise price of at least 100% of such stock award's fair market value on the date of grant, reduce the number of shares available for issuance under our 2008 Equity Incentive Plan by 1.35 shares per share granted pursuant to the stock award. Shares of common stock that revert to and again become available for issuance under our 2008 Equity Incentive Plan and that prior to such reversion were granted pursuant to a stock award that reduced the number of shares available under our 2008 Equity Incentive Plan by 1.35 shares per share granted pursuant to such stock award, will cause the number of shares of our common stock available for issuance under our 2008 Equity Incentive Plan to increase by 1.35 shares upon such reversion.

(2) Includes 2,259,777 shares of common stock available for future issuance under our 2001 Employee Stock Purchase Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related-Person Transactions Policy and Procedures

Related-person transactions have the potential to create actual or perceived conflicts of interest between the Company and its directors and executive officers or their immediate family members. Under its charter, the Audit Committee is charged with the responsibility of reviewing and approving all related-person transactions as required by Nasdaq rules. To assist in identifying such transactions for fiscal year 2008, the Company distributed questionnaires to directors, officers and beneficial owners of more than 5% of any class of the Company's common stock.

Current SEC rules define a related-person transaction to include any transaction, arrangement or relationship in which the Company is a participant and in which any of the following persons has or will have a direct or indirect interest:

- an executive officer, director or director nominee of the Company;
- any person who is known to be the beneficial owner of more than 5% of the Company's common stock;
- any person who is an immediate family member (as defined under Item 404 of Regulation S-K) of an executive officer, director or director nominee or beneficial owner of more than 5% of the Company's common stock; or
- any firm, corporation or other entity in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person, together with any of the foregoing persons, has a 5% or greater beneficial ownership interest.

Although the Company does not have a formal policy in regards to related-person transactions, the Audit Committee may consider the following factors when deciding whether to approve a related-person transaction:

- the nature of the related person's interest in the transaction;
- the material terms of the transaction, including, without limitation, the amount and type of the transaction;
- the importance of the transaction to the related person;
- whether the transaction would impair the judgment of a director or executive officer to act in the best interest of the Company; and
- any other matters deemed appropriate.

Certain Related-Person Transactions

Severance Arrangements

The Company has established a Severance Benefit Plan to provide for the payment of severance benefits to all full-time employees, including executive officers, who do not otherwise have separate employment agreements with the Company and whose employment is involuntarily terminated due to a change-in-control event. The Severance Benefit Plan is described above in the section entitled "Employment, Severance and Change-in-Control Agreements."

Indemnity Agreements

The Company has entered into indemnity agreements with its directors and certain of its executive officers, which provide, among other things, that the Company will indemnify such director or executive officer, under the circumstances and to the extent provided for therein, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings which he or she is or may be made a party by reason of his or her position as a director, officer or other agent of the Company, and otherwise to the fullest extent permitted under Delaware law and the Company's Bylaws.

Independence of The Board of Directors

As required under Nasdaq listing rules, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. The Company's Board of Directors consults with legal counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in the Nasdaq listing rules, as in effect from time to time.

Consistent with these considerations, after review of all relevant transactions or relationships between each director and director nominee, or any of their respective family members, and the Company, its senior management and its independent registered public accountants, the Board has affirmatively determined that the following directors are "independent" within the meaning of the applicable Nasdaq listing rules: Mr. Casey, Mr. Hen, Dr. Hoffman, Dr. Latts, Mr. Leff, Mr. Lynch and Mr. Stout. The Board also determined that William R. Ringo, who resigned as a director of the Company effective June 24, 2008, the date of the Company's 2008 Annual Meeting of Stockholders, was independent within the meaning of the applicable Nasdaq listing rules while serving as a member of the Board. In making these determinations, the Board found that none of the these directors or nominees for director had a material or other disqualifying relationship with the Company. In determining the independence of Messrs. Hen and Leff, the Board took into account that each of Messrs. Hen and Leff are Managing Directors of Warburg Pincus LLC, an affiliate of Warburg. In determining the independence of Dr. Latts, the Board took into account that Dr. Latts provided consulting services to Warburg Pincus LLC during the fiscal year ended December 31, 2008. In determining the independence of Mr. Ringo, the Board took into account that Mr. Ringo formerly served as CEO-in-residence of Warburg Pincus LLC. In determining the independence of Dr. Hoffman, the Board took into account that Dr. Hoffman served as President and Chief Executive Officer of the Company from July 1994 to December 2001. The Board did not believe that any of the foregoing relationships would interfere with the exercise of independent judgment by Messrs. Hen, Leff or Ringo or Drs. Latts or Hoffman in carrying out their responsibilities as directors of the Company. Mr. Berns, the Company's current President and Chief Executive Officer, is not an independent director.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the aggregate fees billed to the Company by PricewaterhouseCoopers LLP, the Company's independent registered public accounting firm, for services performed for each of the fiscal years ending December 31, 2008 and December 31, 2007.

	Audit Fees	Audit-Related Fees	Tax Fees	All Other Fees
2008	$369,765	$—	$ —	$—
2007	$463,965	$—	$9,700	$—

In the above table, in accordance with the SEC's definitions and rules, "Audit Fees" are fees the Company paid PricewaterhouseCoopers LLP for professional services for the audit of the Company's financial statements included in Form 10-K and review of financial statements included in Form 10-Qs,

audits of the effectiveness of internal control over financial reporting, and for services that are normally provided by an accountant in connection with statutory and regulatory filings; and "Tax Fees" are fees for tax advice.

All fees described above were pre-approved by the Audit Committee.

Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company's independent registered public accounting firm. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services, and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent registered public accounting firm or on an individual explicit case-by-case basis before the independent registered public accounting firm is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

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: April 30, 2009

By: /s/ PAUL L. BERNS
Paul L. Berns
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Amendment No. 1 to the report has been signed by the following persons on behalf of the registrant on April 30, 2009, and in the capacities indicated:

Name	Title
* Stephen J. Hoffman	Chairman of Board of Directors and Director
/s/ PAUL L. BERNS Paul L. Berns	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ DAVID C. CLARK David C. Clark	Vice President, Finance and Treasurer (Principal Financial Officer and Principal Accounting Officer)
* Michael D. Casey	Director
* Stewart Hen	Director
* Jeffrey R. Latts	Director
* Jonathan S. Leff	Director
* Timothy P. Lynch	Director
David M. Stout	Director

*By: /s/ PAUL L. BERNS
Paul L. Berns, Attorney-in-Fact

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, 2008.

☐ **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:

Common Stock $.001 Par Value	**NASDAQ Stock Market LLC (NASDAQ Global Market)**
(Title of class)	(Name of each exchange on which registered)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

The aggregate market value of common stock held by nonaffiliates of the registrant (based upon the closing sale price of such shares on the NASDAQ Global Market on June 30, 2008) was $293,509,927. Shares of the registrant's common stock held by each current executive officer and director and by each stockholder 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 Schedules 13D and 13G, if any, filed with the Commission. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 26, 2009, there were 81,349,712 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2009 Annual Meeting of Stockholders to be filed within 120 days after the end of the Registrant's fiscal year ended December 31, 2008 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein.

TABLE OF CONTENTS

		Page
PART I		
ITEM 1.	BUSINESS	3
ITEM 1A.	RISK FACTORS	18
ITEM 1B.	UNRESOLVED STAFF COMMENTS	37
ITEM 2.	PROPERTIES	37
ITEM 3.	LEGAL PROCEEDINGS	37
ITEM 4.	SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS	38
PART II		
ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	39
ITEM 6.	SELECTED FINANCIAL DATA	41
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	42
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	57
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	58
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	58
ITEM 9A.	CONTROLS AND PROCEDURES	58
ITEM 9B.	OTHER INFORMATION	59
PART III		
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	60
ITEM 11.	EXECUTIVE COMPENSATION	60
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	61
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	61
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	61
PART IV		
ITEM 15.	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	62
	SIGNATURES	66

PART I

Allos Therapeutics, Inc., the Allos Therapeutics, Inc. logo 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. 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 projected timelines for the completion of enrollment and announcement of results from our ongoing clinical trials, the Company's intent and projected timeline to submit a New Drug Application for pralatrexate (PDX) as a treatment for patients with relapsed or refractory peripheral T-cell lymphoma, the potential for the results of our Phase 2 PROPEL trial to support marketing approval of pralatrexate; other statements regarding our future product development and regulatory strategies, including our intent to develop or seek regulatory approval for pralatrexate in specific indications; the ability of our third-party manufacturing parties to support our requirements for drug supply; any statements regarding our future financial performance, results of operations or sufficiency of capital resources to fund our operating requirements; and any other statements which are other than statements of historical fact. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," or the negative of such terms and other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our, or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among other things, those discussed under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All forward-looking statements included in this report are based on information available to us as of the date hereof and we undertake no obligation to revise any forward-looking statements in order to reflect any subsequent events or circumstances. Forward-looking statements not specifically described above also may be found in these and other sections of this report.

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative small molecule drugs for the treatment of cancer. We strive to develop proprietary products that have the potential to improve the standard of care in cancer therapy. Our focus is on product opportunities for oncology that leverage our internal clinical development and regulatory expertise and address important markets with unmet medical need. We may also seek to grow our existing portfolio of product candidates through product acquisition and in-licensing efforts.

Our lead product candidate, pralatrexate, is a novel targeted antifolate designed to accumulate preferentially in cancer cells. Based on preclinical studies, we believe that pralatrexate selectively enters cells expressing RFC-1, a protein that is over expressed on cancer cells compared to normal cells. Once inside cancer cells, pralatrexate is efficiently polyglutamylated, which leads to high intracellular drug retention. Polyglutamylated pralatrexate essentially becomes "trapped" inside cancer cells, making it less susceptible to efflux-based drug resistance. Acting on the folate pathway, pralatrexate interferes with DNA synthesis and triggers cancer cell death. We believe pralatrexate has the potential to be delivered as a single agent or in combination therapy regimens.

In February 2009, we announced the final results from PROPEL, our pivotal Phase 2 trial of pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma, or PTCL. Based on the results of this trial, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. This trial was conducted under an agreement reached with the FDA under its special protocol assessment, or SPA process, which provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. The SPA agreement is not a guarantee of approval, and we cannot assure you that the design of, or data collected from, the PROPEL trial will be adequate to demonstrate the safety and efficacy of pralatrexate for the treatment of patients with relapsed or refractory PTCL, or otherwise be sufficient to support FDA or any foreign regulatory approval. In addition to the PROPEL trial, we are committed to evaluating pralatrexate for oncology use as a single agent and in combination with other therapies. We currently have seven ongoing clinical trials involving pralatrexate, including the PROPEL trial, and plan to initiate additional trials to evaluate pralatrexate's potential clinical utility in other hematologic malignancies and solid tumor indications.

Our Strategy

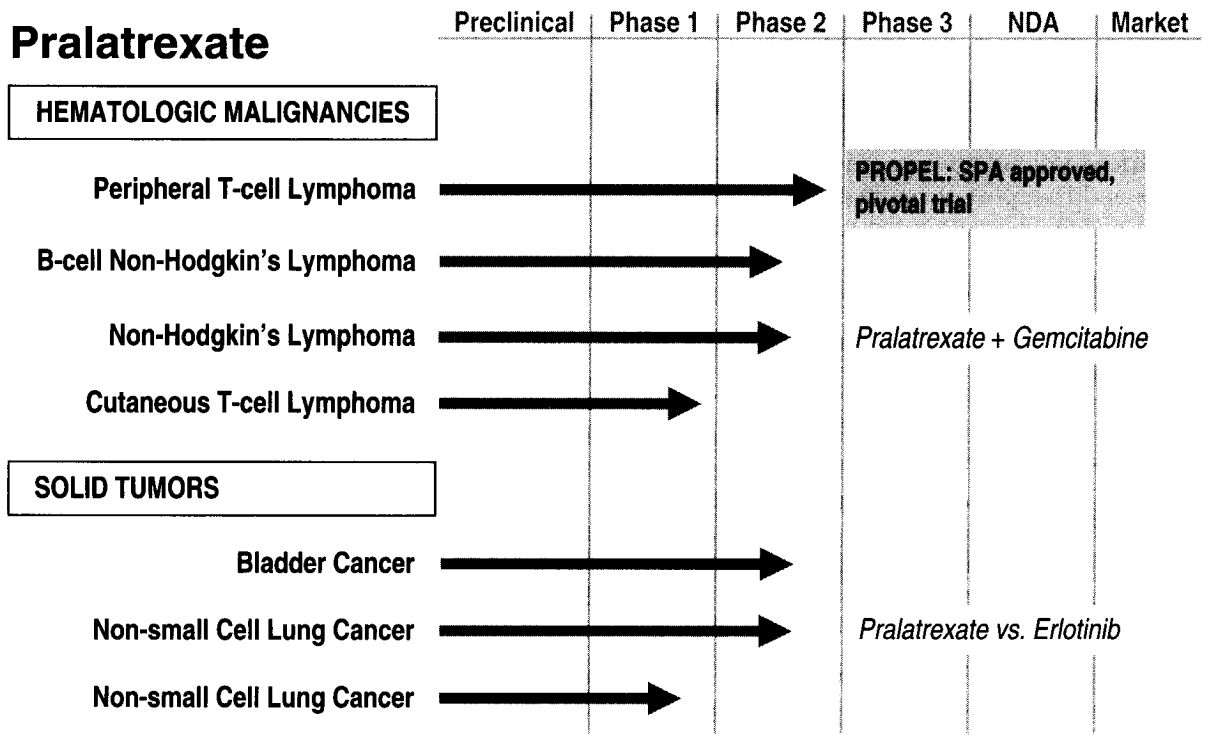
Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners. The key elements of our strategy are to:

- *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 size, demand for safer and more effective cancer treatments, relatively small physician population that can be addressed with a targeted sales force, and potential for expedited regulatory review.
- *Obtain regulatory approval to market pralatrexate.* We are currently focused on obtaining regulatory approval in the United States to market pralatrexate for the treatment of patients with relapsed or refractory PTCL. We recently announced the results of our pivotal Phase 2 PROPEL trial and intend to submit an NDA to the FDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009.
- *Advance our pralatrexate development program.* In addition to the PROPEL trial, we are committed to evaluating pralatrexate for oncology use as a single agent and in combination with other therapies. We currently have seven ongoing clinical trials involving pralatrexate, including the PROPEL trial, and plan to initiate additional trials in the future to evaluate pralatrexate's potential clinical utility in other hematologic malignancies and solid tumor indications.
- *Develop sales and marketing capabilities to commercialize pralatrexate.* We currently retain exclusive worldwide commercial rights to pralatrexate for all indications. We intend to commercialize pralatrexate, if it is approved for marketing, by building an oncology focused U.S.-based sales and marketing organization which may be complemented by co-promotion arrangements with pharmaceutical or biotechnology partners, where appropriate. We intend to enter into co-promotion or out-licensing arrangements with other pharmaceutical or biotechnology firms, where necessary, to reach foreign market segments that are not reachable by a U.S.-based sales force or when deemed strategically and economically advisable.
- *Expand our product candidate portfolio.* We may pursue opportunities from time to time to expand our product candidate portfolio by identifying and evaluating new compounds that have demonstrated potential in preclinical or clinical studies and are strategically aligned with our existing oncology portfolio. Our intent is to build a portfolio of proprietary product candidates that have the potential to improve the standard of care in cancer therapy and provide commercial, regulatory or geographic exclusivity.

Our Product Candidates

The following table summarizes the target indications and clinical development status of our lead product candidate, pralatrexate:

Product Development Pipeline



Pralatrexate (PDX)

Pralatrexate is a novel targeted antifolate designed to accumulate preferentially in cancer cells. Based on preclinical studies, we believe that pralatrexate selectively enters cells expressing RFC-1, a protein that is over expressed on cancer cells compared to normal cells. Once inside cancer cells, pralatrexate is efficiently polyglutamylated, which leads to high intracellular drug retention. Polyglutamylated pralatrexate essentially becomes "trapped" inside cancer cells, making it less susceptible to efflux-based drug resistance. Acting on the folate pathway, pralatrexate interferes with DNA synthesis and triggers cancer cell death. We believe pralatrexate 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 DNA synthesis. Because the cell mistakes them for a normal metabolite, the antimetabolites 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. Pralatrexate is a folic acid analog.

The selectivity of antifolates for tumor cells involves their conversion to a polyglutamated form by the enzyme folypolyglutamyl synthetase. Polyglutamation is a time- and concentration-dependent process that occurs in tumor cells, and to a lesser extent, normal tissue. 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 dihydrofolate reductase, or DHFR.

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

Pralatrexate in the treatment of peripheral T-cell lymphoma

Peripheral T-cell lymphomas, or PTCL, comprise a biologically diverse group of blood cancers that account for approximately 10 to 15 percent of all cases of non-Hodgkin's lymphoma, or NHL, in the United States. According to the American Cancer Society, an estimated 66,000 new cases of NHL were expected to be diagnosed in the United States in 2008. We estimate the current annual prevalence of PTCL in the United States to be approximately 9,500 patients. There are currently no pharmaceutical agents approved for use in the treatment of either first-line or relapsed or refractory PTCL. In addition to those PTCL patients who do not respond to first-line treatment, a significant number of first-line multi-agent chemotherapy responders relapse or become refractory after treatment. According to the clinical literature, patients with aggressive PTCL have an overall five-year survival rate of approximately 25% after first-line therapy.

In February 2009, we announced the final results from PROPEL, our pivotal Phase 2, international, multi-center, open-label, single-arm trial of pralatrexate in patients with relapsed or refractory PTCL. Based on the results of this trial, we intend to submit an NDA to the FDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009.

The PROPEL trial enrolled a total of 115 patients with relapsed or refractory PTCL, 109 of whom were considered evaluable for response according to the trial protocol. We believe the PROPEL trial is the largest prospectively designed single-agent trial conducted to date in patients with relapsed or refractory PTCL. To be eligible for the trial, a patient's disease must have progressed after at least one prior treatment. Patients were considered evaluable if they received at least one dose of pralatrexate and their diagnosis of PTCL was confirmed by independent pathology review. Patients received 30 mg/m^2 of pralatrexate intravenously once every week for six weeks followed by one week of rest per cycle of treatment. Patients also received vitamin B_{12} and folic acid supplementation. The primary endpoint of the trial is objective response rate, as assessed by central independent oncology review using International Workshop Criteria. Duration of response is the key secondary endpoint. Other secondary endpoints include progression-free survival, overall survival and safety and tolerability.

The results of the trial demonstrated that 29 of 109 evaluable patients, or 27%, achieved a response as assessed by central independent oncology review. Of the 29 patients who achieved a response according to central independent oncology review, seven patients had a complete response, or CR, two patients had a complete response unconfirmed, or CRu, and 20 patients had a partial response, or PR. The Kaplan-Meier estimate for the median duration of response was 287 days, or 9.4 months. The most common grade 3/4 adverse events were thrombocytopenia, which was observed in

32% of patients; mucosal inflammation in 21% of patients; neutropenia in 20% of patients; and anemia in 17% of patients.

According to the PROPEL investigators, 42 of 109 evaluable patients, or 39%, achieved a response. Of these, 15 patients had a CR, four patients had a CRu and 23 patients had a PR. PROPEL patients received a median of three prior systemic treatment regimens (range of 1-12), including 18 patients, or 16%, who had previously undergone an autologous stem cell transplant. In the trial, 66% of the patients who responded did so after cycle one of therapy. Patients will continue to be followed for long-term survival.

In accordance with the PROPEL trial protocol, three pre-planned interim analyses of safety data were previously conducted. In January, September and December 2007, we announced that an independent data monitoring committee, or DMC, completed interim analyses of safety data from the first 10, 35 and 65 evaluable patients who completed at least one cycle of treatment with pralatrexate, respectively, and recommended that the trial continue per the protocol at each analysis. No major safety concerns were identified by the DMC that affected the continuation of the trial.

The PROPEL trial was conducted under an agreement reached with the FDA under its SPA process. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of an NDA, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. However, the SPA agreement is not a guarantee of approval, and we cannot assure you that the design of, or data collected from, the PROPEL trial will be adequate to demonstrate the safety and efficacy of pralatrexate for the treatment of patients with relapsed or refractory PTCL, or otherwise be sufficient to support FDA or any foreign regulatory approval. For example, the response rate, duration of response and safety profile required to support FDA approval are not specified in the PROPEL trial protocol and will be subject to FDA review. In addition, the median duration of response reported above is a Kaplan-Meier estimate based on the length of follow up for all responders at the time the PROPEL trial database was locked. As a result, the median duration of response may change based on continued patient follow up.

Pralatrexate has orphan drug designation and fast track designation in the United States for the treatment of patients with T-cell lymphoma and orphan medicinal product designation in Europe for the treatment of PTCL. Under the U.S. Orphan Drug Act, if we are the first company to receive FDA approval for pralatrexate for this orphan drug indication, we will obtain seven years of marketing exclusivity during which the FDA may not approve another company's application for the same drug for the same orphan indication. The FDA's fast track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. In Europe, orphan medicinal product designation, or OMPD, is intended to promote the development of drugs that may provide significant benefit to patients suffering from rare diseases identified as life-threatening or very serious. Under the guidelines of the European Medicines Agency, OMPD provides ten years of potential market exclusivity once the product candidate is approved for marketing for the designated indication in the European Union.

Pralatrexate in the treatment of non-Hodgkin's Lymphoma and Hodgkin's disease

Approximately 66,000 patients were expected to be diagnosed with non-Hodgkin's Lymphoma, or NHL, in the United States in 2008 and approximately 85% of NHL patients represent patients with B-cell lymphoma. The incidence of NHL has increased significantly since the 1970's and is currently growing at approximately 1% to 2% per year. Patients with indolent or low-grade NHL may have survival rates as long as 10 years, yet the disease is frequently incurable. Aggressive lymphomas generally result in shorter median survival times although 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, also known as CHOP. The addition of rituximab in one study increased response rates to nearly 100%. However, a significant number of patients treated with CHOP or rituximab eventually relapse and may be candidates for salvage chemotherapy, or chemotherapy given after recurrence of a tumor.

We are currently evaluating pralatrexate in an ongoing Phase 1/2, open-label, single-center study in patients with relapsed or refractory NHL and Hodgkin's disease. Interim data from this trial, which was most recently presented at the AACR-NCI-EORTC conference in October 2007, showed that responses were observed in 2 of 20, or 10% of, evaluable patients with B-cell lymphoma. This study is currently focused on exploring alternate dosing and administration schedules in patients with B-cell lymphoma to further evaluate pralatrexate's potential clinical utility in this setting.

In May 2007, we initiated patient enrollment in a Phase 1/2a, open-label, multi-center study of pralatrexate and gemcitabine with vitamin B_{12} and folic acid supplementation in patients with relapsed or refractory NHL or Hodgkin's disease. In the Phase 1 portion of this study, patients with either relapsed or refractory NHL (diffuse large B- or T-cell lymphoma, mantle cell lymphoma, transformed large cell lymphomas) or Hodgkin's disease receive pralatrexate either concurrently on the same day with or followed the next day by gemcitabine as part of a weekly schedule for three or four weeks with concurrent vitamin B_{12} and folic acid supplementation. We plan to enroll up to 54 evaluable patients in the Phase 1 portion of the study with the objective of determining the maximum tolerated dose, or MTD, safety, tolerability, and pharmacokinetic profile of escalating doses of sequential pralatrexate and gemcitabine. If the Phase 1 portion of the study is successful, we plan to enroll up to 45 additional patients with relapsed or refractory PTCL in the Phase 2a portion of the trial at the established MTD to assess preliminary efficacy of pralatrexate and gemcitabine.

In December 2008, interim data from this study were presented at the 50th Annual Meeting of the American Society of Hematology. Data were presented on 27 patients, 22 of whom were evaluable for response. Patients were enrolled in eight cohorts with different doses and schedules. Partial responses were observed in 6 of 22 evaluable patients, including five patients on a sequential dosing schedule and one patient on a same-day dosing schedule. Patients received a median of three prior systemic regimens. The most common adverse event was thrombocytopenia, with Grade 3 observed in four patients and Grade 4 observed in seven patients. The MTD for the sequential dosing schedule was established as 10 mg/m^2 of pralatrexate followed by 400 mg/m^2 of gemcitabine, once every two weeks. Enrollment in the trial is ongoing to determine the MTD for the same-day dosing schedule.

In October 2008, the FDA granted orphan drug designation to pralatrexate for the treatment of patients with follicular lymphoma and for the treatment of patients with diffuse large B-cell lymphoma.

Pralatrexate in the treatment of cutaneous T-cell lymphoma

Cutaneous T-cell lymphomas, or CTCL, are comprised of a number of non-Hodgkin's T-cell lymphomas, including mycosis fungoides and Sezary syndrome, which have their primary manifestations in the skin. According to the Lymphoma Research Foundation, CTCL accounts for approximately 2% to 3% of the estimated 66,000 new cases of NHL diagnosed each year in the United States.

In August 2007, we initiated patient enrollment in a Phase 1, open-label, multi-center study of pralatrexate with vitamin B_{12} and folic acid supplementation in patients with relapsed or refractory CTCL. In this study, patients with either relapsed or refractory CTCL receive pralatrexate as part of a weekly schedule for two or three weeks followed by one week of rest. Patients receive starting doses of pralatrexate at 30 mg/m^2, with dose reduction in subsequent cohorts based on toxicity.

In December 2008, interim data from this study were presented at the 50th Annual Meeting of the American Society of Hematology. Data were presented on 24 patients, including 22 evaluable patients

who completed at least one cycle of treatment at doses ranging from 10-30 mg/m^2 as part of a weekly schedule for two or three weeks followed by one week of rest. Responses were observed in 12 of 22 evaluable patients, or 55%, including one complete response and 11 partial responses. Patients received a median of four prior systemic therapies. The most common adverse event was mucosal inflammation, with Grade 1/2 mucosal inflammation observed in 11 of 24 patients and Grade 3 mucosal inflammation observed in 4 of 24 patients. There was no Grade 4 mucosal inflammation and no thrombocytopenia above Grade 1.

We plan to enroll up to 56 evaluable patients in the study with the objective of determining the optimal dose and safety profile of pralatrexate in this population. We plan to enroll at least 20 of these patients at what we believe to be the optimal dose and schedule.

Pralatrexate in the treatment of non-small cell lung cancer

Lung cancer is the most common cause of cancer death in the United States. According to the American Cancer Society, an estimated 215,020 new cases of lung cancer were expected to be diagnosed in the United States in 2008. Non-small cell lung cancer, or NSCLC, is the most common type of lung cancer, accounting for approximately 87% of lung cancer cases, according to the American Cancer Society. More people die of lung cancer than of breast, prostate and colorectal cancers combined. 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 using gemcitabine and vinorelbine, one study found that the one-year survival rate for patients with Stage IIIB or IV NSCLC was approximately 40%.

In January 2008, we initiated patient enrollment in a Phase 2b, randomized, multi-center study comparing pralatrexate and Tarceva (erlotinib), both with vitamin B_{12} and folic acid supplementation, in patients with Stage IIIB/IV NSCLC who are, or have been, cigarette smokers who have failed treatment with at least one prior platinum-based chemotherapy regimen. The objective of this study is to compare the efficacy of pralatrexate to that of Tarceva in patients with Stage IIIB/IV NSCLC. The primary endpoint of the study is overall survival. Secondary endpoints include response rate and progression-free survival, both compared to Tarceva, and the safety and tolerability of pralatrexate. The study will seek to enroll approximately 160 patients in up to 50 investigative sites worldwide. Patients will be randomized 1:1 to either the pralatrexate arm or the Tarceva arm. Patients randomized to the pralatrexate arm will receive pralatrexate as an intravenous, or IV, push administered on days 1 and 15 of a 4-week/28 day cycle. The initial dose of pralatrexate will be 190 mg/m^2, which, based on defined criteria, may be increased to 230 mg/m^2 or reduced in 40 mg/m^2 decrements. Patients randomized to the Tarceva arm will receive Tarceva 150 mg/day orally daily for the 4-week/28 day cycle. Patients in both arms will receive concurrent vitamin therapy of B_{12} and folic acid. Based on current enrollment rates, we expect to complete patient enrollment in this study in the third quarter of 2009.

Our decision to begin this study was based, in part, upon data from a Phase 2 open-label, single-agent study of pralatrexate in patients with relapsed or refractory Stage IIIB or IV NSCLC completed in 2001 by Memorial Sloan-Kettering Cancer Center one of the institutions from which we licensed pralatrexate. This study demonstrated a response rate of 11%, a median time to progression of three months and a median survival time of 13.5 months. However, 21% of the patients suffered grade 3 or 4 stomatitis, or mouth ulcers. As a result of subsequent research that suggested supplementation of pralatrexate with folic acid and vitamin B_{12} may reduce the incidence of clinically significant stomatitis, in January 2005 we initiated a Phase 1 dose escalation study of pralatrexate with vitamin B_{12} and folic acid supplementation in patients with previously treated Stage IIIB/IV advanced NSCLC.

In October 2007, data from this ongoing Phase 1 study were presented at the AACR-NCI-EORTC conference. In the study, a total of 22 patients with relapsed or refractory NSCLC were treated at

doses of 150 to 325 mg/m^2 of pralatrexate. The MTD was determined to be 270 mg/m^2, which is nearly twice the dose used in the previous Phase 2 study discussed above in which pralatrexate was administered without vitamin supplementation, and what we believe to be clinically significant radiologic responses were observed. Greater than 50% of patients, or 13 of 22, received two or more prior treatment regimens. This study was used to establish the dosing regimen for our current Phase 2b study in patients with Stage IIIB/IV NSCLC.

Pralatrexate in the treatment of bladder cancer

Bladder cancer is the ninth most common type of cancer. According to the American Cancer Society, an estimated 68,810 new cases of bladder cancer were expected to be diagnosed in the United States in 2008. Transitional cell carcinoma, or TCC, is the most common form of bladder cancer, accounting for more than 90% of all bladder cancers. There are no approved agents for the treatment of advanced or metastatic relapsed TCC of the urinary bladder.

In July 2008, we initiated patient enrollment in a Phase 2, open-label, single-arm, multi-center study of pralatrexate in patients with advanced or metastatic relapsed TCC of the urinary bladder. The primary endpoint of the study is objective response rate (complete and partial response). Secondary endpoints include duration of response, clinical benefit rate, progression-free survival overall survival and the safety and tolerability of pralatrexate. The study will seek to enroll approximately 41 patients in up to 20 investigative sites worldwide. Patients receive pralatrexate as an IV push administered on days 1 and 15 of a 4-week/28 day cycle. The initial dose of pralatrexate is 190 mg/m^2, which may be adjusted based on criteria defined in the protocol. Patients will receive concurrent vitamin therapy of B_{12} and folic acid.

Pralatrexate in the treatment of other solid tumor indications

In addition to our ongoing NSCLC and bladder cancer studies, we are evaluating the potential future development of pralatrexate for other solid tumor indications, including Stage III/IV head and neck cancer and Stage III/IV breast cancer, among others. There can be no assurances that we will pursue the development of pralatrexate for one or more of these indications or that such development efforts will be ultimately successful.

RH1

Our other product candidate, RH1, is a small molecule chemotherapeutic agent that we believe is bioactivated by the enzyme DT-diaphorase, or DTD, also known as NAD(P)H quinone oxidoreductase, or NQ01. We believe DTD is over-expressed in many tumors, relative to normal tissue, including lung, colon, breast and liver tumors. We believe that because RH1 is bioactivated in the presence of DTD, it may have the potential to provide targeted drug delivery to these tumor types while limiting the amount of toxicity to normal tissue.

In November 2007, we initiated patient enrollment in a Phase 1, open-label, multi-center dose escalation study of RH1 in patients with advanced solid tumors or NHL. We are in the process of closing this study and determining our future development plans, if any, for RH1.

Manufacturing

The production of pralatrexate and RH1 employ small molecule organic chemistry procedures standard for the pharmaceutical industry. We plan to continue to outsource manufacturing responsibilities for these and any additional future products, and we intend to select and rely, at least initially, on single source suppliers to manufacture each of our product candidates. We believe this manufacturing strategy allows us to direct our financial and managerial resources to the development and commercialization of products rather than to the establishment of a manufacturing infrastructure.

We believe it also enables us to minimize fixed costs and capital expenditures, while gaining access to advanced manufacturing process capabilities and expertise. However, if our third party suppliers become unable or unwilling to provide sufficient future drug supply or meet regulatory requirements relating to the manufacture of pharmaceutical agents, we would be forced to incur additional expenses to secure alternative third party manufacturing arrangements and may suffer delays in our ability to conduct clinical trials or commercialize these products.

Pralatrexate

We have entered into arrangements with one third-party manufacturer to produce pralatrexate bulk drug substance and another third-party manufacturer to produce pralatrexate formulated drug product for use in our clinical development programs. We believe these third-party manufacturers have the capability to meet our requirements for all future clinical trial requirements. As we pursue FDA approval to market pralatrexate for the treatment of patients with relapsed or refractory PTCL, we will seek to establish appropriate commercial supply arrangements for the production of pralatrexate bulk drug substance and formulated drug product.

RH1

We have entered into arrangements with one third party manufacturer to produce RH1 bulk drug substance and another third party manufacturer to produce RH1 formulated drug product for use in our clinical development programs. We believe these third party manufacturers have the capability to meet our requirements for any future clinical trials, if any, involving RH1.

Sales and Marketing

We currently retain exclusive worldwide commercial rights to pralatrexate and RH1 for all target indications. If we obtain FDA approval to market pralatrexate, we intend to commercialize pralatrexate in the United States by building a focused sales and marketing organization that may be complemented by co-promotion or other partnering arrangements with pharmaceutical or biotechnology partners, where appropriate. Our sales and marketing strategy is to:

- *Build a U.S. sales force.* We believe that a moderate-sized sales force could effectively reach targeted physicians and medical institutions that treat the majority of patients with PTCL 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 operations 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 foreign market segments that are not reachable by a U.S.-based sales force or when deemed strategically and economically advisable.

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 identical patents and protection periods for a given technology throughout all markets of the world will be difficult because of differences in patent laws. In addition, the protection provided by non-U.S. patents, if any, may be weaker than that provided by U.S. 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 or license 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 or new technologies 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 or in the future. Furthermore, to the extent that we, our consultants, or manufacturing and research collaborators, use intellectual property owned by others in work performed for us, disputes may also arise as to the rights to 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 patent and trademark offices in the United States, the European Union, or other ex-U.S. territories, 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.

Pralatrexate

In December 2002, we entered into a license agreement with Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute, as amended, under which we obtained exclusive worldwide rights to a portfolio of patents and patent applications related to pralatrexate and its uses. The portfolio currently consists of two issued patents in the United States, two granted patents in Europe, and pending patent applications in the United States, Canada, Europe, Australia, Japan, China, Brazil, Indonesia, India, South Korea, Mexico, Norway, New Zealand, the Philippines, Singapore and South Africa. The licensed patents and applications, which expire at various times between July 2017 and May 2025, contain claims covering pralatrexate substantially free of 10-deazaaminopterin, methods to treat tumors with pralatrexate substantially free of 10-deazaaminopterin, treatment of breast, lung, and prostate cancer and leukemia with a combination of pralatrexate and a taxane, treatment of T-cell lymphoma with pralatrexate, treatment of lymphoma with a combination of pralatrexate and gemcitabine, methods of assessing sensitivity of a tumor to pralatrexate, and other methods and compositions.

Under the terms of the agreement, we paid an up-front license fee of $2.0 million upon execution of the agreement and are also required to make certain additional cash payments based upon the achievement of certain clinical development or regulatory milestones or the passage of certain time periods. To date, we have made aggregate milestone payments of $2.5 million based on the passage of time. In the future, we could make an aggregate milestone payment of $500,000 upon the earlier of achievement of a clinical development milestone or the passage of certain time periods, or the Clinical Milestone, and up to $10.3 million upon achievement of certain regulatory milestones, or the Regulatory Milestones, including regulatory approval to market pralatrexate in the United States or Europe. The last scheduled payment towards the Clinical Milestone of $500,000 is currently due on

December 23, 2009. We intend to submit an NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. If the FDA accepts our NDA for review and if we obtain FDA approval to market pralatrexate, we will be obligated to make payments of $1,500,000 and $5,300,000, respectively, which represent a portion of the Regulatory Milestones. The up-front license fee and all milestone payments under the agreement have been or will be recorded to research and development expense when incurred. Under the terms of the agreement, we are required to fund all development programs and will have sole responsibility for all commercialization activities. In addition, we will pay the licensors 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 entered into an agreement with the University of Colorado Health Sciences Center, the University of Salford and Cancer Research Technology, or CRT, 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 paid an up-front license fee of $190,500 upon execution of the agreement and are also required to make certain additional cash payments based upon the achievement of certain clinical development, regulatory and commercialization milestones. We could make aggregate milestone payments of up to $9.2 million upon the achievement of the clinical development, regulatory and commercialization milestones set forth in the agreement. The up-front license fee and all milestone payments under the agreement, as well as the one-time data option fee discussed below, have been recorded to research and development expense. Under the terms of the agreement and related data option agreement, we paid the licensors a one-time data option fee of $360,000 in 2007 for an exclusive license to the results of a Phase 1 study sponsored by Cancer Research UK, CRT's parent institution. This Phase 1 study was completed in 2007 and, under the terms of the agreement, we have since assumed responsibility for all future development costs and activities and have sole responsibility for all commercialization activities. In addition, we will pay the licensors 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. We are in the process of closing our Phase 1 study of RH1 in patients with advanced solid tumors or NHL and determining our future development plans, if any, for RH1.

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 and several biotechnology companies, are developing cancer therapies similar to ours. There are products and technologies currently 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 may have significantly more experience than we do in preclinical testing, human clinical trials, manufacturing, regulatory approval and commercialization procedures. Our competitors may:

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

- commercialize products earlier or more effectively 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.

While there are currently no FDA-approved agents in the United States indicated for the treatment of PTCL, we are aware of multiple investigational agents that are currently being studied in clinical trials. There are also several agents and regimens, such as CHOP, that are currently used by physicians without an FDA label in PTCL that could potentially represent competition for pralatrexate.

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;
- pre-approval inspection of manufacturing facilities and selected clinical investigators; and
- submission to the FDA of an NDA that must be approved.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates 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 and clinical efficacy, and to further test for safety, in each case, 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 an NDA for approval of the marketing and commercial shipment of the product candidate. The FDA may deny an 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 that 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 for pralatrexate 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 U.S. 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. Our third-party 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.

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

The FDA's policies may change and additional government regulations may be enacted in the future that 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. In some countries in the EU, pricing of prescription drugs is subject to government control and agreements must be reached on a national level before marketing may begin in that country. If we are unable to reach agreement on an acceptable price for our products, we may choose not to pursue marketing of our drugs in that country. The foreign regulatory approval process involves all of the risks associated with FDA approval 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.

Results of Operations

We are a development stage company. Since our inception in 1992, we have not generated any revenue from product sales and have experienced significant net losses and negative cash flows from operations. We have incurred these losses principally from costs incurred in our research and development programs, clinical manufacturing and from our marketing, general and administrative expenses. Our primary business activities have been focused on the development of pralatrexate, RH1 and EFAPROXYN (a program which we discontinued in mid-2007). For the years ended December 31, 2008, 2007 and 2006, we had net losses attributable to common stockholders of $51.7 million, $39.4 million, and $30.2 million, respectively. Research and development expenses for the years ended December 31, 2008, 2007 and 2006 were $23.8 million, $17.4 million and $14.3 million, respectively. As of December 31, 2008, we had accumulated a deficit during our development stage of $299.7 million.

Our ability to generate revenue and achieve profitability is dependent on our ability, alone or with partners, to successfully complete the development of pralatrexate, conduct clinical trials, obtain the necessary regulatory approvals, and manufacture and market pralatrexate. The timing and costs to complete the successful development of pralatrexate is highly uncertain, and therefore difficult to estimate. The lengthy process of seeking regulatory approvals for pralatrexate, 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 above. Clinical development timelines, likelihood of success and total costs vary widely and are impacted by a variety of risks and uncertainties, including those discussed in the "Risk Factors" section of Item 1A below. Because of these risks and uncertainties, we cannot predict when or whether we will successfully complete the development of pralatrexate or the ultimate costs of such efforts. Due to these same factors, we cannot be certain when, or if, we will generate any revenue or net cash inflow from pralatrexate.

Even if our clinical trials demonstrate the safety and effectiveness of pralatrexate in its target indications, we do not expect to be able to generate commercial sales of pralatrexate until the second half of 2009, at the earliest. We expect to continue incurring net losses and negative cash flows for the foreseeable future. Although the size and timing of our future net losses are subject to significant uncertainty, we expect them to increase over the next several years as we continue to fund our research and development programs and prepare for the potential commercial launch of pralatrexate.

We anticipate continuing our current development programs and/or beginning other long-term development projects involving pralatrexate. These projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. In addition, we intend to submit an NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. We expect to incur significant costs relating to preparations for the potential commercial launch of pralatrexate, including pre-commercial scale up of manufacturing and development of sales and marketing capabilities, prior to the receipt of regulatory approval to market pralatrexate. Therefore, we will need to raise additional capital to support our future operations, including the potential commercialization of pralatrexate if approved for marketing. Our actual capital requirements will depend on many factors, including those discussed under the "Liquidity and Capital Resources" section below.

We may seek to obtain this additional capital through equity or debt financings, arrangements with corporate partners, or from other sources. Such arrangements, if successfully consummated, may be dilutive to our existing stockholders. However, there is no assurance that additional financing will be available when needed, or that, if available, we will obtain such financing on terms that are favorable to our stockholders or us. In particular, the current instability in the global financial markets and lack of liquidity in the credit and capital markets may adversely affect our ability to secure adequate capital to support our future operations. 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, which we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. 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.

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 operate as a single business segment.

Employees

As of February 26, 2009, we had a total of 81 full-time employees. Of those, 50 are engaged in clinical development, regulatory affairs, biostatistics, manufacturing and preclinical development. The remaining 31 are involved in marketing, corporate development, finance, administration and operations.

Available Information

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 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 Securities and Exchange Commission, or SEC. Once at *www.allos.com*, go to Investors/Media and then to SEC Filings to locate copies of such reports. You may also read and copy materials that we file with SEC at the SEC's Public Reference Room at 100 F Street, NE, 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 at *www.sec.gov* that contains reports, proxy and information statements and other information regarding us and other issuers that file electronically with the SEC.

ITEM 1A. 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 that we currently do not believe are material. If any of the events or circumstances described in the following risk factors actually occurs, they may materially harm our business, financial condition, operating results and cash flow. As a result, the market price of our common stock could decline. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results and financial condition. The following 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 generate revenue or achieve or maintain profitability in the future.

Since our inception in 1992, we have not generated any revenue from product sales and have experienced significant net losses and negative cash flows from operations. To date, we have financed our operations primarily through the public and private sale of securities. For the years ended December 31, 2008, 2007 and 2006, we had net losses attributable to common stockholders of $51.7 million, $39.4 million, and $30.2 million, respectively. As of December 31, 2008, we had accumulated a deficit during our development stage of $299.7 million. We have incurred these losses principally from costs incurred in our research and development programs, clinical manufacturing and from our marketing, general and administrative expenses. We expect to continue incurring net losses for the foreseeable future. Our ability to generate revenue and achieve profitability is dependent on our ability, alone or with partners, to successfully complete the development of pralatrexate (PDX), conduct clinical trials, obtain the necessary regulatory approvals, and manufacture and market pralatrexate. 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 pralatrexate, and in preparing for the potential commercial launch of pralatrexate. 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 near-term prospects are substantially dependent on pralatrexate (PDX), our lead product candidate. If we are unable to successfully develop and obtain regulatory approval for pralatrexate for the treatment of patients with relapsed or refractory PTCL, our ability to generate revenue will be significantly delayed.

We currently have no products that are approved for commercial sale. 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, obtain the necessary regulatory approvals therefor, and successfully commercialize them. Substantially all of our efforts and expenditures over the next few years will be devoted to pralatrexate as we are in the process of closing our current Phase 1 clinical study of RH1 in patients with advanced solid tumors or NHL and determining our future development plans, if any, for RH1. Accordingly, our future prospects are substantially dependent on the successful development, regulatory approval and commercialization of pralatrexate for the treatment of patients with relapsed or refractory PTCL. Even if we receive regulatory approval, pralatrexate is not expected to be commercially available for this or any other indication until at least the second half of 2009. Further, certain of the indications that we are pursuing for pralatrexate have relatively low incidence rates, which may make it difficult for us to enroll a sufficient number of patients in our clinical trials on a timely basis, or at all, and may limit the revenue potential of pralatrexate. If we are unable to successfully develop, obtain regulatory approval for and commercialize pralatrexate for the treatment of patients with relapsed or refractory PTCL, our ability to generate revenue from product sales will be significantly delayed and our stock price would likely decline.

We cannot predict when or if we will obtain regulatory approval to commercialize pralatrexate.

Pralatrexate is in the clinical stage of development and has not been approved for marketing in the United States or any other country. A pharmaceutical product cannot be marketed in the United States or most other countries until it has completed a rigorous and extensive regulatory review and approval process. If we fail to obtain regulatory approval to market pralatrexate, we will be unable to sell pralatrexate 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 pralatrexate, or we may not obtain regulatory review of pralatrexate in a timely manner.

While we have negotiated a special protocol assessment with the FDA relating to our PROPEL trial, this agreement does not guarantee any particular outcome from regulatory review of the trial or the product, including any regulatory approval.

The protocol for the PROPEL trial was reviewed by the FDA under its special protocol assessment, or SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. However, the SPA agreement is not a guarantee of approval, and we cannot be certain that the design of, or data collected from, the PROPEL trial will be adequate to demonstrate the safety and efficacy of pralatrexate for the treatment of patients with relapsed or refractory PTCL, or otherwise be sufficient to support FDA or any foreign regulatory approval. In addition, the response rate, duration of response and safety profile required to support FDA approval are not specified in the PROPEL trial protocol and will be subject to FDA review. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement was entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed upon trial protocols. In addition, the SPA agreement may be changed by us or

the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the PROPEL trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreement, how it will interpret the data and results from the PROPEL trial, or whether pralatrexate will receive any regulatory approvals as a result of the SPA agreement or the PROPEL trial. Therefore, despite the potential benefits of the SPA agreement, significant uncertainty remains regarding the clinical development and regulatory approval process for pralatrexate for the treatment of patients with relapsed or refractory PTCL.

Even if pralatrexate meets safety and efficacy endpoints in clinical trials, regulatory authorities may not approve pralatrexate, or we may face post-approval problems that require withdrawal of pralatrexate from the market.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We will not be able to commercialize pralatrexate until we have obtained regulatory approval. We have limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may place us at risk of delays, overspending and human resources inefficiencies.

Pralatrexate may not be approved even if it achieves its endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors, may disagree with our interpretations of data from preclinical studies and clinical trials. The FDA has substantial discretion in the approval process, and when or whether regulatory approval will be obtained for any drug we develop. For example, even though we established an SPA with the FDA for our PROPEL trial, there is no guarantee that the data generated from the PROPEL trial will be adequate to support FDA approval. Regulatory agencies also may approve a product candidate for fewer conditions than requested or may grant approval subject to the performance of post-marketing studies or risk evaluation and mitigation strategies (REMS) for a product candidate. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of pralatrexate.

Even if we receive regulatory approval, pralatrexate may later produce adverse events that limits or prevents its widespread use or that force us to withdraw pralatrexate from the market. In addition, a marketed product continues to be subject to strict regulation after approval and may be required to undergo post-approval studies. Any unforeseen problems with an approved product or any violation of regulations could result in restrictions on the product, including its withdrawal from the market. Any delay in or failure to receive or maintain regulatory approval for pralatrexate could harm our business and prevent us from ever generating meaningful revenues or achieving profitability.

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

Following any regulatory approval of pralatrexate, 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 pralatrexate. In addition, we or our third-party manufacturers will be required to adhere to regulations setting forth the FDA's current Good Manufacturing Practices, or cGMP. These regulations cover all aspects of the manufacturing, storage, testing, quality control and record keeping relating to pralatrexate. 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 to ensure strict compliance with cGMP or other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. Such inspections may result in

compliance issues that could prevent or delay marketing approval, or require the expenditure of substantial 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.

We will need to raise additional capital to support our future operations. If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop or commercialize pralatrexate.

Based upon the current status of our product development plans, we believe that our cash, cash equivalents, and investments in marketable securities as of December 31, 2008 should be adequate to support our operations through at least the next 12 months, although there can be no assurance that this can, in fact, be accomplished. We anticipate continuing our current development programs and/or beginning other long-term development projects involving pralatrexate. These projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. In addition, we intend to submit an NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. We expect to incur significant costs relating to preparations for the potential commercial launch of pralatrexate, including pre-commercial scale up of manufacturing and development of sales and marketing capabilities. Therefore, we will need to raise additional capital to support our future operations. Our actual capital requirements will depend on many factors, including:

- the timing and outcome of our planned NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL;
- the timing and costs associated with developing sales and marketing capabilities and commercializing pralatrexate, if it is approved for marketing;
- the timing and costs associated with manufacturing clinical and commercial supplies of pralatrexate;
- the timing and amount of revenues generated by our business activities, if any;
- the timing and costs associated with conducting preclinical and clinical development of pralatrexate, as well as our evaluation of, and decisions with respect to, additional therapeutic indications for which we may develop pralatrexate;
- the timing, costs and potential revenue associated with any co-promotion or other partnering arrangements entered into to commercialize pralatrexate, if it is approved for marketing; and
- our evaluation of, and decisions with respect to, potential in-licensing or product acquisition opportunities or other strategic alternatives.

We may seek to obtain this additional capital through equity or debt financings, arrangements with corporate partners, or from other sources. Such financings or arrangements, if successfully consummated, may be dilutive to our existing stockholders. However, there is no assurance that additional financing will be available when needed, or that, if available, we will obtain such financing on terms that are favorable to our stockholders or us. In particular, the current instability in the global financial markets and lack of liquidity in the credit and capital markets may adversely affect our ability to secure adequate capital to support our future operations. 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 might otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. 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.

Budget constraints may force us to delay our efforts to develop pralatrexate for certain indications in favor of developing it for other indications, which may prevent us from commercializing pralatrexate for all desired indications as quickly as possible.

Because we have limited resources, and because research and development is an expensive process, we must regularly assess the most efficient allocation of our research and development budget. As a result, we may have to prioritize development of pralatrexate for certain indications and may not be able to fully realize the value of pralatrexate for other indications in a timely manner, if at all.

If pralatrexate fails to meet safety and efficacy endpoints in clinical trials, it will not receive regulatory approval and we will be unable to market pralatrexate.

Pralatrexate 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. The clinical development and regulatory approval process is expensive and takes many years. Failure can occur at any stage of development, and the timing of any regulatory approval cannot be accurately predicted. In addition, failure to comply with the FDA and other applicable U.S. and foreign regulatory requirements applicable to clinical trials may subject us to administrative or judicially imposed sanctions.

As part of the regulatory process, we must conduct clinical trials for pralatrexate and any other product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. The design of our pralatrexate clinical trials is based on many assumptions about the expected effect of pralatrexate, and if those assumptions prove incorrect, the clinical trials may not demonstrate the safety or efficacy of pralatrexate. Preliminary results may not be confirmed upon full analysis of the detailed results of a trial, and prior clinical trial program designs and results may not be predictive of future clinical trial designs or results. Product candidates in later stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. For example, we terminated the development of EFAPROXYN, one of our former product candidates, when it failed to demonstrate statistically significant improvement in overall survival in the targeted patients in a Phase 3 clinical trial. If pralatrexate fails to show clinically significant benefits, it will not be approved for marketing.

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. 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 clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. 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. If we have to conduct additional clinical trials for pralatrexate, it would significantly increase our expenses and delay potential marketing of pralatrexate.

We announced the final results from our pivotal Phase 2 PROPEL trial in February 2009. Based on the results of the trial, we intend to submit an NDA to the FDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. We cannot assure you that the design of, or data collected from, the PROPEL trial will be adequate to demonstrate the safety and efficacy of pralatrexate for the treatment of patients with relapsed or refractory PTCL, or otherwise be

sufficient to support FDA or any foreign regulatory approval. The FDA may disagree with our interpretation of the results of the trial and determine that the data are not sufficient to support approval. If we fail to obtain regulatory approval for pralatrexate, we will be unable to market and sell pralatrexate and therefore may never generate meaningful amounts of revenue or become profitable.

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

We do not know when our current clinical trials will be completed, if at all. We also cannot accurately predict when other planned clinical trials will begin or be completed. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Other companies are conducting clinical trials and have announced plans for future trials that are seeking or likely to seek patients with the same diseases as those we are studying. Competition for patients in some cancer trials is particularly intense because of the limited number of leading specialist physicians and the geographic concentration of major clinical centers.

As a result of the numerous factors that can affect the pace of progress of clinical trials, our trials may take longer to enroll patients than we anticipate, if they can be completed at all. Delays in patient enrollment in the trials may increase our costs and slow our product development and approval process. Our product development costs will also increase if we need to perform more or larger clinical trials than planned. If other companies' product candidates show favorable results, we may be required to conduct additional clinical trials to address changes in treatment regimens or for our products to be commercially competitive. Any delays in completing our clinical trials will delay our ability to generate revenue from product sales, 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 may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies 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 cGMP and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards; or
- we may not be able to produce sufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, pralatrexate could take a significantly longer time to gain regulatory approval than we expect or may never gain approval, which could reduce or eliminate our revenue by delaying or terminating the potential commercialization of pralatrexate.

Reports of adverse events or safety concerns involving pralatrexate or in related technology fields or other companies' clinical trials could delay or prevent us from obtaining regulatory approval or negatively impact public perception of pralatrexate.

Pralatrexate may produce serious adverse events. These adverse events could interrupt, delay or halt clinical trials of pralatrexate and could result in the FDA or other regulatory authorities denying approval of pralatrexate for any or all targeted indications. An independent data safety monitoring board, the FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. We cannot assure you that pralatrexate or any other product candidate will be safe for human use.

At present, there are a number of clinical trials being conducted by other pharmaceutical companies involving small molecule chemotherapeutic agents. If other pharmaceutical companies announce that they observed frequent adverse events or unknown safety issues in their trials involving compounds similar to, or competitive with, pralatrexate, we could encounter delays in the timing of our clinical trials or difficulties in obtaining the approval of pralatrexate. In addition, the public perception of pralatrexate might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company's product or product candidate.

Due to our reliance on contract research organizations and other third parties to conduct our clinical trials, we are unable to directly control the timing, conduct and expense of our clinical trials.

We rely primarily on third parties to conduct our clinical trials, including the PROPEL trial. As a result, we have had and will continue to have less control over the conduct of our clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, any of which may adversely affect their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

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 pralatrexate for clinical trials and, if approved, for commercial sale. If we are unable to contract for a sufficient supply of pralatrexate 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 pralatrexate, if it is approved for marketing.

Pralatrexate is cytotoxic, which requires the manufacturers of pralatrexate to have specialized equipment and safety systems to handle such a substance. In addition, the starting materials for pralatrexate require custom preparations, which will require us to manage an additional set of suppliers to obtain the needed supplies of pralatrexate.

Given our lack of formal supply agreements and the fact that in many cases our components are supplied by a single source, our third party suppliers may not be able to fulfill our potential commercial needs or meet our deadlines, or the components they supply to us may not meet our specifications and quality policies and procedures. If we need to find an alternative supplier of pralatrexate or its components, we may not be able to contract for those components on acceptable terms, if at all. Any such failure to supply or delay caused by such suppliers would have an adverse effect on our ability to continue clinical development of pralatrexate or commercialize pralatrexate, if it is approved for marketing.

Even if we obtain approval to market pralatrexate in one or more indications, our current or future manufacturers may be unable to accurately and reliably manufacture commercial quantities of pralatrexate at reasonable costs, on a timely basis and in compliance with the FDA's cGMP. 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 pralatrexate will be materially and adversely affected. This risk may be heightened with respect to pralatrexate as there are a limited number of fill/finish manufacturers with the ability to handle cytotoxic products such as pralatrexate. Our reliance on contract manufacturers exposes us to additional risks, including:

- 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 cGMP regulations and similar state and foreign standards, and we do not have control over our contract manufacturers' compliance with these regulations and standards;
- our manufacturers may not be able to comply with applicable regulatory requirements, which would prohibit them from manufacturing products for us;
- our manufacturers may have staffing difficulties, may undergo changes in control or may become financially distressed, adversely affecting their willingness or ability to manufacture products for us;
- 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;
- if we need to change to other commercial manufacturing contractors, the FDA and comparable foreign regulators must approve our use of any new manufacturer, which would require additional testing, regulatory filings 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; 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 result in the delay of clinical trials, regulatory submissions, required approvals or commercialization of pralatrexate. They could also entail higher costs and result in our being unable to effectively commercialize pralatrexate.

If we are unable to effectively protect our intellectual property, we will be unable to prevent third parties from using our technology, which would impair our competitiveness and ability to commercialize pralatrexate. 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 pralatrexate, 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, based on, among other things, obviousness, inequitable conduct, anticipation or enablement. 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 pralatrexate 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 pralatrexate, or fail to obtain a license at a reasonable cost, we will be unable to commercialize pralatrexate 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 that we seek to protect through confidentiality agreements with our collaborators, employees, advisors and consultants. Our employees and consultants are required to enter into confidentiality agreements with us. We also enter into non-disclosure agreements with our collaborators and vendors, which agreements 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 pralatrexate 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. We may be dependent on third parties, including our licensors, for cooperation and information that may be required in connection with the defense and prosecution of our patents and other 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 may explore strategic partnerships that may never materialize or may fail.

We may, in the future, periodically explore a variety of possible strategic partnerships in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic partnership might take. We are likely to face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be complicated and time

consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships.

If we enter into one or more strategic partnerships, we may be required to relinquish important rights to and control over the development of pralatrexate or otherwise be subject to unfavorable terms.

Any future strategic partnerships we enter into could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources in integrating new businesses, technologies and products;
- we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of pralatrexate;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of pralatrexate or any other products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of pralatrexate or any other product candidate or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement;
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic partners could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing pralatrexate or any other product candidate.

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

Even if pralatrexate is approved for marketing, pralatrexate 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 pralatrexate and its potential advantages over existing and newly developed therapeutic products;
- ease of use of pralatrexate;
- reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, 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 pralatrexate.

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate coverage and reimbursement could limit our ability to generate revenue.

Our ability to successfully commercialize pralatrexate will depend, in part, on the extent to which coverage and reimbursement for pralatrexate will be available from government and health administration authorities, private health insurers, managed care programs, and other third-party payors.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease conditions for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for pralatrexate. If government and other third-party payors do not provide adequate coverage and reimbursement levels for pralatrexate, pralatrexate's market acceptance may be reduced.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

We may not obtain orphan drug exclusivity or we may not receive the full benefit of orphan drug exclusivity even if we obtain such exclusivity.

The FDA has awarded orphan drug status to pralatrexate for the treatment of patients with T-cell lymphoma, follicular lymphoma and diffuse large B-cell lymphoma. Under the Orphan Drug Act, if we are the first company to receive FDA approval for pralatrexate for the designated orphan drug indication, we will obtain seven years of marketing exclusivity during which the FDA may not approve another company's application for pralatrexate for the same orphan indication. Orphan drug exclusivity would not prevent FDA approval of a different drug for the orphan indication or the same drug for a different indication.

If we fail to comply with healthcare fraud and abuse laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a biopharmaceutical company, even though we do not and will not control referrals of health care services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse will be applicable to our business. These laws and regulations, include, among others:

- the federal Anti-Kickback statute, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal self-referral laws, such as STARK, which prohibits a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution under the federal Anti-Kickback statute, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to

operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with all applicable federal and state fraud and abuse laws may be costly.

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 pralatrexate effectively.

We have limited experience in sales, marketing and distribution. If it is approved for marketing, we intend to build commercialize pralatrexate by building an oncology-focused U.S. sales and marketing organization that may be complemented by co-promotion arrangements with pharmaceutical or biotechnology partners, where appropriate. We intend to enter into co-promotion or out-licensing arrangements with other pharmaceutical or biotechnology partners where necessary to reach foreign market segments that are not reachable by a U.S.-based sales force or when deemed strategically and economically advisable. To directly market and distribute pralatrexate, we must build a sales and marketing organization with appropriate technical expertise and distribution capabilities. 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 pralatrexate, 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 pralatrexate, our commercial opportunity will be reduced or eliminated.

Even if we obtain the necessary regulatory approvals to market pralatrexate, 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 pralatrexate. 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 pralatrexate.

The testing and marketing of pharmaceutical products entail an inherent risk of product liability. Product liability claims might be brought against us by consumers or 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 pralatrexate. We have obtained limited product liability insurance coverage for our human clinical trials. However, product liability insurance coverage is becoming increasingly

expensive, and we may be unable to maintain such 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 pralatrexate, if it is 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 were named as a defendant in a purported securities class action lawsuit filed in May 2004 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. In an opinion dated October 20, 2005, the U.S. District Court for the District of Colorado concluded that the plaintiffs' complaint failed to meet the legal requirements applicable to its alleged claims and dismissed the lawsuit. On November 20, 2005, the plaintiffs appealed the District Court's decision to the U.S. Court of Appeals for the Tenth Circuit. On February 6, 2008, the parties signed a stipulation of settlement, settling the case for $2,000,000. The settlement was subject to various conditions, including without limitation approval of the District Court. On January 29, 2009, the District Court issued its Order and Final Judgment approving the settlement, including the releases of the defendants for which the settlement provided. Neither we nor our former officer, who was also named as a defendant, admitted any liability in connection with the settlement. The amount of the settlement in excess of our deductible was covered by our insurance carrier. In the event the District Court's approval of the settlement is appealed and the settlement does not become final, we would intend to vigorously defend against the plaintiffs' appeal. If the Court of Appeals then were to reverse the District Court's decision and we were not successful in our defense against the plaintiffs' 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 were successful, the litigation could result in substantial costs and divert management's attention and resources, which could adversely affect our business. As of December 31, 2008, we have recorded $2,000,000 in accrued litigation settlement costs, which represents our best estimate of the potential gross amount of the settlement costs to be paid to the plaintiffs, and $2,000,000 in prepaid expenses and other assets, which represents the approximately $235,000 of remaining deductible under our insurance policy paid by us and $1,765,000 paid by our insurance carrier into the settlement fund escrow in September 2008. A claims administrator appointed by the parties will administer the distribution of the settlement fund to authorized claimants in 2009.

Our success depends on retention of our President and Chief Executive Officer, Chief Medical Officer and other key personnel.

We are highly dependent on our President and Chief Executive Officer, Paul L. Berns, our Chief Medical Officer, Pablo J. Cagnoni, M.D., and other members of our management team. We are named as the beneficiary on a term life insurance policy covering Mr. Berns in the amount of $10.0 million. We also depend on academic collaborators for each of our research and development programs. The loss of any of our key employees or academic collaborators could delay our discovery research program and the development and commercialization of pralatrexate or result in termination of our pralatrexate development program in its entirety. Mr. Berns and Dr. Cagnoni, as well as others on our executive management team, have employment agreements with us, but the agreements provide for "at-will" employment with no specified term. Our future success also will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization of pharmaceutical products. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. If we are unsuccessful in our recruitment and retention efforts, our business will be harmed.

We also rely on consultants, collaborators and advisors to assist us in formulating and conducting our research. All of our consultants, collaborators and advisors are employed by other employers or are self-employed and may have commitments to or consulting contracts with other entities that may limit their ability to contribute to the Company.

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

The development, manufacturing, and, if approved, pricing, marketing, sale and reimbursement of pralatrexate, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We have fewer employees than many other companies that have one or more product candidates in late stage clinical development and we rely heavily on third parties to conduct many important functions.

As a publicly-traded company, we are subject to significant regulations including the Sarbanes Oxley Act of 2002. We cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with the Sarbanes Oxley Act of 2002 or any other regulations we could be subject to a range of consequences, including restrictions on our ability to sell equity securities or otherwise raise capital funds, the de-listing of our common stock from the Nasdaq Global Market, suspension or termination of our clinical trials, failure to obtain approval to market pralatrexate, restrictions on future products or our manufacturing processes, significant fines, or other sanctions or litigation.

If our internal controls over financial reporting are not considered effective, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in this annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, management's assessment of our internal controls over financial reporting.

Our management, including our chief executive officer and principal financial officer, does not expect that our internal controls over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to consider our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

If we do not progress in our programs as anticipated, our stock price could decrease.

For planning purposes, we estimate the timing of a variety of clinical, regulatory and other milestones, such as when a certain product candidate will enter clinical development, when a clinical trial will be initiated or completed, or when an application for regulatory approval will be filed. Some of our estimates are included in this report. Our estimates are based on information available to us as of the date of this report and a variety of assumptions. Many of the underlying assumptions are outside of our control. If milestones are not achieved when we estimated that they would be, investors could be disappointed, and our stock price may decrease.

Warburg Pincus Private Equity VIII, L.P. and Baker Brothers Life Sciences, L.P. each 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 Pincus Private Equity VIII, L.P., or Warburg, 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, or the Exchangeable Preferred, at a price per share of $22.10, for aggregate gross proceeds of approximately $52.0 million. On May 18, 2005, at our Annual Meeting of Stockholders, our stockholders voted to approve the issuance of shares of our common stock upon exchange of shares of the Exchangeable Preferred. As a result of such approval, we issued a total of 23,524,430 shares of common stock upon exchange of 2,352,443 shares of Exchangeable Preferred. In connection with its purchase of the Exchangeable Preferred, Warburg entered into a standstill agreement agreeing not to pursue certain activities the purpose or effect of which may be to change or influence the control of the Company.

On February 2, 2007, we closed an underwritten offering of 9,000,000 shares of common stock, of which Baker Brothers Life Sciences, L.P. and certain other affiliated funds, which are collectively referred to hereinafter as "Baker," purchased 3,300,000 shares, at a price per share of $6.00, for aggregate gross proceeds of approximately $54.0 million. In connection therewith, Baker entered into a standstill agreement agreeing not to pursue certain activities the purpose or effect of which may be to change or influence the control of the Company.

On May 29, 2008, we sold 12,420,000 shares of our common stock in an underwritten public offering at a price of $5.64 per share, for aggregate gross proceeds of approximately $70.0 million. Warburg and Baker purchased 3,500,000 and 1,500,000 shares, respectively, of the 12,420,000 shares sold in such public offering.

As of December 31, 2008, we had 81,238,812 shares of common stock outstanding, of which Warburg owned 26,124,430 shares, or approximately 32.2% of the voting power of our outstanding common stock, and Baker owned 11,248,621 shares, or approximately 13.8% of the voting power of our outstanding common stock. Although each of Warburg and Baker have entered into a standstill agreement with us, they are, and will continue to be, able to exercise substantial influence over any actions requiring stockholder approval. According to filings with the SEC, as of February 6, 2009, Baker owns less than 10% of our outstanding common stock.

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 make 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 either Warburg or Baker because, prior to the dates on which they became interested stockholders, our board of directors approved the transactions that resulted in Warburg and Baker becoming interested stockholders. However, in connection with its purchase of Exchangeable Preferred in March 2005, Warburg entered into a standstill agreement agreeing not to pursue certain activities the purpose or effect of which may be to change or influence the control of the Company. Similarly, in connection with our February 2007 Financing, Baker entered into a standstill agreement agreeing not to pursue certain activities the purpose or effect of which may be to change or influence the control of the Company.

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 our stockholders may consider beneficial by diluting the ability of a potential acquirer to acquire us. Pursuant to the terms of the stockholder rights 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 or making an offer to acquire us. As a result, either by operation of the plan or by its potential deterrent effect, mergers and acquisitions of the Company that our stockholders may consider in their best interests may not occur.

Because Warburg owns a substantial percentage of our outstanding common stock, we amended the stockholder rights plan in connection with Warburg's purchase of Exchangeable Preferred in March 2005 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. Likewise, since Baker owns a substantial percentage of our outstanding common stock, we amended the stockholder rights plan in connection with our February 2007 Financing to provide that Baker and its affiliates will be exempt from the stockholder rights plan, unless Baker becomes, without the prior consent of our board of directors, the beneficial owner of more than 20% of our common stock. Under the stockholder rights plan, our board of directors has express authority to amend the rights plan without stockholder approval.

Unstable market conditions may have serious adverse consequences on our business.

The recent economic downturn and market instability has made the business climate more volatile and more costly. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary equity or debt financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet our expected working capital and capital expenditure requirements for at least the next 12 months, a radical economic downturn or increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. There is a risk that one or more of our current service providers, manufacturers or other partners may encounter difficulties during challenging economic times, which could have an adverse effect on our business, results of operations and financial condition.

Our liquidity, capital resources and results of operations may be adversely affected by declines in the value of our investments in marketable securities.

As of December 31, 2008, we had $84.0 million in cash, cash equivalents, and investments in marketable securities. Until required for use in our business, we invest our cash reserves in bank deposits, money market funds, high-grade corporate notes and U.S. government instruments in accordance with our investment policy. The weighted average duration of the remaining time to maturity for our portfolio of investments in marketable securities as of December 31, 2008 was approximately five months. Our investments in marketable securities as of December 31, 2008 primarily consisted of high-grade corporate notes. We did not hold any derivative instruments, foreign exchange contracts, asset backed securities, mortgage backed securities, auction rate securities, or securities of issuers in bankruptcy in our investment portfolio as of December 31, 2008.

Based upon the current status of our product development and commercialization plans, we believe that our cash, cash equivalents, and investments in marketable securities as of December 31, 2008 should be adequate to support our operations through at least the next 12 months, although there can be no assurance that this can, in fact, be accomplished. In particular, our liquidity, capital resources and results of operations may be adversely affected by declines in the value of our investments in marketable securities. The value of our investments in marketable securities may be adversely affected by rating downgrades or bankruptcies affecting the issuers of such securities, whether caused by instability in the global financial markets, lack of liquidity in the credit and capital markets, or other factors. For example, during the three months ended September 30, 2008, we realized a loss of approximately $552,000 on the sale of certain of our investments in marketable securities, which were sold in order to preserve our principal as the issuers of these securities experienced significant deteriorations in their creditworthiness as evidenced by investment rating downgrades. We have the ability and intent to hold our remaining investments in marketable securities as of December 31, 2008 to their scheduled maturity, although we monitor our investment portfolio with the primary objectives of preserving principal and maintaining proper liquidity to meet our operating needs.

The market price for our common stock has been and may continue to be highly volatile, and an active trading market for our common stock may never exist.

We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. The trading price of our common stock has been and is likely to continue 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 regulatory approvals or non-approvals of pralatrexate or of competing product candidates;
- actual or anticipated results of our clinical trials, involving pralatrexate;
- changes in laws or regulations applicable to pralatrexate;
- 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 of our 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.

Public companies in general and companies included on the Nasdaq Global Market in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets. In the past, following large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company, including in 2004 against us. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

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

If our stockholders sell substantial amounts of our common stock, 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. We have entered into a Registration Rights Agreement with Warburg and the other purchasers of our Exchangeable Preferred pursuant to which such investors are entitled to certain registration rights with respect to the shares of common stock that we issued upon exchange of the Exchangeable Preferred.

In addition, we will need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities, the market price of our common stock may decline and our existing stockholders may experience significant dilution.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

Our corporate headquarters facility consists of approximately 34,536 square feet in Westminster, Colorado. We lease our corporate headquarters facility pursuant to a lease agreement that expires on January 31, 2012. We also lease an office in Princeton, New Jersey which consists of approximately 9,458 square feet. The lease for this office expires on September 30, 2011. We believe that our leased facilities are adequate to meet our needs until such time, if any, as we receive regulatory approval to market pralatrexate.

ITEM 3. LEGAL PROCEEDINGS

We were named as a defendant in a purported securities class action lawsuit filed in May 2004 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. In an opinion dated October 20, 2005, the U.S. District Court for the District of Colorado concluded that the plaintiffs' complaint failed to meet the legal requirements applicable to its alleged claims and dismissed the lawsuit. On November 20, 2005, the plaintiffs appealed the District Court's decision to the U.S. Court of Appeals for the Tenth Circuit. On February 6, 2008, the parties signed a stipulation of settlement, settling the case for $2,000,000. The settlement was subject to various conditions, including without limitation approval of the District Court. On January 29, 2009, the District Court issued its Order and Final Judgment approving the settlement, including the releases of the defendants for which the settlement provided. Neither we nor our former officer, who was also named as a defendant, admitted any liability in connection with the settlement. The amount of the settlement in excess of our deductible was covered by our insurance carrier. In the event the District Court's approval of the settlement is appealed and the settlement does not become final, we would intend to vigorously defend against the plaintiffs' appeal. If the Court of Appeals then were to reverse the District Court's decision and we were not successful in our defense against the plaintiffs' 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 were successful, the litigation could result in substantial costs and divert management's attention and resources, which could adversely affect our business. As of December 31, 2008, we have recorded $2,000,000 in accrued litigation settlement costs, which represents our best estimate of the potential gross amount of the settlement costs to be paid to the plaintiffs, and $2,000,000 in prepaid expenses and other assets, which represents the approximately $235,000 of

remaining deductible under our insurance policy paid by us and $1,765,000 paid by our insurance carrier into the settlement fund escrow in September 2008. A claims administrator appointed by the parties will administer the distribution of the settlement fund to authorized claimants in 2009.

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

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is traded on the Nasdaq Global Market under the symbol "ALTH." The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on the Nasdaq Global Market:

Year Ended December 31, 2008	HIGH	LOW
First Quarter	$ 7.70	$4.88
Second Quarter	$ 7.15	$4.89
Third Quarter	$10.19	$6.61
Fourth Quarter	$ 8.86	$3.82

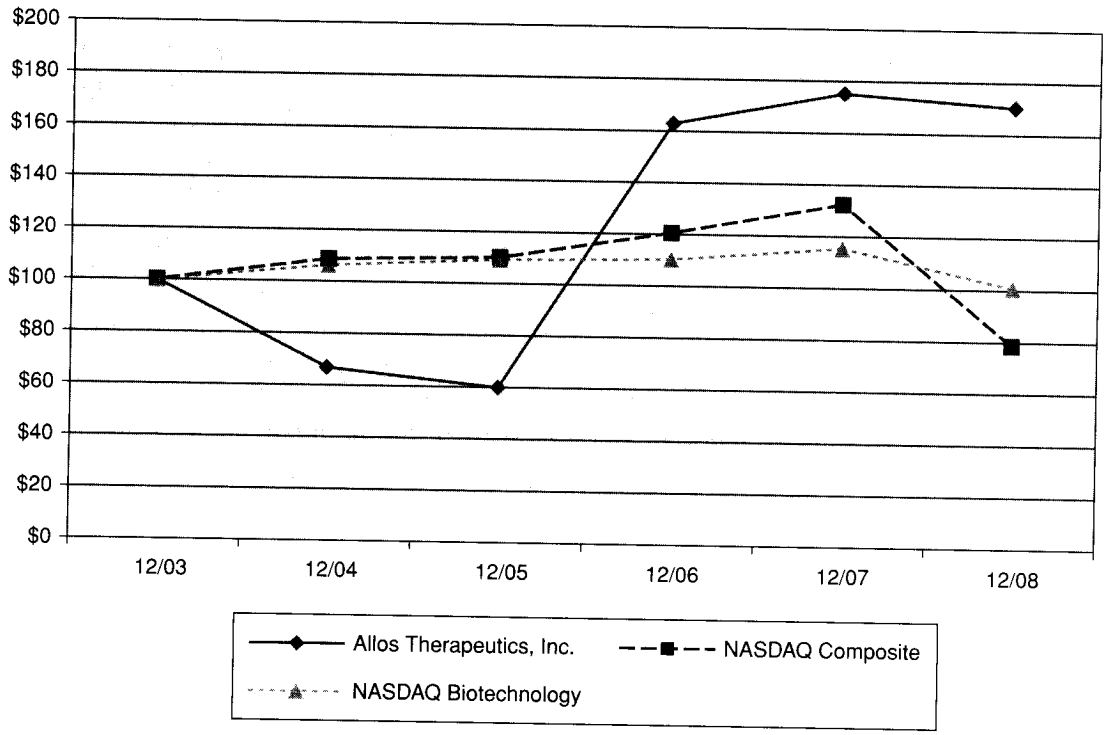
Year Ended December 31, 2007	HIGH	LOW
First Quarter	$8.54	$5.75
Second Quarter	$7.08	$3.91
Third Quarter	$5.90	$3.92
Fourth Quarter	$7.52	$4.70

On February 26, 2009, we had approximately 65 holders of record of our common stock.

Stock Performance Measurement Comparison(1)

The following graph shows the total stockholder return of an investment of $100 in cash on December 31, 2003 for (i) the Company's common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. All values assume reinvestment of the full amount of all dividends and are calculated as of December 31 of each year:

Comparison of 5 year Cumulative Total Return on Investment



Total Return Analysis	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008
Allos Therapeutics, Inc.	$100.00	$ 66.85	$ 59.89	$162.95	$175.21	$170.47
NASDAQ Composite	$100.00	$108.59	$110.08	$120.56	$132.39	$ 78.72
NASDAQ Biotechnology	$100.00	$106.13	$109.14	$110.25	$115.30	$100.75

(1) The information in this section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Dividends

We have never paid dividends to holders of our common stock, and we do not anticipate paying any cash dividends in the foreseeable future as we intend to retain any earnings for use in our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

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, 2008, 2007, 2006, and cumulative period from September 1, 1992 through December 31, 2008, and the balance sheet data as of December 31, 2008 and 2007, 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, 2005 and 2004, and the balance sheet data as of December 31, 2006, 2005 and 2004, 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, 2008
	2008	2007	2006	2005	2004	
	(in thousands, except share and per share data)					
Statement of Operations Data:						
Operating expenses:						
Research and development	$ 23,848	$ 17,444	$ 14,322	$ 11,215	$ 10,158	$ 149,148
Clinical manufacturing	6,747	5,548	2,284	1,266	2,979	41,359
Marketing, general and administrative	23,044	19,672	14,876	9,044	9,194	125,874
Restructuring and separation costs	—	—	646	380	—	1,664
Total operating expenses	53,639	42,664	32,128	21,905	22,331	318,045
Loss from operations	(53,639)	(42,664)	(32,128)	(21,905)	(22,331)	(318,045)
Gain on settlement claims	—	—	—	—	—	5,110
Interest and other income, net	1,909	3,294	1,916	1,768	494	23,512
Net loss	(51,730)	(39,370)	(30,212)	(20,137)	(21,837)	(289,423)
Dividend related to beneficial conversion feature of preferred stock	—	—	—	(623)	—	(10,236)
Net loss attributable to common stockholders	$ (51,730)	$ (39,370)	$ (30,212)	$ (20,760)	$ (21,837)	$(299,659)
Net loss per share: basic and diluted	$ (0.69)	$ (0.60)	$ (0.55)	$ (0.45)	$ (0.70)	
Weighted average shares: basic and diluted	75,399,774	65,188,913	55,299,614	46,070,686	31,139,192	

	As of December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and investments in marketable securities	$ 83,965	$ 57,756	$ 32,796	$ 55,282	$ 23,849
Working capital	77,981	51,958	28,897	52,477	22,745
Total assets	89,340	61,460	36,382	57,081	26,173
Common stock and additional paid-in capital	379,123	300,508	238,109	231,637	181,485
Deficit accumulated during the development stage	(299,659)	(247,929)	(208,559)	(178,347)	(157,587)
Total stockholders' equity	79,464	52,579	29,550	53,290	23,863

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

Overview

We are a biopharmaceutical company focused on developing and commercializing innovative small molecule drugs for the treatment of cancer. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners. We strive to develop proprietary products that have the potential to improve the standard of care in cancer therapy. Our focus is on product opportunities for oncology that leverage our internal clinical development and regulatory expertise and address important markets with unmet medical need. We may also seek to grow our existing portfolio of product candidates through product acquisition and in-licensing efforts.

We currently have two small molecule chemotherapeutic product candidates in clinical development, pralatrexate (PDX) and RH1.

Pralatrexate

Our lead product candidate, pralatrexate, is a novel targeted antifolate designed to accumulate preferentially in cancer cells. Based on preclinical studies, we believe that pralatrexate selectively enters cells expressing RFC-1, a protein that is over expressed on cancer cells compared to normal cells. Once inside cancer cells, pralatrexate is efficiently polyglutamylated, which leads to high intracellular drug retention. Polyglutamylated pralatrexate essentially becomes "trapped" inside cancer cells, making it less susceptible to efflux-based drug resistance. Acting on the folate pathway, pralatrexate interferes with DNA synthesis and triggers cancer cell death. We believe pralatrexate has the potential to be delivered as a single agent or in combination therapy regimens.

In February 2009, we announced the final results from PROPEL, our pivotal Phase 2 trial of pralatrexate in patients with relapsed or refractory peripheral T-cell lymphoma, or PTCL. The trial enrolled a total of 115 patients, 109 of whom were considered evaluable for response according to the trial protocol. The results of the trial demonstrated that 29 of 109 evaluable patients, or 27%, achieved a response as assessed by central independent oncology review, which is the primary endpoint of the trial. The Kaplan-Meier estimate for the median duration of response was 287 days, or 9.4 months. Duration of response is the key secondary endpoint of the trial. The most common grade ¾ adverse events were thrombocytopenia, which was observed in 32% of patients; mucosal inflammation in 21% of patients; neutropenia in 20% of patients; and anemia in 17% of patients.

Based on the results of this trial, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. If it is approved for marketing, we intend to commercialize pralatrexate by building an oncology focused U.S. sales and marketing organization that may be complemented by co-promotion arrangements with pharmaceutical or biotechnology partners, where appropriate. We intend to enter into co-promotion or out-licensing arrangements with other pharmaceutical or biotechnology partners, where necessary to reach foreign market segments that are not reachable by a U.S.-based sales force or when deemed strategically and economically advisable. We currently retain exclusive worldwide commercial rights to pralatrexate for all indications.

The PROPEL trial was conducted under an agreement reached with the FDA under its special protocol assessment, or SPA, process. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a NDA, and provides an agreement that the trial design, including trial size, clinical endpoints and data analyses are acceptable to the FDA. However, the SPA agreement is not a guarantee of approval, and we cannot assure you that the design of, or data collected from, the PROPEL trial will be adequate to demonstrate the safety

and efficacy of pralatrexate for the treatment of patients with relapsed or refractory PTCL, or otherwise be sufficient to support FDA or any foreign regulatory approval. For example, the response rate, duration of response and safety profile required to support FDA approval are not specified in the PROPEL trial protocol and will be subject to FDA review. In addition, the median duration of response reported above is a Kaplan-Meier estimate based on the length of follow up for all responders at the time the PROPEL trial database was locked. As a result, the median duration of response may change based on continued patient follow up.

In addition to the PROPEL trial, we are committed to evaluating pralatrexate for oncology use as a single agent and in combination with other therapies. We currently have seven ongoing clinical trials involving pralatrexate, including the PROPEL trial, and plan to initiate additional trials to evaluate pralatrexate's potential clinical utility in other hematologic malignancies and solid tumor indications. The following clinical trials involving pralatrexate are currently open for enrollment:

- a Phase 2b, randomized, multi-center study comparing pralatrexate and Tarceva (erlotinib), both with vitamin B_{12} and folic acid supplementation, in patients with Stage IIIB/IV non-small cell lung cancer, or NSCLC, who are, or have been, cigarette smokers who have failed treatment with at least one prior platinum-based chemotherapy regimen. We initiated patient enrollment in this study in January 2008. The study will seek to enroll approximately 160 patients in up to 50 investigative sites worldwide. Based on current enrollment rates, we expect to complete patient enrollment in this study in the third quarter of 2009.
- a Phase 2, open-label, single-arm, multi-center study of pralatrexate with vitamin B_{12} and folic acid supplementation in patients with advanced or metastatic relapsed transitional cell carcinoma, or TCC, of the urinary bladder. We initiated patient enrollment in this study in July 2008. The study will seek to enroll approximately 41 patients in up to 20 investigative sites worldwide.
- a Phase 1/2a, open-label, multi-center study of pralatrexate and gemcitabine with vitamin B_{12} and folic acid supplementation in patients with relapsed or refractory non-Hodgkin's lymphoma, or NHL, and Hodgkin's disease. We initiated patient enrollment in this study in May 2007. We plan to enroll up to 54 evaluable patients in the Phase 1 portion of the study and up to 45 additional patients with relapsed or refractory PTCL in the expanded Phase 2a portion of the study.
- a Phase 1, open-label, multi-center study of pralatrexate with vitamin B_{12} and folic acid supplementation in patients with relapsed or refractory cutaneous T-cell lymphoma, or CTCL. We initiated patient enrollment in this study in August 2007. We plan to enroll up to 56 evaluable patients in the study with the objective of determining the optimal dose and safety profile, including at least 20 patients at what we believe to be the optimal dose and schedule.
- a Phase 1/2, open-label, single-center study of pralatrexate with vitamin B_{12} and folic acid supplementation in patients with relapsed or refractory NHL and Hodgkin's disease. This study is currently focused on exploring alternate dosing and administration schedules in patients with B-cell lymphoma to further evaluate pralatrexate's potential clinical utility in this setting.

In addition to our ongoing NSCLC and bladder cancer studies, we are evaluating the potential future development of pralatrexate for other solid tumor indications, including Stage III/IV head and neck cancer and Stage III/IV breast cancer, among others. There can be no assurances that we will pursue the development of pralatrexate for one or more of these indications or that such development efforts will be ultimately successful.

RH1

RH1 is a small molecule chemotherapeutic agent that we believe is bioactivated by the enzyme DT-diaphorase, or DTD, also known as NAD(P)H quinone oxidoreductase, or NQ01. We believe DTD

is over-expressed in many tumors, relative to normal tissue, including lung, colon, breast and liver tumors. We believe that because RH1 is bioactivated in the presence of DTD, it may have the potential to provide targeted drug delivery to these tumor types while limiting the amount of toxicity to normal tissue.

In November 2007, we initiated patient enrollment in a Phase 1, open-label, multi-center dose escalation study of RH1 in patients with advanced solid tumors or NHL. We are in the process of closing this study and determining our future development plans, if any, for RH1.

EFAPROXYN (efaproxiral) Development Discontinued

In mid-2007, we discontinued the development of EFAPROXYN, one of our former product candidates, after announcing top-line results from ENRICH, a Phase 3 clinical trial of EFAPROXYN plus whole brain radiation therapy, or WBRT, in women with brain metastases originating from breast cancer. The study failed to achieve its primary endpoint of demonstrating a statistically significant improvement in overall survival in patients receiving EFAPROXYN plus WBRT, compared to patients receiving WBRT alone. We are currently pursuing the sale of our rights to EFAPROXYN although we may not receive any material consideration for any sale.

Results of Operations

We are a development stage company. Since our inception in 1992, we have not generated any revenue from product sales and have experienced significant net losses and negative cash flows from operations. We have incurred these losses principally from costs incurred in our research and development programs, clinical manufacturing and from our marketing, general and administrative expenses. Our primary business activities have been focused on the development of pralatrexate, RH1 (a program for which we are in the process of determining our future development plans, if any) and EFAPROXYN (a program which we discontinued in mid-2007). For the years ended December 31, 2008, 2007 and 2006, we had net losses attributable to common stockholders of $51.7 million, $39.4 million, and $30.2 million, respectively. Research and development expenses for the years ended December 31, 2008, 2007 and 2006 were $23.8 million, $17.4 million and $14.3 million, respectively. As of December 31, 2008, we had accumulated a deficit during our development stage of $299.7 million.

Our ability to generate revenue and achieve profitability is dependent on our ability, alone or with partners, to successfully complete the development of pralatrexate, conduct clinical trials, obtain the necessary regulatory approvals, and manufacture and market pralatrexate. The timing and costs to complete the successful development pralatrexate is highly uncertain, and therefore difficult to estimate. The lengthy process of seeking regulatory approvals for pralatrexate, 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 Part I, Item 1above. Clinical development timelines, likelihood of success and total costs vary widely and are impacted by a variety of risks and uncertainties, including those discussed in the "Risk Factors" section of Part I, Item 1A above. Because of these risks and uncertainties, we cannot predict when or whether we will successfully complete the development of pralatrexate or the ultimate costs of such efforts. Due to these same factors, we cannot be certain when, or if, we will generate any revenue or net cash inflow from any of our current product candidates.

Even if our clinical trials demonstrate the safety and effectiveness of pralatrexate in its target indications, we do not expect to be able to generate commercial sales of pralatrexate until the second half of 2009, at the earliest. We expect to continue incurring net losses and negative cash flows for the foreseeable future. Although the size and timing of our future net losses are subject to significant uncertainty, we expect them to increase over the next several years as we continue to fund our research and development programs, prepare for the potential commercial launch of pralatrexate, and

commercialize pralatrexate for the treatment of patients with relapsed or refractory PTCL, if it is approved for marketing.

We anticipate continuing our current development programs and/or beginning other long-term development projects involving pralatrexate. These projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. In addition, we intend to submit an NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. We expect to incur significant costs relating to preparations for the potential commercial launch of pralatrexate, including pre-commercial scale up of manufacturing and development of sales and marketing capabilities. Therefore, we will need to raise additional capital to support our future operations, including the potential commercialization of pralatrexate if approved for marketing. Our actual capital requirements will depend on many factors, including those discussed under the "Liquidity and Capital Resources" section below.

We may seek to obtain this additional capital through equity or debt financings, arrangements with corporate partners, or from other sources. Such financings or arrangements, if successfully consummated, may be dilutive to our existing stockholders. However, there is no assurance that additional financing will be available when needed, or that, if available, we will obtain such financing on terms that are favorable to our stockholders or us. In particular, the current instability in the global financial markets and lack of liquidity in the credit and capital markets may adversely affect our ability to secure adequate capital to support our future operations. 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, which we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. 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.

Comparison of Years Ended December 31, 2008, 2007 and 2006

Research and Development. Research and development expenses include the costs of certain personnel, basic research, preclinical studies, clinical trials, regulatory affairs, biostatistical data analysis and licensing fees for our product candidates.

	Years Ended December 31,		
	2008	2007	2006
	(in millions)		
Research and development expenses	$23.8	$17.4	$14.3

The $6.4 million increase in research and development expenses in 2008 as compared to 2007 was primarily due to the following:

- a $6.1 million increase in clinical trial costs involving pralatrexate, including initiation of patient enrollment in two new trials involving pralatrexate during 2008;
- a $1.5 million increase related to key personnel changes and related travel costs, mainly attributable to additional headcount as a result of expanding the development program for pralatrexate and increases in compensation costs year over year; and
- an $830,000 increase in non-cash stock-based compensation expense, as discussed in more detail below.

These increases were partially offset by:

- a $1.0 million decrease in preclinical study costs, primarily related to pralatrexate;
- a $585,000 decrease in clinical trial costs resulting from the discontinuation of the EFAPROXYN development program in mid-2007; and
- a $360,000 decrease related to payment of a non-recurring data option fee for RH1 in the third quarter of 2007, with no corresponding amount in 2008.

The $3.1 million increase in research and development expenses in 2007 as compared to 2006 was primarily due to the following:

- a $2.9 million increase in clinical trial costs involving pralatrexate, mainly attributable to increased costs for PROPEL and initiation of patient enrollment in two new trials involving pralatrexate during 2007;
- a $1.4 million increase related to key personnel changes and related travel costs, mainly attributable to additional headcount and increases in compensation costs year over year;
- a $1.2 million increase in non-cash stock-based compensation expense, as discussed in more detail below;
- a $480,000 increase in preclinical study costs, primarily related to pralatrexate; and
- a $360,000 increase related to payment of a non-recurring data option fee for RH1 in the third quarter of 2007, with no corresponding amount in 2006.

These increases were partially offset by a $3.2 million decrease in clinical trial costs for EFAPROXYN, primarily resulting from the completion of patient enrollment in our Phase 3 ENRICH trial in September 2006.

We expect research and development expenses to increase in 2009 as compared to 2008 due to the following:

- increases in licensing costs for pralatrexate, as $1.5 million of regulatory milestone payments under the license agreement for pralatrexate will become due if the FDA accepts our NDA for review in 2009 and $5.3 million of regulatory milestone payments under the license agreement for pralatrexate will become due if the FDA approves pralatrexate for marketing in the United States in 2009; and
- an increase in non-cash stock-based compensation expense related to our annual equity grants to existing employees.

We charge direct internal and external research and development expenses to the respective development programs. Since our inception through December 31, 2008, we have incurred direct costs of approximately $26.8 million and $1.1 million associated with research and development expenses for pralatrexate and RH1 (a program for which we are in the process of determining our future development plans, if any), respectively, and approximately $45.0 million associated with research and development programs that have been discontinued, including the EFAPROXYN program that was discontinued in mid-2007. 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 our inception through December 31, 2008 represent approximately $76.3 million of research and development expenses.

The following table summarizes our research and development expenses for the years ended December 31, 2008, 2007 and 2006 and for the cumulative period from our inception through December 31, 2008:

	Years Ended December 31,			Cumulative Period from September 1, 1992 through December 31, 2008
	2008	2007	2006	
	(in millions)			
Pralatrexate	$11.6	$ 6.8	$ 3.4	$ 26.8
RH1	0.2	0.6	—	1.0
Discontinued programs	—	1.0	4.3	45.0
Unallocated	12.0	9.0	6.6	76.3
Total research and development expenses	$23.8	$17.4	$14.3	$149.1

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. Clinical development timelines, likelihood of success and total costs vary widely and are impacted by a variety of factors, including those discussed in the "Risk Factors" section of Part I, Item 1A above. Because of these risks and uncertainties, we cannot predict whether or when we will successfully complete the development of pralatrexate or the ultimate costs of such efforts. Due to these same factors, we cannot be certain if, or when, we will generate any revenue or net cash inflow from any of our current product candidates.

Clinical Manufacturing. Clinical manufacturing expenses include the costs of certain personnel, third-party manufacturing costs for development of drug materials for use in clinical trials and preclinical studies, and costs associated with pre-commercial scale-up of manufacturing to support anticipated regulatory and potential commercial requirements.

	Years Ended December 31,		
	2008	2007	2006
	(in millions)		
Clinical manufacturing expenses	$6.7	$5.5	$2.3

The $1.2 million increase in clinical manufacturing expenses in 2008 as compared to 2007 was primarily due to the following:

- a $911,000 increase in consulting expenses, primarily related to preparations for submission of an NDA to the FDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009;
- a $536,000 increase related to key personnel changes and related travel costs, mainly attributable to additional headcount as a result of pre-commercial scale-up of manufacturing to support anticipated regulatory and potential commercial requirements for pralatrexate and increases in compensation costs year over year; and
- a $398,000 increase primarily related to manufacturing pralatrexate drug substance.

This increase was partially offset by a $696,000 decrease primarily related to pralatrexate drug product manufacturing.

The $3.3 million increase in clinical manufacturing expenses in 2007 as compared to 2006 was primarily due to the following:

- a $2.6 million increase in third-party manufacturing costs for clinical trial material and pre-commercial scale-up activities for pralatrexate; and
- a $700,000 increase in third-party manufacturing costs for clinical trial material for RH1.

We expect clinical manufacturing expenses in 2009 to be consistent with those in 2008.

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

	Years Ended December 31,		
	2008	2007	2006
	(in millions)		
Marketing, general and administrative expenses	$23.0	$19.7	$ 14.9

The $3.4 million increase in marketing, general and administrative expenses in 2008 as compared to 2007 was primarily due to the following:

- a $1.4 million increase in pralatrexate portfolio development and commercialization planning activities;
- a $709,000 increase in market research and consulting expenses related to pre-commercial planning activities for pralatrexate;
- a $563,000 increase related to key personnel changes and related travel costs, mainly attributable to additional headcount and increases in compensation costs year over year; and
- a $303,000 increase in non-cash stock-based compensation expense, as discussed in more detail below.

The $4.8 million increase in marketing, general and administrative expenses in 2007 as compared to 2006 was primarily due to the following:

- a $1.8 million increase in non-cash stock-based compensation expense, as discussed in more detail below;
- a $1.4 million increase in personnel costs, mainly attributable to additional headcount and increases in compensation costs year over year;
- a $1.0 million increase in market research and consulting expenses related to our product development and commercialization planning for EFAPROXYN and pralatrexate; and
- a $485,000 increase in travel expenses related to increased headcount, expanded investor relations activities and the development of relationships with key opinion leaders in oncology.

We expect marketing, general and administrative expenses to increase in 2009 as compared to 2008 due to the following:

- an increase in non-cash stock-based compensation expense related to grants for new employees and our annual equity grants to existing employees;
- an increase in costs relating to pre-commercial planning activities for pralatrexate; and
- an increase in personnel costs, primarily resulting from additional headcount related to preparation for the potential commercial launch of pralatrexate, if it is approved for marketing.

Stock-based Compensation Expense. Stock-based compensation expense for the years ended December 31, 2008, 2007 and 2006 has been recognized in our Statements of Operations as follows:

	Year ended December 31,		
	2008	2007	2006
Research and development	$2,701,115	$1,870,767	$ 660,274
Clinical manufacturing	417,469	180,592	113,066
Marketing, general and administrative	4,901,865	4,599,266	2,813,661
Total stock-based compensation expense	$8,020,449	$6,650,625	$3,587,001

Of the $8.0 million of stock-based compensation recognized in the year ended December 31, 2008, $7.5 million was related to our stock option plans, $423,000 related to restricted stock and $59,000 related to our employee stock purchase plan. Of the $6.7 million of stock-based compensation recognized in the year ended December 31, 2007, $5.9 million was related to our stock option plans, $690,000 related to restricted stock and $61,000 related to our employee stock purchase plan. The $1.4 million increase in stock-based compensation expense in 2008 as compared to 2007 was primarily due to the additional stock options granted during the year ended December 31, 2008. The $3.1 million increase in stock-based compensation expense in 2007 as compared to 2006 was primarily due to a higher fair-value for options granted in 2007 compared to options granted in 2006 due to our stock price being higher during the year ended December 31, 2007 as compared to the year ended December 31, 2006.

As of December 31, 2008, the unrecorded stock-based compensation balance related to stock option awards was $7.3 million and will be recognized over an estimated weighted-average amortization period of 1.4 years. As of December 31, 2008, the unrecorded stock-based compensation balance related to restricted stock awards was approximately $329,000 and will be recognized over an estimated weighted-average amortization period of 1.3 years.

Restructuring and Separation Costs. We recorded $0, $0 and $646,000 in restructuring and separation costs during the years ended December 31, 2008, 2007 and 2006, respectively.

In January 2006, Michael E. Hart notified our Board of Directors of his intent to resign from his positions as President, Chief Executive Officer and Chief Financial Officer of the Company once a successor Chief Executive Officer was appointed. On March 3, 2006, we entered into a separation agreement with Mr. Hart to provide certain incentives for his continued employment with the Company while we conducted our search for his successor. On March 9, 2006, we appointed Paul L. Berns as our President, Chief Executive Officer and a member of the Board of Directors and Mr. Hart resigned from his positions in accordance with the terms of the separation agreement. The separation agreement with Mr. Hart was amended on March 9, 2006, and on May 10, 2006. We recorded separation costs of $646,000 during the year ended December 31, 2006 relating to our estimate of our total obligations under the Separation Agreement with Mr. Hart. During the years ended December 31, 2007 and 2006, respectively, we made payments to Mr. Hart under the Separation Agreement of $321,000 and $325,000. As of December 31, 2007, there was no remaining liability relating to the Separation Agreement with Mr. Hart.

Interest and Other Income, Net. Interest income, net of interest expense, for the years ended December 31, 2008, 2007 and 2006 was $1.9 million, $3.3 million, and $1.9 million, respectively. The $1.4 million decrease in 2008 as compared to 2007 was primarily due to lower yields on our cash, cash equivalents and investments in marketable securities, and a realized loss of approximately $552,000 on the sale of certain of our investments in marketable securities during the three months ended September 30, 2008. In response to the instability in the global financial markets, we reviewed our investments in marketable securities and sold certain investments during the three months ended

September 30, 2008 prior to their maturity in order to preserve our principal, as the issuers of these securities experienced significant deteriorations in their creditworthiness as evidenced by investment rating downgrades. We have the ability and intent to hold our remaining investments in marketable securities as of December 31, 2008 to their scheduled maturity, although we monitor our investment portfolio with the primary objectives of preserving principal and maintaining proper liquidity to meet our operating needs. The $1.4 million increase in interest income in 2007 as compared to 2006 primarily resulted from higher average investment balances resulting from our February 2007 financing and higher yields on U.S. government securities, high-grade commercial paper and corporate notes, and money market funds.

Income Taxes. As of December 31, 2008, we had available approximately $174.8 million of net operating loss, or NOL, carryforwards, after taking into consideration NOLs expected to expire unused due to the limitations under Section 382 of the Internal Revenue Code, and which includes approximately $5.2 million of deductions related to stock-based compensation that are not realized as deferred tax assets until current taxes payable can be reduced. These NOL carryforwards will expire beginning in 2009. In addition, we had research and development credit and orphan drug credit carryforwards, after taking into consideration the Section 382 limitation, of $3.5 million and $5.6 million, respectively, as of December 31, 2008, to offset future regular and alternative tax expense. Since our formation, we have raised capital through the issuance of capital stock on several occasions which, combined with shareholders' subsequent disposition of those shares, has resulted in four changes of control in 1994, 1998, 2001 and 2005, as defined by Section 382. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% within a three-year period. As a result of the most recent ownership change in 2005, utilization of our NOLs generated prior to the latest change are subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change in control by the applicable long-term tax-exempt rate resulting in an annual limitation amount of approximately $2.2 million. Any unused annual limitation may be carried over to later years, and the amount of the limitation may, under certain circumstances, be subject to adjustment if the fair value of the Company's net assets are determined to be below or in excess of the tax basis of such assets at the time of the ownership change, and such unrealized loss or gain is recognized during the five-year period after the ownership change. Subsequent ownership changes, as defined in Section 382, could further limit the amount of our NOLs and research and development credits that can be utilized annually to offset future taxable income.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through public and private sales of our equity securities, which have resulted in net proceeds to us of $328.5 million through December 31, 2008. We have also generated $23.5 million of net interest income since our inception from investing the net proceeds of these financings.

As of December 31, 2008, we had $84.0 million in cash, cash equivalents, and investments in marketable securities. Until required for use in our business, we invest our cash reserves in bank deposits, money market funds, high-grade corporate notes and U.S. government instruments in accordance with our investment policy. The weighted average duration of the remaining time to maturity for our portfolio of investments in marketable securities as of December 31, 2008 was approximately five months. Our investments in marketable securities as of December 31, 2008 primarily consisted of high-grade corporate notes. We did not hold any derivative instruments, foreign exchange contracts, asset backed securities, mortgage backed securities, auction rate securities, or securities of issuers in bankruptcy in our investment portfolio as of December 31, 2008. Our liquidity, capital resources and results of operations may be adversely affected by future declines in the value of our investments in marketable securities. The value of our investments in marketable securities may be

adversely affected by rating downgrades or bankruptcies affecting the issuers of such securities, whether caused by instability in the global financial markets, lack of liquidity in the credit and capital markets, or other factors. We have the ability and intent to hold our remaining investments in marketable securities as of December 31, 2008 to their scheduled maturity, although we monitor our investment portfolio with the primary objectives of preserving principal and maintaining proper liquidity to meet our operating needs.

We have used $238.4 million of cash for operating activities from our inception through December 31, 2008. Net cash used to fund our operating activities for the years ended December 31, 2008, 2007 and 2006 was $42.9 million, $30.8 million and $25.1 million, respectively.

For fiscal year 2009, we anticipate that net cash use in operating activities will approximate $50 to $54 million. Though not inclusive of all costs associated with the potential future launch of pralatrexate, this guidance includes the phase-in of certain key investments related to commercial planning and pre-commercial scale-up of manufacturing for pralatrexate, as well as $1.5 million and $5.3 million of potential milestone payments under our license agreement for pralatrexate payable upon FDA acceptance of our NDA for review and FDA approval to market pralatrexate, respectively.

Net cash used in investing activities for the years ended December 31, 2008 and 2007 was $13.2 million and $19.1 million, respectively, and consisted primarily of purchases of investments in marketable securities, partially offset by the proceeds from maturities of investments in marketable securities. Net cash provided by investing activities for the year ended December 31, 2006 was $28.1 million and consisted primarily of proceeds from the maturities of investments in marketable securities, partially offset by the purchase of investments in marketable securities.

Net cash provided by financing activities for the year ended December 31, 2008 was $70.6 million and consisted primarily of the net proceeds from the sale of 12,420,000 shares of our common stock in May 2008 in an underwritten public offering at a price of $5.64 per share, or the May 2008 Financing, and $5.4 million of proceeds from the issuance of common stock associated with stock options exercised by our employees and sales of stock under our employee stock purchase plan. We received net proceeds from the May 2008 Financing of approximately $65.2 million, after deducting $4.2 million of underwriting commissions and $661,000 of offering expenses. The shares of common stock were sold under our shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission, or SEC, on June 5, 2007. Net cash provided by financing activities during the year ended December 31, 2007 was $55.7 million and resulted primarily from the sale of 9,000,000 shares of common stock in February 2007 in an underwritten offering at a price of $6.00 per share, or the February 2007 Financing, $5.5 million of proceeds associated with the exercise of common stock options, common stock warrants and sales of stock under our employee stock purchase plan, and the release of $183,000 of restricted cash in connection with a reduction of the letter of credit required pursuant to the lease for our corporate headquarters facility. We received net proceeds from the February 2007 Financing of approximately $50.3 million, after deducting underwriting commissions of approximately $3.2 million and other offering expenses of approximately $503,000. The shares of common stock were sold under our shelf Registration Statement on Form S-3, declared effective by the SEC on July 10, 2006. Net cash provided by financing activities for the year ended December 31, 2006 was $3.1 million and resulted primarily from proceeds associated with the exercise of common stock options, common stock warrants and sales of stock under our employee stock purchase plan, and the release of $183,000 of restricted cash in connection with a reduction of the letter of credit required pursuant to the lease for our corporate headquarters facility.

On June 5, 2007, our universal shelf Registration Statement on Form S-3 was declared effective by the SEC. Under this registration statement, we are allowed to sell, from time to time, up to $150 million of our common stock, preferred stock, depository shares, debt securities and/or warrants, either individually or in units, in one or more offerings. As of December 31, 2008, we have

approximately $80 million available for issuance under this Registration Statement. We are not required to offer the securities in the future pursuant to the registration statement. The terms of any offering under the registration statement will be established at the time of the offering. Proceeds from the sale of any securities will be used for the purposes described in a prospectus supplement filed at the time of an offering.

Based upon the current status of our product development and commercialization plans, we believe that our cash, cash equivalents, and investments in marketable securities as of December 31, 2008 should be adequate to support our operations through at least the next 12 months, although there can be no assurance that this can, in fact, be accomplished. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

We anticipate continuing our current development programs and/or beginning other long-term development projects involving pralatrexate. These projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. In addition, we intend to submit an NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. We expect to incur significant costs relating to preparations for the potential commercial launch of pralatrexate, including pre-commercial scale up of manufacturing and development of sales and marketing capabilities. Therefore, we will need to raise additional capital to support our future operations. Our actual capital requirements will depend on many factors, including:

- the timing and outcome of our planned NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL;
- the timing and costs associated with developing sales and marketing capabilities and commercializing pralatrexate, if it is approved for marketing;
- the timing and costs associated with manufacturing clinical and commercial supplies of pralatrexate;
- the timing and amount of revenues generated by our business activities, if any;
- the timing and costs associated with conducting preclinical and clinical development of pralatrexate, as well as our evaluation of, and decisions with respect to, additional therapeutic indications for which we may develop pralatrexate;
- the timing, costs and potential revenue associated with any co-promotion or other partnering arrangements entered into to commercialize pralatrexate, if it is approved for marketing; and
- our evaluation of, and decisions with respect to, potential in-licensing or product acquisition opportunities or other strategic alternatives.

We may seek to obtain this additional capital through equity or debt financings, arrangements with corporate partners, or from other sources. Such financings or arrangements, if successfully consummated, may be dilutive to our existing stockholders. However, there is no assurance that additional financing will be available when needed, or that, if available, we will obtain such financing on terms that are favorable to our stockholders or us. In particular, the current instability in the global financial markets and lack of liquidity in the credit and capital markets may adversely affect our ability to secure adequate capital to support our future operations. 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, which we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. 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.

Obligations and Commitments

Below is a schedule of the timing of contractual commitments, by fiscal year, related to our leases, service contracts and license agreements. We currently have no off-balance sheet arrangements.

	2009	2010 to 2011	2012 to 2013	After 2013	Total
Operating lease obligations	$ 792,000	$1,639,000	$46,000	$—	$2,477,000
License agreement obligations:					
Clinical milestone	500,000	—	—	—	500,000
Regulatory milestones	6,800,000	—	—	—	6,800,000
Total obligations	$8,092,000	$1,639,000	$46,000	$—	$9,777,000

Operating lease obligations represent our future minimum rental commitments for non-cancelable operating leases for our facilities. We lease our corporate headquarters facility pursuant to a lease agreement that expires on January 31, 2012. Our lease for an office in Princeton, New Jersey expires on September 30, 2011.

License agreement obligations represent future milestone payments that could be made under our license agreement for pralatrexate. We will make a milestone payment of $500,000 upon the earlier of achievement of a clinical development milestone or the passage of certain time periods, such earlier occurrence, the "Clinical Milestone." The last scheduled payment of $500,000 under the Clinical Milestone is due December 23, 2009. We intend to submit an NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. If the FDA accepts our NDA for review and if we obtain FDA approval to market pralatrexate, we will be obligated to make milestone payments of $1,500,000 and $5,300,000, respectively, under the license agreement for pralatrexate.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. We base our estimates on historical experience, available information and assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and informed management judgments about matters that are inherently uncertain:

- accounting for research and development expenses;
- accounting for clinical manufacturing expenses;
- accounting for cash equivalents and investments in marketable securities; and
- accounting for stock-based compensation expense.

Research and Development. Research and development expenditures are charged to expense as incurred. Research and development expenses include the costs of certain personnel, basic research, preclinical studies, clinical trials, regulatory affairs, biostatistical data analysis and licensing fees for our product candidates. Clinical trial 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 record upfront fees and milestone payments made under our licensing agreements for our product candidates as research and development expense as the services are performed.

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 and preclinical research organizations. We accrue external costs for clinical and preclinical studies based on an evaluation of the following: the progress of the studies, including patient enrollment, dosing levels of patients enrolled, estimated costs to dose patients, invoices received, and contracted costs with clinical sites and third party clinical and preclinical research organizations. 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. During the years ended December 31, 2008, 2007, and 2006, we did not have any changes in estimates that would have resulted in material adjustments to research and development expenses accrued in the prior period. However, during the quarter ended December 31, 2006, we did change our estimate relating to certain costs for our Phase 3 ENRICH trial for EFAPROXYN as a result of new information, which resulted in a reduction of research and development expenses of approximately $400,000 and a corresponding decrease in accrued research and development expenses as of December 31, 2006.

In accordance with certain research and development agreements, we are obligated to make certain upfront payments upon execution of the agreement. We record these upfront payments as prepaid research and development expenses. Such payments are recorded to research and development expense as services are performed. We evaluate on a quarterly basis whether events and circumstances have occurred that may indicate impairment of remaining prepaid research and development expenses.

Clinical Manufacturing. Clinical manufacturing expenses include the costs of certain personnel, third party manufacturing costs for development of drug materials for use in clinical trials and preclinical studies, and costs associated with pre-commercial scale-up of manufacturing to support anticipated regulatory and potential commercial requirements. Our finished drug inventory is expensed to clinical manufacturing since we are still a development stage company and we have not received regulatory approval to market our product candidates. If and when we receive regulatory approval, we will be required to capitalize any future manufacturing costs for our marketed products at the lower of cost or market and then expense the sold inventory as a component of cost of goods sold.

Cash Equivalents and Investments in Marketable Securities. All highly liquid investments with original maturities 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 investments in 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. Our cash and cash equivalents are maintained in a financial institution in amounts that, at times, may exceed federally insured limits. We realized a loss of approximately $552,000 on the sale of certain of our investments in marketable securities during the year ended December 31, 2008. In response to the recent instability in the global financial markets, we reviewed our investments in marketable securities and sold certain investments prior to their maturity in order to preserve our principal, as the issuers of these securities experienced significant deteriorations in their creditworthiness as evidenced by investment rating downgrades. We have the ability and intent to hold our remaining investments in marketable securities as of December 31, 2008 to their scheduled maturity, although we monitor our investment portfolio with the primary objectives of preserving principal and maintaining proper liquidity to meet our operating needs. The weighted average duration of the remaining time to maturity for our portfolio of investments in marketable securities as of December 31, 2008 was approximately five months. As of December 31, 2008, our investments in marketable securities were held in a variety of interest-bearing instruments, consisting mainly of high-grade corporate notes. We did not hold any derivative instruments, foreign exchange contracts, asset backed securities, mortgage backed securities, auction rate securities, or securities of issuers in bankruptcy in our investment portfolio as of December 31, 2008.

Stock-based Compensation Expense. We adopted SFAS No. 123 (Revised 2004), *Share-Based Payment,* or SFAS 123R, effective January 1, 2006. Under the provisions of SFAS 123R, stock-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense over the required service period of the award. Prior to the adoption of SFAS 123R, we accounted for grants of stock-based awards according to the intrinsic value method as prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related Interpretations.

In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or SAB 107 (subsequently amended by SAB 110), relating to SFAS 123R. We applied the provisions of SAB 107 in connection with our adoption of SFAS 123R. We adopted SFAS 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our financial statements as of and for the years ended December 31, 2008, 2007 and 2006 reflect the impact of SFAS 123R. In accordance with the modified prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R.

The adoption of SFAS 123R on January 1, 2006 had a material impact on our net loss and net loss per share for the years ended December 31, 2008, 2007 and 2006. We expect that SFAS 123R will have a material impact on our future financial statements and results of operations. During the years ended December 31, 2008, 2007 and 2006, we recorded stock-based compensation expense of approximately $8.0 million, $6.7 million and $3.6 million, respectively, related to stock-based awards, including stock options, restricted stock and our employee stock purchase plan. As of December 31, 2008, the unrecorded deferred stock-based compensation balance related to these stock-based awards was approximately $7.6 million and will be recognized over the remaining vesting periods of the awards. Judgments and estimates must be made and used in determining the factors used in calculating the fair value of stock-based awards, including the expected forfeiture rate of our stock-based awards, the expected life of our stock-based awards, and the expected volatility of our stock price. For more information on stock-based compensation expense during the year ended December 31, 2008, refer to Note 4 "Stock-Based Compensation Plans" of the Notes to our Financial Statements included in Part IV, Item 15 of this report.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, provides a framework for measuring fair value, and expands the disclosures required for fair value measurements. SFAS No. 157 applies to other accounting pronouncements that require fair value measurements; it does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 and we adopted it on January 1, 2008. The application of SFAS No. 157 to certain items has been deferred and will be effective for fiscal years beginning after November 15, 2008 and interim periods within that year. The adoption of this pronouncement did not have a material impact on our results of operations or financial position for the year ended December 31, 2008. We have no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities, respectively) as of December 31, 2008. 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 carrying value of our money market investments totaling $30.4 million as of December 31, 2008 is included in cash and cash equivalents on our Balance Sheet included in this report and approximates their market values based on quoted market prices, or Level 1 inputs. We account for investments in 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.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115,* which is effective for fiscal years beginning after November 15, 2007 and we adopted it on January 1, 2008. This statement permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. The adoption of this pronouncement did not have a material impact on our results of operations or financial position for the year ended December 31, 2008, as we did not elect to measure any of our financial instruments at fair value.

In June 2007, the Emerging Issues Task Force, or EITF, issued a consensus, EITF 07-3, *Advance Payments for Research and Development Activities*, which states that non-refundable advance payments for goods that will be used or services that will be performed in future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been rendered. EITF 07-3 is to be applied prospectively for new contractual arrangements entered into in fiscal years beginning after December 15, 2007 and we adopted it on January 1, 2008. The adoption did not result in a material change to our current accounting practice.

In November 2007, the EITF issued a consensus, EITF 07-1, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property*, which is focused on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. EITF 07-1 is to be applied retrospectively for collaboration arrangements in fiscal years beginning after December 15, 2008. We currently do not have any such arrangements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. This Statement replaces SFAS No. 141, *Business Combinations,* and requires an acquirer to recognize the assets acquired, the liabilities assumed, including those arising from contractual contingencies, any contingent consideration, and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the statement. SFAS No. 141(R) also requires the acquirer in a business combination achieved in stages (sometimes referred to as a step acquisition) to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values (or other amounts determined in accordance with SFAS No. 141(R)). In addition, SFAS No. 141(R)'s requirement to measure the noncontrolling interest in the acquiree at fair value will result in recognizing the goodwill attributable to the noncontrolling interest in addition to that attributable to the acquirer. SFAS No. 141(R) amends SFAS No. 109, *Accounting for Income Taxes*, to require the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances. It also amends SFAS No. 142, *Goodwill and Other Intangible Assets*, to, among other things, provide guidance on the impairment testing of acquired research and development intangible assets and assets that the acquirer intends not to use. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We are currently evaluating the potential impact of this statement and will apply it to any business combinations in the future. We do not expect any impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 amends Accounting Research Bulletin 51, *Consolidated Financial Statements*, to establish accounting and reporting standards for the noncontrolling interest in a

subsidiary and for the deconsolidation of a subsidiary. It also clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. SFAS No. 160 also changes the way the consolidated income statement is presented by requiring consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest. It also requires disclosure, on the face of the consolidated statement of income, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interest. SFAS No. 160 requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated and requires expanded disclosures in the consolidated financial statements that clearly identify and distinguish between the interests of the parent owners and the interests of the noncontrolling owners of a subsidiary. SFAS No. 160 is effective for fiscal periods, and interim periods within those fiscal years, beginning on or after December 15, 2008. We are currently evaluating the potential impact of this statement. We do not expect any impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*. SFAS No. 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring companies to enhance disclosure about how these instruments and activities affect their financial position, performance and cash flows. SFAS No. 161 also improves the transparency about the location and amounts of derivative instruments in a company's financial statements and how they are accounted for under SFAS No. 133. SFAS No. 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, and interim periods beginning after that date. We are currently evaluating the potential impact of this statement. We do not expect any impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States of America. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board, or PCAOB, amendments to AICPA Codification of Auditing Standards, AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. This amendment was approved by the PCAOB on September 16, 2008. We do not anticipate that the adoption of SFAS No. 162 will materially impact our financial statements.

In June 2008, the FASB issued FASB Staff Position, or FSP, EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions are Participating Securities, or* FSP EITF 03-6-1, to address whether instruments granted in share-based payment transactions are participating securities prior to their vesting and therefore need to be included in the earnings per share calculation under the two-class method described in SFAS No. 128, *Earnings per Share*. This FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents as participating securities and thus, include them in calculations of basic earnings per share. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. We do not anticipate that our adoption of FSP EITF 03-6-1 will materially impact our financial statements or our computation of basic earnings per share upon adoption.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our financial instruments as of December 31, 2008 consisted of cash, cash equivalents, investments in marketable securities, and accounts payable. All highly liquid investments with original maturities of three months or less are considered to be cash equivalents. We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any

single issue, issuer or type of investment. The weighted average duration of the remaining time to maturity for our portfolio of investments in marketable securities as of December 31, 2008 was approximately five months. As of December 31, 2008, our investments in marketable securities of $53.5 million were all classified as held-to-maturity and were held in a variety of interest-bearing instruments, consisting mainly of high-grade corporate notes. We did not hold any derivative instruments, foreign exchange contracts, asset backed securities, mortgage backed securities, auction rate securities, or securities of issuers in bankruptcy in our investment portfolio as of December 31, 2008. The value of our investments in marketable securities may be adversely affected by rating downgrades or bankruptcies affecting the issuers of such securities, whether caused by instability in the global financial markets, lack of liquidity in the credit and capital markets, or other factors. In response to the recent instability in the global financial markets, we reviewed our investments in marketable securities and sold certain investments that we deemed to have increased risk during the three months ended September 30, 2008. We have the ability and intent to hold our remaining investments in marketable securities as of December 31, 2008 to their scheduled maturity, although we monitor our investment portfolio with the primary objectives of preserving principal and maintaining proper liquidity to meet our operating needs.

Investments in fixed-rate interest-earning instruments carry varying degrees of interest rate risk. The fair market value of our fixed-rate securities may be adversely impacted due to a rise in interest rates. In general, securities with longer maturities are subject to greater interest-rate risk than those with shorter maturities. Due in part to this factor, our interest income may fall short of expectations or we may suffer losses in principal if securities are sold that have declined in market value due to changes in interest rates. Due to the short duration of our investment portfolio, we believe an immediate 10% change in interest rates would not be material to our financial condition or results of operations.

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

Disclosure Controls and Procedures

As of the end of the period covered by this report, an evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer and principal financial 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, or the Exchange Act. Based on that evaluation, our management, including our principal executive officer and principal financial officer, concluded that our disclosure controls and procedures were effective as of December 31, 2008 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 the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management 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 officer and principal financial officer 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, 2008. 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, 2008, we maintained effective internal control over financial reporting based on those criteria.

In addition, the effectiveness of our internal control over financial reporting as of December 31, 2008 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.

No Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item concerning our directors is incorporated by reference to the information to be set forth in the section entitled "Proposal 1—Election of Directors" in our definitive Proxy Statement for the 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2008, or the Proxy Statement. The information required by this Item concerning compliance with Section 16(a) of the Exchange Act is incorporated by reference to the information to be set forth in the section of the Proxy Statement entitled "Section 16(a) Beneficial Ownership Reporting Compliance." The information required by this Item concerning the procedures by which our stockholders may recommend nominees to our Board of Directors is incorporated by reference to the information to be set forth in the section of the Proxy Statement entitled "Information Regarding the Director Nomination Process." The information required by this Item concerning our Audit Committee is incorporated by reference to the information to be set forth in the section of the Proxy Statement entitled "Audit Committee." The balance of the information required by this Item, except as otherwise set forth below, is incorporated by reference to the information to be set forth in the section of the Proxy Statement entitled "Executive Officers."

Our Board of Directors has adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees. Stockholders may locate a copy of our Code of Business Conduct and Ethics on our website at *http://www.allos.com* or request a free copy from:

Allos Therapeutics, Inc.
Attention: Investor Relations
11080 CirclePoint Road, Suite 200
Westminster, CO 80020
Telephone: 303-426-6262

To date, there have been no waivers under our Code of Business Conduct and Ethics. We will post any waivers, if and when granted, of our Code of Business Conduct and Ethics on our website.

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 sections of the Proxy Statement entitled "Executive Compensation," "Director Compensation," "Compensation Committee Interlocks and Insider Participation," and "Compensation Committee Report."

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2008:

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted-average exercise price of outstanding options and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	7,236,512	$5.14	7,406,478(1)(2)
Equity compensation plans not approved by security holders	—	—	—
Total	7,236,512	$5.14	7,406,478(1)(2)

(1) Includes 5,146,701 shares of common stock available for future issuance under our 2008 Equity Incentive Plan. All stock awards granted under our 2008 Equity Incentive Plan after the June 24, 2008 effective date thereof, other than stock options and stock appreciation rights granted with an exercise price of at least 100% of such stock award's fair market value on the date of grant, reduce the number of shares available for issuance under our 2008 Equity Incentive Plan by 1.35 shares per share granted pursuant to the stock award. Shares of common stock that revert to and again become available for issuance under our 2008 Equity Incentive Plan and that prior to such reversion were granted pursuant to a stock award that reduced the number of shares available under our 2008 Equity Incentive Plan by 1.35 shares per share granted pursuant to such stock award, will cause the number of shares of our common stock available for issuance under our 2008 Equity Incentive Plan to increase by 1.35 shares upon such reversion.

(2) Includes 2,259,777 shares of common stock available for future issuance under our 2001 Employee Stock Purchase Plan.

Other Information

Other 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."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item regarding certain relationships and related transactions and director independence is incorporated by reference to the information to be set forth in the sections of the Proxy Statement entitled "Transactions with Related Persons" and "Information Regarding the Board of Directors and Corporate Governance."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item regarding principal accounting fees and services is incorporated by reference to the information to be set forth in the section of the Proxy Statement entitled "Proposal 2—Ratification of Selection of Independent Registered Public Accountants."

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(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 exhibits that were previously filed are incorporated by reference.

Exhibit No.	Description	Incorporated by Reference			Filed Herewith
		Form	Filing Date	Number	
3.01	Amended and Restated Certificate of Incorporation.	10-Q	8/7/2006	3.01	
3.02	Certificate of Designation of Series A Junior Participating Preferred Stock.	10-Q	8/7/2006	3.02	
3.03	Certificate of Amendment to Restated Certificate of Incorporation.	10-Q	8/7/2006	3.03	
3.04	Amended and Restated Bylaws of Allos Therapeutics, Inc.	8-K	6/25/2007	3.04	
4.01	Form of Common Stock Certificate.	S-1/A	3/17/2000	4.01	
4.02	Reference is made to Exhibits 3.01, 3.02, 3.03 and 3.04.				
4.03	Rights Agreement dated May 6, 2003 between Allos and Mellon Investor Services LLC.	8-K	5/9/2003	99.2	
4.04	Form of Rights Certificate.	8-K	5/9/2003	99.3	
4.05	Amendment to Rights Agreement dated March 4, 2005 between Allos and Mellon Investor Services LLC.	8-K	3/4/2005	4.06	
4.06	Amendment to Rights Agreement dated January 29, 2007 between Allos and Mellon Investor Services LLC.	8-K	1/30/2007	4.1	
10.01†	Form of Amended and Restated Indemnity Agreement between Allos and each of its directors and officers.	8-K	6/25/2007	10.01	
10.02†	1995 Stock Option Plan, as amended.	S-1	1/26/2000	10.11	

Exhibit No.	Description	Incorporated by Reference			Filed Herewith
		Form	Filing Date	Number	
10.03†	2000 Stock Incentive Compensation Plan, as amended.	8-K	12/22/2005	10.1	
10.03.1†	Form of Incentive Stock Option Letter Agreement under 2000 Stock Incentive Compensation Plan.	8-K	2/11/2005	99.1	
10.03.2†	Form of Nonqualified Stock Option Letter Agreement under 2000 Stock Incentive Compensation Plan.	8-K	2/11/2005	99.2	
10.03.3†	Form of Nonqualified Stock Option Letter Agreement for Non-Employee Directors under 2000 Stock Incentive Compensation Plan.	8-K	2/24/2006	10.1	
10.04†	2001 Employee Stock Purchase Plan and form of Offering.	10-K	3/7/2001	10.26	
10.04.1†	2001 Employee Stock Purchase Plan Offering (Series Beginning July 1, 2007).	8-K	6/25/2007	10.12.1	
10.05*	Office Lease dated April 4, 2001 between Allos and Catellus Development Corporation.	10-Q	8/14/2001	10.27	
10.05.1*	Amended and Restated Second Amendment to Lease dated December 9, 2002 between Allos and Catellus Development Corporation.	10-K	3/28/2003	10.27.1	
10.05.2*	Third Amendment to Lease dated November 28, 2003 between Allos and Catellus Development Corporation.	10-K	3/5/2004	10.27.2	
10.05.3*	Fifth Amendment to Office Lease Agreement dated June 16, 2008 between Allos and Circle Point Properties, LLC.	10-Q	8/5/2008	10.5.3	
10.06	Securities Purchase Agreement dated March 2, 2005 between Allos and the Investors listed on the signature pages thereto.	8-K/A	3/10/2005	10.41	
10.07	Registration Rights Agreement dated March 4, 2005 between Allos and the Investors listed on Schedule I thereto.	8-K/A	3/10/2005	10.42	
10.08	Letter Agreement dated March 4, 2005 among Allos, Warburg Pincus Private Equity VIII, L.P., Warburg Pincus & Co. and Warburg Pincus LLC.	8-K	3/4/2005	10.43	
10.09†	Summary of Compensation Arrangements for Non-Employee Directors.	10-Q	8/7/2007	10.32	
10.10†	Restricted Stock Award Agreement dated March 9, 2006 between Allos and Paul L. Berns.	8-K	3/14/2006	10.2	

Exhibit No.	Description	Incorporated by Reference			Filed Herewith
		Form	Filing Date	Number	
10.11†	2006 Inducement Award Plan, including forms of Stock Option Grant Notice with Stock Option Agreement and Restricted Stock Grant Notice with Restricted Stock Grant Agreement.	8-K	6/6/2006	10.1	
10.12	Letter agreement dated January 28, 2007 among Allos, Baker Bros. Investments, L.P., Baker Bros. Investments II, L.P., Baker/Tisch Investments, L.P., Baker Biotech Fund I, L.P., 14159, L.P. and Baker Brothers Life Sciences, L.P.	8-K	1/30/2007	10.1	
10.13*	License Agreement for 10-Propargyl-10-Deazaaminopterin "PDX" dated December 23, 2002 and amended May 9, 2006 between Allos and SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute.	10-Q	8/7/2007	10.45	
10.13.1*	Second Amendment to License Agreement for 10-Propargyl-10-Deazaaminopterin "PDX" dated November 6, 2007 between Allos and SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute.	10-K	2/27/2008	10.18.1	
10.14†	Corporate Bonus Plan, as amended and restated effective September 15, 2008.	10-Q	11/5/2008	10.1	
10.15†	Amended and Restated Employment Agreement, effective December 13, 2007, between Allos and Paul L. Berns.	10-K	2/27/2008	10.20	
10.16†	Amended and Restated Employment Agreement, effective December 13, 2007, between Allos and Pablo J. Cagnoni, M.D.	10-K	2/27/2008	10.21	
10.17†	Amended and Restated Employment Agreement, effective December 13, 2007, between Allos and James V. Caruso.	10-K	2/27/2008	10.22	
10.18†	Amended and Restated Employment Agreement, effective December 13, 2007, between Allos and Marc H. Graboyes.	10-K	2/27/2008	10.23	
10.19†	Letter agreement, effective January 22, 2008, between Allos and Bruce K. Bennett.	10-K	2/27/2008	10.24	
10.20*	License Agreement, dated as of December 13, 2004, among Allos, The Regents of the University of Colorado, the University of Salford and Cancer Research Technology Limited.	10-K/A	8/25/2008	10.25	
10.21†	Executive Compensation and Equity Awards.	8-K	2/27/2009	10.1	
10.22†	Allos Therapeutics, Inc. 2008 Equity Incentive Plan.	S-8	6/24/2008	99.1	

Exhibit No.	Description	Incorporated by Reference			Filed Herewith
		Form	Filing Date	Number	
10.22.1†	Form of Option Grant Notice and Agreement under the 2008 Equity Incentive Plan.	S-8	6/24/2008	99.2	
10.22.2†	Form of Restricted Stock Award Grant Notice and Agreement under the 2008 Equity Incentive Plan.	S-8	6/24/2008	99.3	
10.22.3†	Form of Restricted Stock Unit Grant Notice and Agreement under the 2008 Equity Incentive Plan.	8-K	2/27/2009	10.2	
10.23†	Allos Therapeutics, Inc. Severance Benefit Plan, as amended and restated effective December 11, 2007.	8-K	2/27/2009	10.3	
10.23.1†	Allos Therapeutics, Inc. Change in Control Severance Benefit Schedule, as amended and restated effective February 23, 2008.	8-K	2/27/2009	10.4	
23.01	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.				X
24.01	Power of Attorney (included on signature page hereto).				X
31.01	Rule 13a-14(a)/15d-14(a) Certification.				X
31.02	Rule 13a-14(a)/15d-14(a) Certification.				X
32.01#	Section 1350 Certification.				X

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

* Indicates confidential treatment has been granted with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

The certifications attached as Exhibit 32.01 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Allos Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

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 3, 2009

By: /s/ PAUL L. BERNS

Paul L. Berns

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Paul L. Berns and David C. Clark, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them 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 3, 2009, and in the capacities indicated:

Name	Title
/s/ STEPHEN J. HOFFMAN Stephen J. Hoffman	Chairman of Board of Directors and Director
/s/ PAUL L. BERNS Paul L. Berns	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ DAVID C. CLARK David C. Clark	Vice President, Finance and Treasurer (Principal Financial and Accounting Officer)
/s/ MICHAEL D. CASEY Michael D. Casey	Director
/s/ STEWART HEN Stewart Hen	Director
/s/ JEFFREY R. LATTS Jeffrey R. Latts	Director
/s/ JONATHAN S. LEFF Jonathan S. Leff	Director
/s/ TIMOTHY P. LYNCH Timothy P. Lynch	Director

(This page has been left blank intentionally.)

Allos Therapeutics, Inc.

Index to Financial Statements

	Page
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Changes in Stockholders' Equity (Deficit)	F-5
Statements of Cash Flows	F-10
Notes to Financial Statements	F-11

Report of Independent Registered Public Accounting Firm

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

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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 and, cumulatively, for the period from September 1, 1992 (date of inception) to December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting, appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide 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.

/s/ PricewaterhouseCoopers LLP
Denver, CO
March 3, 2009

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)
BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,458,424	$ 15,919,664
Restricted cash	237,632	183,334
Investments in marketable securities	53,468,942	41,836,566
Prepaid research and development expenses	919,384	524,704
Prepaid expenses and other assets	2,772,235	2,374,471
Total current assets	87,856,617	60,838,739
Property and equipment, net	1,307,084	621,451
Investments in marketable securities	38,480	—
Other assets	137,423	—
Total assets	$ 89,339,604	$ 61,460,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade accounts payable	$ 280,526	$ 1,191,849
Accrued liabilities	9,594,712	7,689,338
Total current liabilities	9,875,238	8,881,187
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Series A Junior Participating Preferred Stock, $0.001 par value; 1,000,000 shares designated from authorized preferred stock; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized; 81,238,812 and 67,641,943 shares issued and outstanding at December 31, 2008 and December 31, 2007, respectively	81,239	67,642
Additional paid-in capital	379,042,015	300,440,336
Deficit accumulated during the development stage	(299,658,888)	(247,928,975)
Total stockholders' equity	79,464,366	52,579,003
Total liabilities and stockholders' equity	$ 89,339,604	$ 61,460,190

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

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)
STATEMENTS OF OPERATIONS

	Years Ended December 31,			Cumulative Period from September 1, 1992 (date of inception) through December 31, 2008
	2008	2007	2006	
Operating expenses:				
Research and development	$ 23,848,052	$ 17,444,320	$ 14,322,601	$ 149,147,924
Clinical manufacturing	6,747,146	5,547,411	2,283,907	41,359,252
Marketing, general and administrative	23,043,428	19,672,014	14,876,273	125,873,969
Restructuring and separation costs	—	—	645,666	1,663,821
Total operating expenses	53,638,626	42,663,745	32,128,447	318,044,966
Loss from operations	(53,638,626)	(42,663,745)	(32,128,447)	(318,044,966)
Gain on settlement claims	—	—	—	5,110,083
Interest and other income, net	1,908,713	3,294,146	1,915,977	23,512,459
Net loss	(51,729,913)	(39,369,599)	(30,212,470)	(289,422,424)
Dividend related to beneficial conversion feature of preferred stock	—	—	—	(10,236,464)
Net loss attributable to common stockholders	$(51,729,913)	$(39,369,599)	$(30,212,470)	$(299,658,888)
Net loss per share: basic and diluted	$ (0.69)	$ (0.60)	$ (0.55)	
Weighted average shares: basic and diluted	75,399,774	65,188,913	55,299,614	

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

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	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

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance at December 31, 1996	1,822,950	1,823	10,032,500	10,033	12,926,187	(90,000)	—	(7,360,916)	5,487,127
Issuance of common stock upon exercise of stock options for cash of $20,288 and notes receivable of $49,687 at $0.16 - $0.40 per share	175,770	176	—	—	69,799	(49,687)	—	—	20,288
Net loss	—	—	—	—	—	—	—	(6,512,591)	(6,512,591)
Balance at December 31, 1997	1,998,720	1,999	10,032,500	10,033	12,995,986	(139,687)	—	(13,873,507)	(1,005,176)
Issuance of Series C convertible preferred stock at $1.81 per share, net of issuance costs	—	—	9,944,750	9,945	17,937,102	—	—	—	17,947,047
Issuance of common stock upon exercise of stock options for cash of $3,464 at $0.16 - $0.40 per share	13,239	13	—	—	3,451	—	—	—	3,464
Net loss	—	—	—	—	—	—	—	(8,573,923)	(8,573,923)
Balance at December 31, 1998	2,011,959	2,012	19,977,250	19,978	30,936,539	(139,687)	—	(22,447,430)	8,371,412
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 $73,855 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

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	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

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance at December 31, 2004	31,175,783	31,176	—	—	181,453,476	—	(34,820)	(157,586,829)	23,863,003
Issuance of common stock upon exercise of stock options for cash of $197,513 at $.16 - $1.78 per share	352,081	352	—	—	197,161	—	—	—	197,513
Issuance of common stock upon exercise of purchase rights at an exercise price of $1.82 and $1.85 per share	26,675	27	—	—	48,804	—	—	—	48,831
Issuance of Series A Exchangeable Preferred Stock at $22.10 per share, net of issuance costs	—	—	2,352,443	2,352	48,837,479	—	—	—	48,839,831
Beneficial conversion feature related to issuance of preferred stock	—	—	—	—	623,489	—	—	(623,489)	—
Conversion of Series A Exchangeable Preferred Stock to common stock	23,524,430	23,524	(2,352,443)	(2,352)	(21,172)	—	—	—	—
Stock compensation expense	—	—	—	—	443,644	—	—	—	443,644
Deferred compensation related to options	—	—	—	—	(604)	—	34,820	—	34,216
Net loss	—	—	—	—	—	—	—	(20,136,588)	(20,136,588)
Balance at December 31, 2005	55,078,969	55,079	—	—	231,582,277	—	—	(178,346,906)	53,290,450
Issuance of common stock upon exercise of stock options for cash of $561,097 at $.40 - $3.20 per share	413,680	414	—	—	560,683	—	—	—	561,097
Issuance of common stock upon exercise of purchase rights at an exercise price of $1.82, $1.96 and $3.05 per share	44,319	44	—	—	90,627	—	—	—	90,671
Issuance of common stock upon net exercise of warrants at an exercise price of $3.14 per share	37,459	37	—	—	(37)	—	—	—	—
Issuance of common stock upon exercise of warrants for cash of $2,233,187 at an exercise price of $3.14 per share	711,206	711	—	—	2,232,476	—	—	—	2,233,187
Issuance of restricted stock	410,000	410	—	—	(410)	—	—	—	—
Stock compensation expense	—	—	—	—	3,587,001	—	—	—	3,587,001
Net loss	—	—	—	—	—	—	—	(30,212,470)	(30,212,470)
Balance at December 31, 2006	56,695,633	56,695	—	—	238,052,617	—	—	(208,559,376)	29,549,936

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) (Continued)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance at December 31, 2006	56,695,633	56,695	—	—	238,052,617	—	—	(208,559,376)	29,549,936
Issuance of common stock upon exercise of stock options for cash of $3,696,811 at $.40 - $6.38 per share	1,156,471	1,157	—	—	3,695,654	—	—	—	3,696,811
Issuance of common stock upon exercise of purchase rights at an exercise price of $1.82 - $3.89 per share	41,148	41	—	—	124,805	—	—	—	124,846
Issuance of common stock upon net exercise of warrants at an exercise price of $3.14 per share	112,106	112	—	—	(112)	—	—	—	—
Issuance of common stock upon exercise of warrants for cash of $1,669,177 at an exercise price of $3.14 per share	531,585	532	—	—	1,668,645	—	—	—	1,669,177
Issuance of common stock net of offering costs of $3,742,793, at $6.00 per share	9,000,000	9,000	—	—	50,248,207	—	—	—	50,257,207
Issuance of restricted stock	105,000	105	—	—	(105)	—	—	—	—
Stock compensation expense	—	—	—	—	6,650,625	—	—	—	6,650,625
Net loss	—	—	—	—	—	—	—	(39,369,599)	(39,369,599)
Balance at December 31, 2007	67,641,943	67,642	—	—	300,440,336	—	—	(247,928,975)	52,579,003
Issuance of common stock upon exercise of stock options for cash of $5,291,229 at $2.06 - $8.75 per share	1,144,041	1,144	—	—	5,290,085	—	—	—	5,291,229
Issuance of common stock upon exercise of purchase rights at an exercise price of $5.18 and $5.20 per share	22,828	23	—	—	118,447	—	—	—	118,470
Issuance of common stock net of offering costs of $4,863,672, at $5.64 per share	12,420,000	12,420	—	—	65,172,708	—	—	—	65,185,128
Issuance of restricted stock	10,000	10	—	—	(10)	—	—	—	—
Stock compensation expense	—	—	—	—	8,020,449	—	—	—	8,020,449
Net loss	—	—	—	—	—	—	—	(51,729,913)	(51,729,913)
Balance at December 31, 2008	81,238,812	$81,239	—	$ —	$379,042,015	$ —	$ —	$(299,658,888)	$ 79,464,366

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

ALLOS THERAPEUTICS, INC.
(A Development Stage Enterprise)
STATEMENTS OF CASH FLOWS

	Years Ended December 31,			Cumulative Period from September 1, 1992 (date of inception) through December 31, 2008
	2008	2007	2006	
Cash Flows From Operating Activities:				
Net loss	$(51,729,913)	$(39,369,599)	$(30,212,470)	$(289,422,424)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	392,736	361,045	312,251	3,841,045
Stock-based compensation expense	8,020,449	6,650,625	3,587,001	40,302,168
Write-off of long-term investment	—	—	—	1,000,000
Realized loss on sale of marketable securities	551,698	—	—	551,698
Other	18,688	—	—	117,809
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	(929,867)	(283,823)	(2,054,486)	(3,819,042)
Interest receivable on investments	(167,851)	(231,201)	179,326	(833,160)
Trade accounts payable	(911,323)	791,716	34,921	280,526
Accrued liabilities	1,905,374	1,257,817	3,006,617	9,594,712
Net cash used in operating activities	(42,850,009)	(30,823,420)	(25,146,840)	(238,386,668)
Cash Flows From Investing Activities:				
Acquisition of property and equipment	(1,097,057)	(378,976)	(228,043)	(4,912,811)
(Pledge) release of restricted cash	(54,298)	183,333	183,333	(237,632)
Purchases of marketable securities	(93,938,031)	(89,014,032)	(33,847,513)	(609,596,257)
Proceeds from maturities of marketable securities	75,135,828	70,134,192	62,000,000	549,622,797
Proceeds from sales of marketable securities	6,747,500	—	—	6,747,500
Purchase of long-term investment	—	—	—	(1,000,000)
Payments received on notes receivable	—	—	—	49,687
Net cash (used in) provided by investing activities	(13,206,058)	(19,075,483)	28,107,777	(59,326,716)
Cash Flows From Financing Activities:				
Principal payments under capital leases	—	—	—	(422,088)
Proceeds from sales leaseback	—	—	—	120,492
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	—	—	89,125,640
Proceeds from issuance of common stock associated with stock options, stock warrants and employee stock purchase plan	5,409,699	5,490,834	2,884,955	15,010,817
Proceeds from issuance of common stock, net of issuance costs	65,185,128	50,257,207	—	224,336,947
Net cash provided by financing activities	70,594,827	55,748,041	2,884,955	328,171,808
Net increase in cash and cash equivalents	14,538,760	5,849,138	5,845,892	30,458,424
Cash and cash equivalents, beginning of period	15,919,664	10,070,526	4,224,634	—
Cash and cash equivalents, end of period	$ 30,458,424	$ 15,919,664	$ 10,070,526	$ 30,458,424
Supplemental Schedule of Cash and Non-cash Operating and Financing Activities:				
Cash paid for interest	$ —	$ —	$ —	$ 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
Conversion of preferred stock to common stock	—	—	—	89,125,640

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

We are a biopharmaceutical company focused on developing and commercializing innovative small molecule drugs for the treatment of cancer. We currently have two small molecule chemotherapeutic product candidates, pralatrexate (PDX) and RH1.

- **Pralatrexate** (PDX), our lead product candidate, is a novel targeted antifolate designed to accumulate preferentially in cancer cells. Based on preclinical studies, we believe that pralatrexate selectively enters cells expressing RFC-1, a protein that is over expressed on cancer cells compared to normal cells. Once inside cancer cells, pralatrexate is efficiently polyglutamylated, which leads to high intracellular drug retention. Polyglutamylated pralatrexate essentially becomes "trapped" inside cancer cells, making it less susceptible to efflux-based drug resistance. Acting on the folate pathway, pralatrexate interferes with DNA synthesis and triggers cancer cell death. We believe pralatrexate has the potential to be delivered as a single agent or in combination therapy regimens.
- **RH1** is a small molecule chemotherapeutic agent that we believe is bioactivated by the enzyme DT-diaphorase, or DTD, also known as NAD(P)H quinone oxidoreductase, or NQ01. We believe DTD is over-expressed in many tumors, relative to normal tissue, including lung, colon, breast and liver tumors. We believe that 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 amount of toxicity to normal tissue. We currently are in the process of closing our Phase 1 study of RH1 in patients with advanced solid tumors and NHL and determining our future development plans, if any, for RH1.

In mid-2007, we discontinued the development of EFAPROXYN, one of our former product candidates, after announcing top-line results from ENRICH, a Phase 3 clinical trial of EFAPROXYN plus whole brain radiation therapy, or WBRT, in women with brain metastases originating from breast cancer. The study failed to achieve its primary endpoint of demonstrating a statistically significant improvement in overall survival in patients receiving EFAPROXYN plus WBRT, compared to patients receiving WBRT alone. We are currently pursuing the sale of our rights to EFAPROXYN although we may not receive any material consideration for any sale.

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 operate as a single business segment.

Since our inception in 1992, we have not generated any revenue from product sales and have experienced significant net losses and negative cash flows from operations. We have incurred these losses principally from costs incurred in our research and development programs, our clinical manufacturing, and from our marketing, general and administrative expenses. Our primary business activities have been focused on the development of pralatrexate, RH1 (a program for which we are in the process of determining our future development plans, if any) and EFAPROXYN (a program which we discontinued in mid-2007).

1. Formation and Business of the Company (Continued)

Our ability to generate revenue and achieve profitability is dependent on our ability, alone or with partners, to successfully complete the development of pralatrexate, conduct clinical trials, obtain the necessary regulatory approvals, and manufacture and market pralatrexate. The timing and costs to complete the successful development of pralatrexate is highly uncertain, and therefore difficult to estimate. The lengthy process of seeking regulatory approvals for pralatrexate, and the subsequent compliance with applicable regulations, require the expenditure of substantial resources. Clinical development timelines, likelihood of success and total costs vary widely and are impacted by a variety of risks and uncertainties. Because of these risks and uncertainties, we cannot predict when or whether we will successfully complete the development of pralatrexate or the ultimate costs of such efforts. Due to these same factors, we cannot be certain when, or if, we will generate any revenue or net cash inflow from pralatrexate.

Even if our clinical trials demonstrate the safety and effectiveness of pralatrexate in its target indications, we do not expect to be able to generate commercial sales of pralatrexate until the second half of 2009, at the earliest. We expect to continue incurring net losses and negative cash flows for the foreseeable future. Although the size and timing of our future net losses are subject to significant uncertainty, we expect them to increase over the next several years as we continue to fund our research and development programs and prepare for the potential commercial launch of pralatrexate.

As of December 31, 2008, we had $84.0 million in cash, cash equivalents, and investments in marketable securities. Based upon the current status of our product development plans, we believe that our cash, cash equivalents, and investments in marketable securities as of December 31, 2008 should be adequate to support our operations through at least the next 12 months, although there can be no assurance that this can, in fact, be accomplished.

We anticipate continuing our current development programs and/or beginning other long-term development projects involving pralatrexate. These projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. In addition, we intend to submit a New Drug Application, or NDA, for pralatrexate for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, or PTCL, in the first half of 2009. We expect to incur significant costs relating to preparations for the potential commercial launch of pralatrexate, including pre-commercial scale up of manufacturing and development of sales and marketing capabilities. Therefore, we will need to raise additional capital to support our future operations. Our actual capital requirements will depend on many factors, including:

- the timing and outcome of our planned NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL;
- the timing and costs associated with developing sales and marketing capabilities and commercializing pralatrexate, if it is approved for marketing;
- the timing and costs associated with manufacturing clinical and commercial supplies of pralatrexate;
- the timing and amount of revenues generated by our business activities, if any;

1. Formation and Business of the Company (Continued)

- the timing and costs associated with conducting preclinical and clinical development of pralatrexate, as well as our evaluation of, and decisions with respect to, additional therapeutic indications for which we may develop pralatrexate;
- the timing, costs and potential revenue associated with any co-promotion or other partnering arrangements entered into to commercialize pralatrexate, if it is approved for marketing; and
- our evaluation of, and decisions with respect to, potential in-licensing or product acquisition opportunities or other strategic alternatives.

We may seek to obtain this additional capital through equity or debt financings, arrangements with corporate partners, or from other sources. Such financings or arrangements, if successfully consummated, may be dilutive to our existing stockholders. However, there is no assurance that additional financing will be available when needed, or that, if available, we will obtain such financing on terms that are favorable to our stockholders or us. In particular, the current instability in the global financial markets and lack of liquidity in the credit and capital markets may adversely affect our ability to secure adequate capital to support our future operations. 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, which we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. 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.

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 product candidates, raising capital and recruiting personnel. Accordingly, we are considered to be in the development stage at December 31, 2008, as defined in Statement of Financial Accounting Standards, or 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 judgments 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 original maturities 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 investments in

2. Summary of Significant Accounting Policies (Continued)

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. Our cash and cash equivalents are maintained in a financial institution in amounts that, at times, may exceed federally insured limits. We realized a loss of approximately $552,000 on the sale of certain of our investments in marketable securities during the year ended December 31, 2008. In response to the recent instability in the global financial markets, we reviewed our investments in marketable securities and sold certain investments prior to their maturity in order to preserve our principal, as the issuers of these securities experienced significant deteriorations in their creditworthiness as evidenced by investment rating downgrades. We have the ability and intent to hold our remaining investments in marketable securities as of December 31, 2008 to their scheduled maturity, although we monitor our investment portfolio with the primary objectives of preserving principal and maintaining proper liquidity to meet our operating needs. The weighted average duration of the remaining time to maturity for our portfolio of investments in marketable securities as of December 31, 2008 was approximately five months. As of December 31, 2008, our investments in marketable securities were held in a variety of interest-bearing instruments, consisting mainly of high-grade corporate notes. We did not hold any derivative instruments, foreign exchange contracts, asset backed securities, mortgage backed securities, auction rate securities, or securities of issuers in bankruptcy in our investment portfolio as of December 31, 2008.

Restricted Cash

On August 22, 2008, $237,632 of cash was pledged as collateral on a letter of credit related to a lease for administrative office space and was classified as restricted cash on the Balance Sheet.

On May 24, 2001, $550,000 of cash was pledged as collateral on a letter of credit related to a lease for our headquarters facility and was classified as restricted cash on the balance sheet. During the years ended December 31, 2008, 2007 and 2006, in accordance with the terms of the building lease, the amount of the letter of credit was reduced by $183,334, $183,333 and $183,333, respectively and as of December 31, 2008, the letter of credit was fully released.

Prepaid Research and Development Expenses

Research and development expenditures are charged to expense as incurred. In accordance with certain research and development agreements, we are obligated to make certain upfront payments upon execution of the agreement. We record these upfront payments as prepaid research and development expenses. Such payments are recorded to research and development expense as services are performed. We evaluate on a quarterly basis whether events and circumstances have occurred that may indicate impairment of remaining prepaid research and development expenses.

2. Summary of Significant Accounting Policies (Continued)

Prepaid Expenses and Other Assets

Prepaid expenses and other assets are comprised of the following:

	December 31, 2008	December 31, 2007
Prepaid expenses and other assets	$ 772,235	$ 615,471
Receivable and cash in escrow related to pending litigation settlement (see Note 8)	2,000,000	1,759,000
	$2,772,235	$2,374,471

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 $392,736, $361,045 and $312,251 for the years ended December 31, 2008, 2007 and 2006, respectively, and $3,841,045 for the cumulative period from inception through December 31, 2008.

The components of property and equipment are as follows:

	December 31, 2008	December 31, 2007	Estimated Lives
Computer hardware and software	$ 1,752,276	$ 1,520,157	3 years
Office furniture and equipment	1,682,200	1,344,008	5 - 7 years
Leasehold improvements	416,648	394,740	7 years
Lab equipment	28,516	76,763	5 years
Software projects in process	329,086	—	
	4,208,726	3,335,668	
Less accumulated depreciation and amortization	(2,901,642)	(2,714,217)	
Property and equipment, net	$ 1,307,084	$ 621,451	

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 their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

2. Summary of Significant Accounting Policies (Continued)

Accrued liabilities

Accrued liabilities are comprised of the following:

	December 31,	
	2008	2007
Accrued personnel costs	$2,816,404	$2,122,805
Accrued research and development expenses	2,272,219	1,571,975
Accrued litigation settlement costs (see Note 8)	2,000,000	2,000,000
Accrued clinical manufacturing expenses	1,153,028	1,259,799
Accrued expenses—other	1,353,061	734,759
	$9,594,712	$7,689,338

During the year ended December 31, 2007, we recorded $307,817 in research and development expenses and $117,280 in clinical manufacturing expenses related to the discontinuation of the EFAPROXYN development program. These expenses represent estimated costs to be incurred by contract research organizations in connection with closing out our EFAPROXYN clinical trials and estimated costs for the destruction and storage of EFAPROXYN bulk drug substance and formulated drug product. As of December 31, 2008, $101,176 remains accrued, with approximately $323,921 in payments made since the program was discontinued.

Operating Leases

We recognize lease expense on a straight-line basis over the initial lease term. For leases that contain rent holidays, escalation clauses or tenant improvement allowances, we recognize rent expense on a straight-line basis and record the difference between the rent expense and rental amount payable as deferred rent. As of December 31, 2008 and 2007, we had $82,355 and $0, respectively, of deferred rent in accrued liabilities.

Fair Value of Financial Instruments

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which defines fair value, provides a framework for measuring fair value, and expands the disclosures required for fair value measurements. SFAS does not require any new fair value measurements but rather establishes a common definition of fair value applicable to all assets and liabilities measured at fair value. SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy established by SFAS 157 prioritizes the inputs into valuation techniques used to measure fair value. Accordingly, we use valuation techniques

2. Summary of Significant Accounting Policies (Continued)

that maximize the use of observable inputs and minimize the use of unobservable inputs when determining fair value. The three levels of the hierarchy are as follows:

Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to us for identical assets or liabilities;

Level 2: Inputs include quoted prices for similar assets and liabilities in active and inactive markets or that are observable for the asset or liability either directly or indirectly; and

Level 3: Unobservable inputs that are supported by little or no market activity.

We have no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities, respectively) as of December 31, 2008. 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 carrying value of our money market investments totaling $30,361,584 as of December 31, 2008 is included in cash and cash equivalents on our Balance Sheet and approximates their market values based on quoted market prices, or Level 1 inputs. We account for investments in 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.

Stock-Based Compensation

We adopted SFAS No. 123 (Revised 2004), *Share-Based Payment,* or SFAS 123R, effective January 1, 2006. Under the provisions of SFAS 123R, stock-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense over the required service period of the award. Prior to the adoption of SFAS 123R, we accounted for grants of stock-based awards according to the intrinsic value method as prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related Interpretations.

In March 2005, the Securities and Exchange Commission, or SEC, issued Staff Accounting Bulletin No. 107 (subsequently amended by SAB 110), or SAB 107, relating to SFAS 123R. We applied the provisions of SAB 107 in connection with our adoption of SFAS 123R. We adopted SFAS 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our financial statements as of and for the years ended December 31, 2008, 2007 and 2006 reflect the impact of SFAS 123R (see Note 4). In accordance with the modified prospective transition method, our financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R.

2. Summary of Significant Accounting Policies (Continued)

In November 2005, the FASB issued Staff Position, or FSP, No. FAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards*, or FSP 123R-3. We elected to adopt the alternative transition method provided in FSP 123R-3 for calculating the tax effects of stock-based compensation pursuant to SFAS 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital, or APIC, pool related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and our Statements of Cash Flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123R. This adoption did not have an impact on our financial statements.

See Note 4—"Stock-Based Compensation Plans" for additional details regarding the impact of our stock based compensation plans on our financial statements.

Research and Development

Research and development expenditures are charged to expense as incurred. Research and development expenses include the costs of certain personnel, basic research, preclinical studies, clinical trials, regulatory affairs, biostatistical data analysis and licensing fees for our product candidates. We record upfront fees and milestone payments made under our licensing agreements for our product candidates as research and development expense as the services are performed. 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 and preclinical research organizations. We accrue external costs for clinical and preclinical studies based on an evaluation of the following: the progress of the studies, including patient enrollment, dosing levels of patients enrolled, estimated costs to dose patients, invoices received, and contracted costs with clinical sites and third party clinical and preclinical research organizations. 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. During the years ended December 31, 2008, 2007 and 2006, we did not have any changes in estimates that would have resulted in material adjustments to research and development expenses accrued in the prior period. However, during the quarter ended December 31, 2006, we did change our estimate relating to certain costs for our Phase 3 ENRICH trial for EFAPROXYN as a result of new information, which resulted in a reduction of research and development expenses of approximately $400,000 and a corresponding decrease in accrued research and development expenses as of December 31, 2006.

Clinical Manufacturing

Clinical manufacturing expenses include the costs of certain personnel, third party manufacturing costs for development of drug materials for use in clinical trials and preclinical studies, and costs associated with pre-commercial scale-up of manufacturing to support anticipated regulatory and potential commercial requirements. Our finished drug inventory is expensed to clinical manufacturing since we are still a development stage company and we have not received regulatory approval to market our product candidates. If and when we receive regulatory approval, we will be required to capitalize any future manufacturing costs for our marketed products at the lower of cost or market and then expense the sold inventory as a component of cost of goods sold.

2. Summary of Significant Accounting Policies (Continued)

Income Taxes

Income taxes are accounted for under SFAS No. 109, *Accounting for Income Taxes*, or FAS 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.

Net Loss Per Share

Net loss per share is calculated in accordance with SFAS No. 128, *Earnings Per Share*, or SFAS 128. Under the provisions of SFAS 128, basic net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by giving effect to all dilutive potential common stock outstanding during the period, including stock options, restricted stock, stock warrants and shares to be issued under our employee stock purchase plan.

Diluted net loss per share is the same as basic net loss per share for all periods presented because any potential dilutive common shares were anti-dilutive due to our net loss (as including such shares would decrease our basic net loss per share). Potential dilutive common shares that would have been included in the calculation of diluted earnings per share if we had net income are as follows:

	Year ended December 31,		
	2008	2007	2006
Common stock options	2,011,533	1,630,431	1,142,205
Restricted stock	316,322	438,226	410,000
Common stock warrants	—	262,132	255,210
	2,327,855	2,330,789	1,807,415

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, provides a framework for measuring fair value, and expands the disclosures required for fair value measurements. SFAS 157 applies to other accounting pronouncements that require fair value measurements; it does not require any new fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and we adopted it on January 1, 2008. The application of SFAS 157 to certain items has been deferred and will be effective for fiscal years beginning after November 15, 2008 and interim periods within that year. The adoption of this pronouncement did not have a material impact on our results of operations or financial position for the year ended December 31, 2008. We have no assets or liabilities that were measured using quoted prices for similar assets and liabilities or significant unobservable inputs (Level 2 and Level 3 assets and liabilities, respectively) as of December 31, 2008. Our financial instruments include cash and cash equivalents, investments in marketable securities, prepaid expenses, accounts payable and accrued liabilities. The

2. Summary of Significant Accounting Policies (Continued)

carrying amounts of financial instruments approximate their fair value due to their short maturities. We account for investments in 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.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115,* which is effective for fiscal years beginning after November 15, 2007 and we adopted it on January 1, 2008. This statement permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. The adoption of this pronouncement did not have a material impact on our results of operations or financial position for the year ended December 31, 2008, as we did not elect to measure any of our financial instruments at fair value.

In June 2007, the Emerging Issues Task Force, or EITF, issued a consensus, EITF 07-3, *Advance Payments for Research and Development Activities*, which states that non-refundable advance payments for goods that will be used or services that will be performed in future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been rendered. EITF 07-3 is to be applied prospectively for new contractual arrangements entered into in fiscal years beginning after December 15, 2007 and we adopted it on January 1, 2008. The adoption did not result in a material change to our current accounting practice.

In November 2007, the EITF issued a consensus, EITF 07-1, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property*, which is focused on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. EITF 07-1 is to be applied retrospectively for collaboration arrangements in fiscal years beginning after December 15, 2008. We currently do not have any such arrangements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. This Statement replaces SFAS No. 141, *Business Combinations,* and requires an acquirer to recognize the assets acquired, the liabilities assumed, including those arising from contractual contingencies, any contingent consideration, and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the statement. SFAS No. 141(R) also requires the acquirer in a business combination achieved in stages (sometimes referred to as a step acquisition) to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values (or other amounts determined in accordance with SFAS No. 141(R)). In addition, SFAS No. 141(R)'s requirement to measure the noncontrolling interest in the acquiree at fair value will result in recognizing the goodwill attributable to the noncontrolling interest in addition to that attributable to the acquirer. SFAS No. 141(R) amends SFAS No. 109, *Accounting for Income Taxes*, to require the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances. It also amends SFAS No. 142, *Goodwill and Other Intangible Assets*, to, among other things, provide guidance on the impairment testing of acquired research and development intangible

2. Summary of Significant Accounting Policies (Continued)

assets and assets that the acquirer intends not to use. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We are currently evaluating the potential impact of this statement and will apply it to any business combinations in the future. We do not expect any impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 amends Accounting Research Bulletin 51, *Consolidated Financial Statements*, to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. SFAS No. 160 also changes the way the consolidated income statement is presented by requiring consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest. It also requires disclosure, on the face of the consolidated statement of income, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interest. SFAS No. 160 requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated and requires expanded disclosures in the consolidated financial statements that clearly identify and distinguish between the interests of the parent owners and the interests of the noncontrolling owners of a subsidiary. SFAS No. 160 is effective for fiscal periods, and interim periods within those fiscal years, beginning on or after December 15, 2008. We are currently evaluating the potential impact of this statement. We do not expect any impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*. SFAS No. 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring companies to enhance disclosure about how these instruments and activities affect their financial position, performance and cash flows. SFAS No. 161 also improves the transparency about the location and amounts of derivative instruments in a company's financial statements and how they are accounted for under SFAS No. 133. SFAS No. 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, and interim periods beginning after that date. We are currently evaluating the potential impact of this statement. We do not expect any impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States of America. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board, or PCAOB, amendments to AICPA Codification of Auditing Standards, AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. This amendment was approved by the PCAOB on September 16, 2008. We do not anticipate that the adoption of SFAS No. 162 will materially impact our financial statements.

In June 2008, the FASB issued FASB Staff Position, or FSP, EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions are Participating Securities, or* FSP EITF 03-6-1, to address whether instruments granted in share-based payment transactions are

2. Summary of Significant Accounting Policies (Continued)

participating securities prior to their vesting and therefore need to be included in the earnings per share calculation under the two-class method described in SFAS No. 128, *Earnings per Share*. This FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents as participating securities and thus, include them in calculations of basic earnings per share. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. We do not anticipate that our adoption of FSP EITF 03-6-1 will materially impact our financial statements or our computation of basic earnings per share upon adoption.

3. Stockholders' Equity

Common Stock

2000 Initial Public Offering

In March 2000, we completed an Initial Public Offering of 5,000,000 shares of our common stock at a price of $18.00 per share, the IPO. Proceeds to us from the IPO, 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, and 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, 2008. Our Board of Directors is authorized to fix the designation, powers, preferences, and rights of any such series.

2002 Private Placement

In April 2002, we completed a private placement of 2,500,000 shares of common stock at a purchase price of $6.00 per share 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.

2003 Private Placement

In November 2003, we completed a private placement of 5,172,412 shares of common stock at a purchase price of $2.32 per share 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.

2005 Series A Exchangeable Preferred Stock Financing

In March 2005, we entered into a Securities Purchase Agreement with Warburg Pincus Private Equity VIII, L.P., or Warburg, and certain other investors pursuant to which we issued and sold 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, or the Preferred Stock Financing. We incurred offering expenses of $3.2 million in connection with the sale of Exchangeable Preferred, resulting in net cash proceeds to the Company of approximately $48.8 million. The shares of Exchangeable Preferred were sold under our shelf

3. Stockholders' Equity (Continued)

Registration Statement on Form S-3 declared effective by the Securities and Exchange Commission on April 21, 2004. In connection with its purchase of the Exchangeable Preferred, Warburg entered into a standstill agreement agreeing not to pursue certain activities the purpose or effect of which may be to change or influence the control or the Company.

On May 18, 2005, at our 2005 Annual Meeting of Stockholders, our stockholders voted to approve the issuance of shares of our common stock upon exchange of all of the outstanding shares of Exchangeable Preferred. As a result of such approval, we issued a total of 23,524,430 shares of common stock upon exchange of 2,352,443 shares of Exchangeable Preferred, or the Share Exchange.

The Preferred Purchase Price represented a 7.5% discount to the 20-day trailing average closing price of our common stock on the Nasdaq National Market as of March 2, 2005, calculated on an as-exchanged for common stock basis. In connection with the Share Exchange, we recorded a deemed dividend related to the beneficial conversion feature of the Exchangeable Preferred equal to $623,489, representing the difference between the effective conversion price per share of common stock and the market value per share of common stock as of the closing date of the Preferred Stock Financing. This dividend increased the net loss attributable to common stockholders for the year ended December 31, 2005.

In connection with the sale of Exchangeable Preferred, we entered into a Registration Rights Agreement between us and the purchasers of Exchangeable Preferred. Pursuant to this Registration Rights Agreement, beginning on March 4, 2007, the purchasers of Exchangeable Preferred became entitled to certain registration rights with respect to the shares of common stock that were issued upon exchange of the Exchangeable Preferred.

Pursuant to the Securities Purchase Agreement, for so long as Warburg owns at least two-thirds of the shares of common stock issued upon exchange of such Exchangeable Preferred, 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 shares of common stock issued upon exchange of such Exchangeable Preferred, 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; however, our Board of Directors has determined, based on its analysis of Rule 10A-3 under the Securities Exchange Act of 1934, as amended, that the Investor Designees are not eligible to serve as members of the Audit Committee of the Board of Directors due to the size of Warburg's ownership interest. 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 our Board of Directors pursuant to Warburg's right to nominate directors.

2007 Common Stock Financing

On February 2, 2007, we sold 9,000,000 shares of our common stock in an underwritten offering at a price of $6.00 per share, or the February 2007 Financing. We received net proceeds from the offering

3. Stockholders' Equity (Continued)

of approximately $50,257,207, after deducting underwriting commissions of approximately $3,240,000 and other offering expenses of approximately $502,793.

Baker Brothers Life Sciences, L.P. and certain other affiliated funds, collectively Baker, purchased 3,300,000 shares of common stock in the February 2007 Financing. As a result of such purchase, Baker held in excess of 15% of our outstanding common stock following the closing of the February 2007 Financing. In connection with the February 2007 Financing, Baker entered into a standstill agreement with the Company, agreeing not to pursue, for four years, certain activities the purpose or effect of which may be to change or influence control of the Company.

2008 Common Stock Financing

On May 29, 2008, we sold 12,420,000 shares of our common stock in an underwritten public offering at a price of $5.64 per share. The number of shares issued includes 1,620,000 shares purchased by the underwriters pursuant to their exercise in full of their overallotment option. We received net proceeds from the offering of $65,185,128, after deducting $4,202,928 of underwriting commissions and $660,744 of offering expenses.

Common Stock Reserved for Future Issuance

At December 31, 2008, we have reserved shares of common stock for future issuance as follows:

	Outstanding at December 31, 2008	Available for grant at December 31, 2008	Shares of Common Stock Reserved at December 31, 2008
1995 Stock Option Plan	290,108	—	290,108
2001 Employee Stock Purchase Plan	—	2,259,777	2,259,777
2008 Equity Incentive Plan	6,946,404	5,146,701	12,093,105
Total for Equity Incentive Plans	7,236,512	7,406,478	14,642,990

Stock Warrants

In November 2003, in conjunction with the private placement of 5,172,412 shares of common stock to various purchasers, 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. There were 748,187 and 958,706 of these warrants exercised during 2007 and 2006, respectively. As of December 31, 2008 and 2007, no warrants remained outstanding.

3. Stockholders' Equity (Continued)

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 our Board of Directors under which all stockholders of record as of May 28, 2003 received a dividend distribution of one preferred share purchase right, or 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 Exchangeable Preferred to Warburg in March 2005, 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.

In connection with the acquisition of shares of our common stock by Baker in the February 2007 Financing, we amended the Stockholder Rights Plan to provide that Baker will be exempt from the Stockholder Rights Plan, unless Baker becomes, without the Company's prior consent, the beneficial owner of more than 20% of our common stock.

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, 2008, no shares of Series A Junior Participating Preferred Stock were issued or outstanding.

4. Stock-Based Compensation Plans

Expense Information under SFAS 123R

In accordance with the modified prospective transition method of SFAS 123R, stock-based compensation expense for the years ended December 31, 2008, 2007 and 2006 has been recognized in the accompanying Statements of Operations as follows:

	2008	2007	2006
Research and development	$2,701,115	$1,870,767	$ 660,274
Clinical manufacturing	417,469	180,592	113,066
Marketing, general and administrative	4,901,865	4,599,266	2,813,661
Total stock-based compensation expense	$8,020,449	$6,650,625	$3,587,001

We did not recognize a related tax benefit during the years ended December 31, 2008 and 2007, as we maintain net operating loss carryforwards and we have established a valuation allowance against the entire tax benefit as of December 31, 2008 and 2007. No stock-based compensation expense was capitalized on our Balance Sheets as of December 31, 2008 and 2007.

During the year ended December 31, 2006, we entered into a Separation Agreement with our former President and Chief Executive Officer, Michael E. Hart, and we entered into a consulting

4. Stock-Based Compensation Plans (Continued)

agreement with a former member of our Board of Directors, Dr. Marvin E. Jaffe (these arrangements are described in more detail in Note 9 below). Pursuant to these arrangements, the exercise periods of certain stock options held by Mr. Hart and Dr. Jaffe were extended as a result of their consulting relationships and were deemed modified for accounting purposes. We have accounted for the modifications to these options in accordance with SFAS 123R and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, and recorded a one-time stock-based compensation charge of $441,129 during the year ended December 31, 2006.

Stock Options

During 1995, our Board of Directors terminated the 1992 Stock Plan, or the 1992 Plan, and adopted the 1995 Stock Option Plan, or 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 the IPO, the Board of Directors suspended the 1995 Plan and adopted the Allos Therapeutics, Inc. 2000 Stock Incentive Compensation Plan, or the 2000 Plan. The 2000 Plan provided 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 were 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 were authorized to increase the number of shares of common stock that were available annually on the first day of each 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 earnings per share as reported in our Annual Report to Stockholders for the preceding year, or alternatively, by any lesser amount determined by our Board of Directors. On December 21, 2005, our stockholders approved an amendment and restatement of the 2000 Plan to: (i) increase the aggregate number of shares of common stock authorized for issuance under the 2000 Plan by 3,500,000 shares and (ii) provide that the number of shares of common stock that could be granted under the 2000 Plan to any one employee during any calendar year could not exceed 2,000,000 shares.

In January 2002, our Board of Directors approved the Allos Therapeutics, Inc. 2002 Broad Based Equity Incentive Plan, or the 2002 Plan. Under the 2002 Plan, we were 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% of the number of shares underlying all stock awards granted, as determined on certain specific dates.

In June 2006, our Board of Directors approved the Allos Therapeutics, Inc. 2006 Inducement Award Plan, the 2006 Plan. Under the 2006 Plan, we were authorized to issue up to 1,500,000 shares of common stock pursuant to equity awards, including nonstatutory stock options, stock grant awards, stock purchase awards, stock unit awards and other forms of equity compensation. We could grant

4. Stock-Based Compensation Plans (Continued)

awards under the 2006 Plan only to persons not previously an employee or director of ours, or following a bona fide period of non-employment, as an inducement material to such individual's entering into employment with us and to provide incentives for such persons to exert maximum efforts for our success.

At our Annual Meeting of Stockholders held on June 24, 2008, our stockholders approved the Allos Therapeutics, Inc. 2008 Equity Incentive Plan, or the 2008 Plan. The 2008 Plan authorizes the issuance of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and forms of equity compensation, which may be granted to employees, directors and consultants. Only employees may receive incentive stock options. The 2008 Plan succeeds and continues the 2006 Plan, the 2002 Plan and the 2000 Plan, or the Prior Plans. As of June 24, 2008, no additional stock awards will be granted under the Prior Plans and all outstanding stock awards granted under the Prior Plans are deemed to be stock awards granted under the 2008 Plan (but remain subject to the terms of the Prior Plans with respect to which they were originally granted).

12,550,843 shares of our common stock may be issued pursuant to stock awards granted under the 2008 Plan, provided that all stock awards granted after the June 24, 2008 effective date of the 2008 Plan, other than stock options and stock appreciation rights granted with an exercise price of at least 100% of such stock award's fair market value on the date of grant, will reduce the number of shares available for issuance under the 2008 Plan by 1.35 shares per share granted pursuant to the stock award. If a stock award under the 2008 Plan expires or otherwise terminates without being exercised in full, the shares of common stock of the Company not acquired pursuant to the stock award will again become available for issuance under the 2008 Plan. In addition, shares issued pursuant to a stock award that are forfeited to or repurchased by us prior to becoming fully vested and shares that are cancelled pursuant to an exchange or repricing program will become available for the grant of new stock awards under the 2008 Plan. Shares of common stock that revert to and again become available for issuance under the 2008 Plan and that prior to such reversion were granted pursuant to a stock award that reduced the number of shares available under the 2008 Plan by 1.35 shares per share granted pursuant to such stock award, shall cause the number of shares of common stock of the Company available for issuance under the 2008 Plan to increase by 1.35 shares upon such reversion.

The 1995 and 2008 Plans, or the Plans, provide for appropriate adjustments in the number of shares reserved and outstanding 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 our 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 granted under the Plans must equal or exceed the fair market value of our common stock on the date of grant, or 110% of the fair market value per share in the case of a 10% or greater stockholder.

4. Stock-Based Compensation Plans (Continued)

The following table summarizes our stock option activity and related information for the 1995 and 2008 Plans:

	Options Outstanding		Options Exercisable	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2005	3,944,375	$3.87	2,809,991	$4.20
Granted	2,660,343	2.93		
Exercised	(413,680)	1.36		
Canceled	(412,467)	4.15		
Outstanding at December 31, 2006	5,778,571	$3.60	2,900,556	$4.27
Granted	2,731,574	6.53		
Exercised	(1,156,471)	3.20		
Canceled	(948,244)	5.31		
Outstanding at December 31, 2007	6,405,430	$4.68	2,754,274	$3.80
Granted	2,790,312	6.24		
Exercised	(1,144,041)	4.63		
Canceled	(815,189)	6.00		
Outstanding at December 31, 2008	7,236,512	$5.14	3,122,681	$4.15

The following table summarizes information about options outstanding and exercisable as of December 31, 2008:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable	Weighted Average Exercise Price
$1.90 - $2.55	711,636	4.0	$2.31	692,926	$2.28
$2.56 - $2.95	573,237	7.2	2.75	420,764	2.78
$2.96 - $3.13	402,250	7.1	3.12	270,997	3.11
$3.14 - $3.24	737,400	7.1	3.15	514,925	3.14
$3.25 - $5.62	838,412	8.5	4.92	225,841	4.69
$5.63 - $5.84	235,652	7.6	5.72	185,920	5.68
$5.85 - $6.16	1,582,930	8.8	5.90	171,431	5.88
$6.17 - $7.46	1,016,688	8.6	6.35	221,706	6.25
$7.47 - $8.04	1,018,007	8.5	7.47	361,871	7.47
$8.05 - $13.75	120,300	6.5	9.50	56,300	9.21
	7,236,512	7.8	$5.14	3,122,681	$4.15

4. Stock-Based Compensation Plans (Continued)

The following table summarizes information about outstanding stock options that are fully vested and currently exercisable, and outstanding stock options that are expected to vest in the future:

	Number Outstanding	Weighted Average Remaining Contractual Term	Weighted Average Exercise Price	Aggregate Intrinsic Value
As of December 31, 2008:				
Options fully vested and exercisable	3,122,681	6.4	$4.15	$6,857,744
Options expected to vest, including effects of expected forfeitures	3,497,272	8.8	$5.87	2,182,291
Options fully vested and expected to vest	6,619,953	7.6	$5.06	$9,040,035

During the years ended December 31, 2008, 2007 and 2006, we granted stock options with a weighted-average grant-date fair value of $3.88, $4.12 and $1.79 per share, respectively. Stock-based compensation expense related to our stock option plans was $7,538,876, $5,899,387 and $3,048,523 for the years ended December 31, 2008, 2007 and 2006, respectively. As of December 31, 2008, the unrecorded stock-based compensation balance related to stock option awards was $7,300,632 and will be recognized over an estimated weighted-average amortization period of 1.4 years.

The aggregate intrinsic value in the tables above represents the total pretax intrinsic value, based on our closing stock price of $6.12 as of December 31, 2008, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date. The total number of in-the-money options exercisable as of December 31, 2008 was 2,478,804. The total intrinsic value of outstanding stock options as of December 31, 2008 was $9,362,869.

The total intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was $3,168,268, $2,634,426 and $1,104,117, respectively. The total cash received from employees as a result of employee stock option exercises during the years ended December 31, 2008, 2007 and 2006 was $5,291,229, $3,696,811 and $561,097, respectively. We settle employee stock option exercises with newly issued common shares. No tax benefits were realized by us in connection with these exercises during the year ended December 31, 2008 as we maintain net operating loss carryforwards and we have established a valuation allowance against the entire tax benefit as of December 31, 2008.

Valuation assumptions for stock options granted during the years ended December 31, 2008, 2007 and 2006

For stock options granted during the years ended December 31, 2008, 2007 and 2006, the majority vest according to the following schedule: 25% of the shares subject to the award vest one year after the date of grant, and the remaining 75% of the shares subject to the award vest in equal monthly installments thereafter over the next three years, until all such shares are vested and exercisable. Stock-based compensation calculated according to SFAS 123R is expensed over the vesting period of the individual options in accordance with FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option and Award Plans*. The fair value of stock options granted to our employees during the years ended December 31, 2008, 2007 and 2006 was estimated on the date of

4. Stock-Based Compensation Plans (Continued)

each grant using the Black-Scholes option pricing model using the following weighted-average assumptions:

	2008	2007	2006
Stock option plans:			
Expected dividend yield	0%	0%	0%
Expected stock price volatility	74%	80%	81%
Risk free interest rate	2.9%	4.7%	4.7%
Expected life (years)	5.0	4.3	3.9

We used an expected dividend yield of 0%, as we do not expect to pay dividends during the expected life of these awards. The expected stock price volatility is determined using our historical stock volatility over the period equal to the expected life of each award. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term equal to the expected life of each award. During 2006 through the first quarter of 2007, the expected life was determined by factoring the different vesting periods of each award in combination with our employees' expected exercise behavior. In June 2007, we concluded that our historical share option exercise experience would not provide a reasonable basis upon which to estimate expected term going forward, given our relative stage of development and changes in our business given the termination of the EFAPROXYN development program. Beginning in the second quarter of 2007, the expected life of the stock options was estimated using peer data of companies in the life science industry with similar equity plans. As required by SFAS 123R, stock-based compensation expense is recognized net of estimated pre-vesting forfeitures, which results in recognition of expense on options that are ultimately expected to vest over the expected option term. Forfeitures were estimated using actual historical forfeiture experience.

Restricted Stock

The following table summarizes activity and related information for our restricted stock awards:

	Number of Shares	Weighted Average Grant-Date Fair Value
Nonvested as of December 31, 2007	412,500	$3.89
Granted	10,000	7.49
Vested	(128,750)	3.74
Nonvested as of December 31, 2008	293,750	$4.07

During the years ended December 31, 2008, 2007 and 2006, we granted 10,000, 105,000 and 410,000 shares of restricted stock, respectively. The shares of restricted stock vest in four equal annual installments from the date of grant. The grant-date fair value of shares granted during the years ended December 31, 2008, 2007 and 2006 was $74,900, $638,400 and $1,286,300, respectively. The weighted-average grant-date fair value per share for restricted stock awards granted was based on the closing market price of the Company's common stock on the grant dates of the awards and was $7.49, $6.08 and $3.14 for the years ended December 31, 2008, 2007 and 2006, respectively. The total fair value of

4. Stock-Based Compensation Plans (Continued)

shares vested during the year ended December 31, 2008 and 2007 was $751,350 and $643,025, respectively. During the years ended December 31, 2008, 2007 and 2006, we recorded stock-based compensation related to restricted stock awards of $422,505, $689,754 and $502,514, respectively. As of December 31, 2008, the unrecorded stock-based compensation balance related to restricted stock awards was $329,333 and will be recognized over an estimated weighted-average amortization period of 1.3 years.

Employee Stock Purchase Plan

On February 28, 2001, our Board of Directors approved the Allos Therapeutics, Inc. 2001 Employee Stock Purchase Plan, or 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 to have up to 10% of their annual base earnings withheld to purchase shares of our common stock during each offering period. The purchase price of the common 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 22,828, 41,148 and 44,319 shares to employees in 2008, 2007 and 2006, respectively. There were 2,259,777 shares available for sale under the Purchase Plan as of December 31, 2008. The Purchase Plan will terminate on February 27, 2011. Stock-based compensation expense related to our Purchase Plan was $59,068, $61,484 and $35,964 for the years ended December 31, 2008, 2007 and 2006, respectively. As of December 31, 2008, there was no unrecorded deferred stock-based compensation balance related to the Purchase Plan. The weighted-average estimated grant date fair value of purchase awards under the Purchase Plan during the years ended December 31, 2008, 2007 and 2006 was $2.59, $1.42 and $0.96 per share, respectively.

The fair value of purchase awards granted to our employees during the years ended December 31, 2008, 2007 and 2006 was estimated using the Black-Scholes option pricing model using the following weighted-average assumptions:

	2008	2007	2006
Stock purchase plan:			
Expected dividend yield	0%	0%	0%
Expected stock price volatility	65%	55%	46%
Risk free interest rate	2.6%	4.9%	4.7%
Expected life (years)	0.5	0.9	1.0

5. Restructuring and Separation Costs

In January 2005, we executed agreements to sublease approximately three-quarters of the 12,708 square feet of excess space in our corporate offices located in Westminster, Colorado. The term of each sublease agreement was through the term of our office lease, or October 31, 2008. The total rental payments to us under the terms of the sublease agreements approximated $230,000. In the year ended December 31, 2005, we recorded a lease abandonment charge of $380,085 as our obligations under our primary lease were in excess of the sum of the actual and expected sublease rental payments for this excess space. As of December 31, 2008, there was no remaining accrued restructuring and separation costs relating to this lease abandonment charge.

In January 2006, Michael E. Hart notified our Board of Directors of his intent to resign from his positions as President, Chief Executive Officer and Chief Financial Officer of the Company once a successor Chief Executive Officer was appointed. On March 3, 2006, we entered into a separation agreement with Mr. Hart to provide certain incentives for his continued employment with the Company while we conducted our search for his successor. On March 9, 2006, we appointed Paul L. Berns as our President, Chief Executive Officer and a member of the Board of Directors and Mr. Hart resigned from his positions in accordance with the terms of the separation agreement. The separation agreement with Mr. Hart was amended on March 9, 2006 and on May 10, 2006, or as so amended, the Separation Agreement. We recorded separation costs of $645,666 during the year ended December 31, 2006 relating to our estimate of our total obligations under the Separation Agreement with Mr. Hart. During the years ended December 31, 2007 and 2006, we made payments to Mr. Hart under the Separation Agreement of $320,458 and $325,208, respectively. As of December 31, 2007, there was no remaining liability relating to the Separation Agreement with Mr. Hart.

6. Income Taxes

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*, or FIN 48, on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109 and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Based on our evaluation, we have concluded that there are no significant uncertain tax positions requiring recognition in our financial statements. Our evaluation was performed for the periods from December 31, 1993 through December 31, 2008, the tax periods which remain subject to examination by major tax jurisdictions as of December 31, 2008.

We may from time to time be assessed interest or penalties by major tax jurisdictions, although there have been no such assessments historically with material impact to our financial results. In the event we receive an assessment for interest and/or penalties, it would be classified in the financial statements as income tax expense.

6. Income Taxes (Continued)

The income tax benefit computed using our net loss and the federal statutory income tax rate differs from our actual income tax benefit of $0, primarily due to the following for the years ended December 31, 2008, 2007 and 2006:

	2008	2007	2006
Federal income tax benefit at 35%	$(18,105,470)	$(13,779,360)	$(10,574,400)
State income tax, net of federal benefit	(1,448,690)	974,838	(813,900)
Stock-based compensation	554,635	1,160,681	275,600
Research and development and orphan drug credits	(1,244,474)	(3,311,029)	(1,355,693)
Research and development and orphan drug credits to expire related to Section 382 limitation	—	5,880,410	—
Net operating losses to expire related to Section 382 limitation	—	23,086,377	—
Change in valuation allowance	20,208,260	(14,161,720)	12,496,693
Other	35,739	149,803	(28,300)
Benefit for income taxes	$ —	$ —	$ —

The components of our deferred tax assets are as follows, as of December 31:

	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	$ 64,470,656	$ 48,354,464
Amortization of intangibles	1,298,728	943,154
Research and development and orphan drug credit carryforwards	9,110,448	7,195,874
Stock-based compensation	4,736,475	2,989,285
Other	395,516	320,786
Total deferred tax assets	80,011,823	59,803,563
Valuation allowance	(80,011,823)	(59,803,563)
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, 2008, we had available approximately $174.8 million of net operating loss, or NOL, carryforwards, after taking into consideration NOLs expected to expire unused due to the limitations under Section 382 of the Internal Revenue Code, and which includes approximately $5.2 million of deductions related to stock-based compensation that are not realized as deferred tax assets until current taxes payable can be reduced. These NOL carryforwards will expire beginning in 2009. In addition, we had research and development credit and orphan drug credit carryforwards, after taking into consideration the Section 382 limitation, of $3.5 million and $5.6 million, respectively, as of December 31, 2008, to offset future regular and alternative tax expense. Since the Company's formation, it has raised capital through the issuance of capital stock on several occasions which,

6. Income Taxes (Continued)

combined with shareholders' subsequent disposition of those shares, has resulted in four changes of control in 1994, 1998, 2001 and 2005, as defined by Section 382. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% within a three-year period. As a result of the most recent ownership change in 2005, utilization of our NOLs generated prior to the latest change are subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change in control by the applicable long-term tax-exempt rate resulting in an annual limitation amount of approximately $2.2 million. Additionally, we have a recognized built-in gain that will increase the annual limitation by $3.3 million for each of the five years after the 2005 ownership change. Any unused annual limitation may be carried over to later years, and the amount of the limitation may, under certain circumstances, be subject to adjustment if the fair value of the Company's net assets are determined to be below or in excess of the tax basis of such assets at the time of the ownership change, and such unrealized loss or gain is recognized during the five-year period after the ownership change. Subsequent ownership changes, as defined in Section 382, could further limit the amount of our NOL carryforwards and research and development credits that can be utilized annually to offset future taxable income.

7. Employee Benefit Plan

We maintain a defined contribution plan covering substantially all employees under Section 401(k) of the Internal Revenue Code. From January 1, 1999 through December 31, 2006, we provided a 50% match of employees' contributions up to $2,000 per employee per year. Effective January 1, 2007, we provided a 50% match of employees' contributions up to $5,000 per employee per year. We made total contributions of $246,112, $241,227 and $105,675 during the years ended December 31, 2008, 2007 and 2006, respectively. Company contributions are fully vested after four years of employment.

8. Commitments and Contingencies

Lease Commitments

We lease offices under agreements that expire at various dates through 2012, and which contain clauses for renewal at our option for one additional three year term. Total rent expense for the years ended December 31, 2008, 2007 and 2006 and the cumulative period from inception through December 31, 2008 was $714,594, $686,606, $586,010 and $5,778,377, respectively.

The aggregate future minimum rental commitments as of December 31, 2008, for non-cancelable operating leases with initial or remaining terms in excess of one year are as follows:

Year Ending December 31:	
2009	$ 791,713
2010	850,712
2011	788,769
2012	46,048
Total	$2,477,242

8. Commitments and Contingencies (Continued)

Royalty and License Fee Commitments

In December 2002, we entered into a license agreement with Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute, as amended, under which we obtained exclusive worldwide rights to a portfolio of patents and patent applications related to pralatrexate (PDX) and its uses. Under the terms of the agreement, we paid an up-front license fee of $2.0 million upon execution of the agreement and are also required to make certain additional cash payments based upon the achievement of certain clinical development or regulatory milestones or the passage of certain time periods. To date, we have made aggregate milestone payments of $2.5 million based on the passage of time. In the future, we could make an aggregate milestone payment of $500,000 upon the earlier of achievement of a clinical development milestone or the passage of certain time periods, or the Clinical Milestone, and up to $10.3 million upon achievement of certain regulatory milestones, or the Regulatory Milestones, including regulatory approval to market pralatrexate in the United States or Europe. The last scheduled payment towards the Clinical Milestone of $500,000 is currently due on December 23, 2009. We intend to submit an NDA for pralatrexate for the treatment of patients with relapsed or refractory PTCL in the first half of 2009. If the U.S. Food and Drug Administration, or FDA, accepts our NDA for review and if we obtain FDA approval to market pralatrexate, we will be obligated to make payments of $1,500,000 and $5,300,000, respectively, which represent a portion of the Regulatory Milestones. The up-front license fee and all milestone payments under the agreement have been or will be recorded to research and development expense when incurred. Under the terms of the agreement, we are required to fund all development programs and will have sole responsibility for all commercialization activities. In addition, we will pay the licensors 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.

In December 2004, we entered into an agreement with the University of Colorado Health Sciences Center, the University of Salford and Cancer Research Technology, or CRT, 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 paid an up-front license fee of $190,500 upon execution of the agreement and are also required to make certain additional cash payments based upon the achievement of certain clinical development, regulatory and commercialization milestones. We could make aggregate milestone payments of up to $9.2 million upon the achievement of the clinical development, regulatory and commercialization milestones set forth in the agreement. The up-front license fee and all milestone payments under the agreement, as well as the one-time data option fee discussed below, have been recorded to research and development expense. Under the terms of the agreement and related data option agreement, we paid the licensors a one-time data option fee of $360,000 in 2007 for an exclusive license to the results of a Phase 1 study sponsored by Cancer Research UK, CRT's parent institution. This Phase 1 study was completed in 2007 and, under the terms of the agreement, we have since assumed responsibility for all future development costs and activities and have sole responsibility for all commercialization activities. In addition, we will pay the licensors 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. We are currently in the process of closing our Phase 1 study of RH1 in patients with advanced solid tumors or NHL and determining our future development plans, if any, for RH1.

8. Commitments and Contingencies (Continued)

Contingencies

We were named as a defendant in a purported securities class action lawsuit filed in May 2004 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. In an opinion dated October 20, 2005, the U.S. District Court for the District of Colorado concluded that the plaintiffs' complaint failed to meet the legal requirements applicable to its alleged claims and dismissed the lawsuit. On November 20, 2005, the plaintiffs appealed the District Court's decision to the U.S. Court of Appeals for the Tenth Circuit. On February 6, 2008, the parties signed a stipulation of settlement, settling the case for $2,000,000. The settlement was subject to various conditions, including without limitation approval of the District Court. On January 29, 2009, the District Court issued its Order and Final Judgment approving the settlement, including the releases of the defendants for which the settlement provided. Neither we nor our former officer, who was also named as a defendant, admitted any liability in connection with the settlement. The amount of the settlement in excess of our deductible was covered by our insurance carrier. In the event the District Court's approval of the settlement is appealed and the settlement does not become final, we would intend to vigorously defend against the plaintiffs' appeal. If the Court of Appeals then were to reverse the District Court's decision and we were not successful in our defense against the plaintiffs' 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 were successful, the litigation could result in substantial costs and divert management's attention and resources, which could adversely affect our business. As of December 31, 2008, we have recorded $2,000,000 in accrued litigation settlement costs, which represents our best estimate of the potential gross amount of the settlement costs to be paid to the plaintiffs, and $2,000,000 in prepaid expenses and other assets, which represents the approximately $235,000 of remaining deductible under our insurance policy paid by us and $1,765,000 paid by our insurance carrier into the settlement fund escrow in September 2008. A claims administrator appointed by the parties will administer the distribution of the settlement fund to authorized claimants in 2009.

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 or the use of our product candidates. 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. The estimated fair value of the indemnification provisions of these agreements is minimal as of December 31, 2008, and accordingly, we have no corresponding liabilities recorded as of December 31, 2008.

9. Related Party Transactions

Dr. Donald Abraham

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. Starting in June 2004, this agreement was renewed each year for successive one-year terms through June 30, 2007. The agreement was not renewed after June 30, 2007. For the years ended December 31, 2008, 2007, 2006 and the cumulative period from inception through December 31, 2008, we paid Dr. Abraham consulting fees of $0, $30,000, $60,000 and $288,000, respectively.

Dr. Stephen Hoffman

Dr. Stephen J. Hoffman has served as a member of our Board of Directors since 1994 and as our Chairman of the Board since December 2001. He also served as our President and Chief Executive Officer from July 1994 to December 2001. On January 12, 2000, we granted Dr. Hoffman a stock option to purchase 328,971 shares of common stock at $2.42 per share, or the 1995 Plan Option, under the terms of our 1995 Stock Option Plan. Effective February 28, 2003, we entered into a two-year consulting agreement, or the Consulting Agreement, with Dr. Hoffman and terminated the employment agreement previously entered into with him in January 2001.

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. According to the Consulting Agreement, Dr. Hoffman's then-outstanding 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 FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, and we recorded a recovery of non-cash stock-based compensation of $2,488 and $170,118 during 2004 and 2005 and stock-based compensation of $173,963 during 2003, respectively. Stock options granted to Dr. Hoffman in 2007, 2006 and 2005 related to Board of Director services.

The Consulting Agreement expired in accordance with its terms on February 28, 2005. On May 18, 2005, in recognition of Dr. Hoffman's efforts and services on behalf of the Company and as an incentive for Dr. Hoffman's continued service as our Chairman of the Board, our Board of Directors approved an amendment to the 1995 Plan Option to extend the exercise period for such option until the earlier of: (i) January 12, 2010 (the expiration date of such option), or (ii) three months after the date that Dr. Hoffman ceases to serve as a director of the Company. Prior to such amendment, the 1995 Plan Option would have expired on May 28, 2005, or three months after the expiration of Dr. Hoffman's Consulting Agreement with the Company. Except as set forth above, the 1995 Plan Option remains in full force and effect in accordance with its original terms. In conjunction with this amendment to the 1995 Plan Option, we recorded non-cash stock-based compensation expense of $462,000 during the year ended December 31, 2005. This expense is reflected in marketing, general and administrative expenses in our Statement of Operations.

9. Related Party Transactions (Continued)

Dr. Marvin Jaffe, M.D.

Dr. Marvin E. Jaffe served as a member of our Board of Directors from 1994 to May 10, 2006. On March 11, 2006, Dr. Jaffe tendered his resignation as a director of the Company effective immediately prior to our 2006 annual meeting of stockholders and notified the Board that he did not intend to stand for reelection. As a result of Dr. Jaffe's resignation as a director, on May 10, 2006, we entered into a consulting agreement with Dr. Jaffe in order to allow us to retain the benefit of Dr. Jaffe's knowledge and expertise regarding the Company's business and the potential clinical development and commercialization strategies for our products (the "Jaffe Consulting Agreement"). Pursuant to the Jaffe Consulting Agreement, Dr. Jaffe agreed to provide up to 10 hours of consulting service per month as and when requested from time to time by the Company. In connection with the performance of his consulting services, we granted Dr. Jaffe a nonqualified stock option under the Company's 2000 Stock Incentive Compensation Plan to purchase 20,000 shares of common stock at an exercise price equal to $2.94 per share, which equals the closing sale price of a share of our common stock on the effective date of the Jaffe Consulting Agreement (as reported by the Nasdaq National Market). This option is subject to the terms and conditions of the 2000 Stock Incentive Compensation Plan, as further provided in our 2008 Equity Incentive Plan, and vests in eighteen equal monthly installments commencing July 1, 2006. Dr. Jaffe is not entitled to any additional compensation or benefits in connection with the performance of his consulting services. The Jaffe Consulting Agreement terminated on December 31, 2007.

Michael E. Hart

Pursuant to the Separation Agreement with Mr. Hart (as discussed in Note 5) and as a result of Mr. Hart's resignation as a director, on May 10, 2006, we entered into a consulting agreement with Mr. Hart in order to allow us to retain the benefit of Mr. Hart's historical knowledge regarding the Company's operations and corporate development strategies, or the Hart Consulting Agreement. Pursuant to the Hart Consulting Agreement, Mr. Hart agreed to provide an average of at least 10 hours of consulting services per month as and when requested from time to time by the Company. Mr. Hart is not entitled to any compensation or benefits in connection with the performance of his consulting services, except for those payments and benefits being provided to him under the Separation Agreement. The Hart Consulting Agreement terminated on December 31, 2007.

10. Quarterly Information (Unaudited)

The results of operations on a quarterly basis for the years ended December 31, 2008 and 2007 were as follows:

	March 31, 2008	June 30, 2008	Sept. 30, 2008	Dec. 31, 2008	March 31, 2007	June 30, 2007	Sept. 30, 2007	Dec. 31, 2007
Operating expenses:								
Research and development	$ 5,973,612	$ 5,403,924	$ 6,360,950	$ 6,109,566	$ 3,289,428	$ 4,360,787	$ 4,394,726	$ 5,399,379
Clinical manufacturing	1,586,558	1,485,052	1,727,630	1,947,906	1,147,304	1,384,804	1,506,255	1,509,048
Marketing, general and administrative	5,011,364	5,438,764	5,326,357	7,266,943	4,747,596	5,514,923	4,240,704	5,168,791
Total operating expenses	12,571,534	12,327,740	13,414,937	15,324,415	9,184,328	11,260,514	10,141,685	12,077,218
Loss from operations	(12,571,534)	(12,327,740)	(13,414,937)	(15,324,415)	(9,184,328)	(11,260,514)	(10,141,685)	(12,077,218)
Interest and other income, net	564,935	504,025	254,416	585,337	773,464	909,140	843,542	768,000
Net loss	$(12,006,599)	$(11,823,715)	$(13,160,521)	$(14,739,078)	$(8,410,864)	$(10,351,374)	$ (9,298,143)	$(11,309,218)
Net loss per share: basic and diluted	$ (0.18)	$ (0.16)	$ (0.16)	$ (0.18)	$ (0.14)	$ (0.16)	$ (0.14)	$ (0.17)
Weighted average shares: basic and diluted	67,266,819	72,382,487	80,752,024	80,894,796	62,151,400	65,645,678	66,042,023	66,855,484

(This page has been left blank intentionally.)

(This page has been left blank intentionally.)

(This page has been left blank intentionally.)

CORPORATE INFORMATION

Board of Directors

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

Paul L. Berns
President and Chief Executive Officer

Michael D. Casey
Pharmaceutical Industry Consultant

Stewart Hen
Managing Director, Warburg Pincus LLC

Jeffrey R. Latts, M.D.
Pharmaceutical Industry Consultant

Jonathan S. Leff
Managing Director, Warburg Pincus LLC

Timothy P. Lynch
General Partner, Stonepine Capital

David M. Stout
Pharmaceutical Industry Consultant

Executive Management

Paul L. Berns
President and Chief Executive Officer

Bruce K. Bennett
Vice President, Pharmaceutical Operations

Pablo J. Cagnoni, M.D.
Senior Vice President, Chief Medical Officer

James V. Caruso
Executive Vice President, Chief Commercial Officer

David C. Clark
Vice President, Finance

Marc H. Graboyes
Senior Vice President, General Counsel

Corporate Headquarters

Allos Therapeutics, Inc.
11080 CirclePoint Rd., Suite 200
Westminster, CO 80020
303.426.6262
303.426.4731 Fax

Website

www.allos.com

Independent Registered Public Accounting Firm

PricewaterhouseCoopers LLP
1670 Broadway, Suite 1000
Denver, CO 80202

General Counsel

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

Transfer Agent and Registrar

Communications concerning stock transfer requirements, lost certificates and changes of address should be directed to the Transfer Agent:

BNY Mellon Shareowner Services
480 Washington Blvd.
Jersey City, NJ 07310-1900
1.800.851.9677
www.bnymellon.com/shareowner/isd

Stock Listing

Our common stock is listed on the NASDAQ Global Market under the symbol ALTH.

Annual Meeting

The 2009 annual meeting of stockholders will be held at 8:00 a.m. on June 23, 2009 at the following location:

Westin Westminster Hotel
10600 Westminster Blvd.
Westminster, CO 80020

Stockholder Inquiries

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

Monique Greer
Vice President, Investor Relations
11080 CirclePoint Rd., Suite 200
Westminster, CO 80020
303.426.6262
investorrelations@allos.com

Safe Harbor Statement

This report contains forward-looking statements regarding the potential safety and efficacy of our product candidates; our projected timelines for the initiation of new trials and announcement of results from our ongoing trials; the potential for the results of our Phase 2 PROPEL trial to support marketing approval of PDX; other statements regarding our future product development and regulatory strategies, including our intent to develop or seek regulatory approval for our product candidates in specific indications; and other statements that are other than statements of historical facts. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "intends," "plans," anticipates," "believes," "estimates," "predicts," "projects," "potential," "continue," and other similar terminology or the negative of these terms, but their absence does not mean that a particular statement is not forward-looking. Such forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those anticipated by the forward-looking statements. These risks and uncertainties include, among others: that the design of or data collected from the PROPEL trial may not be adequate to demonstrate the safety and efficacy of pralatrexate for the treatment of patients with relapsed or refractory PTCL, or otherwise be sufficient to support FDA approval; that the Company's New Drug Application may not be accepted for priority review or at all by the FDA; that the FDA may disagree with the Company's interpretations of data from preclinical studies and clinical trials involving pralatrexate, including the PROPEL trial, or otherwise determine such data are not sufficient to support approval; that the Company may experience difficulties or delays in the initiation, progress or completion of its clinical trials, whether caused by competition, adverse events, investigative site initiation rates, patient enrollment rates, regulatory issues or other factors; and that the Company may lack the financial resources and access to capital to support its future operations, including the potential commercialization of pralatrexate if approved for marketing. Additional information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, and in the Company's other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this report. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this report, except as required by law.

ALLOS THERAPEUTICS, INC.

www.allos.com

11080 CirclePoint Rd.
Suite 200
Westminster, CO 80020
303.426.6262