



# 2008 Annual Report

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#### FORM 10-K

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and (2) has been subject to such filing rec	juirements for the past 90 day	s.	
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Indicate by check mark if disclosure of de	elinquent filers pursuant to Ite	em 405 of Regulation S-K is	s not contained herein, and will not be
contained, to the best of registrant's know	vledge, in definitive proxy or :	information statements inc	corporated by reference in Part III of
this Form 10-K or any amendment to this	Form 10-K. [ ]		•
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The aggregate market value of the registrant's common stock held by nonaffiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the price at which the common stock was last sold, as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$163 million.

Yes [ ] No [X]

As of March 6, 2009, the registrant had 86,357,681 shares of common stock outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Definitive Proxy Statement for the 2009 Annual Meeting of Stockholders.

#### TABLE OF CONTENTS

PAKII			
	Item 1: Item 1A: Item 1B: Item 2: Item 3: Item 4:	Business Risk Factors Unresolved Staff Comments Properties Legal Proceedings Submission of Matters to a Vote of Security Holders	1 16 28 28 28 28
PART II			
	Item 5:	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	29
	Item 6:	Selected Financial Data	32
	Item 7:		0.0
	Item 1: Business Item 1A: Risk Factors Item 1B: Unresolved Staff Comments Item 2: Properties Item 3: Legal Proceedings Item 4: Submission of Matters to a Vote of Security Holders  PART II  Item 5: Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Item 6: Selected Financial Data Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations Item 7A: Quantitative and Qualitative Disclosures About Market Risk Item 8: Financial Statements and Supplementary Data Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure Item 9A: Controls and Procedures Item 9B: Other Information  PART III  Item 10: Directors, Executive Officers and Corporate Governance Item 11: Executive Compensation Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters Item 13: Certain Relationships and Related Transactions, and Director Independence Item 14: Principal Accounting Fees and Services		33
			46 50
		Financial Statements and Supplementary Data	30
	Item 9:	Changes in and Disagreements with Accountants on	<b>7</b> 1
	T: 0.4		71
			71
PART III	item 75.		
IAKIM			
	Item 10:	Directors, Executive Officers and Corporate Governance	72
	Item 11:		72
	Item 12:		<b>-</b>
			72
	Item 13:		72
	- a		7.
	Item 14:	Principal Accounting Fees and Services	7.
PART IV			
	Item-15:	Exhibits, Financial Statement Schedules	7

#### PART I

#### **ITEM 1: BUSINESS**

The following Business Section contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors (see Part I, Item 1A: Risk Factors). Unless the content requires otherwise, references to "ARIAD," "we," "our," and "us," in this Annual Report on Form 10-K refer to ARIAD Pharmaceuticals, Inc. and our subsidiaries.

#### Overview

#### Our Business and Strategy

ARIAD's vision is to transform the lives of cancer patients with breakthrough medicines. Our mission is to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest and most urgent unmet medical need – aggressive cancers where current therapies are inadequate. Our goal is to build a fully integrated oncology company focused on novel, molecularly targeted therapies to treat solid tumors and hematologic cancers, as well as the spread of primary tumors to distant sites. Our business strategy is to:

- build a fully integrated oncology company and become a leader in the discovery, development and commercialization of molecularly targeted oncology therapies;
- broadly develop our lead oncology product candidates and build a pipeline of innovative follow-on product candidates;
- enter into partnerships with major pharmaceutical or biotechnology companies, after obtaining
  definitive clinical data, to assist in developing our cancer product candidates and commercializing
  them in selected markets;
- license our NF-κB and ARGENT cell-signaling regulation technologies to pharmaceutical and biotechnology companies; and
- leverage the market potential of our product candidates by licensing them to other companies for development and commercialization in potential non-oncology indications or non-core applications.

#### **Our Product Candidates**

Our lead cancer product candidate, deforolimus (previously known as AP23573), is an internally discovered, potent inhibitor of the protein mTOR, a "master switch" in cancer cells. Blocking mTOR creates a starvation-like effect in cancer cells by interfering with cell growth, division, metabolism and angiogenesis.

We are developing deforolimus in partnership with Merck & Co., Inc., or Merck, under a collaboration agreement signed in July 2007. The collaboration agreement provides that we together with Merck will conduct a broad-based development program in multiple potential indications. The collaboration agreement establishes responsibilities for development, manufacturing, promotion, distribution and sales of the product, governance of the collaboration, termination provisions and other matters.

The collaboration agreement provides for (i) an up-front payment of \$75 million which was paid to us in July 2007, (ii) sharing of the costs of development, (iii) up to \$652 million in milestone payments based on successful development of and achievement of specific sales thresholds related to deforolimus, and (iv) the availability of up to \$200 million of repayable advances to fund ongoing development upon obtaining regulatory approval to market deforolimus. The collaboration agreement also provides for profit-sharing

and royalties upon successful commercialization of deforolimus. See "Our Licenses to Third Parties" under this Part I for a detailed description of our collaboration agreement with Merck.

Pursuant to a global development plan established by us and Merck, we are developing deforolimus in multiple potential cancer indications, both as a single agent and in combination with various targeted agents. In 2007, we initiated our first Phase 3 clinical trial of oral deforolimus in patients with metastatic soft-tissue and bone sarcomas and, in 2008, we and Merck initiated Phase 2 clinical trials of oral deforolimus in patients with endometrial, breast and prostate cancers, and Phase 1 studies of deforolimus in combination with other agents, all as part of our global development plan.

Deforolimus is also being developed pursuant to license agreements with medical device companies for use on drug-eluting stents to prevent restenosis, or reblockage, of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. We have entered into two such license agreements to date, one with Medinol Ltd., or Medinol, and another with ICON Medical Corp., or ICON, and have retained the right to enter into one additional non-exclusive agreement in this area.

Our second product candidate, AP24534, is a novel multi-targeted kinase inhibitor that we believe has broad potential applications in cancer and is wholly owned by us. Kinases are a large family of cell-signaling proteins that control many aspects of cell behavior, and are often inappropriately activated in cancer cells. In preclinical studies, AP24534 demonstrated potent inhibition of Bcr-Abl, a kinase that causes chronic myeloid leukemia, or CML, as well as mutants of this kinase, including the T315I mutant, that is resistant to all of the currently marketed therapies for CML. In preclinical studies, AP24534 was also shown to inhibit Flt3, a kinase involved in acute myeloid leukemia, or AML, as well as kinases that control angiogenesis, or new blood vessel formation, a process important in the progression of multiple solid tumors. AP24534 has undergone extensive preclinical testing, including efficacy and safety assessment studies, which we believe indicate that it should be well tolerated at anticipated therapeutic dose levels in cancer patients. In 2008, we initiated a Phase 1 clinical trial of AP24534 in patients with refractory CML, AML and other hematological malignancies.

We also have a focused drug discovery program centered on small-molecule therapies, molecularly targeted to cell-signaling pathways implicated in cancer. Our drug discovery program builds on our expertise in cell signaling, cancer biology, structure-based drug design and computational chemistry in designing and characterizing small-molecule drugs, such as deforolimus and AP24534, to treat disease. In 2009, we plan to initiate preclinical studies of our third internally discovered drug candidate, an anaplastic lymphoma kinase, or ALK, inhibitor. We believe this product candidate has the potential to regulate multiple cancer pathways and to change the treatment of patients with various cancers, including non-small cell lung cancer, lymphoma and neuroblastoma.

See the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K for a description of the risks related to our business and our clinical and preclinical programs.

#### Our Technologies

We are the exclusive licensee of a family of patents, three in the U.S. and one in Europe, including a pioneering U.S. patent covering methods of treating human disease by regulating NF-κB cell-signaling activity, hereinafter referred to as the '516 Patent, awarded to a team of inventors from The Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology and Harvard University. NF-κB is a protein that can be generally thought of as a "biological switch" that can be turned off using these treatment methods to treat disorders such as inflammation, cancer, sepsis and osteoporosis. We permit broad use of our NF-κB intellectual property, at no cost, by investigators at academic and not-for-profit institutions to conduct non-commercial research. Our goal is to license our NF-κB technology to pharmaceutical and biotechnology companies that are conducting research to discover and develop drugs that modulate NF-κB cell signaling and/or that are marketing such drugs. We have entered into two license agreements for use of our NF-κB cell-signaling technology for research and development purposes. However, the '516 Patent is the subject of two outstanding lawsuits and a proceeding before

the United States Patent and Trademark Office, or PTO. See Part I, Item 3 entitled "Legal Proceedings" and Part I, Item IA entitled "Risk Factors" of this Annual Report on Form 10-K for a description of the status of these proceedings and related risks.

We have also developed a proprietary portfolio of cell-signaling regulation technologies, our ARGENT technology, to control intracellular processes with small molecules, which may be useful in the development of therapeutic vaccines and gene and cell therapy products and which provide versatile tools for applications in cell biology, functional genomics and drug discovery research. We distribute our ARGENT technologies at no cost to academic investigators in the form of our Regulation Kits to use in various research applications in an academic setting. In addition, we have licensed the ARGENT technology to several pharmaceutical and biotechnology companies for research and development and/or commercial purposes.

#### **Our Lead Development Programs**

#### Potential Oncology Indications of our mTOR Inhibitor, Deforolimus

Human cells, both healthy and malignant, share an elaborate system of molecular pathways that carry signals back and forth from the cell surface to the nucleus and within the cell. Such signaling is essential to cell functioning and viability. When disrupted or over-stimulated, such pathways may trigger diseases such as cancer. For example, growth and proliferation of cancer cells are dependent on signals from external growth factors, as well as signals indicating the availability of sufficient nutrients and blood supply. These signals are conveyed along well-defined pathways, several of which are regulated by the protein called the mammalian target of rapamycin, or mTOR.

Our lead cancer product candidate, deforolimus, is an internally discovered, potent mTOR inhibitor. The protein, mTOR, serves as a "master switch" and has a central function in cancer cells. Blocking mTOR creates a starvation-like effect in cancer cells by interfering with cell growth, division, metabolism and angiogenesis.

As part of our global clinical development plan and registration strategy, we have studied deforolimus as a single agent in multiple Phase 1 and Phase 2 clinical trials in the U.S. and Europe in patients with solid tumors, including sarcomas, hormone refractory prostate cancer, endometrial cancer, brain cancer and certain leukemias and lymphomas. We have also conducted several multi-center Phase 1b trials of deforolimus in combination with other anti-cancer therapies. These trials focused primarily on patients with various types of solid tumors. Intravenous and oral tablet formulations of deforolimus have been studied in these trials.

In clinical trials to date, deforolimus has been well tolerated at the doses administered, and adverse events were generally mild to moderate in severity and manageable. The most common treatment-related adverse events experienced by patients in the trials were mouth sores, rash, fatigue, anemia, nausea and lipid abnormalities.

We are developing deforolimus in partnership with Merck pursuant to our collaboration agreement signed in July 2007. We have established and are implementing with Merck a global development plan which provides for the development of deforolimus in multiple potential cancer indications, including sarcomas, breast, prostate, non-small cell lung and endometrial cancers. Deforolimus is being studied as a single agent and in combination with various targeted agents. The global development plan encompasses multiple corporate sponsored clinical trials of deforolimus, the majority of which will be Phase 2 and Phase 3 trials of oral deforolimus, supplemented by investigator and cooperative group-led trials, subject to review of clinical data by the companies. As part of the plan, deforolimus is being studied in countries throughout the world, including Japan.

Our most advanced potential indication and initial registration path for deforolimus is sarcomas. In a multi-center Phase 2 trial of 212 patients with advanced sarcomas, at least 90 percent of whom had

progressive disease, deforolimus demonstrated efficacy and was well tolerated. The primary endpoint of the trial – evidenced by clinical-benefit response, or CBR, rates – was achieved in the three most prevalent types of sarcoma (i.e., bone sarcoma, leiomyosarcoma and liposarcoma). Treatment with deforolimus more than doubled progression-free survival when compared to historical control data published by the European Organization for Research and Treatment of Cancer, or EORTC.

In September 2007, we initiated our first Phase 3 clinical trial of deforolimus in patients with metastatic soft-tissue and bone sarcomas. The SUCCEED (Sarcoma Multi-Center Clinical Evaluation of the Efficacy of Deforolimus) trial is a randomized, double-blind, placebo-controlled study designed to assess the impact of oral deforolimus on progression-free survival, or PFS, the primary endpoint of the trial, and several secondary endpoints, in metastatic soft-tissue and bone sarcoma patients who have achieved a favorable response to chemotherapy. Continued treatment with traditional chemotherapeutic drugs has not been established to provide additional clinical benefit after such a response. Thus, absent new alternatives, physicians generally either continue potentially toxic chemotherapy until the side effects become unacceptable or, more commonly, monitor patients carefully for disease progression, or tumor growth, prior to initiating another line of chemotherapy. Therefore, the placebo arm represents a current standard of care for patients in this clinical setting.

The SUCCEED trial is designed to evaluate approximately 650 patients who will be randomized one-to-one to oral deforolimus or placebo at over 125 sites worldwide. The trial is 90 percent powered to detect a 33 percent increase in median PFS comparing the deforolimus arm with the placebo arm. We are planning two interim efficacy analyses. We have agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment, or SPA, for the SUCCEED trial. The European Medicines Agency, or EMEA, has provided protocol advice consistent with that of the FDA regarding the trial design as part of its Protocol Assistance program. We expect to complete enrollment of patients in this Phase 3 clinical trial in late 2009.

The FDA and the EMEA have designated deforolimus as an orphan drug for treatment of soft-tissue and bone sarcomas. The FDA has also designated deforolimus as a fast-track product for the same potential indication.

In addition to the ongoing conduct of the SUCCEED clinical trial, in 2008, pursuant to the global development plan established with Merck, we and Merck have initiated multiple clinical trials, including Phase 2 trials in endometrial, breast and prostate cancers, and Phase 1 clinical trials of deforolimus in combination with other agents. The global development plan also includes a focused biomarker research program that exploits the companies' expertise in cell-signaling, mTOR biology and diverse state-of-the-art molecular profiling technologies. We believe this program will help characterize and identify rational combinations with deforolimus, identify responder profiles and inform decisions in alignment with the development plan.

#### Potential Cardiovascular Indications of our mTOR Inhibitor, Deforolimus

As an mTOR inhibitor, deforolimus has also been shown to potently block the growth, proliferation and migration of vascular smooth muscle cells, the primary cause of narrowing and blockage of injured vessels and is an analog of sirolimus, another mTOR inhibitor that has been approved for use in drugeluting stents. Recent clinical studies have found lower reblockage rates in patients treated with stents that deliver small-molecule drugs, such as sirolimus or paclitaxel, a cytotoxic agent, locally to the site of vascular injury. Such stents have become the standard of care for patients undergoing interventional procedures to open narrowed coronary arteries.

We have entered into license agreements with Medinol, a leading innovator in stent technology, in January 2005, and with ICON, an emerging medical device company, in October 2007, to develop and commercialize stents and other medical devices to deliver deforolimus to prevent restenosis, or reblockage, of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. We have retained the right to enter into one additional non-exclusive license

agreement, in addition to the licenses granted to ICON and Medinol, to develop and commercialize medical devices delivering deforolimus for use in vascular disease.

#### Additional Potential Non-Oncology Indications of our mTOR Inhibitor, Deforolimus

We believe that inhibition of the mTOR pathway may be useful for additional indications beyond oncology and drug-delivery stents, and we are evaluating with Merck such indications as part of a broader potential development plan for deforolimus. Such a development plan for potential non-oncology indications would be subject to a separate negotiation of terms specific to such plans pursuant to our collaboration agreement with Merck.

#### Our Multi-Targeted Kinase Inhibitor, AP24534

Our second oncology product candidate, AP24534, is an internally discovered novel oral multi-targeted kinase inhibitor that we believe has broad potential applications in cancer, including various forms of leukemia, a blood-based cancer. In preclinical studies, AP24534 was shown to be a potent inhibitor of Bcr-Abl, a target associated with drug-resistant chronic myeloid leukemia, or CML. Preclinical studies showed that AP24534 demonstrated efficacy and oral dosing flexibility in animal models of CML, including forms of CML caused by clinically relevant variants of the target protein, Bcr-Abl. Specifically, AP24534 potently inhibited a specific mutant, T315I, which is resistant to all currently marketed drugs. Additional preclinical studies demonstrated that AP24534 also inhibits Flt3, a target associated with acute myeloid leukemia, or AML.

In addition, AP24534 has demonstrated in preclinical studies potent inhibition of additional targets that control the process of angiogenesis, or blood vessel growth, including the receptors for vascular endothelial growth factors, or VEGFRs, fibroblast growth factors, or FGFRs, and angiopoietin, or Tie2. Inhibiting angiogenesis is a clinically validated approach to treating multiple solid tumors. Based on AP24534's differentiated profile, we believe these findings support the broad potential of the drug not only in drug-resistant CML, but also in other hematological cancers, such as AML, and various solid tumors.

We completed extensive preclinical studies of AP24534, including efficacy and safety assessment studies, which we believe indicate that the drug candidate should be well tolerated at anticipated therapeutic dose levels in cancer patients. In 2008, we initiated a Phase 1 clinical trial of AP24534 in patients with drug-resistant and refractory CML and other hematologic malignancies. This multi-center, sequential dose-escalation study in approximately 50 patients is designed to determine the safety and tolerability of AP24534, as well as its pharmacokinetics (the behavior of AP24534 in patients) and its pharmacodynamics (the effects of AP24534 on patients' cells). Clinical proof of concept data on AP24534 is expected from this study in the second half of 2009.

#### **Our Discovery Programs**

Our research and development programs are focused on discovering and developing small-molecule drugs that regulate cell signaling. Many of the critical functions of cells, such as cell growth, differentiation, gene transcription, metabolism, motility and survival, are dependent on signals carried back and forth from the cell surface to the nucleus and within the cell through a system of molecular pathways. When disrupted or over-stimulated, such pathways may trigger diseases such as cancer. From our inception, our research has focused on exploring cell-signaling pathways, identifying their role in specific diseases, and discovering drug candidates to treat those diseases by interfering with the aberrant signaling pathways of cells. The specific cellular proteins blocked by our product candidates have been well characterized and validated as targets. Product candidates like AP24534 and our ALK inhibitor have been developed in-house through the integrated use of structure-based drug design and computational chemistry, and their targets have been validated with techniques such as functional genomics, proteomics, and chemical genetics.

We have a focused drug discovery program centered on small-molecule therapies, molecularly targeted to cell-signaling pathways implicated in cancer. Our drug discovery program builds on our expertise in cell signaling, cancer biology, structure-based drug design and computational chemistry in designing and characterizing small-molecule drugs, such as deforolimus, AP24534 and our ALK inhibitor, to treat disease.

#### **Our Proprietary Technologies**

#### NF-kB Cell-signaling Technology

Dr. David Baltimore, former director of the Whitehead Institute for Biomedical Research, Dr. Phillip Sharp of the Massachusetts Institute of Technology, and Dr. Thomas Maniatis of Harvard University, together with a team of scientists in their respective laboratories, discovered a family of genes that encode proteins they called NF-κB and I-κB, its inhibitor; the critical role played by NF-κB cell signaling in regulating cellular processes involved in various difficult-to-treat diseases; methods to identify compounds to regulate NF-κB cell-signaling activity; and methods of treating disease by inhibiting NF-κB activity. NF-κB can be generally thought of as a "biological switch" that can be turned off using these methods to treat disorders, such as inflammation, cancer, sepsis and osteoporosis.

We have an exclusive license from these academic institutions to pioneering technology and patents related to methods of treating human disease by regulating NF-κB cell-signaling activity, and the discovery and development of drugs to regulate NF-κB cell-signaling activity. We have a program to license this technology and these treatment methods to pharmaceutical and biotechnology companies that are conducting research to discover and develop drugs that modulate NF-κB cell-signaling and/or that are marketing such drugs. One of the NF-κB patents is the subject of reexamination proceedings in the U.S. Patent and Trademark Office, or PTO, a patent infringement lawsuit filed in 2002 by us and the academic institutions against Eli Lilly and Company, or Lilly, and a lawsuit filed in April 2006 against us by Amgen Inc., or Amgen, and certain affiliated entities. See Part I, Item 3 entitled "Legal Proceedings" of this Annual Report on Form 10-K for a description of the status of these proceedings.

#### ARGENT Cell-signaling Regulation Technology

Our proprietary portfolio of cell-signaling regulation technologies includes the ARGENT signaling and transcription technologies. Our ARGENT technologies allow intracellular processes to be controlled with small molecules, which may be useful in the development of therapeutic vaccines and gene and cell therapy products, and which provide versatile tools for applications in cell biology, functional genomics and drug-discovery research, including three-hybrid screening approaches to discover and characterize targets and lead molecules. To maximize their use by the scientific community, we distribute our technologies at no cost to academic investigators in the form of our Regulation Kits. As of February 28, 2009, we have entered into more than 1,550 material transfer agreements with more than 550 different institutions in 35 countries for the use of this technology in diverse areas of research, and more than 300 scientific papers describing their use have been published. In addition, we have licensed the ARGENT technology to several pharmaceutical and biotechnology companies for research and development and/or commercial purposes.

#### **Our Intellectual Property**

Patents and other intellectual property rights are essential to our business. We file patent applications to protect our technology, inventions and improvements to our inventions that are considered important to the development of our business.

As of February 28, 2009, our patent portfolio contained 64 U.S. patents and 33 pending U.S. patent applications, which together with their various foreign counterparts, are owned, co-owned or exclusively licensed by us. We also have several nonexclusive technology licenses from certain institutions in

support of our research programs, and may seek additional such licenses where applicable technology complements our research and development efforts.

Approximately one-half of the patents and patent applications in our portfolio relate generally to our mTOR inhibitor, deforolimus; to our multi-targeted kinase inhibitor, AP24534; or to our preclinical drug discovery programs. These patents cover deforolimus and its uses, the related use of biomarkers, related therapies and inventions involving the mTOR gene, as well as AP24534, and our various families of novel kinase inhibitors. Our patent protection for deforolimus currently extends to at least 2023. The remainder of the portfolio is primarily focused on our ARGENT and NF-κB cell-signaling regulation technologies. These patents and pending applications cover technologies for biological regulation, including critical nucleic acid components and small-molecule drugs, the identification and use of dimerizer hormone mimetics, and various uses of the technologies in health care and drug discovery. Patents issued to date include 34 patents covering our cell-signaling regulation technologies.

We also rely on unpatented trade secrets and proprietary know-how, some of which is not believed to be adequately protectable through patents. In order to protect our trade secrets, we enter into confidentiality agreements with our employees, consultants, investigators, clinical trial sites, contractors, collaborators and other third parties to whom we disclose confidential information, although protection of trade secrets is generally recognized as challenging.

#### **Our Licenses to Third Parties**

Our Collaboration with Merck & Co., Inc.

On July 11, 2007, we entered into a collaboration agreement with Merck for the joint global development and commercialization of deforolimus. Under the terms of the agreement, Merck and we are conducting a broad-based development program in which clinical trials, preclinical studies and biomarker studies are being conducted concurrently in multiple potential cancer indications, pursuant to a global development plan agreed upon by the parties. Each party funds 50 percent of the global development costs, except that Merck funds 100 percent of any cost of development that is specific to development or commercialization of deforolimus outside the United States. The agreement provides that, in certain circumstances, either party may opt out of conducting and funding certain late-stage clinical trials, which would result in changes in development and commercialization responsibilities and compensation arrangements. We are responsible for supplying the active pharmaceutical ingredient used in deforolimus drug product, and Merck is responsible for the formulation of the finished product, all under a separate supply agreement between the parties.

The collaboration agreement provides that, in the United States, we and Merck will co-promote deforolimus, we will distribute and sell deforolimus for all cancer indications and record all sales, and each party will receive 50 percent of the net profit from such sales. Outside the United States, Merck will distribute, sell and promote deforolimus and book all sales, and Merck will pay us tiered double-digit royalties on such sales. Royalties are payable by Merck, on a country by country basis, until the later of (i) the expiration of the last valid claim of any patent rights owned by either us or Merck that cover deforolimus, (ii) a specified number of years from first commercial sale, or (iii) the last date upon which we supply active pharmaceutical ingredient to Merck under the supply agreement, subject to partial reduction in certain circumstances.

Under the terms of the collaboration agreement, Merck paid us an initial up-front payment of \$75 million in July 2007, and has agreed to pay up to \$452 million in milestone payments based on the successful development of deforolimus in multiple potential cancer indications, of which \$31.0 million has been paid to us through December 31, 2008, and up to \$200 million in milestone payments based on achievement of specified product sales thresholds. Merck has also agreed to provide us with up to \$200 million in interest-bearing, repayable, development cost advances to cover a portion of our share of global development costs, after we have paid \$150 million in global development costs and have obtained regulatory approval to market deforolimus from the FDA in the United States or similar regulatory

authorities in Europe or Japan. All amounts to be paid to us by Merck, with the exception of any development cost advances, are non-refundable.

The collaboration agreement may be terminated (i) by either party based on insolvency or uncured breach by the other party, (ii) by Merck on or after the third anniversary of the effective date by providing at least 12 months prior written notice, (iii) by Merck upon the failure of deforolimus to meet certain developmental and safety requirements, or (iv) after discussions between the parties, in the event Merck concludes it is not advisable to continue the development of deforolimus for use in a potential cancer indication. Upon termination of the collaboration agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of deforolimus and continuing royalty obligations.

Under the terms of the collaboration agreement, we and Merck have established a series of joint committees which are responsible for the development and commercialization of deforolimus. Under the committee structure, if the committees are unable to reach a decision, the matter is referred to senior executives of the parties. Each party has ultimate decision making authority with respect to a specified limited set of issues, and for all other issues, the matter must be resolved by consensus of the parties. Either party may choose not to appoint members to any of the joint committees and such a determination by either party has no impact on the financial or other terms of the collaboration.

#### Our Stent Collaborations

In January 2005, we entered into a license agreement with Medinol to develop and commercialize deforolimus-eluting stents and other medical devices to prevent restenosis, or reblockage, of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. In October 2007, we entered into a license agreement with ICON to develop and commercialize deforolimus-eluting stents to prevent restenosis of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. We have retained the right to enter into one additional non-exclusive license agreement, in addition to the licenses granted to ICON and Medinol, to develop and commercialize medical devices delivering deforolimus for use in vascular disease.

#### Other

We have a program to license our NF- $\kappa$ B cell-signaling technology and treatment methods to pharmaceutical and biotechnology companies conducting research to discover and develop drugs that modulate NF- $\kappa$ B cell-signaling and/or marketing such drugs. To date, we have entered into several licenses for this technology with pharmaceutical companies and companies manufacturing and commercializing kits, technologies and tools for research applications.

We also have a program to license our ARGENT cell-signaling regulation technologies to pharmaceutical and biotechnology companies to develop and commercialize innovative therapeutic products and to conduct drug discovery research. To date, we have entered into several licenses for use of our ARGENT cell-signaling regulation technologies for a variety of applications, including the development of therapeutic vaccines and gene and cell therapy products and for use in drug discovery. In addition, several biotechnology companies have conducted collaborative studies of these technologies for use in gene and cell therapy applications.

#### **Our Licenses from Third Parties**

In 1991, we entered into an exclusive license agreement with Massachusetts Institute of Technology and the Whitehead Institute (on behalf of themselves and Harvard University) to the rights to our NF-kB cell-signaling technologies and treatment methods. This license agreement was amended in 1995 and provides for the payment by us to these academic institutions of an up-front fee, license maintenance fees, a milestone payment, sublicense fees, and royalties based on commercial sales of products and processes developed using the NF-kB cell-signaling technologies and treatment methods. The license agreement

also grants us the right to undertake the enforcement and/or defense of these patent rights at our sole expense, subject to our right to withhold a percentage of the royalties otherwise due the academic institutions to be applied toward reimbursement of our fees and expenses in connection with any such litigation, including our litigation against Lilly and Amgen. The license agreement also provides that we will share a percentage of any damages, net of fees and expenses, awarded in such litigations with the academic institutions.

We have entered into license agreements with various institutions and universities pursuant to which we are the licensees of certain technologies relating to our research and development programs. In particular, in 1997, we entered into an amended and restated exclusive license agreement with Stanford University (on behalf of itself and Harvard University) to rights to certain of our ARGENT cell-signaling regulation technologies. This license agreement provides for the payment by us of an up-front fee, license maintenance fees, milestone payments based on achievement of development and commercial milestones and royalties on commercial sales of products, including therapies and research reagents.

In some instances, our third-party licenses also impose insurance, development, sublicensing and other obligations. Failure by us to comply with these requirements could result in the termination of the applicable agreement, which, depending upon the technologies which are the subject of the applicable agreement, could have a material adverse effect on our business, financial condition, and results of operations.

#### Research and Development Spending

During each of the three years ended December 31, 2008, 2007 and 2006, we spent approximately \$50.8 million, \$39.6 million and \$43.3 million, respectively, on our research and development activities.

#### Manufacturing

Our drug candidates and preclinical compounds are small molecules that can be readily synthesized by processes that we have developed. We are able to manufacture in-house the quantities of our product candidates necessary for certain preclinical studies. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We contract with third-party manufacturers to assist in the development and optimization of our manufacturing processes and methods and to supply sufficient quantities of our product candidates in bulk quantities and in suitable dosage forms for use in our clinical trials. We also expect to depend on third-party manufacturers for the supply of our products upon commercialization.

Our lead product candidate, deforolimus, is produced by an established manufacturing process using conventional synthetic and natural-product fermentation techniques. The production of deforolimus is based in part on technology that we believe is proprietary to us. Pursuant to our collaboration agreement and a separate supply agreement with Merck, we are responsible for supplying the active pharmaceutical ingredient used in deforolimus drug product and Merck is responsible for the formulation of the finished product. We, with Merck, may license this technology to contract manufacturers to enable them to manufacture deforolimus for us. In addition, a contract manufacturer may develop process technology related to the manufacture of our drug candidates that the manufacturer owns either independently or jointly with us. This would increase our reliance on that manufacturer or require us to obtain a license from that manufacturer in order to have our product manufactured by other parties. We are negotiating with our existing suppliers and other third-party manufacturers to secure the long-term supply and manufacture of the active pharmaceutical ingredient used in deforolimus at commercially reasonable costs with appropriate redundancy for commercialization.

Contract manufacturers are subject to extensive governmental regulation and we depend on them to manufacture our product candidates in accordance with the FDA's current good manufacturing practice regulations, or cGMPs. We have an established quality assurance program intended to ensure that third-party manufacturers under contract produce our compounds in accordance with cGMPs, and other

applicable domestic and foreign regulations. We believe that our current contractors comply with such regulations.

#### Competition

The pharmaceutical and biotechnology industries are intensely competitive. We compete directly and indirectly with other pharmaceutical companies, biotechnology companies and academic and research organizations, many of whom have greater resources than us. We compete with companies who have products on the market or in development for the same indications as our product candidates. We may also complete with organizations that are developing similar technology platforms.

In the area of oncology, pharmaceutical and biotechnology companies such as Amgen Inc., AstraZeneca PLC, Bristol-Myers Squibb Company, Eli Lilly and Company, Genentech, Inc., GlaxoSmithKline plc, Hoffmann LaRoche & Co., Johnson & Johnson, Merck & Co., Inc., Merck KGaA, Novartis AG, Pfizer, Inc., and Wyeth Corp. are developing and marketing drugs to treat cancer, including mTOR inhibitors. Specifically, Wyeth Corp. and Novartis AG are developing mTOR inhibitors for use in cancer and Wyeth's mTOR inhibitor, temsirolimus, has been approved to treat patients with advanced renal cell carcinoma. Biotechnology companies such as Amgen Inc., Biogen-Idec, Inc., Onyx Pharmaceuticals, Inc. and OSI Pharmaceuticals, Inc., are developing and, in some cases, marketing drugs to treat various diseases, including cancer, by inhibiting cell-signaling pathways. Other companies have products on the market or in development against which our drug candidates, if approved, may have to compete. Specifically, PharmaMar, a wholly owned subsidiary of Zeltia Group, has a product, trabectedin, approved for the treatment of soft-tissue sarcomas in Europe, and IDM Pharma, Inc. has an immunotherapy approved in Europe for bone sarcomas. We may also experience competition from companies that have acquired or may acquire technology from companies, universities, and other research institutions. As these companies develop their technologies, they may develop proprietary positions that may materially and adversely affect us.

#### Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. The process of obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

#### **United States Drug Development Process**

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. Our products must be approved by the FDA through the new drug application, or NDA, process before they may be legally marketed in the United States, which generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become
  effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the
  drug is produced to assess compliance with cGMP to assure that the facilities, methods and controls
  are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

As part of the IND, an IND sponsor must submit to the FDA the results of preclinical tests, which may include laboratory evaluations and animal studies, together with manufacturing information and analytical data, and the proposed clinical protocol for the first phase of the clinical trial of the drug. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a "clinical hold," pending resolution between the IND sponsor and the FDA of any outstanding concerns. Clinical holds may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance by the sponsor.

All clinical trials must be conducted under the supervision of a qualified investigator(s) in accordance with good clinical practice regulations. An institutional review board, or IRB, must also review and approve each new clinical protocol and patient informed consent form prior to commencement of the corresponding clinical trial at that institution. Protocols detail, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor patient safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1:* The drug is introduced into healthy human subjects or patients (in the case of certain inherently toxic products for severe or life-threatening diseases) and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- *Phase* 2: Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the study participants are being exposed to an unacceptable health risk.

If a drug is intended to treat a serious or life threatening condition for which there is an unmet medical need, a company may request that the FDA consider the drug for a fast track development program at the time of submitting its IND or at any time prior to receiving marketing approval. The fast track program is designed to facilitate the development and expedite the review of a new drug for the treatment of the specific conditions. If the FDA agrees that the drug meets the criteria for fast track development for treatment of one or more conditions, it will grant fast track status. The FDA granted fast track status to deforolimus for treatment of soft tissue sarcomas and bone sarcomas.

#### United States Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. Once the submission is accepted for filing, the FDA begins an in-depth and substantive review. The FDA may seek advice and a recommendation from an external advisory committee as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require submission of additional clinical or other data and information which, upon agency review and interpretation, may or may not be deemed by the FDA to satisfy the criteria for approval. The FDA may also issue a "complete response" letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA.

NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If approved by the FDA, the product's use may be limited to specific diseases, dosages or indications. In addition, the FDA may require us to conduct post-NDA approval, or Phase 4, testing which involves further nonclinical studies or clinical trials designed to further assess the drug's safety and effectiveness and may require additional testing and surveillance programs to monitor the safety of the drug in the marketplace.

#### Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or noninfringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This threeyear exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. The current pediatric exclusivity provision under the FDCA was reauthorized on September 27, 2007.

#### Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition which is defined as one affecting fewer than 200,000 individuals in the United States or more than 200,000 individuals where there is no reasonable expectation that the product development cost will be recovered from product sales in the United States. Orphan drug designation must be requested before submitting an NDA and does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If an orphan drug-designated product subsequently receives the first FDA approval for the disease for which it was designed, the product will be entitled to seven years of product exclusivity. If a competitor obtains approval of the same drug, as defined by the FDA, or if our product candidate is determined to be contained within the competitor's product for the same indication or disease, the competitor's exclusivity could block the approval of our product candidate in the designated orphan indication for seven years. The FDA granted two orphan drug designations for deforolimus; the first for the treatment of soft tissue sarcoma and the second for the treatment of bone sarcoma.

#### Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. 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. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs 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. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. For example, on September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with a risk evaluation and mitigation strategy approved by the FDA. Additionally, the new law expands the clinical trial registry so that sponsors of all clinical trials, except for Phase I trials, are required to submit certain clinical trial information for inclusion in the clinical trial registry data bank. Failure to comply with any requirements under the new law may result in significant penalties. In addition to new legislation, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

#### Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

As in the U.S., the European Union may grant orphan drug status for specific indications if the request is made before an application for marketing authorization is made. The European Union considers an orphan medicinal product to be one that affects less than five of every 10,000 people in the European Union. A company whose application for orphan drug designation in the European Union is approved is eligible to receive, among other benefits, regulatory assistance in preparing the marketing application, protocol assistance and reduced application fees. Orphan drugs in the European Union also enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication, unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product. We have been granted orphan designation in the European Union for deforolimus for the treatment of soft tissue sarcoma and bone sarcoma.

#### Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. We anticipate third-party payors, including Medicare, will provide reimbursement for our products. However, Medicare or other third-party reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

We expect that there will continue to be a number of federal and state proposals, including changes to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

#### **Our Employees**

As of February 28, 2009, we had 150 employees, 81 of whom hold post-graduate medical or science degrees, including 45 with a Ph.D. or M.D. Most of our employees are engaged directly in research and development. We have entered into confidentiality, assignment of inventions and non-disclosure agreements with all of our employees and non-competition agreements with all of our senior level employees. None of our employees are covered by a collective bargaining agreement, and we consider relations with our employees to be good.

#### **Our Company**

ARIAD was organized as a Delaware corporation in April 1991. Our principal executive offices are located at 26 Landsdowne Street, Cambridge, Massachusetts 02139-4234, and our telephone number is (617) 494-0400. We maintain an internet website at http://www.ariad.com, the contents of which are not incorporated herein. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and all amendments to such reports are made available free of charge through the Investor Relations section of our website as soon as reasonably practicable after they have been electronically filed with or furnished to the United States Securities and Exchange Commission, or SEC.

ARIAD and the ARIAD logo are our registered trademarks. ARGENT is our trademark. Other service marks, trademarks and trade names appearing in this report are the property of their respective owners.

#### Merger of ARIAD Gene Therapeutics, Inc. into ARIAD Pharmaceuticals, Inc.

On September 11, 2008, ARIAD Pharmaceuticals, Inc. or ARIAD, and ARIAD Gene Therapeutics, Inc., or AGTI, entered into an agreement pursuant to which AGTI was merged with and into ARIAD on September 12, 2008, with ARIAD as the surviving company. Prior to the merger, AGTI was an 80 percent owned subsidiary of ARIAD. AGTI owned or licensed from others the intellectual property related to our ARGENT technology and know-how, as well as the product candidates developed from the application of this technology, including deforolimus. We effectuated the merger to eliminate conflicts of interest between ARIAD and AGTI, to ensure that ARIAD will receive benefits from the successful commercialization of its products proportionate to its investment and to create additional value for our stockholders.

Under the terms of the merger agreement, each outstanding share of AGTI common stock owned by AGTI's minority stockholders, a total of 1,126,064 AGTI shares, was converted into the right to receive two shares of ARIAD common stock. Under Delaware law, any of the AGTI minority stockholders had the right to demand appraisal of his or her AGTI shares and to seek judicial determination of the fair value of such shares. Four AGTI stockholders holding a total of 226,426 shares of AGTI common stock notified us of their intent to pursue appraisal of their shares. We reached a settlement with such AGTI stockholders in January 2009 pursuant to which these AGTI stockholders received two shares of ARIAD common stock plus approximately \$2.43 in cash for each share of AGTI common stock they owned. In total, in exchange for all of the AGTI common stock owned by the AGTI minority stockholders, we issued 2,252,128 shares of ARIAD common stock, or approximately 3.1 percent of the outstanding common stock of ARIAD at the time of the merger, and \$550,000 in cash. The total cost of the acquisition of the 20 percent minority interest of AGTI was approximately \$5.9 million.

#### ITEM 1A: RISK FACTORS

THE RISKS AND UNCERTAINTIES DESCRIBED BELOW ARE THOSE THAT WE CURRENTLY BELIEVE MAY MATERIALLY AFFECT OUR COMPANY. IF ANY OF THE FOLLOWING RISKS ACTUALLY OCCUR, THEY MAY MATERIALLY HARM OUR BUSINESS, OUR FINANCIAL CONDITION AND OUR RESULTS OF OPERATIONS.

#### **Risks Relating to Our Business**

We have no product candidates that have been approved by the FDA or any foreign regulatory authority, and we and our partners may never succeed in obtaining regulatory approval for any products, developing marketable products or generating product revenues.

We are a biopharmaceutical company focused on the discovery and development of drugs to provide therapeutic intervention in treating human diseases at the cellular level. As with all scientific endeavors, we face much trial and error, and we may fail at numerous stages along the way, which would inhibit us from successfully developing, manufacturing and marketing our drug candidates.

Our lead product candidate, deforolimus, is currently being developed by us in collaboration with Merck for potential cancer indications and by our partners, Medinol and ICON, for use in stents or other medical devices to reduce reblockage of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. Deforolimus is currently being studied in a Phase 3 clinical trial in patients with metastatic sarcomas and in multiple Phase 1 and Phase 2 clinical trials in various potential cancer indications and in combination with other agents. Our second product candidate, AP24534, is currently being studied in a Phase 1 clinical trial in patients with hematologic malignancies. We do not currently have any products on the market and have no product revenues. Therefore, our success is substantially dependent on (1) our ability to work in collaboration with Merck to obtain marketing approval for deforolimus for metastatic sarcoma and other cancer indications, (2) the ability of our partners, Medinol and ICON, to obtain marketing approval for stents or other medical devices delivering deforolimus, and (3) our ability to successfully complete clinical development and obtain marketing approval for AP24534.

Neither we nor our partners have submitted any new drug applications for deforolimus, AP24534 or any other product candidate of ours to the FDA or foreign regulatory authorities for marketing approval. Factors which could affect the ability to obtain regulatory approval and to achieve market acceptance and gain market share for deforolimus, AP24534 and any other product candidate of ours include, among other factors, product formulation, dose, dosage regimen, the ability to obtain timely and sufficient patient enrollment in clinical trials, the risk of occurrence of adverse side effects in patients participating in clinical trials, the ability to manufacture, directly or indirectly, sufficient and cost-effective quantities of product candidates, the ability to fund commercial development and to build or access a sales force in the marketplace, the ability to successfully differentiate product candidates from competitive product(s) and to sell, market and distribute, directly or indirectly, such product candidates.

In addition, positive results from early-stage clinical trials may not be replicated in later-stage Phase 3 clinical trials. Similarly, positive results from preclinical studies of a product candidate may not be predictive of similar results in humans during clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed preclinical studies and clinical trials for deforolimus may not be predictive of the results to be obtained in the SUCCEED Phase 3 clinical trial, and the promising activity we have seen in AP24534 in preclinical studies may not be predictive of the results obtained in clinical trials.

Although we have entered into a collaboration agreement with Merck for the joint global development and commercialization of deforolimus, we do not currently have any partners to assist in developing and commercializing our other cancer product candidates. We will depend heavily on Merck for the

successful development and commercialization of deforolimus, particularly with respect to the commercialization of deforolimus outside of the United States. We would expect to be dependent upon other partners, if we enter into arrangements with one or more of them, to successfully develop and commercialize our other cancer product candidates, including AP24534. There can be no assurance that our collaboration with Merck will be successful or that we will be able to secure any other partners on terms favorable to us, or at all.

We and our medical device partners have limited experience in designing, conducting and managing the clinical trials necessary to obtain regulatory approval of stents or other medical devices that deliver small-molecule drugs. We are dependent upon the success of Medinol and ICON and any future medical device partner to successfully develop, manufacture and market stents or other medical devices to deliver deforolimus to reduce blockage of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. If Medinol or ICON is not successful and/or if we are not able to enter into an agreement with an additional medical device company experienced in the development, manufacture, and marketing of medical devices to deliver deforolimus, we will not be able to generate revenues from the marketing of stents or other medical devices that deliver deforolimus.

We do not expect to have any products on the market before 2010, at the earliest, and, ultimately, we and our partners may not succeed in developing or commercializing any products which will generate product revenues for our company. If we and our partners are not successful in developing or marketing deforolimus or other product candidates, we will not be profitable.

If our collaboration with Merck relating to the development and commercialization of deforolimus is unsuccessful, our ability to commercialize deforolimus on a timely basis, or at all, could be affected and our business could be materially harmed.

In July 2007, we entered into a collaboration agreement with Merck for the joint global development and commercialization of deforolimus, our lead product candidate, for use in cancer. Other than with respect to our collaborative efforts in developing deforolimus to date, we do not have a history of working together with Merck and cannot predict the success of this collaboration. The collaboration involves a complex allocation of responsibilities, costs and benefits and provides for milestone payments to us upon the achievement of specified clinical, regulatory and sales milestones.

With respect to responsibilities and control over decisions, we and Merck have established a series of joint committees which are responsible for the development and commercialization of deforolimus. Under the committee structure, if the committees are unable to reach a decision, the matter is referred to senior executives of the parties. Each party has ultimate decision making authority with respect to a specified limited set of issues, and for all other issues, the matter must be resolved by consensus of the parties. Accordingly, Merck's failure to devote sufficient resources to the development and commercialization of deforolimus or the failure of the parties to reach consensus on development or commercialization activities may delay its clinical development, which could lead to the delay in payment of clinical and regulatory milestones under the collaboration agreement and may delay commercialization of deforolimus.

The collaboration agreement provides that, in certain circumstances, either party may opt out of conducting and funding certain late-stage clinical trials, which would result in changes in development and commercialization responsibilities and compensation arrangements. Furthermore, the collaboration agreement may be terminated by Merck (i) based on an uncured breach by us, (ii) on or after the third anniversary of the effective date of the agreement by providing at least 12 months prior written notice, (iii) upon the failure of deforolimus to meet certain developmental and safety requirements, or (iv) after discussions between the parties, in the event Merck concludes that it is not advisable to continue the development of deforolimus for use in a potential cancer indication. In addition, unrelated to our deforolimus collaboration, Merck's research and development plans may be affected by its corporate, business or other developments, such as its recently announced pending merger with Schering-Plough Corporation, which may impact the joint development plans for deforolimus. Any loss of Merck as a

collaborator in the development or commercialization of deforolimus, any dispute over the terms of, or decisions regarding, the collaboration, or any other adverse developments in our relationship with Merck could result in our inability to fully develop and/or commercialize deforolimus, or at all, could materially harm our business and could accelerate our need for additional capital.

Insufficient funding may jeopardize our research and development programs and may require us to reduce our operations or prevent commercialization of our products and technologies.

We have funded our operations to date through sales of equity securities, debt, the upfront and milestone payments received from Merck since July 2007, and, to a limited extent, operating revenues. Most of our operating revenue to date has been generated through previous collaborative research and development agreements and existing licenses. Although our collaboration agreement with Merck for the global development and commercialization of deforolimus is structured to provide substantial funding for the remaining development of deforolimus if we are successful in meeting specified milestones, we will require substantial additional funding for our other research and development programs (including preclinical development and clinical trials), for the pursuit of regulatory approvals and for establishing or accessing manufacturing, marketing and sales capabilities related to other product candidates, and for other operating expenses (including intellectual property protection and enforcement) as well as capital expenditures to maintain and improve our facility, equipment and systems. We may from time to time access funding by issuing common stock or other securities in private placements or under our universal shelf registration statement under which we currently have approximately \$40 million available for issuance. We may also from time to time seek additional funding from other product-based collaborations, technology licensing, issuance of debt, and public or private financings. However, such additional funding may not be available on terms acceptable to us, or at all. Accordingly, we may not be able to secure the significant funding which is required to maintain our operations or continue to fund current or future research and development programs at their current levels or at levels that may be required in the future. If we cannot secure adequate financing, we may be required to reduce our operations, to delay, scale back, eliminate or terminate clinical trials for one or more of our other research and development programs, or to enter into licenses, settlements or other arrangements with third parties on terms that may be unfavorable to us to purchase, commercialize or otherwise obtain rights in our product candidates, approved products, technologies or intellectual property.

Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may seek to raise the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaboration and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect our stockholders' rights. Under an existing loan agreement with a bank, we are required to maintain certain financial and non-financial covenants, including covenants limiting or restricting our ability to incur additional debt or declare dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

#### We have incurred significant losses to date and may never be profitable.

We have incurred significant losses in each year since our formation in 1991, including a net loss of \$71.1 million in 2008, and have an accumulated deficit of \$438.6 million through December 31, 2008. Our losses have resulted principally from costs incurred in research and development of our product candidates, including clinical development of deforolimus and AP24534, and from general and administrative costs, including costs incurred to prosecute and protect our intellectual property, associated with our operations. Although the collaboration with Merck is structured so that the expected milestone payments to be paid by Merck to us should largely offset our share of the costs of development of deforolimus over

the first three years of the collaboration, it is likely that we will incur significant operating losses for the foreseeable future, and we expect such losses to increase as we continue our research and development activities and begin to build a sales and marketing organization in anticipation of obtaining regulatory approval to market deforolimus in the United States, which approval may never occur. We currently have no product revenues, limited license revenues and limited commitments for future licensing revenues, and may not be able to generate such revenues in the future. If our losses continue and we and our existing partners or potential future partners are unable to successfully develop, commercialize, manufacture and market our product candidates and/or we are unable to enter into agreements and licenses of our intellectual property, we may never generate sufficient revenues to achieve profitability. Even if we and our partners are able to commercialize products and we are able to enter into agreements or licenses in the future, we may never generate sufficient revenues to have profitable operations.

We have limited manufacturing experience and are dependent upon the ability of third parties, including Merck, to manufacture our product candidates, which raises uncertainty as to our ability to develop and commercialize our product candidates.

Under our collaboration with Merck, we are responsible for providing the active pharmaceutical ingredient used in deforolimus drug product and Merck is responsible for the formulation of the finished product. Under our agreements with Medinol and ICON, we are responsible for providing the deforolimus to be delivered by the stents or medical devices being developed by Medinol and ICON. We have no experience in manufacturing any of our product candidates on a large scale and have contracted and expect to continue to contract with third-party manufacturers, including Merck, to provide material for clinical trials and potential commercial launch, and to assist in the development and optimization of our manufacturing processes and methods. Our ability to conduct clinical trials and commercialize our product candidates will depend on the ability of such third parties to manufacture our products on a large scale at a competitive cost and in accordance with current good manufacturing practices, or cGMPs, and other regulatory requirements. If we are not able to obtain contract manufacturing on commercially reasonable terms, obtain or develop the necessary materials and technologies for manufacturing, or obtain intellectual property rights necessary for manufacturing, or if our contract manufacturers fail to provide us with the quantities and quality of the products we require in a timely manner, we may not be able to conduct or complete clinical trials or commercialize our product candidates, including deforolimus. There can be no assurance that we will be able to obtain such requisite terms, materials, technologies and intellectual property necessary to successfully manufacture our product candidates for clinical trials or commercialization.

We have limited experience in conducting clinical trials and are dependent upon the ability of third parties, including Merck, contract research organizations, collaborative academic groups, clinical trial sites and investigators, to conduct or to assist us in conducting clinical trials for our product candidates, which raises uncertainty as to our ability to develop and commercialize our product candidates.

We have limited experience in designing, initiating, conducting and monitoring the clinical trials necessary to obtain regulatory approval of our product candidates. Our collaboration agreement with Merck provides that the development and commercialization of deforolimus, our lead product candidate, will be jointly conducted pursuant to a global development plan. Pursuant to the global development plan, we are conducting multiple clinical trials of deforolimus in multiple potential cancer indications. Together with the efforts of Merck, contract research organizations, advisory boards, review committees, collaborative academic groups, clinical trial sites and investigators, we are heavily dependent on our and their ability to successfully initiate, enroll, conduct and monitor our SUCCEED Phase 3 clinical trial and other clinical trials of deforolimus, particularly outside the United States. In particular, we are dependent upon the review, advice and/or services of several independent committees, consultants and contractors with respect to protocol design, patient enrollment, data monitoring, radiology review, pathology and drug distribution to clinical trial sites for our SUCCEED trial and other clinical trials of deforolimus. We are also dependent upon our ability and the ability of Merck and our contractors to coordinate with us and to timely and accurately collect and report to regulatory authorities worldwide the patient data generated in our SUCCEED trial and other clinical trials of deforolimus. We, Merck, and our respective

contractors, collaborative academic groups, clinical trial sites or investigators may lack sufficient personnel, technology, expertise, experience or resources to effectively initiate clinical trial sites, recruit and enroll patients, conduct and monitor clinical trials, and to collect and report patient data relating to our SUCCEED trial or other clinical trials of deforolimus, either generally or in specific countries.

We also initiated in 2008 and are conducting a Phase 1 clinical trial of AP24534 in patients with hematologic malignancies. We do not currently have a partner for the development and commercialization of AP24534 and are dependent upon our ability and/or the ability of our contractors, collaborative academic groups, clinical trial sites and investigators, to successfully design, initiate, conduct and monitor clinical trials of AP24534, including the ongoing Phase 1 trial. Failure by us or our partners, contractors, collaborative academic groups, clinical trial sites or investigators to timely and effectively initiate, conduct and monitor our clinical trials could significantly delay or materially impair our ability to complete clinical trials and/or obtain regulatory approval of deforolimus, AP24534 or our other product candidates and, consequently, could delay or materially impair our ability to generate revenues therefrom.

We will continue to expend significant resources on the enforcement and licensing of our NF- $\kappa$ B patent portfolio and may be unable to generate material revenues from these efforts if we are unable to enforce against, or license our NF- $\kappa$ B patents to, pharmaceutical and biotechnology companies.

We are the exclusive licensee of a family of patents, three in the U.S. and one in Europe, including a pioneering U.S. patent covering methods of treating human disease by regulating NF-kB cell-signaling activity, hereinafter referred to as the '516 Patent, awarded to a team of inventors from The Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology and Harvard University. Dr. David Baltimore, the former president of the California Institute of Technology and one of our consultants and scientific founders, is a lead inventor of the '516 Patent and a member of the board of directors of Amgen Inc. We have a licensing program to generate revenues from the discovery, development, manufacture and sale of products covered by our NF-kB patent portfolio. These patents have been, and in the future may be, challenged and may be subsequently narrowed, invalidated, declared unenforceable or circumvented, any of which could materially impact our ability to generate licensing revenues from them.

We are currently engaged in two litigations concerning the '516 Patent. Together with the academic institutions, we filed a lawsuit in June 2002 in the United States District Court for the District of Massachusetts, against Lilly, alleging infringement of certain claims of the '516 Patent through sales of Lilly's osteoporosis drug, Evista®, and its septic shock drug, Xigris®. Both a jury and a bench trial were held in this case in 2006. We prevailed with favorable verdicts in both trials followed by entry of a final judgment in September 2007. Lilly then filed a notice of appeal on March 10, 2008 which appeal was heard on February 6, 2009 and for which we are awaiting the court's ruling. We are also the defendant in a lawsuit filed by Amgen and certain affiliated entities in the U.S. District Court for the District of Delaware seeking a declaratory judgment that each of the claims contained in the '516 Patent is invalid and that Amgen has not infringed any of the claims of the '516 Patent based on activities related to Amgen's products, Enbrel® and Kineret®. We have filed a counterclaim against Amgen, and, for purposes of trial, we are alleging infringement of the '516 Patent based on activities related to Enbrel. In addition, upon requests filed by Lilly and by a third party, the PTO is reexamining the patentability of certain claims of the '516 Patent in reexamination proceedings that are currently pending. See a description of the status of these matters in the section entitled "Legal Proceedings" in Part I, Item 3 of this Annual Report on Form 10-K. We cannot provide any assurance that other third parties, who may be infringing our NF-kB patents, will not seek to initiate similar, further proceedings for declaratory relief or reexamination with regard to the '516 Patent or other NF-kB patents. As exclusive licensee of the '516 Patent, we are obligated for the costs expended for its prosecution in the PTO, for its enforcement in the above noted litigations and otherwise. Therefore, we will continue to expend significant capital and management resources pursuing these matters in court and in the reexamination process in the PTO, and the outcome is uncertain.

If some of the claims of the '516 Patent are invalidated by the PTO or in the courts or found not to be infringed in these matters, we will not realize any revenues on sales of the above-named products, and could be liable under certain limited circumstances in these litigation proceedings for litigation costs and potentially attorneys' fees. Additionally, although we have prevailed in the jury and bench trials in the Lilly litigation, the damages awarded to us and the other Plaintiffs could be subsequently eliminated or limited by an adverse ruling upon appeal, or in the event that the claims of the '516 Patent are invalidated at trial or on appeal in the Amgen litigation or by the PTO. Invalidation of any of the claims of the '516 Patent by the PTO or in the courts would have a significant adverse impact on our ability to generate revenues from our NF-kB licensing program from any potential licensee. Moreover, significant expenditures to enforce these patent rights, particularly with respect to the pending litigation initiated by Amgen, without generating revenues or accessing additional capital or other funding, could adversely impact our ability to further our clinical programs and our research and development programs at the current levels or at levels that may be required in the future.

## The loss of key members of our scientific and management staff could delay and may prevent the achievement of our research, development and business objectives.

Our performance as a specialized scientific business is substantially dependent on our key officers and members of our scientific staff responsible for areas such as drug development, clinical trials, regulatory affairs, drug discovery, manufacturing, marketing, business development and intellectual property protection and licensing. We also are dependent upon a few of our scientific advisors to assist in formulating our research and development strategy. While we have entered into employment agreements with all of our executive officers, these officers may terminate their employment with us at any time. The loss of, and failure to promptly replace, any member of our management team could significantly delay and may prevent the achievement of our research, development and business objectives.

## We are dependent upon the ability of our medical device partners to develop, manufacture, test and market stents or other medical devices to deliver deforolimus.

We have no experience in the development of medical devices and do not intend ourselves to develop stents or other medical devices to deliver deforolimus. Instead, we have granted two licenses (to Medinol and to ICON) and, under those license agreements, we may grant one additional license, under our rights to deforolimus to a medical device company for its use in developing and commercializing such medical devices to reduce blockage of injured vessels following stent-assisted angioplasty.

While we expect to supply deforolimus to our medical device partners and any additional partner, we will be otherwise dependent upon them to develop and commercialize stents or other medical devices to deliver deforolimus. Such medical device partners have varying degrees of scientific, technical, medical and regulatory experience and resources to, directly or through third parties, develop, manufacture, test or market stents or other medical devices to deliver deforolimus. Their ability to conduct clinical trials and commercialize such medical devices will be dependent on both the safety profile of their medical devices and deforolimus, as well as their ability to manufacture and supply medical devices for clinical trials and marketing purposes and our ability to manufacture and supply deforolimus, either directly or through third parties, at a competitive cost and in accordance with cGMPs and other regulatory requirements. Although, under our collaboration with Merck, Merck is responsible for the formulation of deforolimus finished product for potential indications covered by the collaboration, we depend upon third-party manufacturers or collaborative partners for the production of deforolimus for clinical trials to be conducted by our medical device partners, and we intend to use third-party manufacturers to produce deforolimus on a commercial scale, if any partner receives regulatory approval. Our reliance on thirdparty manufacturers and their potential inability to meet our supply commitments to one or more of our partners could adversely impact the ability of our partners to commercialize stents or other medical devices to deliver deforolimus.

We anticipate that our partners will seek to develop and commercialize stents or other medical devices to deliver deforolimus that do not infringe third-party patents. However, there can be no assurance that the devices delivering deforolimus marketed by our partners will not be subject to third-party claims. Furthermore, the patents issued to us or our partners covering deforolimus and/or medical devices, including stents, may be subject to challenge and may be subsequently narrowed, invalidated or circumvented. Any such event would adversely impact the ability of one or more of our partners to market their stents or other medical devices to deliver deforolimus.

Our existing license agreements with Medinol and ICON allow either party to terminate under certain circumstances, including our partner's reasonable business judgment that development of a medical device to deliver deforolimus is not feasible. Medinol or ICON may be unable to develop a medical device to deliver deforolimus and we may also not be able to enter into any additional licensing agreements with any other medical device companies to develop such devices on terms which are acceptable to us, or at all. Our inability to enter into such transactions, or the inability of one or more of our partners to develop or commercialize stents or other medical devices to deliver deforolimus for any reason, will adversely impact our ability to generate revenues from any licenses of deforolimus.

# We may not be able to protect our intellectual property relating to our research programs, technologies and product candidates.

We and our licensors have issued patents and pending patent applications covering research methods useful in drug discovery, new chemical compounds discovered in our drug discovery programs including, among others, deforolimus, certain components, configurations and uses of our cell-signaling regulation technologies and products-in-development, methods and materials for manufacturing our products-in-development and other pharmaceutical products and methods and materials for conducting pharmaceutical research. Pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or sell our products or in countries where others develop, manufacture and sell products using our technologies. In addition, patents issued to us or our licensors may be challenged, as is the case with the PTO proceeding and the Lilly and Amgen litigations regarding the NF-kB '516 Patent, and they may be subsequently narrowed, invalidated or circumvented. In that event, such patents may not afford meaningful protection for our technologies or product candidates, which would materially impact our ability to develop and market our product candidates and to generate licensing revenues from our patent portfolio. Certain technologies utilized in our research and development programs are already in the public domain. Moreover, a number of our competitors have developed technologies, filed patent applications or obtained patents on technologies, compositions and methods of use that are related to our business and may cover or conflict with our patent applications, technologies or product candidates. Such conflicts could limit the scope of the patents that we may be able to obtain or may result in the denial of our patent applications. If a third party were to obtain intellectual property protection for any of the foregoing, we may be required to challenge such protection, terminate or modify our programs impacted by such protection or obtain licenses from such third parties, which might not be available on acceptable terms, or at all. Also, if a third party were to introduce a product into the market which we believe infringes our patents, we may be required to enforce our patent rights or seek to obtain an injunction or other relief, which could be time-consuming and expensive.

## We may be unable to develop or commercialize our product candidates if we are unable to obtain or maintain certain licenses on commercial terms or at all.

We have entered, and will continue to enter, into agreements, with third parties to test compounds, blood and tissue samples, to perform gene expression analysis and to develop biological tests for use with our product candidates, which testing may yield new inventions and discoveries requiring us to obtain licenses in order to exclusively develop or market new products, alone or in combination with our product candidates, or to develop or market our product candidates for new indications. We have also entered into license agreements for some of our technologies. We use third parties to test blood and tissue samples and other biological materials in our clinical programs and to develop biological tests,

with respect to which we may be required to obtain licenses or pay royalties or other fees in order to commercialize such tests for use with our product candidates. We also use gene sequences or proteins encoded by those sequences and other biological materials in each of our research programs which are, or may become, patented by others and to which we would be required to obtain licenses in order to develop or market our product candidates. Manufacturing and/or use of our products may also require licensing biological materials, technologies and intellectual property from third parties. Our inability to obtain any one or more of these licenses, on commercially reasonable terms, or at all, or to circumvent the need for any such license, could cause significant delays and cost increases and materially affect our ability to develop and commercialize or prevent us from developing and commercializing our product candidates. Obtaining licenses for these discoveries, materials and technologies may require us to make cumulative royalty payments or other payments to several third parties, potentially reducing amounts paid to us or making the cost of our products commercially prohibitive.

Some of our licenses obligate us to exercise diligence in pursuing the development of product candidates, to make specified milestone payments and to pay royalties. In some instances, we are responsible for the costs of filing and prosecuting patent applications and actions to enforce our rights against infringers. These licenses generally expire upon the earlier of a fixed term of years after the date of the license or the expiration of the applicable patents, but each license is also terminable by the other party upon default by us of our obligations. Our inability or failure to meet our diligence requirements or make any payments required under these licenses would result in a reversion to the licensor of the rights granted which, with respect to the licenses pursuant to which we have obtained exclusive rights, would materially and adversely affect our ability to develop and market products based on our licensed technologies.

Competing technologies may render some or all of our programs or future products noncompetitive or obsolete.

Many well-known pharmaceutical, healthcare and biotechnology companies, academic and research institutions and government agencies, which have substantially greater capital, research and development capabilities and experience than us or our potential partners, are presently engaged in one or more of the following activities:

- developing products based on cell signaling, cancer biology, and computational chemistry;
- conducting research and development programs for the treatment of the various potential disease indications in which we are focused; and
- manufacturing, promoting, marketing and selling pharmaceutical or medical device products for treatment of diseases in all of the various disease indications in which we or our current or possible future partners are focused.

Some of these entities already have competitive products on the market or product candidates in clinical trials or in more advanced preclinical studies than we do. Many of these entities also have substantially greater research, development, manufacturing and marketing resources and experience than us. In particular, we are aware that Wyeth and Novartis have mTOR inhibitors on the market and/or in development which are competitive with deforolimus, our lead product candidate. Additionally, PharmaMar has a marine derived antitumoral agent currently approved for the treatment of soft tissue sarcomas in Europe. By virtue of having or introducing competitive products on the market before us, these entities may gain a competitive advantage. Competing technologies may render some or all of our programs or future products noncompetitive or obsolete, and we may not be able to make the enhancements to our technology necessary to compete successfully with newly emerging technologies. If we are unable to successfully compete in our chosen markets, we will not become profitable.

#### If our product candidates are not accepted by patients, physicians and insurers, we will not be successful.

Our success is dependent on the acceptance of any approved products. Our product candidates may not achieve market acceptance among patients, physicians or third-party payors, even if we obtain necessary regulatory and reimbursement approvals. Physicians and health care payors may conclude that any of our product candidates are not as safe and/or effective as competing therapies or are not as attractive based on a cost/benefit analysis as alternative treatments. Failure to achieve significant market acceptance of our product candidates will harm our business. We believe that recommendations by physicians and health care payors will be essential for market acceptance of any product candidates.

# If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to do so, we may be unable to successfully market and sell any products.

Pursuant to our collaboration with Merck, we will distribute, sell and with Merck co-promote deforolimus for all cancer indications in the United States, and Merck will distribute, sell and promote deforolimus outside the United States. We are currently establishing a commercial oncology organization, but we have no experience in marketing or selling any products. Accordingly, we may be unable to successfully, directly or indirectly, sell deforolimus or any other product candidates that we obtain marketing approval to sell. If we are unable to effectively sell our products, our ability to generate revenues will be materially adversely affected. We may not be able to hire, in a timely manner, the qualified sales and marketing personnel we need, if at all. In addition, we may not be able to enter into any marketing or distribution agreements on acceptable terms, if at all. If we cannot establish sales, marketing and distribution capabilities as we intend, either by developing our own capabilities or entering into agreements with third parties, sales of future products, if any, may be harmed.

# If we develop a product for commercial use, a subsequent product liability-related claim or recall could have an adverse effect on our business.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of pharmaceutical products. Prior to obtaining regulatory approval to market our products, we or our partners are required to test such products in human clinical trials at health care institutions pursuant to agreements which indemnify such institutions in case of harm caused to patients by our products. We may not be able to avoid significant product liability exposure resulting from use of our products. A product liability-related claim or recall could be detrimental to our business. In addition, except for insurance covering product use in our clinical trials, we do not currently have any product liability insurance, and we may not be able to obtain or maintain such insurance on acceptable terms, or we may not be able to obtain any insurance to provide adequate coverage against potential liabilities, including liabilities arising from our clinical trials. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products that we or our partners may develop.

# Significant additional losses or insufficient funding may cause us to default on certain covenants of our loan documents.

At December 31, 2008, we had \$13.0 million outstanding under a term loan agreement with a bank, pursuant to which we are required to maintain certain financial and non-financial covenants, including minimum cash, cash equivalents and investments of \$15 million, a default of any of which would allow the bank to demand payment of its loan. We currently have sufficient liquidity to fund payment of this loan if demand for payment were made. However, if we are unable to raise adequate financing to fund continuing operations or otherwise to refinance our loan, we may not be able to maintain compliance with loan covenants, may be required to pay off the loan and may be required to reduce our spending on operations.

#### Risks Relating to Governmental Approvals

We have limited experience in conducting clinical trials, which may cause delays in commencing and completing clinical trials of our product candidates.

Clinical trials must meet applicable FDA and foreign regulatory requirements. We have limited experience in designing, conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approval for our product candidates in any country and no experience in conducting and managing post-approval studies of any products. We or our collaborative partners may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to manufacture sufficient quantities of cGMP materials for use in our clinical trials, conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, our partners, the FDA or foreign regulatory agencies may suspend clinical trials of our product candidates at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks as a result of adverse events occurring in our trials or if we or they find deficiencies in the clinical trial process or conduct of the investigation. If clinical trials of any of our product candidates fail, we or our partners will not be able to market the product candidate which is the subject of the failed clinical trials. The FDA and foreign regulatory agencies could also require additional clinical trials before or after granting of marketing approval for any products, which would result in increased costs and significant delays in the development and commercialization of such products and could result in the withdrawal of such products from the market after obtaining marketing approval. Our failure, or the failure of our partners, to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent obtaining marketing approval of the product candidate and, after obtaining marketing approval, data from post-approval studies could result in the product being withdrawn from the market, either of which would likely have a material adverse effect on our business.

#### We may not be able to obtain government regulatory approval to market our product candidates.

To date, neither we nor our partners have submitted a marketing application for any of our product candidates to the FDA or any foreign regulatory agency, and none of our product candidates has been approved for commercialization in any country. Prior to commercialization, each product candidate will be subject to an extensive and lengthy governmental regulatory approval process in the United States and in other countries. We or our partners may not be able to obtain regulatory approval for any product candidates, or even if approval is obtained, the labeling for such products may place restrictions on their use that could materially impact the marketability and profitability of the product subject to such restrictions. Satisfaction of these regulatory requirements, which includes satisfying the FDA and foreign regulatory authorities that the product is both safe and effective for its intended uses, typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Uncertainty with respect to meeting the regulatory requirements governing our product candidates may result in excessive costs or extensive delays in the regulatory approval process, adding to the already lengthy review process. If regulatory approval of a product is granted, such approval will be limited to those disease states and conditions for which the product is proven safe and effective, as demonstrated by clinical trials, and may not include all of the indications necessary to successfully market the product. Even though we have obtained orphan drug designation from the FDA and EMEA for deforolimus in bone and soft-tissue sarcomas, this designation may be challenged by others or may prove to be of no practical benefit. In addition, even though we have reached agreement on a Special Protocol Assessment, or SPA, with the FDA with respect to our SUCCEED Phase 3 clinical trial of deforolimus for metastatic sarcoma, the FDA is not obligated to approve deforolimus as a result of the SPA, even if the clinical outcome of the SUCCEED trial is positive. Therefore, we cannot provide assurance that positive results in the SUCCEED trial will be sufficient for FDA approval of deforolimus.

We will not be able to sell our product candidates if we, Merck or our third-party manufacturers fail to comply with FDA manufacturing and quality requirements.

Under our collaboration with Merck, we are responsible for providing the active pharmaceutical ingredient used in deforolimus drug product, and Merck will be responsible for the formulation of the finished product. Under our agreements with Medinol and ICON, we are responsible for providing the deforolimus to be delivered by the stents or other medical devices being developed by Medinol and ICON. Before approving any of our product candidates, the FDA will inspect the facility or facilities at which the drug product is manufactured and will not approve the drug candidate unless it is satisfied with our or our third-party manufacturer's compliance with manufacturing and quality requirements. The manufacturing of our product candidates must comply with cGMP requirements of the FDA and similar requirements of regulatory agencies in other countries. These requirements govern, among other things, quality control and documentation procedures. We, Merck or any third-party manufacturer of product candidates, may not be able to comply with these requirements, which would prevent us from obtaining approval for or selling such products. Material changes to the manufacturing processes of products after approvals have been granted are also subject to review and approval by the FDA or other regulatory agencies. Following approval, such facilities are subject to continuing FDA and foreign regulatory inspections and failure to comply with cGMPs or similar regulations can result in regulatory action up to and including cessation of shipment of product.

Even if we or our partners bring products to market, we or they may be unable to effectively price the products or obtain adequate reimbursement for sales of the products, which would prevent the products from becoming profitable.

If we or our partners succeed in bringing any product candidates to the market, they may not be considered cost-effective, and coverage and adequate payments may not be available or may not be sufficient to allow us to sell such products on a competitive basis. In both the United States and elsewhere, sales of medical products and the availability or acceptance of treatments are dependent, in part, on the availability of reimbursement from third-party payors, such as health maintenance organizations and other private insurance plans and governmental programs such as Medicare. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and medical procedures. Our business may be affected by the efforts of government and third-party payors to contain or reduce the cost of health care through various means. In the United States, there have been and will continue to be a number of federal and state proposals to implement government controls on pricing. Similar government pricing controls exist in varying degrees in other countries. In addition, the emphasis on managed care in the United States has increased and will continue to increase the pressure on the pricing of pharmaceutical products. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009. This law provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate any policies for public or private payors, it is not clear what if any effect the research will have on the sales of our product candidates if any such product or the condition that it is intended to treat is the subject of a study. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

We cannot predict whether any other legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

#### **Risks Relating to Our Common Stock**

Results of our operations, general market conditions for biotechnology stocks and other factors could result in a sudden change in the value of our stock.

As a biopharmaceutical company, we have experienced significant volatility in our common stock. In 2008, our stock price ranged from a high of \$4.48 to a low of \$0.72. Factors that can contribute to such volatility may include: announcements regarding results and timing of preclinical studies and clinical trials for our product candidates; announcements regarding our collaborations and partnerships; evidence of the safety or efficacy of our product candidates; announcements regarding product developments or regulatory approvals obtained by companies developing competing products; decisions by regulatory agencies that impact or may impact our product candidates; the results and timing of efforts by our partner or future partners to develop stents or other medical devices to deliver deforolimus; announcements of new collaborations or failure to enter into collaborations; our funding requirements; announcements of new equity or debt financings; announcements of technological innovations or new therapeutic products; developments relating to intellectual property rights, including licensing, litigation and governmental regulation and, in particular, our litigation with Lilly and with Amgen and reexamination proceedings in the PTO with respect to the '516 Patent; healthcare or costcontainment legislation; general market trends for the biotechnology industry and related hightechnology industries; the impact of exchange rates for the U.S. dollar; the impact of changing interest rates and policies of the Federal Reserve; and public policy pronouncements. These and other factors could have a significant impact on the value and volatility of our common stock in future periods.

Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and our stockholders' rights plan, or poison pill, could make a third-party acquisition of us difficult.

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the General Corporation Law of Delaware, which prohibits us from engaging in certain business combinations, unless the business combination is approved in a prescribed manner. In addition, our certificate of incorporation and our bylaws, each as currently in effect, also contain certain provisions that may make a third-party acquisition of us difficult, including:

- a classified board of directors, with three classes of directors each serving a staggered three-year term;
- the ability of the board of directors to issue preferred stock; and
- the inability of our stockholders to call a special meeting.

We also have implemented a stockholders' rights plan, also called a poison pill, which could make it uneconomical for a third party to acquire our company on a hostile basis. These provisions, as well as Section 203, may discourage certain types of transactions in which our stockholders might otherwise receive a premium for their shares over the current market price, and may limit the ability of our stockholders to approve transactions that they think may be in their best interests.

#### **ITEM 1B: UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2: PROPERTIES**

We have leased approximately 100,000 square feet of laboratory and office space at 26 Landsdowne Street, Cambridge, Massachusetts through July 2012, with two consecutive five-year renewal options. We believe that our currently leased facility will be adequate for our research and development and other business activities at least through the year 2010. We believe that any additional space we may require will be available on commercially reasonable terms.

#### ITEM 3. LEGAL PROCEEDINGS

We are from time to time involved in legal proceedings regarding patent, contract and other matters. Legal proceedings that management believes have or may have a material impact on ARIAD are described below and more fully in Note 13 of the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K, which is incorporated herein by reference.

Certain of our patents are the subject of a patent infringement lawsuit filed in June 2002 in the U.S. District Court in Massachusetts by us and others against Lilly and a lawsuit filed in April 2006 in the U.S. District Court in Delaware against us by Amgen and certain affiliated entities. One of these patents is also the subject of reexamination proceedings in the PTO.

A shareholder derivative complaint was filed in the Delaware Court of Chancery in February 2009 by a stockholder alleging breaches of fiduciary duties and naming each of the members of our board of directors as a defendant and ARIAD as a nominal defendant. We believe these claims are without merit and that the complaint constitutes a frivolous lawsuit. We and our directors intend to vigorously oppose the lawsuit.

#### ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the quarter ended December 31, 2008.

#### PART II

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

#### **Market Information**

Our common stock is traded on The NASDAQ Global Market under the symbol "ARIA". The following table sets forth the high and low sales prices of our common stock as quoted on The NASDAQ Global Market for the periods indicated.

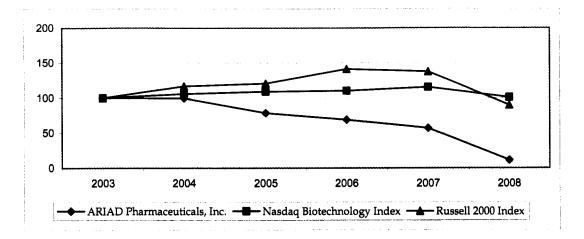
2008:	High			Low
First Quarter	\$	4.48	\$	2.66
Second Quarter		3.72		2.37
Third Quarter		3.55		2.10
Fourth Quarter		2.49		0.72
2007:				
First Quarter	\$	5.68	\$	4.07
Second Quarter		5.80		4.19
Third Quarter		6.40		3.84
Fourth Quarter		5.29		4.05

On March 10, 2009, the last reported sale price of our common stock was \$1.30.

#### Stock Performance Graph

The following graph compares the yearly percentage change in the cumulative total stockholder return on our common stock since December 31, 2003, with the total cumulative return of the NASDAQ Biotechnology Index and the Russell 2000® Index, each of which ARIAD is a member. The Russell 2000 Index is a market capitalization-weighted index of stock price performance for the 2,000 smallest companies in the Russell 3000® Index. Since the Russell 2000 Index is specifically designed to measure the stock price trends of smaller companies, we believe it is a meaningful index against which to compare our stock price performance.

The price of a share of common stock is based upon the closing price per share as quoted on The NASDAQ Global Market on the last trading day of the year shown. The graph lines merely connect year-end values and do not reflect fluctuations between those dates. The comparison assumes \$100 was invested on December 31, 2003 in our common stock and in each of the foregoing indices. We did not declare or pay any dividends during the comparison period. The stock price performance as shown in the graph below is not necessarily indicative of future stock price performance.



	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>
ARIAD Pharmaceuticals, Inc.	100.00	99.73	78.52	68.99	57.05	11.41
Nasdaq Biotechnology Index	100.00	106.13	109.14	110.25	115.30	100.75
Russell 2000 Index	100.00	117.00	120.88	141.43	137.55	89.68

The performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

#### Stockholders

As of February 28, 2009, the approximate number of holders of record of our common stock was 454, and the approximate total number of beneficial holders of our common stock was 45,000.

#### **Dividends**

We have not declared or paid dividends on our common stock in the past and do not intend to declare or pay such dividends in the foreseeable future. Our long-term debt agreement prohibits the payment of cash dividends.

#### **Unregistered Sales of Securities**

On September 11, 2008, we entered into an agreement and plan of merger, or the Merger Agreement, pursuant to which our 80 percent owned subsidiary, AGTI, was merged with and into ARIAD effective as of September 12, 2008. Pursuant to the Merger Agreement, each of the 1,126,064 outstanding shares of AGTI common stock owned by AGTI's minority stockholders was converted into the right to receive two shares of ARIAD common stock. In October 2008, pursuant to the Merger Agreement, we issued an aggregate of 1,799,276 shares of ARIAD common stock to former AGTI minority stockholders who had not exercised appraisal rights under Delaware law. In addition, in January 2009, we reached a settlement with the former AGTI minority stockholders who had exercised their appraisal rights, pursuant to which we issued an aggregate of 452,852 shares of ARIAD common stock and made cash payments, as detailed in Note 3 to our financial statements included in this Annual Report on Form 10-K. Accordingly, a total of 2,252,128 shares of our common stock were issued in connection with the AGTI merger.

The shares of ARIAD common stock issued in connection with the merger were not registered under the Securities Act of 1933, as amended (the "Securities Act"), and were issued in reliance on the exemption from registration provided by Section 4(2) of the Securities Act (and the regulations promulgated thereunder, including Regulation D) relating to sales by an issuer not involving a public offering.

#### **Issuer Purchases of Equity Securities**

Not applicable.

#### ITEM 6: SELECTED FINANCIAL DATA

The selected financial data set forth below as of December 31, 2008, 2007, 2006, 2005 and 2004 and for each of the years then ended have been derived from the audited consolidated financial statements of the Company, of which the financial statements as of December 31, 2008 and 2007 and for the years ended December 31, 2008, 2007 and 2006 are included elsewhere in this Annual Report on Form 10-K, and are qualified by reference to such financial statements. The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited consolidated financial statements, and the notes thereto, and other financial information included herein.

	Years Ended December 31,										
In thousands, except share and per share data	2008 2007		2007	2006		2005		2004			
Consolidated Statements of Operations Data:											
License and collaboration revenue	\$	7,082	\$	3,583	\$	896	\$	1,217	\$	742	
Operating expenses:										_	
Research and development		50,841		39,565		43,312		45,916		27,711	
General and administrative		28,092		24,712		21,251		12,261		9,442	
Operating expenses		78,933		64,277		64,563		58,177		37,153	
Loss from operations		(71,851)		(60,694)		(63,667)		(56,960)		(36,411)	
Other income (expense):				-	-						
Interest income		1,349		2,509		2,222		1,900		1,110	
Interest expense		(550)		(337)		(483)		(422)		(272)	
Other income, net		799		2,172		1,739		1,478		838	
Net loss	\$	(71,052)	\$	(58,522)	\$	(61,928)	\$	(55,482)	<u>\$</u>	(35,573)	
Net loss per share	\$	(1.02)	\$	(0.86)	\$	(0.99)	\$	(0.99)	\$	(0.69)	
Weighted average number of shares of common stock outstanding	69,790,784		68,215,803		62,679,807		56,283,948		51,294,160		
	As of December 31,										
In thousands		2008	2007		2006		2005		2004		
Consolidated Balance Sheet Data:											
Cash, cash equivalents and marketable securities	\$	39,068	\$	85,198	\$	39,804	\$	81,516	\$	75,506	
Working capital		14,174		64,591		25,859		65,971		68,874	
Total assets		68,188		101,105		51,043		96,174		87,189	
Total deferred revenue		97,264		85,845		454		875		1,117	
Long-term debt		11,550		0		3,815		5,735		7,655	
Accumulated deficit		(438,600)		(367,549)		(309,026)		(247,098)		(191,616)	
Stockholders' equity (deficit)		(69,198)		(7,900)		30,262		71,378		67,440	

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

Unless stated otherwise, references in this Annual Report on Form 10-K to "we," "us," or "our" refer to ARIAD Pharmaceuticals, Inc., a Delaware corporation, and our subsidiaries unless the context requires otherwise.

#### Overview

Our vision is to transform the lives of cancer patients with breakthrough medicines. Our mission is to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest and most urgent unmet medical need – aggressive cancers where current therapies are inadequate. Our goal is to build a fully integrated oncology company focused on novel, molecularly targeted therapies to treat solid tumors and hematologic cancers, as well as the spread of primary tumors to distant sites.

Our lead cancer product candidate, deforolimus, previously known as AP23573, is being studied in multiple clinical trials in patients with various types of cancers. In July 2007, we entered into a global collaboration with Merck & Co., Inc., or Merck, to jointly develop and commercialize deforolimus for use in cancer. We initiated patient enrollment in our initial Phase 3 clinical trial of deforolimus in patients with metastatic sarcoma in the third quarter of 2007. In addition, in 2008 we and Merck initiated patient enrollment in Phase 2 clinical trials in patients with metastatic breast cancer, advanced endometrial cancer and advanced prostate cancer, and Phase 1 clinical trials of deforolimus in combination with other agents.

Our collaboration with Merck for the global development and commercialization of deforolimus anticipates that we together with Merck will conduct a broad-based development program in multiple potential indications. The collaboration agreement provides that each party will fund 50 percent of global development costs, except for certain specific costs to be funded 100 percent by Merck. The collaboration agreement establishes responsibilities for supply of the product for development and commercial purposes, promotion, distribution and sales of the product, governance of the collaboration, termination provisions and other matters.

In addition to cost-sharing provisions, the collaboration agreement provides for an up-front payment by Merck of \$75 million, which was paid to us in July 2007, up to \$452 million in milestone payments based on the successful development of deforolimus in multiple potential cancer indications, of which \$31.0 million has been paid to us through December 31, 2008, and up to \$200 million in milestone payments based on achievement of specified product sales thresholds. The upfront payment and milestone payments, when earned by us and paid by Merck, are non-refundable. Merck has also agreed to provide us with up to \$200 million in interest-bearing, repayable, development cost advances to cover a portion of our share of global development costs, after we have paid \$150 million in global development costs and have obtained regulatory approval to market deforolimus from the FDA in the United States or similar regulatory authorities in Europe or Japan. The collaboration agreement provides that each party will receive 50 percent of the profit from the sales of deforolimus in the United States, and Merck will pay us tiered double-digit royalties on sales of deforolimus outside the United States.

Our second product candidate, AP24534, has entered clinical development. We filed an Investigational New Drug application, or IND, for this product candidate with the FDA in the fourth quarter of 2007 and initiated a Phase 1 clinical trial in patients with hematologic cancers in the second quarter of 2008.

In addition to our lead development programs, we have a focused drug discovery program centered on small-molecule, molecularly targeted therapies and cell-signaling pathways implicated in cancer. We also have an exclusive license to a family of patents, three in the United States and one in Europe, including a pioneering U.S. patent covering methods of treating human disease by regulating NF-κB cell-signaling activity. Additionally, we have developed a proprietary portfolio of cell-signaling regulation technologies, our ARGENT technology, to control intracellular processes with small molecules, which

may be useful in the development of therapeutic vaccines and gene and cell therapy products and which provide versatile tools for applications in cell biology, functional genomics and drug discovery research.

Since our inception in 1991, we have devoted substantially all of our resources to our research and development programs. We receive no revenue from the sale of pharmaceutical products, and most of our revenue to date was received in connection with a joint venture we had with a major pharmaceutical company from 1997 to 1999. Except for the gain on the sale of our 50 percent interest in that joint venture in December 1999, which resulted in net income for the year ended December 31, 1999, we have not been profitable since inception. As a result of our collaboration with Merck for the development and commercialization of deforolimus, we expect that our license and collaboration revenue will increase in future periods. However, we expect to incur substantial and increasing operating losses for the foreseeable future, primarily due to costs associated with our pharmaceutical product development programs, including costs for clinical trials and product manufacturing, pre-commercial activities, personnel and our intellectual property. We expect such costs and operating losses will be offset in part by development cost-sharing provisions and license revenue from our collaboration with Merck for the development and commercialization of deforolimus. We expect that losses will fluctuate from quarter to quarter and that these fluctuations may be substantial.

On September 11, 2008, we entered into a merger agreement with our 80 percent owned subsidiary, ARIAD Gene Therapeutics, Inc., or AGTI, pursuant to which AGTI was merged with and into ARIAD on September 12, 2008, as described in more detail in Note 3 to the accompanying financial statements.

As of December 31, 2008, we had cash, cash equivalents and marketable securities of \$39.1 million, working capital of \$14.2 million and total stockholders' deficit of \$69.2 million. Subsequently, on February 25, 2009, we raised net proceeds of \$22.8 million from the sale of 14,378,698 shares of our common stock and warrants to purchase an additional 10,784,024 shares of our common stock to institutional investors.

#### General

Our operating losses are primarily due to the costs associated with our pharmaceutical product development programs, personnel and intellectual property protection and enforcement. As our product development programs progress, we incur significant costs for toxicology and pharmacology studies, product development, manufacturing, clinical trials and regulatory support. We also incur costs related to planning for potential regulatory approval and commercial launch of products, including market research and assessment. These costs can vary significantly from quarter to quarter depending on the number of product candidates in development, the stage of development of each product candidate, the number of patients enrolled in and complexity of clinical trials and other factors. Costs associated with our intellectual property include legal fees and other costs to prosecute, maintain, protect and enforce our intellectual property, which can fluctuate from quarter to quarter depending on the status of patent issues being pursued, including our on-going patent litigation.

Historically, we have relied primarily on the capital markets as our source of funding. We may also obtain funding from collaborations with pharmaceutical, biotechnology and/or medical device companies for development and commercialization of our product candidates, such as our collaboration with Merck for the global development and commercialization of deforolimus. These collaborations can take the form of licensing arrangements, co-development or joint venture arrangements or other structures. In addition, we utilize long-term debt to supplement our funding, particularly as a means of funding investment in property and equipment and infrastructure needs. If funding from these various sources is unavailable on reasonable terms, we may be required to reduce our operating expenses in order to conserve cash and capital by delaying, scaling back or eliminating one or more of our product development programs.

## **Critical Accounting Policies and Estimates**

Our financial position and results of operations are affected by subjective and complex judgments, particularly in the areas of revenue recognition, the carrying value of intangible assets, deferred compensation benefits for executives, and stock-based compensation.

For the year ended December 31, 2008, we reported license and collaboration revenue of \$7.1 million. License and collaboration revenue is recorded based on up-front payments, periodic license payments and milestone payments received or deemed probable of receipt, spread over the estimated performance period of the license or collaboration agreement. Regarding our collaboration with Merck for the development and commercialization of deforolimus, as of December 31, 2008, we have received an up-front payment of \$75 million and we have received and/or earned milestone payments totaling \$31.0 million. We are recognizing revenues related to such payments on a straight-line basis through 2023, the estimated patent life of the underlying technology. Changes in development plans could impact the probability of earning future milestone payments on which revenue recognition is based. In addition, changes in estimated performance periods, including changes in patent lives of underlying technology, could impact the rate of revenue recognition in any period. Such changes in revenue could have a material impact on our statement of operations.

At December 31, 2008, we reported \$9.9 million of intangible assets, consisting of the recorded value of the technology associated with our acquisition in September 2008 of the 20 percent minority interest of AGTI that we did not previously own, as well as capitalized costs related primarily to purchased and issued patents, patent applications and licenses, net of accumulated amortization. These costs are being amortized over the estimated useful lives of the underlying technology, patents or licenses. Changes in these lives or a decision to discontinue using the technologies could result in material changes to our balance sheet and statements of operations. We have concluded that the carrying value of our intangible assets is not currently impaired because such carrying value does not exceed the future net cash flows expected to be generated by such intangible assets. If we were to abandon the ongoing development of the underlying product candidates or technologies or terminate our efforts to pursue collaborations or license agreements, we may be required to write off a portion of the carrying value of our intangible assets. The net book value as of December 31, 2008 of intangible assets related to our NF-kB technology is \$361,000. If the patentability of our NF-kB patents, one of which is currently the subject of litigation and reexamination proceedings, is successfully challenged and such patents are subsequently narrowed, invalidated or circumvented, we may be required to write off some or all of the net book value related to such technology.

Under our deferred executive compensation plans, we are required to adjust our recorded obligations to our officers on a periodic basis based on the quoted market value of certain underlying mutual funds. Fluctuations in the quoted market value of such mutual funds can result in uneven expense charges or credits to our statements of operations. If, for example, the quoted market prices of the underlying mutual funds were 10 percent higher at December 31, 2008, we would have recognized an additional \$191,000 in compensation expense in 2008.

In determining expense related to stock-based compensation, we utilize the Black-Scholes valuation model to estimate the fair value of stock options granted to employees, consultants and directors. Application of the Black-Scholes option valuation model requires the use of factors such as the market value and volatility of our common stock, a risk-free discount rate and an estimate of the life of the option contract. Fluctuations in these factors can result in adjustments to our statements of operations. If, for example, the market value of our common stock, its volatility, or the expected life of stock options granted during the year ended December 31, 2008 were 10 percent higher or lower than used in the valuation of such stock options, our valuation of, and total stock-based compensation expense to be recognized for, such awards would have increased or decreased by up to \$541,000, \$335,000, or \$199,000 respectively.

#### **Results of Operations**

#### Years Ended December 31, 2008 and 2007

#### Revenue

We recognized license and collaboration revenue of \$7.1 million for the year ended December 31, 2008, compared to \$3.6 million for the year ended December 31, 2007. The increase in license and collaboration revenue was due primarily to an increase in the revenue recognized from the Merck collaboration, based on the non-refundable up-front and milestone payments, totaling \$106.0 million, paid by Merck through December 31, 2008, in accordance with our revenue recognition policy. We entered into this collaboration with Merck in July 2007, and thus our statement of operations reflects a full year of revenue recognition in 2008 as compared to a partial year in 2007. We expect our license and collaboration revenue will increase in 2009 based on the expected receipt of additional milestone payments in accordance with the Merck collaboration agreement.

# **Operating Expenses**

Research and Development Expenses

Research and development expenses increased by \$11.2 million, or 28 percent, to \$50.8 million in 2008, compared to \$39.6 million in 2007. The research and development process necessary to develop a pharmaceutical product for commercialization is subject to extensive regulation by numerous governmental authorities in the United States and other countries. This process typically takes years to complete and requires the expenditure of substantial resources. Current requirements include:

- preclinical toxicology, pharmacology and metabolism studies, as well as in vivo efficacy studies in relevant animal models of disease;
- manufacturing of drug product for preclinical studies and clinical trials and ultimately for commercial supply;
- submission of the results of preclinical studies and information regarding manufacturing and control
  and proposed clinical protocol to the U.S. Food and Drug Administration, or FDA, in an
  Investigational New Drug application, or IND (or similar filings with regulatory agencies outside the
  United States);
- conduct of clinical trials designed to provide data and information regarding the safety and efficacy of the product candidate in humans; and
- submission of all the results of testing to the FDA in a New Drug Application, or NDA (or similar filings with regulatory agencies outside the United States).

Upon approval by the appropriate regulatory authorities, including in some countries approval of product pricing, we may commence commercial marketing and distribution of the product.

We group our research and development, or R&D, expenses into two major categories: direct external expenses and all other R&D expenses. Direct external expenses consist of costs of outside parties to conduct laboratory studies, to develop manufacturing processes and manufacture product candidates, to conduct and manage clinical trials and similar costs related to our clinical and preclinical studies. These costs are accumulated and tracked by product candidate. All other R&D expenses consist of costs to compensate personnel, to purchase lab supplies and services, to lease, operate and maintain our facility, equipment and overhead and similar costs of our research and development efforts. These costs apply to work on our clinical and preclinical candidates as well as our discovery research efforts. These costs have not been tracked by product candidate because the number of product candidates and projects in R&D may vary from time to time and because we utilize internal resources across multiple projects at the same time.

Direct external expenses are further categorized as costs for clinical programs and costs for preclinical programs. Preclinical programs include product candidates undergoing toxicology, pharmacology, metabolism and efficacy studies and manufacturing process development required before testing in humans can begin. Product candidates are designated as clinical programs once we have filed an IND with the FDA, or a similar filing with regulatory agencies outside the United States, for the purpose of commencing clinical trials in humans.

Our R&D expenses for 2008 as compared to 2007 were as follows:

Year ended December 31,					Increase/		
	2008		2007	(decrease)			
\$	24,168	\$	10,026	\$	14,142		
			3,881		(3,881)		
	26,673		25,658		1,015		
\$	50,841	\$	39,565	\$	11,276		
		2008 \$ 24,168  26,673	\$ 24,168 \$ 26,673	\$ 24,168 \$ 10,026 3,881 26,673 25,658	2008       2007       (de         \$ 24,168       \$ 10,026       \$ 3,881          3,881       25,658		

In 2008, our clinical programs consisted of our development of deforolimus, for which we initiated clinical development in 2003, and of AP24534, for which we initiated clinical development in 2008. Prior to 2008, we classified AP24534 as a preclinical program.

Direct external expenses for deforolimus were \$20.4 million in 2008, an increase of \$10.4 million, as compared to the corresponding period in 2007. This increase is due to an increase in clinical trial costs of \$9.8 million, costs of non-clinical studies of \$3.6 million and manufacturing costs of \$1.9 million in 2008 as compared to 2007, offset in part by an increase in Merck's share of expenses of \$10.4 million in 2008. In addition, costs for Merck's services provided to the collaboration increased by \$4.5 million in 2008 as compared to 2007. Clinical trial costs and contract manufacturing costs increased due primarily to increasing enrollment in our Phase 3 clinical trial of deforolimus in patients with metastatic sarcomas and initiation of enrollment in 2008 in Phase 2 clinical trials of deforolimus in patients with breast cancer and endometrial cancer. Costs of non-clinical studies increased due to the initiation and conduct of toxicology studies of deforolimus required to support regulatory filings with the FDA. We expect our direct external expenses for deforolimus will increase in 2009 due to initiation of and enrollment of patients in new clinical trials as well as ongoing enrollment in existing clinical trials for this product candidate.

Direct external expenses for our second clinical program, AP24534, were \$3.7 million in 2008, which consisted primarily of clinical trial costs of \$923,000, toxicology costs of \$812,000 and contract manufacturing costs of \$1.8 million as we initiated enrollment in our first Phase 1 clinical trial of this product candidate. We expect our direct external expenses for AP24534 will increase in 2009 as we continue to enroll patients in our Phase 1 trial and perform related manufacturing and non-clinical studies for this product candidate.

We incurred no direct external expenses for preclinical programs in 2008 as, during that year, no R&D programs were designated as preclinical programs. All programs other than clinical and preclinical programs are designated as discovery research and are included in "all other R&D expenses" in the above table. Direct external expenses for preclinical programs for the period ended December 31, 2007 relate primarily to costs for toxicology and contract manufacturing studies for AP24534 in support of the filing of the IND for this product candidate in late 2007. We expect to nominate our next clinical candidate, an anaplastic lymphoma kinase, or ALK, inhibitor, and move it into preclinical testing in 2009. The direct external expenses to be incurred in 2009 upon nomination of this clinical candidate will be reflected in this analysis as a preclinical program.

All other R&D expenses increased by \$1.0 million in 2008 as compared to 2007. This increase is due primarily to an increase in personnel expenses of \$3.1 million, related to the hiring of additional R&D personnel and related expenses (\$3.9 million) offset in part by reduced stock-based compensation expense (\$796,000) resulting from previous year stock-option awards fully vested prior to 2008 and forfeitures in 2008, and an increase in overhead expenses of \$1.8 million due to the expiration of a sub-

lease agreement for a portion of our office and laboratory facility in July 2007, as well as miscellaneous increases in lab supplies and services and professional services. These variances were offset in part by an increase in Merck's allocated share of such expenses under the terms of the collaboration agreement of \$5.3 million in 2008. We expect that all other R&D expenses will increase in 2009 in support of continuing discovery research and product development activities.

The successful development of our product candidates is uncertain and subject to a number of risks. We cannot be certain that any of our product candidates will prove to be safe and effective or will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval. Data from preclinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory clearance. We, the FDA or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our products under development. Delays or rejections may be encountered based on additional governmental regulation, legislation, administrative action or changes in FDA or other regulatory policy during development or the review process. Other risks associated with our product development programs are described in the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of completion of any of our drug development programs and the period in which material net cash inflows from any of our drug development programs will commence are unavailable.

#### General and Administrative Expenses

General and administrative expenses increased by \$3.4 million, or 14 percent, from \$24.7 million in 2007 to \$28.1 million in 2008. Professional fees increased by \$2.1 million to \$18.9 million in 2008 as compared to \$16.8 million in 2007, due primarily to costs related to corporate and commercial development initiatives, including costs related to the development of systems and processes to support growth, and to our patent infringement litigations against Eli Lilly and Company, or Lilly, and Amgen Inc., or Amgen. Personnel and related costs increased by \$1.8 million due to an increase in the number of personnel and salary adjustments (\$2.1 million), offset in part by reduced stock-based compensation expense (\$349,000) resulting from previous year stock-option awards fully vested prior to 2008 and forfeitures in 2008. These increases were partially offset by an increase in Merck's allocated share of such expenses under the terms of the collaboration agreement. We expect that our general and administrative expenses will decrease in 2009 reflecting primarily an expected decrease in activity related to our patent infringement litigation and certain corporate initiatives.

We expect that our operating expenses in total, net of Merck's share of development costs of deforolimus, will increase in 2009 for the reasons described above. Operating expenses may fluctuate from quarter to quarter. The actual amount of any increase in operating expenses will depend on, among other things, the progress of our product development programs, including the planned increase in clinical trials and other studies related to deforolimus pursuant to our collaboration with Merck, product manufacturing and increased clinical trials related to AP24534, and developments in our patent infringement litigation.

# Interest Income / Expense

Interest income decreased by 46 percent to \$1.3 million in 2008 from \$2.5 million in 2007, as a result of lower interest yields from our cash equivalents and marketable securities and a lower average balance of funds invested in 2008.

Interest expense increased by 63 percent to \$550,000 in 2008 from \$337,000 in 2007, due to higher average loan balances in 2008, as a result of our amendment of our loan agreement in March 2008 which, among other things, provided us an additional \$10 million in loan proceeds, offset in part by lower interest rates in 2008.

#### **Operating Results**

We reported a loss from operations of \$71.9 million in 2008 compared to a loss from operations of \$60.7 million in 2007, an increase in loss of \$11.2 million, or 18 percent. We also reported a net loss of \$71.1 million in 2008 compared to a net loss of \$58.5 million in 2007, an increase in net loss of \$12.5 million or 21 percent, and a net loss per share of \$1.02 and \$0.86, in 2008 and 2007, respectively. Such increases were due primarily to the net effect of changes in R&D expenses and general and administrative expenses noted above. We expect that our loss from operations and our net loss in 2009 will increase as compared to 2008 due to the various factors described under "Revenue" and "Operating Expenses" above. Actual losses will depend on the progress of our product development programs, the progress of our discovery research programs, the impact of commercial and business development activities and developments in our legal proceedings, among other factors. The extent of such losses will also depend on the sufficiency of funds on hand or available from time to time, which will influence the amount we will spend on operations and capital expenditures, as well as the development timelines for our product candidates.

## Years Ended December 31, 2007 and 2006

#### Revenue

We recognized license and collaboration revenue of \$3.6 million for the year ended December 31, 2007 compared to \$896,000 for the year ended December 31, 2006. The increase in license and collaboration revenue was due primarily to the revenue recognized from the Merck collaboration, based on the non-refundable up-front and milestone payments, totaling \$88.5 million, paid by Merck in the third and fourth quarters of 2007, in accordance with our revenue recognition policy.

# **Operating Expenses**

Research and Development Expenses

Research and development expenses decreased by \$3.7 million, or 9 percent, to \$39.6 million in 2007, compared to \$43.3 million in 2006, as follows:

	Y	Increase/					
In thousands	2007			2006	(decrease)		
Direct external expenses:							
Clinical programs	\$	10,026	\$	15,584	\$	(5,558)	
Preclinical programs		3,881		843		3,038	
All other R&D expenses		25,658		26,885		(1,227)	
<u>-</u>	\$	39,565	\$	43,312	\$	(3,747)	

Deforolimus was our only clinical program in 2007 and 2006. Commencing in the third quarter of 2007, the direct external expenses for deforolimus reflect our share of such expenses pursuant to the cost-sharing arrangements of our collaboration with Merck. Direct external expenses for deforolimus decreased by \$5.6 million in 2007 as compared to 2006 due primarily to the impact of Merck's share of such expenses in 2007 of \$4.2 million, plus lower clinical trial and manufacturing costs related to a lower number of patients in trials in 2007 as compared to 2006.

Our preclinical program in 2007 and 2006 consisted of our second product candidate, AP24534, for which we filed an IND in late 2007. Direct external expenses on preclinical programs will increase or decrease over time depending on the status and number of programs in this stage of development and the mix between external and internal efforts applied to such programs. Direct external expenses for preclinical programs increased by \$3.0 million in 2007 as compared to 2006 due primarily to the cost of certain toxicology studies and contract manufacturing we conducted for AP24534 in 2007 in support of the filing of the IND for this product candidate in the fourth quarter of 2007.

All other R&D expenses decreased by \$1.2 million in 2007 as compared to 2006 due to the impact of Merck's allocated share of such expenses of \$2.2 million, and a decrease in depreciation and amortization expenses of \$2.2 million reflecting an increase in the useful life of leasehold improvements upon the extension of the term of the lease of our laboratory and office facility. These favorable variances were partially offset by an increase in personnel expenses of \$1.3 million, primarily related to stock-based compensation expense of \$797,000 resulting from grants of stock options in 2007 and an increase in the number of personnel and related expenses of \$515,000, an increase in overhead expenses of \$1.2 million due to the expiration of a sub-lease agreement for a portion of our office and laboratory facility in July 2007 and increases in other miscellaneous expenses, including maintenance and travel.

#### General and Administrative Expenses

General and administrative expenses increased by \$3.5 million, or 16 percent, from \$21.3 million in 2006 to \$24.7 million in 2007. Professional fees increased by \$3.3 million to \$16.8 million in 2007 as compared to \$13.5 million in 2006 due primarily to costs related to corporate and business development initiatives and to our patent infringement litigations against Eli Lilly and Company, or Lilly, and Amgen Inc., or Amgen, respectively. Personnel and related costs increased by \$1.1 million due to an increase in the number of personnel and salary adjustments (\$365,000) and stock-based compensation expense (\$633,000) resulting from grants of stock options in 2007. These increases were partially offset by decreases in miscellaneous expenses, including taxes and travel.

## Interest Income / Expense

Interest income increased by 13 percent to \$2.5 million in 2007 from \$2.2 million in 2006, due to a higher average balance of funds invested in 2007, offset in part by lower interest yields from our cash equivalents and marketable securities in 2007.

Interest expense decreased by 30 percent to \$337,000 in 2007 from \$483,000 in 2006, as a result of lower interest rates and lower average loan balances in 2007 compared to 2006.

#### **Operating Results**

We reported a loss from operations of \$60.7 million in 2007 compared to a loss from operations of \$63.7 million in 2006, a decrease in loss of \$3.0 million, or 5 percent. We also reported a net loss of \$58.5 million in 2007 compared to a net loss of \$61.9 million in 2006, a decrease in net loss of \$3.4 million or 5 percent, and a net loss per share of \$0.86 and \$0.99, in 2007 and 2006, respectively. Such decreases were due primarily to the net effect of changes in R&D expenses and general and administrative expenses noted above and the increase in license and collaboration revenue of \$2.7 million as a result of the Merck collaboration.

#### Selected Quarterly Financial Data

Summarized unaudited quarterly financial data are as follows:

	2008											
In thousands, except per share amounts  Total license and collaboration revenue Net loss Net loss per share		First		Second		Third	Fourth					
		1,495 \$ (17,011) (0.25)		1,450 (17,267) (0.25)	\$	1,536 (19,993) (0.29)	\$	2,601 (16,781) (0.24)				
				20	07							
In thousands, except per share amounts	_	First		Second		Third		Fourth				
Total license and collaboration revenue Net loss Net loss per share	\$	190 (14,951) (0.23)	!	\$ 189 (17,005) (0.25)	\$	1,602 (10,850) (0.16)	\$	1,602 (15,716) (0.23)				

# Liquidity and Capital Resources

We have financed our operations and investments to date primarily through sales of our common stock to institutional investors and, to a lesser extent, through issuances of our common stock pursuant to our stock option and employee stock purchase plans, supplemented by the issuance of long-term debt. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. Our collaboration with Merck for the development and commercialization of deforolimus provides for additional funding in the form of upfront and potential milestone payments, as well as the sharing of development costs for deforolimus. We seek to balance the level of cash, cash equivalents and marketable securities on hand with our projected needs and to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms.

#### Sources of Funds

During the years ended December 31, 2008, 2007 and 2006, our sources of funds were as follows:

In thousands	2008		 2007	2006	
Up-front payment from Merck, included in cash provided by operating activities	<u> </u>		\$ 75,000		
Maturities of marketable securities,					
net of purchases	\$	2,902	(8,460)	\$	49,642
Proceeds from long-term borrowings		10,505			
Sales/issuances of common stock:					
In common stock offerings			12,300		14,271
Pursuant to stock option and employee					
stock purchase plans		385	 2,071		1,955
	\$	13,792	\$ 80,911	\$	65,868

Our up-front payment from Merck of \$75 million was received pursuant to our collaboration agreement for the development and commercialization of deforolimus. This up-front payment is included in cash provided by operating activities in our consolidated statement of cash flows for the year ended December 31, 2007 but is presented separately in this analysis due to the non-recurring nature of this payment. The agreement also provides for, among other things, the payment by Merck of up to \$452 million in development and regulatory milestones during the remaining development of deforolimus, including \$31.0 million in milestone payments received through December 31, 2008 related to the start of various Phase 2 and the Phase 3 clinical trials, and up to \$200 million based on the achievement of specified product sales thresholds. Milestone payments, including the \$31.0 million in payments referred to above, are reflected as a reduction of cash used in operating activities in "Uses of Funds" later in this analysis.

We manage our marketable securities portfolio to provide cash for payment of our obligations. We purchase marketable securities to enhance our yield on invested funds and when such amounts are not needed for near-term payment of obligations. We generally hold our marketable securities to maturity. Upon maturity of such marketable securities, a portion may be retained as cash to provide for payment of current obligations while the remainder will be reinvested in accordance with our investment policy. For the years ended December 31, 2008, 2007 and 2006, proceeds from maturities of marketable securities, purchases of marketable securities and the resulting net amount retained as cash for payment of obligations or reinvested were as follows:

In thousands	2008	2007	2006		
Proceeds from maturities of marketable	 <del></del>				
securities	\$ 60,168	\$ 59,197	\$	92,561	
Purchases of marketable securities	(57,266)	(67,657)		(42,919)	
	\$ 2,902	\$ (8,460)	\$	49,642	

The amount of funding we raise through sales of our common stock depends on many factors, including, but not limited to, the status and progress of our product development programs, projected cash needs, availability of funding from other sources, our stock price and the status of the capital markets. In 2006 and 2007, we completed sales of our common stock for net proceeds of \$14.3 million and \$12.3 million, respectively. We had no common stock financings in 2008. The following table details our common stock sales in 2006 and 2007:

	Number of Shares	Price Per Share	Net Cash Proceeds		
October, 2006	3,112,945	\$4.65	In thousands \$14,271		
March, 2007	3,072,393	\$4.07	\$12,300		

We have filed shelf registration statements with the SEC, from time to time, to register shares of our common stock or other securities for sale, giving us the opportunity to raise funding when needed or otherwise considered appropriate. On January 30, 2007, we filed a shelf registration statement with the SEC for the issuance of common stock, preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, with a total value of up to \$100 million, from time to time at prices and on terms to be determined at the time of any such offerings. This filing was declared effective on February 6, 2007.

In March 2007, we sold 3,072,393 shares of our common stock to Azimuth Opportunity Ltd. pursuant to an equity financing facility between the parties dated February 14, 2007. We received aggregate gross proceeds from this sale of \$12.5 million, or \$12.3 million net of issuance expenses. These shares were registered under our shelf registration statement filed on January 30, 2007. The equity financing facility expired on September 1, 2008. Following this sale, and as of December 31, 2008, we had \$87.5 million of securities available for sale under our shelf registration statement.

In March 2008, we amended our existing term loan with a bank. The amendment provided for an increase of \$10.5 million in our loan balance to \$14.0 million, the extension of the maturity date from March 31, 2008 to March 31, 2013, and changes to the repayment provisions. The amended terms of the loan require us to maintain at least \$15.0 million in unrestricted cash, cash equivalents and investments. The agreement also contains certain covenants that restrict additional indebtedness, additional liens, and sales of assets, and dividends, distributions or repurchases of common stock. At December 31, 2008, the balance outstanding on our term loan agreement was \$13.0 million.

#### **Uses of Funds**

The primary uses of our cash are to fund our operations and working capital requirements and, to a lesser degree, to repay our long-term debt, to invest in intellectual property and to invest in our property and equipment as needed for our business. Our uses of cash during the years ended December 31, 2008, 2007 and 2006 were as follows:

In thousands		2008	2007	2006		
Net cash (provided by) used in operating activities	\$	48,522	\$ (33,988)	\$	56,038	
Less up-front payment from Merck			75,000			
Adjusted net cash used in operating activities		48,522	41,012		56,038	
Repayment of long-term borrowings		1,370	1,920		1,920	
Investment in intangible assets		1,091	497		568	
Investment in property and equipment		6,651	1,346		1,067	
	\$	57,634	\$ 44,775	\$	59,593	

Net cash (provided by) used in operating activities is comprised of our net losses, adjusted for non-cash expenses, deferred revenue, including deferrals of the up-front and milestone payments received from Merck, and working capital requirements. Adjusted net cash used in operating activities excludes the favorable impact of the non-recurring, up-front payment from Merck of \$75.0 million in the third quarter of 2007 pursuant to our collaboration agreement. As noted above, our net loss increased in 2008, due primarily to the increased costs of advancing our product candidates through clinical phases of development, expansion of business and commercial development initiatives and patent litigation, and decreased in 2007, due primarily to the favorable impacts of the Merck collaboration. Our adjusted net cash used in operating activities as presented above varied from year to year for the same reasons, including the favorable impact of milestone payments received from Merck of \$13.5 million in 2007 and \$17.5 million in 2008. As noted above, we expect that our net loss will increase in 2009 due to ongoing development of our product candidates. However, we expect that our milestone payments from Merck related to development of deforolimus will also increase and such increase will more than offset the impact of the increase in net loss on our cash used in operating activities. Thus, we expect that our net cash used in operating activities will decrease in 2009 when compared to 2008. We expect that our investment in intangible assets, consisting of our intellectual property will increase in 2009 in support of our product development activities. We also expect that our investment in property and equipment will decrease in 2009 due to completion of certain renovations in 2008 and fewer needs for replacement of equipment in 2009.

#### **Off-Balance Sheet Arrangements**

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities for financial partnerships, such as entities often referred to as structured finance or special purpose entities which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of December 31, 2008, we maintained an outstanding letter of credit of \$699,000 in accordance with the terms of our long-term lease for our office and laboratory facility.

## **Contractual Obligations**

We have substantial fixed contractual obligations under various research and licensing agreements, consulting and employment agreements, lease agreements and long-term debt agreement. These contractual obligations were comprised of the following as of December 31, 2008:

In thousands	Payments Due By Period										
	Total		Ir	a 2009	2010 through 2012		2013 through 2014		-	After 2014	
Long-term debt	\$	12,950	\$	1,400	\$	10,325	\$	1,225	\$		
Operating leases		7,660		2,161		5,499					
Employment agreements		15,494		5,637		9,249		608			
Other long-term obligations		4,399		1,116		2,297		591		395	
	\$	40,503	\$	10,314	\$	27,370	\$	2,424	\$	395	

Long-term debt consists of scheduled principal payments on such debt. Interest on our long-term debt is based on variable interest rates. Assuming a constant interest rate of 3.65 percent, the interest rate on our debt at December 31, 2008, over the remaining term of the debt, our interest expense would total approximately \$447,000 in 2009.

Other long-term obligations are comprised primarily of obligations under our deferred executive compensation plans and license agreements. The license agreements generally provide for payment by us of annual license fees, milestone payments and royalties upon successful commercialization of products. All license agreements are cancelable by us. The above table reflects remaining license fees for the lives of the agreements but excludes milestone and royalty payments, as such amounts are not probable or estimable at this time.

#### Liquidity

At December 31, 2008, we had cash, cash equivalents and marketable securities totaling \$39.1 million and working capital of \$14.2 million, compared to cash, cash equivalents and marketable securities totaling \$85.2 million and working capital of \$64.6 million at December 31, 2007. The decrease in cash, cash equivalents, and marketable securities and working capital is primarily attributable to operating losses and changes in working capital requirements.

On February 25, 2009, we raised net proceeds of \$22.8 million from the sale of 14,378,698 shares of our common stock and warrants to purchase 10,784,024 shares of our common stock from our existing shelf registration statement. Following this transaction, we have approximately \$40.0 million of securities remaining available for issuance under our existing shelf registration statement.

Based on our current operating plans, including the continued clinical development of deforolimus, in conjunction with Merck, and AP24534, we expect to incur a net loss for the year ending December 31, 2009 in the range of \$78 million to \$82 million. In addition, we expect to receive approximately \$50 million in milestone payments from Merck in 2009 related to the start of various Phase 2 and Phase 3 clinical trials of deforolimus. Accordingly, we expect to report cash used in operating activities for the year ending December 31, 2009 in the range of \$24 million to \$28 million. While we believe that the milestone payments from Merck will be received as forecasted, we do have contingency plans in place should the receipt of the milestone payments be deferred into the first part of 2010, which plans focus on the reduction of spending on non-critical research and development activities. Based on these plans and projections, we believe that our cash, cash equivalents and marketable securities on hand at December 31, 2008 and the \$22.8 million in net proceeds raised in February 2009 are sufficient to fund our operations through at least the next twelve months.

There are numerous factors that are likely to affect our spending levels, including the extent of clinical trials and other development activities for deforolimus in collaboration with Merck, the timing and amount of milestone payments to be received from Merck, the rate of enrollment of patients in clinical trials for deforolimus and AP24534, the progress of our discovery research and preclinical programs, the impact of potential business development activities, and developments in our NF-κB patent litigation and reexamination proceedings, among other factors. These variables could result in higher or lower spending levels which could impact the sufficiency of our current funds if we are to continue operations in accordance with our current plans and achieve our intended timelines for development. In any event, we will require substantial additional funding for our R&D programs, including preclinical development and clinical trials, for operating expenses, including intellectual property protection and enforcement, for the pursuit of regulatory approvals, and for establishing manufacturing, marketing and sales capabilities. In order to fund our needs, we may, among other things, (1) sell our securities through public or private offerings as market conditions permit, (2) enter into new long-term debt or other credit agreements, (3) enter into or amend partnership agreements for development and commercialization of our product candidates, and/or (4) license our cell-signaling technologies, including our ARGENT and NF-xB intellectual property portfolios.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to: (1) delay, limit, reduce or terminate preclinical studies, clinical trials or other clinical development activities for one or more of our product candidates; (2) delay, limit, reduce or terminate our discovery research or preclinical development activities; or (3) delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

#### Recently Adopted or Issued Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard No. 157 ("SFAS No. 157"), *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The Company has adopted the provisions of SFAS No. 157 as of January 1, 2008, for financial instruments. Although the adoption of SFAS No. 157 did not materially impact its financial condition, results of operations, or cash flow, the Company is now required to provide additional disclosures as part of its financial statements.

SFAS No. 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset's or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The Company's marketable securities are classified as available for sale and are stated at fair value based on quoted market prices, which are considered Level 1 inputs within the fair value hierarchy.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which provides companies with the option to measure specified financial instruments and certain other items at fair value. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company did not elect to apply the fair value method to any of its financial instruments at January 1, 2008.

In June 2007, the Emerging Issues Task Force ("EITF") issued EITF No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities. EITF No. 07-3 states that nonrefundable advance payments for goods or services that will be used for future research and development activities should be deferred and capitalized and that such amounts should be recognized as an expense as the goods are delivered or the services are performed. EITF No. 07-3 is effective for fiscal years beginning after December 15, 2007. The adoption of EITF No. 07-3 did not have a material impact on the Company's financial statements.

In December 2007, the EITF issued EITF No. 07-1, *Accounting for Collaborative Arrangements*. EITF No. 07-1 provides guidance on the determination of a collaborative arrangement, reporting of costs incurred and revenue generated on sales to third parties in the statement of operations, and classification of payments made between participants in a collaborative arrangement in the statement of operations. EITF No. 07-1 is effective for fiscal years beginning after December 15, 2008. The adoption of this EITF is not expected to have a material impact on the Company's financial statements.

In April 2008, the FASB issued FASB Staff Position ("FSP") No. FAS 142-3, *Determination of the Useful Life of Intangible Assets*, which requires companies, in estimating the useful life of a recognized intangible asset, to consider the company's historical experience in renewing or extending similar arrangements. In the absence of historical experience, the company shall consider assumptions that market participants would use that are consistent with the highest and best use of the asset. FSP No. FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. The Company does not expect the impact of FSP No. FAS 142-3 to have a material impact on its consolidated financial statements.

## ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our available funds in accordance with our investment policy 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.

We invest cash balances in excess of operating requirements first in short-term, highly liquid securities, with original maturities of 90 days or less, and money market accounts. Depending on our level of available funds and our expected cash requirements, we may invest a portion of our funds in marketable securities, consisting generally of corporate debt and U.S. government and agency securities. Maturities of our marketable securities are generally limited to periods necessary to fund our liquidity needs and may not in any case exceed three years. These securities are classified as available-for-sale. Available-for-sale securities are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of stockholders' equity (accumulated other comprehensive income or loss). Realized gains and losses on marketable security transactions, if any, are reported on the specific-identification method. Interest income is recognized when earned. A decline in the market value of any available-for-sale security below cost that is deemed other than temporary results in a charge to earnings and establishes a new cost basis for the security.

Our investments are sensitive to interest rate risk. We believe, however, that the effect, if any, of reasonably possible near-term changes in interest rates on our financial position, results of operations and cash flows generally would not be material due to the current short-term nature of these investments. In particular, at December 31, 2008, because our available funds were invested solely in cash equivalents and short-term marketable securities with maturities of six months or less, our risk of loss due to changes in interest rates is not material.

We have a deferred executive compensation plan which provides participants with deferred compensation based on the value of certain designated mutual funds. The fair value of our obligations under this program is reflected as a liability on our balance sheet. In the event of a hypothetical 10 percent increase in the fair market value of the underlying mutual funds as of December 31, 2008, we would have incurred approximately \$191,000 of additional compensation expense for the year ended December 31, 2008.

At December 31, 2008, we had \$13.0 million outstanding under a bank term note which bears interest at prime or, alternatively, LIBOR +1.25 to 2.25 percent. This note is sensitive to changes in interest rates. In the event of a hypothetical 10 percent increase in the interest rate on which the loan is based (36.5 basis points at December 31, 2008), we would incur approximately \$45,000 of additional interest expense per year based on expected balances over the next twelve months.

#### Certain Factors That May Affect Future Results of Operations

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Annual Report on Form 10-K contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be made directly in this Annual Report, and they may also be made a part of this Annual Report by reference to other documents filed with the SEC, which is known as "incorporation by reference." Such statements in connection with any discussion of future operating or financial performance are identified by use of words such as "may," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," and other words and terms of similar meaning. Such statements are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such forward-looking statements. These risks include, but are not limited to, the costs associated with our research, development, manufacturing and other activities, the conduct and results of preclinical and clinical studies of our product candidates, difficulties or delays in obtaining regulatory approvals to market products resulting from our development efforts, our reliance on our strategic partners and licensees and other key parties for the successful development, manufacturing and commercialization of products, the adequacy of our capital resources and the availability of additional funding, patent protection and third-party intellectual property claims relating to our and any partner's product candidates, the timing, scope, cost and outcome of legal proceedings, future capital needs, risks related to key employees, markets, economic conditions, prices, reimbursement rates and competition, and other factors. Please also see the discussion under "Risk Factors" in Part I, Item 1A appearing elsewhere in this Annual Report on Form 10-K for more details regarding these and other risks.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference in this Annual Report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

# Management's Report on Internal Control over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company's internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment we believe that, as of December 31, 2008, the Company's internal control over financial reporting is effective based on those criteria.

Deloitte & Touche LLP, the independent registered public accounting firm that audited the Company's consolidated financial statements, has issued an attestation report on the Company's internal control over financial reporting as of December 31, 2008, which is included below.

### Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of ARIAD Pharmaceuticals, Inc. Cambridge, Massachusetts

We have audited the internal control over financial reporting of ARIAD Pharmaceuticals, Inc. and subsidiaries (the "Company") 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. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, 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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being

made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2008 of the Company and our report dated March 12, 2009 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts March 12, 2009

#### ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of ARIAD Pharmaceuticals, Inc. Cambridge, Massachusetts

We have audited the accompanying consolidated balance sheets of ARIAD Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of ARIAD Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2009 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts March 12, 2009

# ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

·		Decen	ıber :	31,
In thousands, except share and per share data		2008	_	2007
ASSETS				
Current assets:				
Cash and cash equivalents	\$	24,243	\$	67,864
Marketable securities (Note 4)		14,825		17,334
Inventory and other current assets		4,055		2,374
Amounts due under collaboration agreement (Note 2)		5,580	_	4,588
Total current assets	_	48,703	_	92,160
Property and equipment:				
Leasehold improvements		22,004		18,400
Equipment and furniture		14,991	_	11,749
Total		36,995		30,149
Less accumulated depreciation and amortization		(27,402)	_	(25,134)
Property and equipment, net		9,593		5,015
Intangible and other assets, net (Note 5)		9,892		3,930
Total assets	\$	68,188	\$	101,105
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:				
Accounts payable	\$	9,370	\$	5,049
Current portion of long-term debt (Note 6)	*	1,400	•	3,815
Accrued compensation and benefits		817		523
Accrued product development expenses		9,936		7,287
Other accrued expenses		3,990		4,331
Current portion of deferred executive compensation (Note 7)		941		745
Current portion of deferred revenue (Note 2)		6,982		5,819
Current portion of capital lease payable		70		
Accrued merger consideration (Note 3)		1,023		
Total current liabilities	_	34,529	-	27,569
Long-term debt (Note 6)	_	11,550	_	
Capital lease payable	_	72	_	
Deferred revenue (Note 2)	_	90,282	_	80,026
Deferred executive compensation (Note 7)	_	953		1,410
Commitments and contingent liabilities (Notes 1, 8, 13)	_			1,110
Stockholders' equity (deficit) (Notes 9, 10 and 11): Preferred stock, \$.01 par value, authorized 10,000,000 shares, none issued and outstanding				
Common stock, \$.001 par value, authorized 145,000,000 shares, issued and outstanding 71,365,339 shares in 2008, 69,241,490 shares in 2007		71		69
Additional paid-in capital		369,313		359,576
Accumulated other comprehensive income		18		3
Accumulated deficit		(438,600)	_	(367,548)
Total stockholders' equity (deficit)	_	(69,198)	_	(7,900)
Total liabilities and stockholders' equity (deficit)	\$_	68,188	\$	101,105
See notes to consolidated financial statements.				

# ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,									
In thousands, except share and per share data	2008	2007	2006							
License and collaboration revenue (Note 2)	\$7,082	\$3,583	\$896							
Operating expenses:										
Research and development	50,841	39,565	43,312							
General and administrative	28,092	24,712	21,251							
Operating expenses	78,933	64,277	64,563							
Loss from operations	(71,851)	(60,694)	(63,667)							
Other income (expense):										
Interest income	1,349	2,509	2,222							
Interest expense	(550)	(337)	(483)							
Other income, net	799	2,172	1,739							
Net loss	\$ (71,052)	\$ (58,522)	\$ (61,928)							
Net loss per share	\$(1.02)	\$(0.86)	\$(0.99)							
Weighted average number of shares of common stock outstanding	69,790,784	68,215,803	62,679,807							

See notes to consolidated financial statements.

ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) For the Years Ended December 31, 2006, 2007 and 2008

Stockholders'	Equity (Deficit)	71,378 14,271 1,955 4,559	(61,928)	(61,901)	30,262	12,300 2,071 5,989	(58,522)	385 4,603 4,751	(71,052)	(71 037)	
Accumulated	Deficit E	(247,098) \$	(61,928)	l	(309,026)		(367,548)		(71,052)		(438,600) \$
Accu		<del>\$</del>									€
Accumulated Other Comprehensive	Income (Loss)	(24)		27	3		3			15	18
Acc	Inco	<del>•</del>									€
Deferred	Compensation	(246)			0		0				0
Com	Com	<del>\$5</del>									€
Additional Paid-in	Capital	\$ 318,684 14,268 1,955 4,559 (246)			339,220	12,297 2,070 5,989	359,576	385 4,601 4,751			\$ 369,313
Stock	Amount	\$ 3			65	1 3	69	7			\$ 71
Common Stock	Shares	61,698,129 3,112,945 580,273			65,391,347	3,072,393 777,750	69,241,490	324,573 1,799,276			71,365,339
	In thousands, except share data	Balance, January 1, 2006 Issuance of common stock, net of issuance costs Issuance of shares pursuant to ARIAD stock plans Stock-based compensation Elimination of deferred compensation	Comprehensive loss:  Net loss Other comments income (loss)	Officer comprehensive income (1958)  Net unrealized gains on marketable securities Comprehensive loss	Balance, December 31, 2006	Issuance of common stock, net of issuance costs Issuance of shares pursuant to ARIAD stock plans Stock-based compensation	Comprehensive loss: Net loss Balance, December 31, 2007	Issuance of shares pursuant to ARIAD stock plans Issuance of shares to minority shareholders of AGTI Stock-based compensation	Comprehensive loss: Net loss	Other comprehensive income (loss)  Net unrealized gains on marketable securities	Comprehensive loss Balance, December 31, 2008

See notes to consolidated financial statements.

# ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

		Year	d December	er 31,			
In thousands		2008		2007	2006		
Cash flows from operating activities:							
Net loss	\$	(71,052)	\$	(58,522)	\$	(61,928)	
Adjustments to reconcile net loss to net cash provided by		, ,		, ,		, ,	
(used in) operating activities:							
Depreciation and amortization		3,016		2,307		4,634	
Accretion of discount on marketable securities		(381)		(798)		(1,628)	
Stock-based compensation		4,751		5,989		4,559	
Deferred executive compensation expense		402		955		888	
Increase (decrease) from:							
Inventory and other current assets		(1,681)		(535)		386	
Amounts due under collaboration agreement		(992)		(4,588)			
Other assets		7		(9)		34	
Accounts payable		4,321		1,046		42	
Accrued compensation and benefits		294		95		(69)	
Accrued product development expenses		2,649		675		(1,832)	
Other accrued expenses		(341)		2,490		(256)	
Deferred revenue		11,419		85,391		(421)	
Deferred executive compensation paid		(663)		(508)		(447)	
Net cash provided by (used in) operating activities		(48,251)	`	33,988		(56,038)	
Cash flows from investing activities:	******						
Acquisitions of marketable securities		(57,264)		(67,657)		(42,919)	
Proceeds from maturities of marketable securities		60,169		59,197		92,561	
Investment in property and equipment		(6,651)		(1,346)		(1,067)	
Investment in intangible assets		(1,091)		(497)		(568)	
Net cash provided by (used in) investing activities		(4,837)		(10,303)		48,007	
Cash flows from financing activities:		(1)007)		(10,000)		10,007	
Proceeds from long-term borrowings		10,505					
Repayment of long-term borrowings		(1,370)		(1,920)		(1,920)	
Proceeds from issuance of common stock, net of issuance costs		( , ,		12,300		14,271	
Principal payments under capital lease obligation		(53)		, .			
Proceeds from issuance of common stock pursuant to		` ,					
stock option and purchase plans		385		2,071		1,955	
Net cash provided by financing activities		9,467		12,451		14,306	
Net increase (decrease) in cash and cash equivalents		(43,621)		36,136		6,275	
Cash and cash equivalents, beginning of year		67,864		31,728		25,453	
Cash and cash equivalents, end of year	\$	24,243	\$	67,864	\$	31,728	
	-						
Interest paid	\$	511	\$	379	\$	517	
Supplemental disclosure on non-cash activities:	<b>ተ</b>	105	æ		ø		
Property and equipment acquired through capital lease	\$	195	\$		\$		

See notes to consolidated financial statements.

# ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of Business and Summary of Significant Accounting Policies

Nature of Business

ARIAD's vision is to transform the lives of cancer patients with breakthrough medicines. The Company's mission is to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest and most urgent unmet medical need – aggressive cancers where current therapies are inadequate. The Company's goal is to build a fully integrated oncology company focused on novel, molecularly targeted therapies to treat solid tumors and hematologic cancers, as well as the spread of primary tumors to distant sites. The Company's lead cancer product candidate, deforolimus, previously known as AP23573, has been or is being studied in multiple clinical trials in patients with various types of cancers, including sarcomas, hormone refractory prostate cancer, endometrial cancer, brain cancer and leukemias and lymphomas. The Company entered into a global collaboration in July 2007 with Merck & Co., Inc. ("Merck") to jointly develop and commercialize deforolimus for use in cancer. The Company also has partnerships with two medical device companies to develop and commercialize stents to deliver deforolimus to prevent restenosis, or reblockage, of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. The Company's second product candidate, AP24534, is in a Phase 1 clinical trial in patients with hematologic cancers.

The Company has a focused drug discovery program centered on small molecule, molecularly targeted therapies and cell-signaling pathways implicated in cancer. The Company also has an exclusive license to pioneering technology and patents related to certain NF-kB cell-signaling activity, which may be useful in treating certain diseases. Additionally, the Company has developed a proprietary portfolio of cell-signaling regulation technologies, the Company's ARGENT technology, to control intracellular processes with small molecules, which may be useful in the development of therapeutic vaccines and gene and cell therapy products, and which provide versatile tools for use in cell biology, functional genomics and drug discovery research.

Since its inception, the Company has incurred significant operating losses related to its research and development programs and supporting activities. The Company has funded its losses through the sale of equity securities, debt and cash received pursuant to collaboration agreements, including its collaboration agreement with Merck for the development and commercialization of deforolimus. At December 31, 2008, the Company had cash, cash equivalents and marketable securities totaling \$39.1 million. In February 2009, the Company raised net proceeds of \$22.8 million from the sale of common stock and warrants to institutional investors (see Note 15).

The Company expects to incur a net loss in the range of \$78 million to \$82 million during the year ending December 31, 2009. The Company also anticipates that it will receive approximately \$50 million in milestone payments from Merck in 2009 related to the start of various Phase 2 and Phase 3 clinical trials of deforolimus, of which \$22.5 million has been received or is expected to be received in the first half of the 2009 (see Note 2). Accordingly, the Company expects to report cash used in operating activities for the year ending December 31, 2009 in the range of \$24 million to \$28 million. While management believes that the milestone payments from Merck will be received as forecasted, it does have contingency plans in place should the receipt of the milestone payments be deferred into the first part of fiscal 2010, which plans focus primarily on the reduction of spending on non-critical research and development activities. Based on these projections and its contingency plans, the Company believes that its cash, cash equivalents and marketable securities at December 31, 2008, together with the net proceeds of \$22.8 million received in February 2009 from the sale of common stock and warrants are sufficient to fund its anticipated spending through at least the next twelve months.

#### Principles of Consolidation

The consolidated financial statements include the accounts of ARIAD Pharmaceuticals, Inc. and its wholly-owned subsidiaries, ARIAD Corporation, ARIAD Pharma S.A. and ARIAD Pharma Ltd. Intercompany accounts and transactions have been eliminated in consolidation. Until September 12, 2008, the consolidated financial statements also included the accounts of ARIAD Gene Therapeutics, Inc. ("AGTI"), an 80 percent owned subsidiary of ARIAD Pharmaceuticals, Inc. which was merged with and into ARIAD Pharmaceuticals, Inc. on that date (see Note 3).

# Fair Value of Financial Instruments

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. Marketable securities are recorded in the consolidated financial statements at aggregate fair value (see Note 4). The carrying amount of the Company's bank term note of \$13.0 million at December 31, 2008 approximates fair value due to its variable interest rate (see Note 6). The Company's obligation under its executive compensation plans (see Note 7) is based in part on the current fair market value of underlying securities, which is therefore stated at its estimated fair value.

#### Accounting Estimates

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

#### Cash Equivalents

Cash equivalents include short-term, highly liquid investments, which consist principally of United States government and agency securities, purchased with remaining maturities of 90 days or less, and money market accounts.

#### Marketable Securities

The Company has classified its marketable securities as "available-for-sale" and, accordingly, carries such securities at aggregate fair value. The difference between fair value and original cost is reflected as a component of accumulated other comprehensive income (loss). Fair value has been determined based on quoted market prices, in a dealer market, at the closing bid price for each individual security held.

#### Inventory

Inventory consists of bulk pharmaceutical material to be used for multiple development programs. Inventories are carried at cost using the first-in, first-out method and are charged to research and development expense when consumed. The carrying value of inventory amounted to \$1.1 million and \$1.3 million at December 31, 2008 and 2007, respectively.

## Property and Equipment

Property and equipment are recorded at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Leasehold improvements are amortized over the shorter of their useful lives or lease term using the straight-line method.

#### Intangible and Other Assets

Intangible and other assets consist primarily of purchased technology and capitalized patent and license costs. The cost of purchased technology, patents and patent applications, costs incurred in filing patents

and certain license fees are capitalized. Capitalized costs related to purchased technology are amortized over the estimated useful life of the technology. Capitalized costs related to issued patents are amortized over a period not to exceed seventeen years or the remaining life of the patent, whichever is shorter, using the straight-line method. Capitalized license fees are amortized over the periods to which they relate. In addition, capitalized costs are expensed when it becomes determinable that the related patents, patent applications or technology will not be pursued.

#### Impairment of Long-Lived Assets

The Company reviews its long-lived assets, including the above-mentioned intangible assets, for impairment when events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

#### Revenue Recognition

The Company generates revenue from license and collaboration agreements with third parties related to use of the Company's technology and/or development and commercialization of product candidates. Such agreements may provide for payment to the Company of up-front payments, periodic license payments, milestone payments and royalties.

The Company recognizes revenue in accordance with the Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 101, Revenue Recognition in Financial Statements, SAB No. 104, Revenue Recognition, and Emerging Issues Task Force ("EITF") No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. Consideration received is allocated to the separate units of accounting based on the fair value of each unit and the appropriate revenue recognition principles are applied to each unit.

Up-front and annual license fees associated with collaboration and license agreements are recorded as deferred revenue upon receipt and recognized as revenue on a systematic basis over the period of time they are earned in accordance with the terms of the agreements. Milestone payments are also recognized as revenue on a systematic basis over the remaining performance period of the agreements, commencing when the milestone has been achieved or is probable of achievement. Royalty payments will be recognized as revenue based on contract terms and reported sales of licensed products, when reported sales are reliably measurable and collectability is reasonably assured.

#### Income Taxes

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standard ("SFAS") No. 109, Accounting for Income Taxes, which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for differences between the financial statement basis and the income tax basis of assets and liabilities that will result in taxable or deductible amounts in the future. Such deferred income tax computations are based on enacted tax laws and rates applicable to the years in which the differences are expected to affect taxable income. A valuation allowance is established when it is necessary to reduce deferred income tax assets to the expected realized amounts.

On January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48 ("FIN 48"), Accounting for Uncertainties in Income Taxes. FIN 48 defines the

threshold for recognizing the benefits of tax-return positions in the financial statements as "more-likely-than-not" to be sustained by the taxing authorities. FIN 48 also requires explicit disclosure requirements about a company's uncertainties related to its income tax positions, including a detailed roll-forward of tax benefits taken that do not quality for financial statement recognition. Adoption of FIN 48 did not have a material impact on the Company's financial statements.

#### Segment Reporting

The Company organizes itself into one segment reporting to the chief executive officer. No revenues from product sales or services occurred in 2008, 2007 or 2006.

#### Stock-Based Compensation

The Company awards stock options and other equity-based instruments to its employees, directors and consultants and provides employees the right to purchase common stock (collectively "share-based payments"), pursuant to stockholder approved plans. The Company accounts for stock options and other share-based payments in accordance with SFAS No. 123R, Share-Based Payment.

Under the provisions of SFAS No. 123R, the Company recognizes compensation expense in its financial statements associated with awards of stock options and other equity-based instruments to employees, directors and consultants. Compensation cost is measured based on the fair value of the instrument on the grant date and is recognized on a straight-line basis over the requisite service period, which generally equals the vesting period. All of the Company's stock-based compensation is based on grants of equity instruments and no liability awards have been granted.

#### Earnings Per Share

Basic earnings per common share are computed using the weighted average number of common shares outstanding during each year. Diluted earnings per common share reflect the effect of the Company's outstanding options using the treasury stock method, except where such items would be anti-dilutive. In years in which a net loss is reported, basic and diluted per share amounts are the same. In 2008, 2007 and 2006, options amounting to 7,424,428, 7,568,044 and 6,571,341 shares of common stock, respectively, were not included in the computation of dilutive earnings per share, because the effect would be anti-dilutive. There were no other potential common stock equivalents outstanding at December 31, 2008, 2007 or 2006.

# Executive Compensation Plan

The Company maintains a deferred executive compensation plan, established in 1997 (the "1997 Plan"), which provides participants, in lieu of a cash bonus, an option to purchase certain designated mutual funds at a discount. EITF No. 02-8, Accounting for Options Granted to Employees in Unrestricted, Publicly Traded Shares of an Unrelated Party, and SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities require that the Company account for such benefits as derivatives. Under these pronouncements, the Company records the fair value of the awards as an asset and a liability and amortizes the asset to expense over the vesting period of the awards. Subsequent changes in the fair value of the liability are included in the determination of net income or loss.

The Company has a deferred executive compensation plan (the "2005 Plan") that defers the payment of annual bonus awards to future periods as specified in each award. The Company accrues a liability based on the value of the awards ratably over the vesting period. The recorded balances of such awards are increased or decreased based on the actual total return and quoted market prices of specified mutual funds.

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard No. 157 ("SFAS No. 157"), *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The Company has adopted the provisions of SFAS No. 157 as of January 1, 2008, for financial instruments. Although the adoption of SFAS No. 157 did not materially impact its financial condition, results of operations, or cash flow, the Company is now required to provide additional disclosures as part of its financial statements.

SFAS No. 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset's or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. The Company's marketable securities are classified as available for sale and are stated at fair value based on quoted market prices which are considered Level 1 inputs within the fair value hierarchy. There are no other financial assets or liabilities that are subject to fair value measurements under this pronouncement.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which provides companies with the option to measure specified financial instruments and certain other items at fair value. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company has not elected to apply the fair value method to any of its financial instruments.

In June 2007, the Emerging Issues Task Force ("EITF") issued EITF No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities. EITF No. 07-3 states that nonrefundable advance payments for goods or services that will be used for future research and development activities should be deferred and capitalized and that such amounts should be recognized as an expense as the goods are delivered or the services are performed. EITF No. 07-3 is effective for fiscal years beginning after December 15, 2007. The adoption of EITF No. 07-3 did not have a material impact on the Company's financial statements.

In December 2007, the EITF issued EITF No. 07-1, *Accounting for Collaborative Arrangements*. EITF No. 07-1 provides guidance on the determination of a collaborative arrangement, reporting of costs incurred and revenue generated on sales to third parties in the statement of operations, and classification of payments made between participants in a collaborative arrangement in the statement of operations. EITF No. 07-1 is effective for fiscal years beginning after December 15, 2008. The adoption of this EITF is not expected to have a material impact on the Company's financial statements.

In April 2008, the FASB issued FASB Staff Position ("FSP") No. FAS 142-3, *Determination of the Useful Life of Intangible Assets*, which requires companies, in estimating the useful life of a recognized intangible asset, to consider a company's historical experience in renewing or extending similar arrangements. In the absence of historical experience, a company shall consider assumptions that market participants would use that are consistent with the highest and best use of the asset. FSP No. FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. The Company does not expect the impact of FSP No. FAS 142-3 to have a material impact on its consolidated financial statements.

#### 2. Collaboration Agreement with Merck & Co., Inc.

In July 2007, the Company entered into a collaboration agreement with Merck & Co., Inc. ("Merck") for the joint global development and commercialization of deforolimus, the Company's lead product candidate, for use in cancer (the "Collaboration Agreement").

Under the terms of the Collaboration Agreement, Merck and the Company will conduct a broad-based development program in multiple types of cancer, pursuant to a global development plan agreed upon by the parties. Each party will fund 50 percent of the global development costs, except that Merck will fund 100 percent of any cost of development that is specific to development or commercialization of deforolimus outside the United States. The Collaboration Agreement provides that, in certain circumstances, either party may opt out of conducting and funding certain late-stage clinical trials, which would result in changes in development and commercialization responsibilities and compensation arrangements. The Company is responsible for supplying the active pharmaceutical ingredient used in the product and Merck is responsible for the formulation of the finished product, all under a separate supply agreement between the parties entered into in May 2008.

The Collaboration Agreement provides that, in the United States, the Company and Merck will copromote the product, the Company will distribute and sell the product for all cancer indications and record all sales, and each party will receive 50 percent of the profit from such sales. Outside the United States, Merck will distribute, sell and promote the product and book all sales, and Merck will pay the Company tiered double-digit royalties on such sales. Royalties are payable by Merck, on a country by country basis, until the later of (i) the expiration of the last valid claim of any patent rights owned by either the Company or Merck that cover the product, (ii) a specified number of years from first commercial sale, or (iii) the last date upon which the Company supplies the active pharmaceutical ingredient to Merck under the supply agreement, subject to partial reduction in certain circumstances.

Under the terms of the Collaboration Agreement, Merck paid the Company an initial up-front payment of \$75 million in July 2007, and has agreed to pay up to \$452 million in milestone payments of which \$31.0 million has been paid through December 31, 2008, based on the successful development of deforolimus in multiple potential cancer indications, and up to \$200 million in milestone payments based on achievement of specified product sales thresholds. Merck has also agreed to provide the Company with up to \$200 million in interest-bearing, repayable, development cost advances to cover a portion of the Company's share of global development costs, after the Company has paid \$150 million in global development costs and has obtained regulatory approval to market deforolimus from the FDA in the United States or similar regulatory authorities in Europe or Japan. All amounts to be paid to the Company by Merck, with the exception of any development cost advances, are non-refundable.

Through December 31, 2008, ARIAD has received the following up-front and milestone payments under the Collaboration Agreement. These up-front and milestone payments have been deferred and are being recognized as revenue on a straight-line basis through 2023, the estimated expiration of the patents related to the underlying technology.

 mount millions)	Period <u>Received</u>	<u>Event</u>
\$ 75.0	3Q2007	Up-front payment
13.5	4Q2007	Initiation of Phase 3 clinical trial in patients with metastatic soft-tissue and bone sarcomas
15.0	3Q2008	Initiation of Phase 2 clinical trial in patients with advanced breast cancer
 2.5	4Q2008	Initiation of Phase 2 clinical trial in patients with advanced endometrial cancer
\$ 106.0		

In addition, ARIAD has announced the initiation of additional clinical trials for which it has received or expects to receive additional milestone payments under the Collaboration Agreement upon treatment of the first patient in each of the trials, as follows:

 nount nillions)	Period <u>Received</u>	<u>Event</u>
\$ 12.5	1Q09	Initiation of Phase 2 clinical trial in patients with advanced prostate cancer
10.0	Expected 1H09	Initiation of Phase 2 clinical trial in patients with non- small-cell lung cancer
\$ 22.5		

Development costs under the Collaboration Agreement are aggregated and split between the Company and Merck in accordance with the terms of the agreement. The Company's share of such development costs are reflected in operating expenses in the Company's statement of operations. Any amounts due to or from Merck in respect of such development costs and milestone payments earned but not received are recorded as such on the Company's balance sheet. At December 31, 2008, the Company has recorded an amount due from Merck under the collaboration agreement of \$5.6 million.

# 3. Merger of AGTI into ARIAD Pharmaceuticals, Inc.

On September 11, 2008, ARIAD and AGTI entered into a merger agreement, pursuant to which AGTI was merged with and into ARIAD on September 12, 2008, with ARIAD as the surviving company. Prior to the merger, AGTI was an 80 percent owned subsidiary of ARIAD. The minority stockholders of AGTI included Harvey J. Berger, M.D., the Company's Chairman and Chief Executive Officer, Jay R. LaMarche, the Company's former Chief Financial Officer and a member of the Board of Directors of the Company, several of the Company's current and former officers and scientific advisors, Harvard University, and Stanford University. ARIAD effectuated the merger to eliminate conflicts of interest between ARIAD and AGTI, to ensure that ARIAD will receive benefits from the successful commercialization of its products proportionate to its investment and to create additional value for its stockholders.

Under the terms of the merger agreement, each outstanding share of AGTI common stock owned by AGTI's minority stockholders, a total of 1,126,064 AGTI shares, was converted into the right to receive two shares of ARIAD common stock. Under Delaware law, any of the AGTI minority stockholders had the right to demand appraisal of his or her AGTI shares and to seek judicial determination of the fair value of such shares. Four AGTI stockholders holding a total of 226,426 shares of AGTI common stock notified the Company of their intent to pursue appraisal of their shares. The Company reached a settlement with such AGTI stockholders in January 2009 pursuant to which these AGTI stockholders received two shares of ARIAD common stock plus approximately \$2.43 in cash for each share of AGTI common stock they owned. In total, in exchange for all of the AGTI common stock owned by the AGTI minority stockholders, ARIAD issued 2,252,128 shares of ARIAD common stock, or approximately 3.1 percent of the outstanding common stock of ARIAD at the time of the merger, and \$550,000 in cash. The total value of the acquisition of the 20 percent minority interest of AGTI was approximately \$5.9 million. The shares of ARIAD common stock issued to the former minority stockholders of AGTI were not registered under the Securities Act of 1933, as amended, and were issued in reliance on an exemption from registration related to sales by an issuer not involving a public offering.

The total cost of the acquisition of the 20 percent minority interest of \$5.9 million was accounted for using the purchase method of accounting. The cost has been allocated to intangible assets and will be amortized over approximately fifteen years, the remaining life of the patents related to AGTI's technology. The cost of the settlement reached in January 2009 with the dissenting stockholders of AGTI is reflected in the cost of the intangible asset and is recorded as a liability at December 31, 2008.

#### 4. Marketable Securities

The Company has classified its marketable securities as available-for-sale and, accordingly, carries such securities at aggregate fair value. At December 31, 2008 and 2007, all of the Company's marketable securities consisted of United States government agency securities.

At December 31, 2008, the aggregate fair value and amortized cost of the Company's marketable securities were \$14,825,000 and \$14,807,000, respectively. Gross unrealized gains and losses were \$18,000 and \$0, respectively, at December 31, 2008.

At December 31, 2007, the aggregate fair value and amortized cost of the Company's marketable securities were \$17,334,000 and \$17,331,000, respectively. Gross unrealized gains and losses were \$4,000 and \$0, respectively, at December 31, 2007.

Realized gains and losses on investment security transactions are reported on the specific-identification method. There were no realized gains and losses on sales of marketable securities in 2008, 2007 and 2006. Changes in market values resulted in a decrease in net unrealized losses or increase in net unrealized gains of \$15,000, \$1,000 and \$27,000 in 2008, 2007 and 2006, respectively.

#### 5. Intangible and Other Assets, Net

Intangible and other assets, net, were comprised of the following at December 31:

In thousands		2008	 2007
Capitalized patent and license costs	\$	11,107	\$ 10,290
Purchased technology (see Note 3)		5,901	 
		17,008	10,290
Less accumulated amortization	********	(7,142)	 (6,393)
		9,866	3,897
Other	<del></del>	26	 33
	\$	9,892	\$ 3,930

Amortization expense for intangible assets amounted to \$749,000, \$851,000 and \$750,000 in 2008, 2007 and 2006 respectively. The weighted average amortization period for intangible assets was 14.8 years, 13.8 years and 13.5 years in 2008, 2007 and 2006, respectively. In addition, the Company expensed unamortized patent and license costs of \$1,000, \$36,000 and \$174,000 in 2008, 2007 and 2006, respectively, related to patent applications or technology no longer being pursued. The estimated future amortization expenses for capitalized patent and license costs and purchased technology are \$808,000 for 2009, \$788,000 for 2010, \$718,000 for 2011, \$718,000 for 2012 and \$718,000 for 2013.

#### 6. Long-Term Debt

Long-term debt was comprised of the following at December 31:

In thousands		2008	2007
Bank term note at prime rate or LIBOR +1.25% to 2.25% (effective interest rate of 3.65% at December 31, 2008)	<u> </u>	12,950	\$ 3,815
Less current portion		(1,400)	 (3,815)
	\$	11,550	\$ ****

In March 2008, the Company amended its term loan with the bank, increasing the balance due to \$14.0 million, extending the maturity date from March 2008 to March 2013 and providing for repayment of the loan in quarterly payments of principal, increasing from 2.5 percent of the total loan amount in the second quarter of 2008 to 8.75 percent of the total loan amount in the first quarter of 2013, together with

interest. The loan as amended bears interest at LIBOR plus 1.25 to 2.25 percent, depending on the percentage of the Company's liquid assets on deposit with or invested through the bank, or at the prime rate, as provided in the amendment. The loan is secured by a lien on all assets of the Company excluding intellectual property, which the Company has agreed not to pledge to any other party. The loan, as amended, also requires the Company to maintain a minimum of \$15.0 million in unrestricted cash, cash equivalents and investments. The agreement also contains certain covenants that restrict additional indebtedness, additional liens and sales of assets, and dividends, distributions or repurchases of common stock.

The annual aggregate future principal payments of the above loan, as amended, are \$1.4 million in 2009, \$1.9 million in 2010, \$3.7 million in 2011, \$4.7 million in 2012 and \$1.2 million in 2013.

#### 7. Executive Compensation Plans

Under the Company's deferred executive compensation plan established in 1997 (the "1997 Plan"), the Company recorded an asset and a liability on the date of grant equal to the fair value of awards granted under the 1997 Plan. The asset is amortized to expense over the vesting period and the liability is revalued and adjusted to fair value at each reporting period. Under the Company's 2005 Plan, the Company accrues a liability for the value of the awards ratably over the vesting period. The value of awards made in 2008 and 2007 under the 2005 Plan were \$812,000 and \$1,535,000, respectively. There were no awards made in 2006. The net expense for these plans was \$403,000, \$955,000 and \$888,000 in 2008, 2007 and 2006, respectively. The estimated future expenses for awards made through December 31, 2008 are \$560,000, \$416,000, \$217,000 and \$38,000 for 2009, 2010, 2011 and 2012, respectively.

#### 8. Leases, Licensed Technology and Other Commitments

#### Facility Lease

The Company conducts its operations in a 100,000 square foot office and laboratory facility under a non-cancelable operating lease. The lease was amended in 2006 and provides that the current lease term extends to July 2012 with two consecutive five-year renewal options. The Company maintains an outstanding letter of credit of \$699,000 in accordance with the terms of the amended lease. The Company subleased approximately 31,000 square feet of space to one tenant and such sublease expired in July 2007. Rent expense, net of sublease income of \$710,000 and \$1.3 million in 2007, and 2006 respectively, amounted to \$2.1 million, \$1.3 million and \$636,000 in 2008, 2007 and 2006 respectively. Future minimum annual rental payments through July 2012 are \$2.1 million for 2009 through 2011 and \$1.2 million in 2012.

#### Licensed Technology

The Company has entered into agreements with several universities under the terms of which the Company has received exclusive licenses to technology and intellectual property. The agreements, which are generally cancelable by the Company, provide for the payment of license fees and/or minimum payments, which are generally creditable against future royalties. Fees paid by the Company amounted to \$145,000 in each of 2008, 2007 and 2006, and are expected to amount to approximately \$145,000 annually in 2009 and thereafter. In addition, the agreements provide for payments upon the achievement of certain milestones in product development. The agreements also require the Company to fund certain costs associated with the filing and prosecution of patent applications.

#### Other Commitments

The Company has entered into various employment agreements with eighteen officers of the Company. The agreements provide for aggregate annual base salaries of \$5.6 million for 2009, \$5.4 million for 2010, \$2.5 million for 2011, \$1.3 million for 2012 and \$608,000 for 2013, and remaining terms of employment of up to five years.

#### 9. Stockholders' Equity

# Preferred Stock

The Company has authorized 10,000,000 shares of preferred stock which the Board of Directors is authorized to designate and issue in different series. At December 31, 2008, the Board of Directors had designated 500,000 shares as series A preferred stock for potential issuance under the Company's stockholder rights plan and 9,500,000 shares remained undesignated.

#### Common Stock

On January 30, 2007, the Company filed a shelf registration statement with the SEC for the issuance of common stock, preferred stock, various series of debt securities and warrants to purchase any of such securities, either individually or in units, with a total value of up to \$100 million, from time to time at prices and on terms to be determined at the time of any such offering. This filing was declared effective on February 6, 2007.

In March 2007, the Company sold 3,072,393 shares of its common stock to Azimuth Opportunity Ltd. pursuant to an equity financing facility between the parties dated February 14, 2007. The Company received aggregate gross proceeds from this sale of \$12.5 million, or \$12.3 million net of issuance expenses. These shares were registered under the Company's shelf registration statement filed on January 30, 2007. The equity financing facility expired on September 1, 2008. As of December 31, 2008, the Company had \$87.5 million of securities remaining available for issuance under its shelf registration statement. As noted in Note 15, in February 2009, the Company raised net proceeds of \$22.8 million from the sale of 14,378,698 shares of common stock and warrants to purchase 10,784,024 shares of common stock. Following this transaction, the Company had approximately \$40 million of securities remaining available for issuance under its shelf registration statement.

#### Stockholder Rights Plan

The Board of Directors of the Company adopted a Rights Agreement, dated as of June 8, 2000 (the "Rights Agreement"), between the Company and State Street Bank and Trust Company, as Rights Agent, and approved the declaration of a dividend distribution of one Preferred Share Purchase Right (a "Right") on each outstanding share of its Common Stock. In general, the Rights become exercisable if a person or group hereafter acquires 15 percent or more of the Common Stock of the Company or announces a tender offer for 15 percent or more of the Common Stock. The Board of Directors will, in general, be entitled to redeem the Rights at one cent per Right at any time before any such person hereafter acquires 15 percent or more of the outstanding Common Stock. The plan is designed to protect the Company's stockholders in the event that an attempt is made to acquire the Company without an offer of fair value.

If a person hereafter acquires 15 percent or more of the outstanding Common Stock of the Company (the "Acquiring Person"), each Right will entitle its holder to purchase, for an initial exercise price of \$65, a number of shares of Common Stock having a market value at that time of twice the Right's exercise price. Rights held by the Acquiring Person will become void. If the Company is acquired in a merger or other business combination transaction after a person acquires 15 percent or more of the Company's Common Stock, each Right will entitle its holder to purchase, at the Right's then-current exercise price, a number of the acquiring company's common shares having a market value at that time of twice the Right's exercise price.

The dividend distribution of Rights was payable on July 19, 2000 to shareholders of record on June 19, 2000. The Rights distribution is not taxable to the Company's stockholders. The Rights Agreement will expire on June 8, 2010.

#### 10. Stock Plan

#### ARIAD Stock Option and Stock Plans

The Company's 1991, 1994, 2001 and 2006 stock option and stock plans (the "Plans") provide for the awarding of nonqualified and incentive stock options, stock grants and restricted stock units to officers, directors, employees and consultants of the Company. Stock options become exercisable as specified in the related option certificate, typically over a four-year period, and expire ten years from the date of grant. Stock grants and restricted stock units provide the recipient with ownership of common stock subject to any rights the Company may have to repurchase the shares granted or other restrictions. The 1991 and 1994 Plans have expired according to their terms and the 2001 Plan has no shares remaining available for grant, although existing stock options granted under these Plans remain outstanding. As of December 31, 2008, there are 1,953,556 shares available for awards under the 2006 Plan.

#### Employee Stock Purchase Plan

In 1997, the Company adopted the 1997 Employee Stock Purchase Plan and reserved 500,000 shares of common stock for issuance under this plan. In June 2008, the Plan was amended to reserve an additional 500,000 shares of common stock for issuance. Under this plan, substantially all of the Company's employees may, through payroll withholdings, purchase shares of the Company's common stock at a price of 85 percent of the lesser of the fair market value at the beginning or end of each three-month withholding period. In 2008, 2007 and 2006, 92,698, 52,113 and 37,421 shares of common stock were issued under the plan, respectively.

# 11. Stock-Based Compensation

The Company awards stock options and other equity-based instruments to its employees, directors and consultants and provides employees the right to purchase common stock (collectively "share-based payments"), pursuant to stockholder approved plans. The Company's statement of operations included total compensation cost from share-based payments for the years ended December 31, as follows:

In thousands	2	2008	2	2007	 2006
Compensation cost from:	·				
Stock options	\$	3,798	\$	5,254	\$ 3,773
Stock and stock units		900		662	737
Purchases of common stock at a discount		53		73	49
	\$	4,751	\$	5,989	\$ 4,559
Compensation cost included in:					
Research and development expenses	\$	2,441	\$	3,237	\$ 2,440
General and administrative expenses		2,310		2,752	2,119
•	\$	4,751	\$	5,989	\$ 4,559

#### Stock Options

Stock options are granted with an exercise price equal to the closing market price of the Company's common stock on the date of grant. Stock options generally vest ratably over four years and have contractual terms of ten years. Stock options are valued using the Black-Scholes option valuation model and compensation cost is recognized based on such fair value over the period of vesting on a straight-line basis.

The following table summarizes information about stock options as of and for the years ended December 31, 2008, 2007 and 2006:

In thousands, except per share amounts		2008_		2007		2006	
Weighted average fair value of options granted, per share	\$	1.83	\$	3.24	\$	4.33	
Total cash received from exercises of stock options		154		1,872		1,791	
Total intrinsic value of stock options exercised		90		1,388		1,403	
Total fair value of stock options vested		4,114		4,742		4,320	

The weighted average fair value of options granted in the years ended December 31, 2008; 2007 and 2006, reflect the following weighted-average assumptions:

	2008	2007	2006
Expected life of options granted (in years)	7.04	7.54	7.02
Expected volatility	69.37%	68.03%	70.65%
Risk-free rate	3.04%	4.41%	4.68%
Expected dividends	0%	0%	0%

The expected life assumption is based on an analysis of historical behavior of participants related to options awarded over time. The expected volatility assumption for the years ended December 31, 2008, 2007 and 2006 is based on the implied volatility of the Company's common stock, derived from analysis of historical traded and quoted options on the Company's common stock over the period commensurate with the expected life of the options granted. The risk-free rate is based on the forward U.S. Treasury yield curve. The expected dividends reflect the Company's current and expected future policy for dividends on its common stock.

Based on the Company's historical employee departure rates, an estimated forfeiture rate of 8.47 percent has been used in calculating compensation cost. Under the provisions of SFAS No. 123R, additional expense is recorded if the actual forfeiture rate is lower than estimated, and a recovery of prior expense is recorded if the actual forfeiture rate is higher than estimated. In 2008, actual forfeitures exceeded estimated forfeitures for certain historical stock option grants and compensation expense was adjusted accordingly.

Stock option activity under the Company's stock plans for the year ended December 31, 2008 was as follows:

	Wei Av Number of Exerci Shares Per		
Options outstanding, January 1, 2008	7,568,044	\$	5.30
Granted .	1,182,465		2.70
Forfeited	(1,246,706)		4.98
Exercised	(79,375)		1.94
Options outstanding, December 31, 2008	7,424,428	\$	4.98
Options exercisable, December 31, 2008	4,271,372	\$	5.43

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

		Options utstanding	E	Options Exercisable		Options Expected To Vest	
Number of options	-	7,424,428		4,721,372		2,231,983	
Weighted-average exercise price per share	\$	4.98	\$	5.43	\$	4.27	
Aggregate intrinsic value (in 000's)	\$	18	\$	18	\$		
Weighted average remaining contractual term (in years)		5.84		4.36		8.43	

Options expected to vest consist of options scheduled to vest in the future less expected forfeitures.

At December 31, 2008, total unrecognized compensation cost related to non-vested stock options outstanding amounted to \$7.9 million. That cost is expected to be recognized over a weighted-average period of 1.9 years.

#### Stock and Stock Unit Grants

Stock and stock unit grants are provided to non-employee directors as compensation and generally carry no restrictions as to resale. Stock grants to officers carry restrictions as to resale for periods of time specified in the grant. Stock and stock unit grants are valued at the closing market price of the Company's common stock on the date of grant and compensation is recognized over the requisite service period or period during which restrictions remain on the common stock or stock units granted.

Stock and stock units amounting to 612,500, 134,000 and 80,000 were granted to non-employee directors and officers in the years ended December 31, 2008, 2007 and 2006, respectively. The weighted-average fair value of stock and stock unit awards granted in the years ended December 31, 2008, 2007 and 2006 was \$3.57, \$4.94 and \$6.43, respectively. At December 31, 2008, total unrecognized compensation cost related to stock and stock unit awards amounted to \$1.1 million.

Purchase of Common Stock Pursuant to Employee Stock Purchase Plan

Purchases of common stock by employees are provided pursuant to the Company's employee stock purchase plan. Purchase price is calculated as 85 percent of the lower of the closing price of our common stock on the first trading day or last trading day of each calendar quarter. Compensation cost is equal to the fair value of the discount on the date of grant and is recognized as compensation in the period of purchase.

#### 12. Income Taxes

The components of deferred income taxes were as follows at December 31:

In thousands		2008	2007		
Deferred tax liabilities:					
Intangible and other assets	\$	3,946	\$	1,559	
Deferred tax assets:					
Net operating loss carryforwards		124,991		135,536	
Federal and State tax credit carryovers		22,043	19,48		
Depreciation		4,422		4,407	
Deferred revenue		32,011		68	
Stock-based compensation		1,799		1,426	
Other		871		960	
Total deferred tax assets		186,137		161,885	
Deferred tax assets, net		182,191		160,326	
Valuation allowance		(182,191)		(160,326)	
Total deferred taxes	\$		\$ \$		

In 2008, the Company generated taxable income of approximately \$5 million due primarily to the inclusion in taxable income in 2008 of the up-front payment of \$75 million received from Merck which was deferred for tax purposes in 2007. This taxable income was offset by utilization of net operating loss carryforwards and available tax credits in 2008, thereby eliminating any income tax liability in 2008.

At December 31, 2008, the Company had available estimated net operating loss carryforwards and research and development credit carryforwards for federal and state tax reporting purposes as follows:

	Amount		Expiring if not utilized
	(	(in 000s)	
Net operating loss carryforwards:			
Federal	\$	354,497	2009 through 2027
State	\$	74,359	2009 through 2013
Research and development credit carryforwards:			
Federal	\$	14,948	2009 through 2028
State	\$	6,597	2009 through 2023

Since the Company has not yet achieved sustained profitable operations, management believes the tax benefits as of December 31, 2008 and 2007 do not satisfy the realization criteria set forth in SFAS No. 109 and has recorded a valuation allowance for the entire net deferred tax asset. The increase in the valuation allowance of \$21.9 million in 2008 resulted primarily from revenue recognized for tax purposes but not book purposes offset in part by utilization of net operating loss carryforwards. The increase in the valuation allowance of \$21.8 million in 2007 resulted primarily from net operating losses and tax credits from operations in that year that were not benefited.

#### 13. Legal Proceedings

## NF-xB Patent Infringement Litigation and Reexamination

# Lilly Litigation

In 2002, the Company, together with Massachusetts Institute of Technology ("MIT"), The Whitehead Institute for Biomedical Research ("Whitehead") and Harvard University ("Harvard") (collectively, the Plaintiffs) filed a lawsuit in the United States District Court for the District of Massachusetts (the "U.S. District Court") against Eli Lilly and Company ("Lilly") alleging infringement of four claims (the "NF-κB '516 Claims") of the Plaintiffs' U.S. Patent No. 6,410,516 (the "'516 Patent"), covering methods of treating human disease by regulating NF-κB cell-signaling activity through sales of Lilly's drugs, Evista® and Xigris®. In 2006, a jury rendered a verdict in favor of the Plaintiffs and awarded damages of \$65.2 million to the Plaintiffs, plus further damages equal to 2.3 percent of U.S. sales of Evista and Xigris from February 28, 2006 through the year 2019, when the patent expires. On March 10, 2008, Lilly filed a notice of appeal of the jury's verdict and other rulings by the U.S. District Court with the U.S. Court of Appeals for the Federal Circuit (the "CAFC"). That appeal was heard at the CAFC on February 6, 2009. The ruling of the CAFC on this appeal is pending.

#### Amgen Litigation

In April 2006, Amgen Inc. and certain affiliated entities ("Amgen") filed a lawsuit against the Company in the U.S. District Court for the District of Delaware (the "Delaware Court") seeking a declaratory judgment that each of the claims contained in the '516 Patent is invalid and that Amgen has not infringed any of the claims of the '516 Patent based on activities related to Amgen's products, Enbrel® and Kineret®. In April 2007, the Company, together with MIT, Whitehead, and Harvard, filed a counterclaim against Amgen, alleged infringement of the '516 Patent based on activities related to Enbrel and Kineret, as well as the Company's answer to Amgen's complaint, counter-claim and demand for jury trial.

On September 19, 2008, the Delaware Court issued a series of rulings that, among other things: (i) granted Amgen's motion for summary judgment of non-infringement of the asserted seven (7) claims of the '516 Patent based on the Delaware Court's interpretation of these claims to exclude extracellular methods of reducing NF-kB activity, (ii) granted the Company's motion seeking to dismiss for lack of jurisdiction under the Declaratory Judgment Act Amgen's challenges to the validity of claims of the '516 Patent that are not being asserted against Enbrel, and (iii) granted in part and denied in part the Company's motion for partial summary judgment with respect to Amgen's inequitable conduct defense.

With leave of the Delaware Court, on October 6, 2008, the Company filed in the CAFC a notice of appeal of the Delaware Court's summary judgment ruling 72 in order to seek reinterpretation of the asserted '516 Patent claims by the CAFC so that the Company's infringement case against Amgen may proceed in the Delaware Court. The CAFC has not yet scheduled oral argument on the issues presented for appeal.

#### PTO Reexamination

On April 4, 2005, Lilly filed a request in the PTO to reexamine the patentability of certain claims of the '516 Patent. An unrelated third party filed a similar request in the PTO on December 2, 2005 to reexamine the patentability of certain claims of the '516 Patent. These two requests have been granted and were merged by the PTO into a single reexamination proceeding.

On October 16, 2008, the PTO issued a final office action confirming as patentable 53 claims of the '516 patent, while rejecting 45 of the remaining claims, including claims relating to the Lilly litigation and claims relating to the Amgen litigation, and also rejecting the eight new claims filed by the Company on October 22, 2007. The Company's response to the final office action was filed on January 26, 2009. The PTO replied on February 14, 2009 to the Company's response and set a due date of March 16, 2009 for submission of a further response by the Company. The Company intends to submit a response by the March 16, 2009 deadline and to appeal the PTO's ruling if deemed necessary.

#### Shareholder Derivative Suit

On February 13, 2009, a shareholder derivative complaint alleging breaches of fiduciary duties was filed in the Delaware Court of Chancery, naming each member of the Company's board of directors as a defendant and the Company as a nominal defendant. The complaint, filed by a stockholder of the Company, alleges breaches of fiduciary duties by the defendants related to the merger of AGTI with and into ARIAD, the departure of the Company's former chief legal officer and changes in the by-laws of the Company and roles and responsibilities of members of the Board of Directors, and seeks unspecified damages plus reimbursement of the legal and other costs of the plaintiffs. The Company believes that the claims are without merit and that the complaint constitutes a frivolous lawsuit. The Company and its directors intend to vigorously oppose the lawsuit.

The timing and ultimate outcome of the legal proceedings described above cannot be determined at this time.

## 14. Related Party Transactions

In June 2007, the Company entered into an agreement with its chief executive officer and with a member of its Board of Directors in their individual capacities as shareholders of AGTI. The agreement contains provisions regarding (i) confidentiality of material non-public information provided to them and their advisors in the course of evaluation of any potential transaction to acquire the 20 percent interest in AGTI that the Company did not own, (ii) reimbursement by the Company of certain reasonable expenses incurred by them to retain financial advisors and legal counsel to advise them in connection with any potential transaction, (iii) indemnification of them by the Company for claims arising out of or relating to any potential transaction and (iv) the maintenance by the Company of liability insurance for their benefit. For the years ended December 31, 2008 and 2007, the Company has reimbursed \$259,000 and \$290,000, respectively, in expenses pursuant to this agreement. AGTI was merged with and into ARIAD Pharmaceuticals, Inc. on September 12, 2008 and the 20 percent minority interest in AGTI was acquired by the Company consequent to the merger (see Note 3).

## 15. Subsequent Event

On February 25, 2009, the Company sold 14,378,698 shares of its common stock in a registered direct offering to institutional investors, at a purchase price of \$1.69 per share, resulting in net proceeds of approximately \$22.8 million. The investors also received warrants to purchase an additional 10,784,024 shares of the Company's common stock exercisable at a price of \$2.15 per share or pursuant to the net exercise provisions of the warrants. The warrants have a three-year term from the date of issuance and are exercisable beginning six months after the date of issuance. Following this offering, the Company has approximately \$40.0 million of securities remaining available under its shelf registration statement.

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

Not applicable.

### ITEM 9A: CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in paragraph (e) of Rules 13a-15 and 15d-15 under the Securities Exchange Act of 1934) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, particularly during the period in which this Annual Report on Form 10-K was being prepared.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their desired control objectives. Our principle executive officer and principle financial officer have concluded that our controls and procedures are effective at that reasonable assurance level.

(b) Changes in Internal Controls. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B: OTHER INFORMATION** 

Not applicable.

#### **PART III**

## ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Board of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Corporate Code of Conduct and Ethics" in the Company's Definitive Proxy Statement for the 2009 Annual Meeting of Stockholders.

### ITEM 11: EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Executive Compensation," "Compensation Discussion and Analysis", "Compensation Committee Report" and "Board of Directors" in the Company's Definitive Proxy Statement for the 2009 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Company's Definitive Proxy Statement for the 2009 Annual Meeting of Stockholders.

# ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Board of Directors" and "Certain Relationships and Related Transactions" in the Company's Definitive Proxy Statement for the 2009 Annual Meeting of Stockholders.

### ITEM 14: PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Proposal 3: Ratification of Selection of Independent Registered Public Accounting Firm" in the Company's Definitive Proxy Statement for the 2009 Annual Meeting of Stockholders.

#### **PART IV**

## ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a)(1) The following Consolidated Financial Statements, Notes thereto and Report of Independent Registered Public Accounting Firm have been presented in Item 8:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Stockholders' Equity (Deficit)

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedules:

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto.

- (a)(3) The Exhibits listed in the Exhibit Index are filed herewith in the manner set forth therein.
- (b) See (a) (3) above.
- (c) See (a) (2) above.

### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge and Commonwealth of Massachusetts on the 12<sup>th</sup> day of March, 2009.

## ARIAD PHARMACEUTICALS, INC.

By:

/s/ Harvey J. Berger, M.D.

Name:

Harvey J. Berger, M.D.

Title:

Chairman, Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Harvey J. Berger, M.D. Harvey J. Berger, M.D.	Chairman of the Board of Directors, Chief Executive Officer and President (Principal Executive Officer)	March 12, 2009
/s/ Edward M. Fitzgerald Edward M. Fitzgerald	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2009
/s/ Jay R. LaMarche Jay R. LaMarche	Director	March 12, 2009
/s/ Athanase Lavidas, Ph.D. Athanase Lavidas, Ph.D.	Director	March 12, 2009
/s/ Massimo Radaelli, Ph.D. Massimo Radaelli, Ph.D.	Director	March 12, 2009
<u>/s/ Wayne Wilson</u> Wayne Wilson	Director	March 12, 2009

## ARIAD Pharmaceuticals, Inc.

## Form 10-K for the year ended December 31, 2008

## **Exhibit List**

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
3.1	Certificate of Incorporation of ARIAD		S-8	06/30/04	333-116996
	Pharmaceuticals, Inc., as amended		(Exhibit 4.2)		
3.2	Restated By-laws of ARIAD		8-K	11/05/08	000-21696
	Pharmaceuticals, Inc., as amended		(Exhibit 3.1)		
4.1	Specimen common stock certificate of		S-3	10/14/94	33-85166
	ARIAD Pharmaceuticals, Inc.		(Exhibit 4.5)		
4.2	Rights Agreement, dated as of June 8,		8-A	06/19/00	000-21696
	2000, between the ARIAD	ļ	(Exhibit 1)		
}	Pharmaceuticals, Inc. and State Street				
	Bank and Trust Company, which				
	includes the Form of Certificate of				
	Designations in respect of the Series A				
	Preferred Stock, as Exhibit A, the Form				
	of Right Certificate as Exhibit B and the				
	Summary of Rights to Purchase Series A				
	Preferred Stock as Exhibit C				<u> </u>

Exhibit Number		Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
Leases and	l Cred	it Agreements				····
10.1	.1	Lease Agreement, dated January 8, 1992, between ARIAD Pharmaceuticals, Inc. and Forest City Cambridge, Inc.		10 (Exhibit 10.1)	04/30/93	000-21696
	.2	Eighth Amendment to Lease dated October 30, 2006		10-K (Exhibit 10.57)	03/14/07	000-21696
10.2	.1	Credit Agreement, dated as of March 12, 2003, by and among ARIAD Pharmaceuticals, Inc., ARIAD Corporation and ARIAD Gene Therapeutics, Inc. and Citizens Bank of Massachusetts		10-Q (Exhibit 10.1)	05/13/03	000-21696
	.2	Amendment No. 1 to Credit Agreement, dated as of December 31, 2003		10-K (Exhibit 10.57)	03/02/04	000-21696
	.3	Amendment No. 2 to Credit Agreement dated as of December 31, 2004		10-K (Exhibit 10.52)	02/18/05	000-21696
	.4	Amendment No. 3 to Credit Agreement, dated as of March 26, 2008, by and among ARIAD Pharmaceuticals, Inc., ARIAD Corporation and ARIAD Gene Therapeutics, Inc. and RBS Citizens, National Association, successor by merger to Citizens Bank of Massachusetts		8-K (Exhibit 10.2.4)	03/27/08	000-21696
10.3		Security Agreement - All Assets, dated as of March 12, 2003, by and between ARIAD Pharmaceuticals, Inc. and Citizens Bank of Massachusetts		10-Q (Exhibit 10.3)	05/13/03	000-21696
10.4		Security Agreement - All Assets, dated as of March 12, 2003, by and between ARIAD Corporation and Citizens Bank of Massachusetts		10-Q (Exhibit 10.4)	05/13/03	000-21696
10.5		Security Agreement - All Assets, dated as of March 12, 2003, by and between ARIAD Gene Therapeutics, Inc. and Citizens Bank of Massachusetts		10-Q (Exhibit 10.5)	05/13/03	000-21696
10.6		Third Amended and Restated Term Note, dated March 26, 2008, issued by ARIAD Pharmaceuticals, Inc., ARIAD Corporation and ARIAD Gene Therapeutics, Inc. to RBS Citizens, National Association, successor by merger to Citizens Bank of Massachusetts		8-K (Exhibit 10.2.4)	03/27/08	000-21696

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
Agreements v	vith Respect to Collaborations, Licenses, Resea	rch and De			
10.7	License Agreement dated August 19, 1991 by and among The Massachusetts Institute of Technology, The Whitehead Institute and ARIAD Pharmaceuticals, Inc.*		10-Q (Exhibit 10.1)	05/10/06	000-21696
10.8	Amended and Restated Agreement, dated as of December 12, 1997, between The Board of Trustees of The Leland Stanford Junior University and ARIAD Gene Therapeutics, Inc.*		10-K (Exhibit 10.14)	03/10/98	000-21696
10.9	Revised and Restated Research and Development Agreement, dated as of March 15, 2002, by and between ARIAD Pharmaceuticals, Inc. and ARIAD Corporation		10-K (Exhibit 10.53)	03/22/02	000-21696
10.10	License Agreement, effective January 26, 2005, by and between ARIAD Pharmaceuticals, Inc. and Medinol Ltd.*		10-Q (Exhibit 10.1)	05/10/05	000-21696
10.11	Supply Agreement, entered into as of January 26, 2005, by and between ARIAD Pharmaceuticals, Inc. and Medinol Ltd.*		10-Q (Exhibit 10.2)	05/10/05	000-21696
10.12	Collaboration Agreement, dated July 11, 2007, by and among ARIAD Pharmaceuticals, Inc., ARIAD Gene Therapeutics, Inc. and Merck & Co., Inc.*		10-Q (Exhibit 10.1)	11/09/07	000-21696
10.13	Deforolimus API and Tablet Supply Agreement dated May 7, 2008 among ARIAD Pharmaceuticals, Inc., ARIAD Gene Therapeutics, Inc. and Merck & Co., Inc.*		10-Q (Exhibit 10.2)	08/11/08	000-21696

Exhibit Number		Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
Agreemen	ts with	Executive Officers and Directors				· <del>L., </del>
10.14	.1	Executive Employment Agreement, dated as of January 1, 1992, between ARIAD Pharmaceuticals, Inc. and Harvey J. Berger, M.D.+		10 (Exhibit 10.3)	04/30/93	000-21696
	.2	Amendment to Executive Employment Agreement, dated April 19, 1994+		S-1 (Exhibit 10.25)	05/10/94	33-76414
	.3	Amendment to Executive Employment Agreement, dated June 30, 1994+		10-K (Exhibit 10.23)	03/31/95	000-21696
	.4	Amendment to Executive Employment Agreement, dated as of January 1, 2006+		10-K (Exhibit 10.56)	03/16/06	000-21696
	.5	Amendment to Executive Employment Agreement, dated October 14, 2008 (solely to extend term)+	X (See Ex. 10.23)			
	.6	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to §409A)+	X (See Ex. 10.24)			
10.15	.1	Executive Employment Agreement dated May 1, 1992, between ARIAD Pharmaceuticals, Inc. and John Iuliucci, Ph.D., as amended March 2, 1994, January 1, 1997, January 1, 1999 and June 8, 2000+		10-Q (Exhibit 10.3)	08/10/00	000-21696
	.2	Amendment to Executive Employment Agreement, dated September 2, 2003+		10-Q (Exhibit 10.6)	11/04/03	000-21696
	.3	Amendment to Executive Employment Agreement, dated April/May 2007+		10-Q (Exhibit 10.2)	08/09/07	000-21696
	.4	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to §409A)+	X (See Ex. 10.24)			
10.16	.1	Executive Employment Agreement, dated August 1, 1993, between ARIAD Pharmaceuticals, Inc. and David L. Berstein, J.D., as amended March 2, 1994, January 1, 1997 and June 8, 2000+		10-Q (Exhibit 10.4)	08/10/00	000-21696
	.2	Amendment to Executive Employment Agreement, dated as of January 1, 2001+		10-Q (Exhibit 10.2)	05/14/01	000-21696
	.3	Amendment to Executive Employment Agreement, dated September 2, 2003+		10-Q (Exhibit 10.3)	11/04/03	000-21696
	.4	Amendment to Employment Agreement, dated April 14, 2008+	Х			
	.5	Amendment to Executive Employment Agreement, dated October 14, 2008 (solely to extend term)+	X (See Ex. 10.23)			
	.6	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to §409A)+	X (See Ex. 10.24)			
10.17	.1	Executive Employment Agreement, dated May 6, 2002, between ARIAD Pharmaceuticals, Inc. and Edward M. Fitzgerald+		10-Q (Exhibit 10.1)	05/09/02	000-21696
	.2	Amendment to Executive Employment Agreement, dated September 2, 2003+		10-Q (Exhibit 10.5)	11/04/03	000-21696

Exhibit Number		Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
	.3	Amendment to Executive Employment Agreement, dated October 14, 2008 (solely to extend term)+	X (See Ex. 10.23)			
	.4	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to §409A)+	X (See Ex. 10.24)			
10.18	.1	Executive Employment Agreement, dated June 8, 2000, between ARIAD Pharmaceuticals, Inc. and Timothy Clackson, Ph.D.+		10-K (Exhibit 10.49)	03/14/03	000-21696
	.2	Amendment to Executive Employment Agreement, dated July 1, 2001+	atr.	10-K (Exhibit 10.50)	03/14/03	000-21696
	.3	Amendment to Executive Employment Agreement, dated June 12, 2002+		10-K (Exhibit 10.51)	03/14/03	000-21696
	.4	Amendment to Executive Employment Agreement, dated September 2, 2003+		10-Q (Exhibit 10.4)	11/04/03	000-21696
	.5	Amendment to Executive Employment Agreement, dated October 14, 2008 (solely to extend term)+	X (See Ex. 10.23)			
	.6	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to §409A)+	X (See Ex. 10.24)			
10.19	.1	Executive Employment Agreement, dated May 29, 2007, by and between ARIAD Pharmaceuticals, Inc. and Pierre F. Dodion+		10-Q (Exhibit 10.1)	08/09/07	000-21696
	.2	Amendment to Executive Employment Agreement, dated October 14, 2008 (solely to extend term)+	X (See Ex. 10.23)			
	.3	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to §409A)+	X (See Ex. 10.24)			
10.20	.1	Executive Employment Agreement, dated November 4, 2008, between ARIAD Pharmaceuticals, Inc. and Daniel M. Bollag, Ph.D.+	Х			
	.2	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to \$409A)+	X (See Ex. 10.24)			
10.21	.1	Executive Employment Agreement, dated February 1, 2008, between ARIAD Pharmaceuticals, Inc. and Raymond T. Keane, Esq.+	Х			
	.2	Amendment to Executive Employment Agreement, dated October 14, 2008 (solely to extend term)+	X (See Ex. 10.23)			
	.3	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to \$409A)+	X (See Ex. 10.24)			
10.22	.1	Executive Employment Agreement, dated October 25, 2007, between ARIAD Pharmaceuticals, Inc. and Matthew E. Ros+	X			

Exhibit Number		Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
	.2	Amendment to Executive Employment Agreement, dated October 14, 2008 (solely to extend term)+	X (See Ex. 10.23)			
	.3	Amendment to Executive Employment Agreement, dated December 31, 2008 (related to §409A)+	X (See Ex. 10.24)			
	.4	Amendment to Employment Agreement dated January 8, 2009+	Х		`	
10.23		Amendments to Executive Employment Agreements, dated October 14, 2008 (solely to extend term)+	X			
10.24		Amendments to Executive Employment Agreements, dated December 31, 2008 (related to §409A)+	Х			
10.25	.1	Executive Employment Agreement, dated as of March 4, 2002, between ARIAD Pharmaceuticals, Inc. and Laurie A. Allen, Esq.+		10-K (Exhibit 10.56)	03/22/02	000-21696
	.2	Amendment to Executive Employment Agreement, dated September 2, 2003+		10-Q (Exhibit 10.2)	11/04/03	000-21696
	.3	Amendment to Executive Employment Agreement, dated April/May 2007+		10-Q (Exhibit 10.2)	08/09/07	000-21696
	.4	Amendment to Executive Employment Agreement, dated September 11, 2008+		8-K (Exhibit 10.3)	09/17/08	000-21696
10.26		Indemnity Agreement, dated September 11, 2008, by and between ARIAD Pharmaceuticals, Inc. and Laurie A. Allen, Esq.+		8-K (Exhibit 10.1)	09/17/08	000-21696
10.27		Indemnity Agreement, dated September 11, 2008, by and between ARIAD Gene Therapeutics, Inc. and Laurie A. Allen, Esq.+		8-K (Exhibit 10.2)	09/17/08	000-21696
10.28		Guarantee, dated September 11, 2008, by and between ARIAD Gene Therapeutics, Inc. and Laurie A. Allen, Esq.+		8-K (Exhibit 10.4)	09/17/08	000-21696
10.29		Consulting Agreement, dated September 11, 2008, by and between ARIAD Gene Therapeutics, Inc. and Laurie A. Allen, Esq.+		8-K (Exhibit 10.5)	09/17/08	000-21696
10.30	.1	ARIAD Pharmaceuticals, Inc. 1997 Executive Compensation Plan+		10-K (Exhibit 10.41)	03/10/98	000-21696
	.2	Amendment to ARIAD Pharmaceuticals, Inc. 1997 Executive Compensation Plan+		10-Q (Exhibit 10.2)	11/09/05	000-21696
10.31		ARIAD Pharmaceuticals, Inc. 2005 Executive Compensation Plan (as amended and restated effective October 1, 2008)+	Х			
10.32		Director Compensation Arrangements+		10-K (Exhibit 10.53)	03/14/07	000-21696
10.33		Form of Indemnity Agreement between ARIAD Pharmaceuticals, Inc. and its directors and officers+	Х			

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.34	Letter Agreement, dated June 19, 2007, by and among ARIAD Pharmaceuticals, Inc. Harvey J. Berger, M.D. and Jay LaMarche+		8-K (Exhibit 10.1)	06/21/07	000-21696

Exhibit Number		Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
<b>Equity Co</b>	mpen	sation Plans				
10.35	.1	ARIAD Pharmaceuticals, Inc. 1991 Stock Option Plan for Employees and Consultants, as amended+		10-K (Exhibit 10.13)	03/31/95	000-21696
	.2	Amendment to the 1991 Stock Option Plan for Employees and Consultants+		10-Q (Exhibit 10.36)	08/12/97	000-21696
10.36		ARIAD Pharmaceuticals, Inc. 1991 Stock Option Plan for Directors+		10 (Exhibit 10.15)	04/30/93	000-21696
10.37	.1	ARIAD Pharmaceuticals, Inc. 1994 Stock Option Plan for Non-Employee Directors+		10-K (Exhibit 10.24)	03/31/95	000-21696
	.2	Amendment to the 1994 Stock Option Plan for Non-Employee Directors.+		10-Q (Exhibit 10.37)	08/12/97	000-21696
10.38		Amended and Restated ARIAD Pharmaceuticals, Inc. 1997 Employee Stock Purchase Plan+		Def 14A (Appendix A)	04/29/08	000-21696
10.39		ARIAD Pharmaceuticals, Inc. 2001 Stock Plan, as amended and restated+		10-Q (Exhibit 10.3)	11/09/05	000-21696
10.40	.1	ARIAD Pharmaceuticals, Inc. 2006 Long- Term Incentive Plan+		Def 14A (Appendix A)	04/28/06	000-21696
	.2	Form of Stock Option Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+		10-Q (Exhibit 10.2)	08/08/06	000-21696
	.3	Form of Stock Grant Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+		10-Q (Exhibit 10.3)	08/08/06	000-21696
	.4	Form of Restricted Stock Unit Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+		10-Q (Exhibit 10.4)	08/08/06	000-21696
21.1		Subsidiaries of ARIAD Pharmaceuticals, Inc.	Х			
23.1		Consent of Deloitte & Touche LLP	Х			
31.1		Certification of the Chief Executive Officer	Х			
31.2		Certification of the Chief Financial Officer	Х			
32.1		Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Х			

<sup>(+)</sup> Management contract or compensatory plan or arrangement.

<sup>(\*)</sup> Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.